CHEMICAL SAFETY REPORT

Substance Name: diantimony trioxide

EC Number: 215-175-0

CAS Number: 1309-64-4

Registrant's Identity: Campine NV Lead Registrant of Diantimony trioxide- JS ATO- i2a

Final Report

5th Revision

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Part B

Introductory note:

The scientific background of this chemical safety report has largely been adopted from the European Union Risk Assessment Report for Diantimony trioxide which has been carried out in accordance with Council Regulation (EEC) 793/93 on the evaluation and control of the risks of "existing" substances. The report was finalised in 2008 and is publicly available via the following link: (http://esis.jrc.ec.europa.eu/doc/existing-chemicals/risk_assessment/REPORT/datreport415.pdf)

1. IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

1.1. Name and other identifiers of the substance

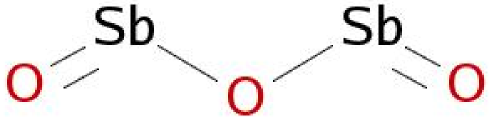
The substance **diantimony trioxide** is a mono constituent substance (origin: inorganic) having the following characteristics and physical–chemical properties (see the IUCLID dataset for further details).

The following public name is used: Diantimony trioxide.

Table 1. Substance identity

EC number:	215-175-0
EC name:	diantimony trioxide
CAS number (EC inventory):	1309-64-4
CAS name:	diantimony trioxide
IUPAC name:	dioxodistiboxane
Description:	white powder
Annex I index number:	051-005-00-X
Molecular formula:	Sb2O3
Molecular weight range:	291.5182

Structural formula:



1.2. Composition of the substance

Name: Diantimony trioxide (Representative sample)

Description: inorganic trivalent antimony compound

Degree of purity: > 98.0 — <100 % (w/w)

Table 2. Constituents Diantimony trioxide (Representative sample)

Constituent	Typical concentration	Concentration range	Remarks
diantimony trioxide EC no.: 215-175-0		> 98.0 — <100 % (w/w)	Powder, Particle size 0.2-44µm

Table 3. Impurities Diantimony trioxide (Representative sample)

Impurity	Typical concentration	Concentration range	Remarks
diarsenic trioxide EC no.: 215-481-4	< 0.1 % (w/w)		
lead monoxide EC no.: 215-267-0	< 0.25 % (w/w)		**Impurity is relevant for C&L of the substance.**
other impurities	<= 1.75 % (w/w)		other impurities for which the individual composition does not exceed 0.1% and/or are not classified and/or are not relevant for diantimony trioxide classification

Name: Diantimony trioxide - Composition medium PbO

Description: inorganic trivalent antimony compound

Degree of purity: > 97.1 — <= 99.6 % (w/w)

Table 4. Constituents Diantimony trioxide - Composition medium PbO

Constituent	Typical concentration	Concentration range	Remarks
diantimony trioxide EC no.: 215-175-0		> 97.1 — <= 99.6 % (w/w)	Powder

Table 5. Impurities Diantimony trioxide - Composition medium PbO

Impurity	Typical concentration	Concentration range	Remarks
diarsenic trioxide EC no.: 215-481-4	< 0.1 % (w/w)		
lead monoxide EC no.: 215-267-0		>= 0.25 — < 0.3 % (w/w)	**Impurity is relevant for C&L of the substance.**

other impurities	<= 2.6 % (w/w)		other impurities for which the individual composition does not exceed 0.1 % and/or are not classified and/or are not relevant for diantimony trioxide classification

Name: Diantimony trioxide - Composition high PbO

Description: inorganic trivalent antimony compound

Degree of purity: > 97.0 — <= 99.6 % (w/w)

Table 6. Constituents

Constituent	Typical concentration	Concentration range	Remarks
diantimony trioxide EC no.: 215-175-0		> 97.0 — <= 99.6 % (w/w)	powder

Table 7. Impurities

Impurity	Typical concentration	Concentration range	Remarks
diarsenic trioxide EC no.: 215-481-4	< 0.1 % (w/w)		
lead monoxide EC no.: 215-267-0		>= 0.3 — < 2.5 % (w/w)	**Impurity is relevant for C&L of the substance.**
other impurities	<= 0.4 % (w/w)		other impurities for which the individual composition does not exceed 0.1% and are not classified and are not relevant for diantimony trioxide classification

1.3. Physico-chemical properties

Table 8. Overview of physico-chemical properties

Property	Results	Remarks
Physical state at 20° C and 1013 hPa	The commercial product is a white, odourless, crystalline powder.	Value used for CSA: solid at 20°C and 101.3 kPa
Melting / freezing point	The melting point of diantimony trioxide is 656° C	Value used for CSA: 656° C at 1013 hPa
Boiling point	The boiling point of diantimony trioxide is 1425° C.	Value used for CSA: 1425° C at 1013 hPa
Relative density	relative density of submission substance (Antimony trioxide) = 5.897 Density differs from crystalline structure: Senarmontite: 5.2-5.252 g/cm3 Valentinite: 5.67-5.72 g/cm3	Value used for CSA: 5.897 at 20° C

Vapour pressure	Antimony trioxide has a vapour pressure of 1mm Hg at 574° C.	Value used for CSA: 133 Pa at 574° C
Water solubility	Dissolved concentration of 370 ± 37 µg/L was obtained with a loading of 10 mg/L after 7 days of exposure. Temperature varied between 20.8° C (t=0; start of the test) and 22.9° C (please refer to the IUCLID endpoint study records for additional information)	
Granulometry	Particle size 0.2-44µm The median particle size of the test items are (please refer to the IUCLID endpoint study records for further information): Antimony Trioxide "A": 5.8 µm Antimony Trioxide "B": 1.2 µm Antimony Trioxide "C": 0.8 µm Diantimony trioxide "1": 3.1 µm Diantimony trioxide "2": 0.9 µm Diantimony trioxide "3": 1.6 µm Diantimony trioxide "4": 6.0 µm Diantimony trioxide "5": 1.3 µm	

Data waiving

Information requirement: Surface tension

Reason: other justification

Justification: This study only needs to be conducted if based on the structure surface activity is expected or can be predicted, which is not the case for this substance: diantimony trioxide is a solid inorganic substance of very low water solubility, yielding dissociated antimony aqua-complexes. Neither the dissolved antimony aqua complexes nor the anions are expected to exert any surface active properties. Furthermore, the study does not need to be conducted if the water solubility is below 1 mg/L at 20°C (cf. Annex VII section 7.6 Column 2 of regulation (EC) 1907/2006).

Information requirement: Partition coefficient n-octanol/water (log value)

Reason: other justification

Justification: This study does not need to be conducted for inorganic substances (cf. Annex VII section 7.8 Column 2 of regulation 1907/2006).

Information requirement: Flash point

Reason: other justification

Justification: This study is only relevant for liquids or low melting point solids, which is not the case for this substance. Further, this study does not need to be conducted for inorganic substances (cf. Annex VII section 7.9 Column 2 of regulation (EC) 1907/2006).

Information requirement: Flammability / pyrophoric properties

Reason: study scientifically unjustified

Justification: Testing diantimony trioxide for pyrophoric properties of solids is considered unwarranted, since this substance is stable at ambient temperature and does not contain any chemical groups that might lead to spontaneous ignition a short time after coming in contact with air at room temperature (circa 20°C). Furthermore, long-term industrial experience in handling shows that the substance does not ignite in contact with air (in accordance with section 1 of REACH Annex XI).

Thus diantimony trioxide can be designated as non-flammable.

Information requirement: Flammability in contact with water

Reason: study scientifically unjustified

Justification: Testing for flammability in contact with water is not considered to be required, because the substance does not contain groups that might lead to a reaction with water or damp air, leading to the development of dangerous amounts of gas or gases which may be highly flammable. Furthermore, long-term industrial experience in practical handling of the substance shows that it does not react with water, and recent experimental testing for water solubility has also not reported any formation of gases (in accordance with section 1 of REACH Annex XI).

Thus Diantimony trioxide can be designated as non-flammable.

Information requirement: Flammability: further reaction with oxygen

Reason: study scientifically unjustified

Justification: Diantimony trioxide is already in a high oxidation state (+III), so that further reaction with oxygen in the sense of combustion that would be of relevance for flammability is highly unlikely.

Thus diantimony trioxide can be designated as non-flammable.

Information requirement: Explosive properties

Reason: study scientifically unjustified

Justification: This substance is void of any chemical structures commonly associated with explosive properties, such as metal peroxides, peroxo-acid-anions, azides, and halogen oxides. Further, it is noted that despite long-term industrial use of the substance, it is not classified for explosive properties according to UN transport regulations (in accordance with section 1 of REACH Annex XI).

Diantimony trioxide exhibits no chemical groups indicating explosive properties (e. g. peroxide). Therefore, diantimony trioxide can be designated as non explosive.

Information requirement: Self-ignition temperature

Reason: study scientifically unjustified

Justification: Self-ignition is not considered to be of relevance for this substance, since this would require heat to be developed either by reaction of this substance with oxygen or by exothermic decomposition and which is not lost rapidly enough to the surroundings. In conclusion, the conduct of further experimental verification is not considered to be required (in accordance with section 1 of REACH Annex XI).

Information requirement: Oxidising properties

Reason: other justification

Justification: This test item does not contain a surplus of oxygen or any structural groups known to be correlated with a tendency to react exothermally with combustible material (cf. Annex VII section 7.13 Column 2 of regulation 1907/2006).

Diantimony trioxide is a chemically inert substance. Based on the chemical structure it can be concluded that oxygen is not released. Therefore diantimony trioxide can be designated as a non-oxidising substance.

Information requirement: Stability in organic solvents and identity of relevant degradation products

Reason: other justification

Justification: This study does not need to be conducted for inorganic substances (cf. Annex IX section 7.15 Column 2 of regulation (EC) 1907/2006).

Information requirement: Dissociation constant

Reason: study scientifically unjustified

Justification: In accordance with section 1 of REACH Annex XI, the study does not need to be conducted. The substance does not contain relevant functional groups for which an assessment of the dissociation behaviour would provide information for risk assessment purposes. Therefore, the determination of a dissociation constant is not considered to be required (Guidance on information requirements and chemical safety assessment Chapter R.7a: Endpoint specific guidance, section R.7.1.17.1).

Information requirement: Viscosity

Reason: study scientifically unjustified

Justification: Viscosity is a property of fluids. Since diantimony trioxide is a solid at ambient temperature (ca. 20° C) such a study does not need to be conducted for this substance (melting point:656° C) (in accordance with section 1 of REACH Annex XI).

Discussion of physico-chemical properties

Data for the physical and chemical properties of diantimony trioxide were provided based on studies or peer reviewed handbook data for the following endpoints: melting/freezing point, boiling point, relative density, vapour pressure, water solubility, particle size distribution (granulometry) are reported here. The results of these studies are reported here as well as in the accompanying IUCLID database. Data for several endpoints were waived due to intrinsic properties of diantimony trioxide or based onthe criteria as laid down in regulation (EC) 1907/2008 as described above.

2. MANUFACTURE AND USES

Quantities

The tonnages typical for each registrant will be provided in its own personal IUCLID section 3.2, as this CSR is submitted by the Lead Registrant in the name of all members of the joint submission for diantmony trioxide and doesn't include any member specific information on estimated quantities. In the Exposure Scenarios covered in section 9 of this CSR generic tonnages were taken into account for the environmental assessment.

2.1. Manufacture

Diantimony trioxide is currently (2010) being produced at four sites in EU27. Two sites ceased production in the past.

Diantimony trioxide is produced via two routes:

a) Re-volatilizing of crude diantimony trioxide

b) Oxidation of antimony metal

Oxidation of antimony metal dominates in Europe. Diantimony trioxide manufacturers typically purchase antimony metal on the open market.

There are several processes for the production of crude diantimony trioxide or metallic antimony from virgin material. The choice of process depends on the composition of the ore and other factors. Typical steps include mining, crushing and grinding of ore, sometimes followed by flotation and separation of the metal using pyrometallurgical processes (smelting or roasting) or in a few cases (e.g. when the ore is rich in precious metals) by hydrometallurgical processes. These steps do not take place in the EU but closer to the mining location.

a) Re-volatilizing of crude diantimony trioxide

Step 1) Crude stibnite is oxidised to crude diantimony trioxide using furnaces operating at approximately 850 to 1,000° C. The reaction is the following:

$2\ Sb_2S_3 + 9\ O_2 \Rightarrow 2\ Sb_2O_3 + 6\ SO_2$

Step 2) The crude diantimony trioxide from the first step is vaporised and condensed according to the following schematic formula (detailed process conditions are considered confidential):

Sb_2O_3 (solid) + heat => Sb_2O_3 (gas)

b) Oxidation of antimony metal

Antimony metal is oxidized to diantimony trioxide in furnaces. The reaction is exothermic. Diantimony trioxide is formed through sublimation and recovered in bag filters (bag house). The size of the formed particles is controlled by process conditions in furnace and gas flow. The reaction can be schematically described by:

$4\ Sb + 3\ O_2 \Rightarrow 2\ Sb_2O_3$

(EBC, 2008).

2.2. Identified uses

Table 9. Manufacture

Identifiers	Use descriptors	Other information
M-1: Use of antimony metal in the production of diantimony trioxide	**Environmental release category (ERC):** ERC 1: Manufacture of substances **Process category (PROC):** PROC 21: Low energy manipulation of substances bound in materials and/or articles PROC 22: Potentially closed processing operations with minerals/metals at elevated temperature. Industrial setting PROC 23: Open processing and transfer operations with minerals/metals at elevated temperature PROC 26: Handling of solid inorganic substances at ambient temperature	Tonnage of substance: 9000.0 Remarks: : Use of antimony metal in the production of diantimony trioxide

Table 10. Uses by workers in industrial settings

Confidential	IU number	Identified Use (IU) name	Substance supplied to that use	Use descriptors

Table 11. Uses at industrial sites

Identifiers	Use descriptors	Other information
IW-1: Use of diantimony trioxide in PET (films/fibres, resin) production	**Environmental release category (ERC):** ERC 5: Industrial use resulting in inclusion into or onto a matrix ERC 6b: Industrial use of reactive processing aids **Process category (PROC):** PROC 1: Use in closed process, no likelihood of exposure PROC 3: Use in closed batch process (synthesis or formulation)	Tonnage of substance: 250.0 Substance supplied to that use: As such In a mixture Subsequent service life relevant for that use: yes Remarks: Use of diantimony trioxide in

Identifiers	Use descriptors	Other information
	PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 6: Calendering operations PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 14: Production of preparations or articles by tabletting, compression, extrusion, pelletisation PROC 15: Use as laboratory reagent PROC 21: Low energy manipulation of substances bound in materials and/or articles PROC 22: Potentially closed processing operations with minerals/metals at elevated temperature. Industrial setting PROC 24: High (mechanical) energy work-up of substances bound in materials and/or articles PROC 25: Other hot work operations with metals **Product Category used:** PC 32: Polymer preparations and compounds **Sector of end use:** SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys) SU 12: Manufacture of plastics products, including compounding and conversion **Technical function of the substance during formulation:**	PET (films/fibres, resin) production

Identifiers	**Use descriptors**	**Other information**
	Flame retardants catalyst	
IW-2: Industrial use of diantimony trioxide in the plastics and rubber industry	**Environmental release category (ERC):** ERC 5: Industrial use resulting in inclusion into or onto a matrix **Process category (PROC):** PROC 1: Use in closed process, no likelihood of exposure PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 6: Calendering operations PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 10: Roller application or brushing PROC 13: Treatment of articles by dipping and pouring PROC 14: Production of preparations or articles by tabletting, compression, extrusion, pelletisation PROC 15: Use as laboratory reagent PROC 21: Low energy manipulation of substances bound in materials and/or articles PROC 24: High (mechanical) energy work-up of	Tonnage of substance: 2500.0 Substance supplied to that use: As such In a mixture Subsequent service life relevant for that use: yes Remarks: Industrial use of diantimony trioxide in the plastics and rubber industry.

Identifiers	Use descriptors	Other information
	substances bound in materials and/or articles PROC 26: Handling of solid inorganic substances at ambient temperature **Product Category used:** PC 19: Intermediate PC 21: Laboratory chemicals PC 24: Lubricants, greases, release products PC 26: Paper and board dye, finishing and impregnation products: including bleaches and other processing aids PC 32: Polymer preparations and compounds PC 33: Semiconductors **Sector of end use:** SU 5: Manufacture of textiles, leather, fur SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys) SU 11: Manufacture of rubber products SU 12: Manufacture of plastics products, including compounding and conversion SU 16: Manufacture of computer, electronic and optical products, electrical equipment SU 17: General manufacturing, e.g. machinery, equipment, vehicles, other transport equipment SU 18: Manufacture of furniture SU 20: Health services SU 23: Electricity, steam, gas water supply and sewage treatment **Technical function of the substance during formulation:** Flame retardants	
IW-3: Industrial use of diantimony trioxide in the manufacture of flame	**Environmental release category (ERC):** ERC 5: Industrial use resulting in inclusion into or onto a matrix	Tonnage of substance: 280.0 Substance supplied to that use: As such

Identifiers	Use descriptors	Other information
retarded textiles	**Process category (PROC):** PROC 1: Use in closed process, no likelihood of exposure PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 6: Calendering operations PROC 7: Industrial spraying PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 10: Roller application or brushing PROC 12: Use of blowing agents in manufacture of foam PROC 13: Treatment of articles by dipping and pouring PROC 21: Low energy manipulation of substances bound in materials and/or articles PROC 22: Potentially closed processing operations with minerals/metals at elevated temperature. Industrial setting PROC 24: High (mechanical) energy work-up of substances bound in materials and/or articles PROC 26: Handling of solid inorganic substances at ambient temperature **Product Category used:** PC 23: Leather tanning, dye, finishing, impregnation and care products PC 32: Polymer preparations and compounds PC 34: Textile dyes, finishing and impregnating	In a mixture Subsequent service life relevant for that use: yes Remarks: Industrial use of diantimony trioxide in the manufacture of flame retarded textiles

Identifiers	Use descriptors	Other information
	products; including bleaches and other processing aids **Sector of end use:** SU 5: Manufacture of textiles, leather, fur SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys) **Technical function of the substance during formulation:** Flame retardants	
IW-4: Industrial use of diantimony trioxide in the production of glass, enamels, functional ceramics and semi-conductors	**Environmental release category (ERC):** ERC 5: Industrial use resulting in inclusion into or onto a matrix ERC 6a: Industrial use resulting in manufacture of another substance (use of intermediates) **Process category (PROC):** PROC 1: Use in closed process, no likelihood of exposure PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 3: Use in closed batch process (synthesis or formulation) PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 7: Industrial spraying PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 10: Roller application or brushing	Tonnage of substance: 75.0 Substance supplied to that use: As such In a mixture Subsequent service life relevant for that use: yes Remarks: Industrial use of diantimony trioxide in the production of glass, enamels, functional ceramics and semi-conductors.

Identifiers	Use descriptors	Other information
	PROC 13: Treatment of articles by dipping and pouring PROC 14: Production of preparations or articles by tabletting, compression, extrusion, pelletisation PROC 15: Use as laboratory reagent PROC 21: Low energy manipulation of substances bound in materials and/or articles PROC 22: Potentially closed processing operations with minerals/metals at elevated temperature. Industrial setting PROC 23: Open processing and transfer operations with minerals/metals at elevated temperature PROC 24: High (mechanical) energy work-up of substances bound in materials and/or articles PROC 26: Handling of solid inorganic substances at ambient temperature **Product Category used:** PC 0: Other: C23.1, UCN-G15000/15100 PC 9a: Coatings and paints, thinners, paint removes PC 19: Intermediate PC 21: Laboratory chemicals PC 33: Semiconductors **Sector of end use:** SU 8: Manufacture of bulk, large scale chemicals (including petroleum products) SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys) SU 13: Manufacture of other non-metallic mineral products, e.g. plasters, cement SU 15: Manufacture of fabricated metal products, except machinery and equipment SU 16: Manufacture of computer, electronic and optical products, electrical equipment **Technical function of the substance during formulation:**	

Identifiers	Use descriptors	Other information
	Flame retardants Semiconductors and photovoltaic agents Colouring agents, pigments clarifying aid in glass, opacifier	
IW-5: Industrial use of diantimony trioxide in the production of pigments, paints, coatings, ceramics, brake pads and production and formulation of fine chemicals	**Environmental release category (ERC):** ERC 5: Industrial use resulting in inclusion into or onto a matrix ERC 6a: Industrial use resulting in manufacture of another substance (use of intermediates) **Process category (PROC):** PROC 1: Use in closed process, no likelihood of exposure PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 6: Calendering operations PROC 7: Industrial spraying PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 10: Roller application or brushing PROC 13: Treatment of articles by dipping and pouring PROC 14: Production of preparations or articles by	Tonnage of substance: 500.0 Substance supplied to that use: As such In a mixture Subsequent service life relevant for that use: yes Remarks: Industrial use of diantimony trioxide in the production of pigments, paints, coatings, ceramics, brake pads and production and formulation of fine chemicals.

Identifiers	Use descriptors	Other information
	tabletting, compression, extrusion, pelletisation PROC 15: Use as laboratory reagent PROC 19: Hand-mixing with intimate contact and only PPE available. PROC 21: Low energy manipulation of substances bound in materials and/or articles PROC 22: Potentially closed processing operations with minerals/metals at elevated temperature. Industrial setting PROC 23: Open processing and transfer operations with minerals/metals at elevated temperature PROC 24: High (mechanical) energy work-up of substances bound in materials and/or articles PROC 26: Handling of solid inorganic substances at ambient temperature **Product Category used:** PC 9a: Coatings and paints, thinners, paint removes PC 9b: Fillers, putties, plasters, modelling clay PC 9c: Finger paints PC 18: Ink and toners PC 19: Intermediate PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents PC 32: Polymer preparations and compounds **Sector of end use:** SU 8: Manufacture of bulk, large scale chemicals (including petroleum products) SU 9: Manufacture of fine chemicals SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys) SU 13: Manufacture of other non-metallic mineral products, e.g. plasters, cement SU 17: General manufacturing, e.g. machinery, equipment, vehicles, other transport equipment SU 19: Building and construction work SU 23: Electricity, steam, gas water supply and	

Identifiers	Use descriptors	Other information
	sewage treatment **Technical function of the substance during formulation:** Flame retardants Laboratory chemicals Colouring agents, pigments opacifier	
IW-6: Industrial use of diantimony trioxide in wood adhesives	**Environmental release category (ERC):** ERC 5: Industrial use resulting in inclusion into or onto a matrix **Process category (PROC):** PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 14: Production of preparations or articles by tabletting, compression, extrusion, pelletisation PROC 21: Low energy manipulation of substances bound in materials and/or articles PROC 24: High (mechanical) energy work-up of substances bound in materials and/or articles PROC 26: Handling of solid inorganic substances at ambient temperature **Product Category used:** PC 1: Adhesives, sealants **Sector of end use:** SU 6a: Manufacture of wood and wood products **Technical function of the substance during formulation:** Flame retardants	Tonnage of substance: 15.0 Substance supplied to that use: As such In a mixture Subsequent service life relevant for that use: yes Remarks: Industrial use of diantimony trioxide in wood adhesives.

Table 12. Uses by professional workers

Identifiers	**Use descriptors**	**Other information**
PW-1: Professional uses of diantimony trioxide preparations	**Environmental release category (ERC):** ERC 8c: Wide dispersive indoor use resulting in inclusion into or onto a matrix ERC 8f: Wide dispersive outdoor use resulting in inclusion into or onto a matrix **Process category (PROC):** PROC 10: Roller application or brushing PROC 11: Non industrial spraying PROC 19: Hand-mixing with intimate contact and only PPE available. PROC 23: Open processing and transfer operations with minerals/metals at elevated temperature PROC 13: Treatment of articles by dipping and pouring PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities **Product Category used:** PC 1: Adhesives, sealants PC 9a: Coatings and paints, thinners, paint removes PC 18: Ink and toners PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents PC 24: Lubricants, greases, release products PC 26: Paper and board dye, finishing and impregnation products: including bleaches and other processing aids PC 32: Polymer preparations and compounds PC 34: Textile dyes, finishing and impregnating products; including bleaches and other processing aids **Technical function of the substance during formulation:**	Tonnage of substance: 6.0 Substance supplied to that use: In a mixture Subsequent service life relevant for that use: no Remarks: Professional uses of diantimony trioxide preparations.

Identifiers	Use descriptors	Other information
	Flame retardants	
PW-2: Profesional uses of diantimony trioxide contained in articles	**Environmental release category (ERC):** ERC 8c: Wide dispersive indoor use resulting in inclusion into or onto a matrix ERC 8f: Wide dispersive outdoor use resulting in inclusion into or onto a matrix **Process category (PROC):** PROC 21: Low energy manipulation of substances bound in materials and/or articles PROC 24: High (mechanical) energy work-up of substances bound in materials and/or articles **Technical function of the substance during formulation:** Flame retardants	Tonnage of substance: 6.0 Substance supplied to that use: In a mixture Subsequent service life relevant for that use: yes Remarks: Profesional uses of diantimony trioxide contained in articles.

Table 13. Consumer uses

Identifiers	Use descriptors	Other information
C-1: Service life/Use of articles with diantimony trioxide being embedded into the matrix	**Environmental release category (ERC):** ERC 8c: Wide dispersive indoor use resulting in inclusion into or onto a matrix ERC 8f: Wide dispersive outdoor use resulting in inclusion into or onto a matrix **Technical function of the substance during formulation:** Flame retardants Colouring agents, pigments Semiconductors and photovoltaic agents opacifier, clarifying aid in glass Laboratory chemicals	Tonnage of substance: 6.0 Substance supplied to that use: As such In a mixture Subsequent service life relevant for that use: yes Remarks: Service life/Use of articles with diantimony trioxide being embedded into the matrix
C-2: Service life/Use of back-coated	**Environmental release category (ERC):** ERC 8c: Wide dispersive indoor use resulting in	Tonnage of substance: 6.0

Identifiers	Use descriptors	Other information
textile	inclusion into or onto a matrix ERC 8f: Wide dispersive outdoor use resulting in inclusion into or onto a matrix **Technical function of the substance during formulation:** Flame retardants	Substance supplied to that use: In a mixture As such Subsequent service life relevant for that use: yes Remarks: Service life/Use of back-coated textile
C-3: Service life/Use, wearing of articles made of PET/PES polymers	**Environmental release category (ERC):** ERC 8c: Wide dispersive indoor use resulting in inclusion into or onto a matrix ERC 8f: Wide dispersive outdoor use resulting in inclusion into or onto a matrix **Technical function of the substance during formulation:** catalyst Flame retardants	Tonnage of substance: 6.0 Subsequent service life relevant for that use: yes Remarks: Service life/Use, wearing of articles made of PET/PES polymers.
C-4: Service life/ Wearing of clothes containing antimony trioxide for fire resistance	**Environmental release category (ERC):** ERC 8c: Wide dispersive indoor use resulting in inclusion into or onto a matrix ERC 8f: Wide dispersive outdoor use resulting in inclusion into or onto a matrix **Technical function of the substance during formulation:** Flame retardants	Tonnage of substance: 6.0 Substance supplied to that use: As such In a mixture Subsequent service life relevant for that use: yes Remarks: Service life/ Wearing of clothes containing antimony trioxide for fire resistance.

Table 14. Article service life

Identifiers	Use descriptors	Other information
SL-2: Profesional uses of diantimony trioxide contained in articles	**Article category related to subsequent service life (AC):** AC 1: Vehicles AC 4: Stone, plaster, cement, glass and ceramic articles AC 5: Fabrics, textiles and apparel AC 6: Leather articles AC 7: Metal articles AC 8: Paper articles AC 10: Rubber articles AC 11: Wood articles AC 13: Plastic articles AC 2: Machinery, mechanical appliances, electrical/electronic articles AC 3: Electrical batteries and accumulators **Environmental release category (ERC):** ERC 10a: Wide dispersive outdoor use of long-life articles and materials with low release ERC 11a: Wide dispersive indoor use of long-life articles and materials with low release ERC 12a: Industrial processing of articles with abrasive techniques (low release) **Process category (PROC):** PROC 21: Low energy manipulation of substances bound in materials and/or articles PROC 24: High (mechanical) energy work-up of substances bound in materials and/or articles **Technical function of the substance during formulation:** Flame retardants Colouring agents, pigments Semiconductors and photovoltaic agents opacifier, clarifying aid in glass	Article used by: workers Tonnage of substance: 6.0 Remarks: Profesional uses of diantimony trioxide contained in articles.
SL-3: Service	**Article category related to subsequent service life**	Article used by:

Identifiers	Use descriptors	Other information
Life/Use of articles with diantimony trioxide being embedded into the matrix	**(AC):** AC 1: Vehicles AC 2: Machinery, mechanical appliances, electrical/electronic articles AC 3: Electrical batteries and accumulators AC 5: Fabrics, textiles and apparel AC 7: Metal articles AC 10: Rubber articles AC 11: Wood articles AC 13: Plastic articles **Environmental release category (ERC):** ERC 10a: Wide dispersive outdoor use of long-life articles and materials with low release ERC 11a: Wide dispersive indoor use of long-life articles and materials with low release ERC 12a: Industrial processing of articles with abrasive techniques (low release) **Technical function of the substance during formulation:** Flame retardants	consumers Tonnage of substance: 6.0 Remarks: Service Life/Use of articles with diantimony trioxide being embedded into the matrix.
SL-4: Service life / Use of back-coated textiles	**Article category related to subsequent service life (AC):** AC 5: Fabrics, textiles and apparel **Environmental release category (ERC):** ERC 10a: Wide dispersive outdoor use of long-life articles and materials with low release ERC 11a: Wide dispersive indoor use of long-life articles and materials with low release ERC 12a: Industrial processing of articles with abrasive techniques (low release) **Technical function of the substance during formulation:**	Article used by: consumers Tonnage of substance: 6.0 Remarks: Service life / Use of back-coated textiles.

Identifiers	Use descriptors	Other information
	Flame retardants	
SL-5: Service Life / Use, wearing of articles made op PET/PES polymers	**Article category related to subsequent service life (AC):** AC 5: Fabrics, textiles and apparel AC 6: Leather articles AC 8: Paper articles AC 13: Plastic articles **Environmental release category (ERC):** ERC 10a: Wide dispersive outdoor use of long-life articles and materials with low release ERC 11a: Wide dispersive indoor use of long-life articles and materials with low release ERC 12a: Industrial processing of articles with abrasive techniques (low release) **Technical function of the substance during formulation:** Flame retardants catalyst	Article used by: consumers Tonnage of substance: 6.0 Remarks: Service Life / Use, wearing of articles made op PET/PES polymers.
SL-6: Service Life / Wearing of clothes containing antimony trioxide for fire resistance	**Article category related to subsequent service life (AC):** AC 5: Fabrics, textiles and apparel **Environmental release category (ERC):** ERC 10a: Wide dispersive outdoor use of long-life articles and materials with low release ERC 11a: Wide dispersive indoor use of long-life articles and materials with low release ERC 12a: Industrial processing of articles with abrasive techniques (low release) **Technical function of the substance during formulation:** Flame retardants	Article used by: consumers Tonnage of substance: 6.0 Remarks: Service Life / Wearing of clothes containing antimony trioxide for fire resistance.

Identifiers	Use descriptors	Other information
SL-1: Professional uses of diantimony trioxide preparations	**Environmental release category (ERC):** ERC 10a: Wide dispersive outdoor use of long-life articles and materials with low release ERC 11a: Wide dispersive indoor use of long-life articles and materials with low release ERC 12a: Industrial processing of articles with abrasive techniques (low release) **Process category (PROC):** PROC 23: Open processing and transfer operations with minerals/metals at elevated temperature **Technical function of the substance during formulation:** Flame retardants Colouring agents, pigments	Article used by: workers Tonnage of substance: 6.0 Remarks: Professional uses of diantimony trioxide preparations.

Table 15. Waste types, amounts and waste treatment processes for antimony from manufacturing

Waste from	Type of waste	Suitable waste code	Amount (t/y)	Composition	Waste treatment process/ recycling	Information source
Manufacture	Sludge from on-site WWTP	06 05 02* 06 05 03 19 02 05* 19 02 06	Range: 0 – 7,500 t/y.	Range: 200 – 10,0000 mg Sb/kg dw.	Internal or external landfilling Recycling internally Incineration Recycled in other applications	In house questionnaire 2012
	Dust	10 08 04 10 08 15* 10 08 16	Range: 0 – 120 t/y.	Range: 800,000 – 1,000,000 mg Sb/kg dw.	Internal or external landfilling Recycling internally Recycled in other applications	
	Slags	10 08 08* 10 08 09	Range: 0 – 120 t/y.	Range: 400,000 –	Internal or external landfilling	

				800,000 mg Sb/kg dw.	Recycling internally Recycled in another application	
	Packaging materials	15 01 06 15 01 10*	Range: 0 – 3 t/y.	Range: 50,000 – 60,000 mg Sb/kg dw.	Recycled externally Internal or external landfilling	

Table 16. Waste types, amounts and waste treatment processes for antimony from identified uses

Waste from	Type of waste	Suitable waste code	Amount (t/y)	Composition	Waste treatment process/ recycling	Information source
Downstream use	Dusts, sludges, contaminated material, off-specification batches, …	02 01 10 15 01 06 15 01 10* 16 06 01* 19 12 03 …	0.058% from the Sb downstream use tonnage ends up in hazardous waste		Treated as hazardous waste	Waste report ARCHE 2012

Table 17. Waste types, amounts and treatment of waste from service life sated subsequent to the identified uses for antimony from identified uses

Waste from	Type of waste	Suitable waste code	Amount (t/y)	Composition	Waste treatment process/ recycling	Information source
Municipal waste and EoL	Solid municipal waste: Paper/card-board, Metal, Glass, Plastics, Textile, Organic matter,	20 01 34 20 01 40 20 03 01 20 03 07	179,430 ktonnes dry weight	Average concentration: 31 mg Sb/kg dw	Municipal waste landfill Municipal waste incineration Recycling	EUROSTAT 2009 Waste report ARCHE 2011

	Other					

Most common technical function of substance (what it does):

Flame retardants

Remarks:
ATO greatly increases flame retardant effectiveness when used as a synergist in combination with halogenated flame retardants in plastics, paints, adhesives, sealants, rubber and textile back coatings. ATO is the major catalyst for the production of PET plastic used in the packaging of mineral water and soft drinks.
ATO is also used:

- as a clarifying aid in certain glasses,
- as a coating used on certain grades of TiO_2 pigments,
- as a component in the manufacturing of complex inorganic colored rutile pigments and
- as an opacifier in cast iron bath and sinking enameling.

2.3. Uses advised against

This section is not applicable for diantimony trioxide, as no uses were identified that need to be advised against.

3. CLASSIFICATION AND LABELLING

3.1. Classification and labelling according to CLP / GHS

Name: Diantimony trioxide (Representative sample)

Implementation: EU

State/form of the substance: powder

Related composition: Diantimony trioxide (Representative sample)

Remarks: legal classification as laid out in regulation (EC) 1272/2008, Annex VI, Index No. 051-005-00-X

Classification

The substance is classified as follows:

- for physical-chemical properties:

Endpoint	Hazard category	Hazard statement	Reason for no classification	CSR section*)
Explosives:			conclusive but not sufficient for classification	6.1
Flammable gases:			conclusive but not sufficient for classification	6.2
Flammable aerosols:			conclusive but not sufficient for classification	6.2
Oxidising gases:			conclusive but not sufficient for classification	6.3
Gases under pressure:			conclusive but not sufficient for classification	
Flammable liquids:			conclusive but not sufficient for classification	6.2
Flammable solids:			conclusive but not sufficient for classification	6.2
Self-reactive substances and mixtures:			conclusive but not sufficient for classification	
Pyrophoric liquids:			conclusive but not sufficient for classification	6.2
Pyrophoric solids:			conclusive but not sufficient for classification	6.2
Self-heating substances and			conclusive but not sufficient for	

mixtures:			classification	
Substances and mixtures which in contact with water emit flammable gases:			conclusive but not sufficient for classification	6.2
Oxidising liquids:			conclusive but not sufficient for classification	6.3
Oxidising solids:			conclusive but not sufficient for classification	6.3
Organic peroxides:			conclusive but not sufficient for classification	
Corrosive to metals:			conclusive but not sufficient for classification	

*) Justification for (non) classification can be found in the CSR section indicated

- for health hazards:

Endpoint	**Hazard category**	**Hazard statement**	**Reason for no classification**	**CSR section*)**
Acute toxicity - oral:			conclusive but not sufficient for classification	5.2.3
Acute toxicity - dermal:			conclusive but not sufficient for classification	5.2.3
Acute toxicity - inhalation:			conclusive but not sufficient for classification	5.2.3
Skin corrosion / irritation:			conclusive but not sufficient for classification	5.3.4 and 5.4.3
Serious damage / eye irritation:			conclusive but not sufficient for classification	5.3.4
Respiration sensitization:			conclusive but not sufficient for classification	5.5.3
Skin sensitation:			conclusive but not sufficient for classification	5.5.3
Aspiration hazard:			conclusive but not sufficient for classification	5.2.3
Reproductive Toxicity:			conclusive but not sufficient for classification	5.9.3
Reproductive			conclusive but	5.9.3

Toxicity: Effects on or via lactation:			not sufficient for classification	
Germ cell mutagenicity:			conclusive but not sufficient for classification	5.7.3
Carcinogenicity:	Carc. 2	H351: Suspected of causing cancer by inhalation		5.8.3
Specific target organ toxicity - single:			conclusive but not sufficient for classification	5.2.3 and 5.3.4
Specific target organ toxicity - repeated:			conclusive but not sufficient for classification	5.6.3

*) Justification for (non) classification can be found in the CSR section indicated

- for environmental hazards:

Endpoint	**Hazard category**	**Hazard statement**	**Reason for no classification**	**CSR section*)**
Hazards to the aquatic environment (acute/short-term):			conclusive but not sufficient for classification	7.5
Hazards to the aquatic environment (long-term):			conclusive but not sufficient for classification	7.5
Hazardous to the ozone layer:			conclusive but not sufficient for classification	7.5

*) Justification for (non) classification can be found in the CSR section indicated

Labelling

Signal word: Warning

Hazard pictogram:

GHS08: health hazard

Hazard statements:

H351: Suspected of causing cancer by inhalation

Precautionary statements:

P202: Do not handle until all safety precautions have been read and understood.
P280: Wear protective gloves/protective clothing/eye protectionP308+P313: IF exposed or concerned: Get

medical advice/attention.
P405: Store locked up.

Name: Diantimony trioxide - Composition medium PbO

Implementation: EU

State/form of the substance: powder

Related composition: Diantimony trioxide - Composition medium PbO

Remarks: See composition section 1.2 Classification

Classification based on legal classification as laid down in regulation (EC) 1272/2008, Annex VI, Index No. 051-005-00-X. The higher PbO impurity level leads to a different classification than for the representative sample.

Classification

The substance is classified as follows:

- for physical-chemical properties:

Endpoint	Hazard category	Hazard statement	Reason for no classification	CSR section*)
Explosives:			conclusive but not sufficient for classification	6.1
Flammable gases:			conclusive but not sufficient for classification	6.2
Flammable aerosols:			conclusive but not sufficient for classification	6.2
Oxidising gases:			conclusive but not sufficient for classification	6.3
Gases under pressure:			conclusive but not sufficient for classification	
Flammable liquids:			conclusive but not sufficient for classification	6.2
Flammable solids:			conclusive but not sufficient for classification	6.2
Self-reactive substances and mixtures:			conclusive but not sufficient for classification	
Pyrophoric liquids:			conclusive but not sufficient for classification	6.2
Pyrophoric solids:			conclusive but not sufficient for classification	6.2

Self-heating substances and mixtures:			conclusive but not sufficient for classification	
Substances and mixtures which in contact with water emit flammable gases:			conclusive but not sufficient for classification	6.2
Oxidising liquids:			conclusive but not sufficient for classification	6.3
Oxidising solids:			conclusive but not sufficient for classification	6.3
Organic peroxides:			conclusive but not sufficient for classification	
Corrosive to metals:			conclusive but not sufficient for classification	

*) Justification for (non) classification can be found in the CSR section indicated

- for health hazards:

Endpoint	Hazard category	Hazard statement	Reason for no classification	CSR section*)
Acute toxicity - oral:			conclusive but not sufficient for classification	5.2.3
Acute toxicity - dermal:			conclusive but not sufficient for classification	5.2.3
Acute toxicity - inhalation:			conclusive but not sufficient for classification	5.2.3
Skin corrosion / irritation:			conclusive but not sufficient for classification	5.3.4 and 5.4.3
Serious damage / eye irritation:			conclusive but not sufficient for classification	5.3.4
Respiration sensitization:			conclusive but not sufficient for classification	5.5.3
Skin sensitation:			conclusive but not sufficient for classification	5.5.3
Aspiration hazard:			conclusive but not sufficient for classification	5.2.3
Reproductive Toxicity:			conclusive but not sufficient for classification	5.9.3

Reproductive Toxicity: Effects on or via lactation:			conclusive but not sufficient for classification	5.9.3
Germ cell mutagenicity:			conclusive but not sufficient for classification	5.7.3
Carcinogenicity:	Carc. 2	H351: Suspected of causing cancer by inhalation		5.8.3
Specific target organ toxicity - single:			conclusive but not sufficient for classification	5.2.3 and 5.3.4
Specific target organ toxicity - repeated:			conclusive but not sufficient for classification	5.6.3

*) Justification for (non) classification can be found in the CSR section indicated

- for environmental hazards:

Endpoint	**Hazard category**	**Hazard statement**	**Reason for no classification**	**CSR section*)**
Hazards to the aquatic environment (acute/short-term):			conclusive but not sufficient for classification	7.5
Hazards to the aquatic environment (long-term):	Aquatic Chronic 3	H412: Harmful to aquatic life with long lasting effects.		7.5
Hazardous to the ozone layer:			conclusive but not sufficient for classification	7.5

*) Justification for (non) classification can be found in the CSR section indicated

Labelling

Signal word: Warning

Hazard pictogram:

GHS08: health hazard

Hazard statements:

H351: Suspected of causing cancer by inhalation
H412: Harmful to aquatic life with long lasting effects.

Precautionary statements:

P202: Do not handle until all safety precautions have been read and understood.
P280: Wear protective gloves/protective clothing/eye protectionP308+P313: IF exposed or concerned: Get medical advice/attention.
P405: Store locked up.
P273: Avoid release to the environment.
P501: Dispose of contents/container to: in accordance with local regulations.

Name: Diantimony trioxide - Composition high PbO

Implementation: EU

State/form of the substance: powder

Related composition: Diantimony trioxide - Composition high PbO

Remarks: See composition section 1.2 Classification

Classification based on legal classification as laid down in regulation (EC) 1272/2008, Annex VI, Index No. 051-005-00-X. The higher PbO impurity level leads to a different classification than for the representative sample.

Classification

The substance is classified as follows:

- for physical-chemical properties:

Endpoint	Hazard category	Hazard statement	Reason for no classification	CSR section*)
Explosives:			conclusive but not sufficient for classification	6.1
Flammable gases:			conclusive but not sufficient for classification	6.2
Flammable aerosols:			conclusive but not sufficient for classification	6.2
Oxidising gases:			conclusive but not sufficient for classification	6.3
Gases under pressure:			conclusive but not sufficient for classification	
Flammable liquids:			conclusive but not sufficient for classification	6.2
Flammable solids:			conclusive but not sufficient for classification	6.2
Self-reactive substances and mixtures:			conclusive but not sufficient for classification	
Pyrophoric liquids:			conclusive but not sufficient for classification	6.2

Pyrophoric solids:			conclusive but not sufficient for classification	6.2
Self-heating substances and mixtures:			conclusive but not sufficient for classification	
Substances and mixtures which in contact with water emit flammable gases:			conclusive but not sufficient for classification	6.2
Oxidising liquids:			conclusive but not sufficient for classification	6.3
Oxidising solids:			conclusive but not sufficient for classification	6.3
Organic peroxides:			conclusive but not sufficient for classification	
Corrosive to metals:			conclusive but not sufficient for classification	

*) Justification for (non) classification can be found in the CSR section indicated

- for health hazards:

Endpoint	**Hazard category**	**Hazard statement**	**Reason for no classification**	**CSR section*)**
Acute toxicity - oral:			conclusive but not sufficient for classification	5.2.3
Acute toxicity - dermal:			conclusive but not sufficient for classification	5.2.3
Acute toxicity - inhalation:			conclusive but not sufficient for classification	5.2.3
Skin corrosion / irritation:			conclusive but not sufficient for classification	5.3.4 and 5.4.3
Serious damage / eye irritation:			conclusive but not sufficient for classification	5.3.4
Respiration sensitization:			conclusive but not sufficient for classification	5.5.3
Skin sensitation:			conclusive but not sufficient for classification	5.5.3
Aspiration hazard:			conclusive but not sufficient for classification	5.2.3

Reproductive Toxicity:	Repr. 1A Specific effect: H360D: May damage the unborn child	H360: May damage the unborn child		5.9.3
Reproductive Toxicity: Effects on or via lactation:			conclusive but not sufficient for classification	5.9.3
Germ cell mutagenicity:			conclusive but not sufficient for classification	5.7.3
Carcinogenicity:	Carc. 2	H351: Suspected of causing cancer by inhalation		5.8.3
Specific target organ toxicity - single:			conclusive but not sufficient for classification	5.2.3 and 5.3.4
Specific target organ toxicity - repeated:	STOT Rep. Exp. 1 Affected organs: May cause damage to the central nervous system and systems for reproduction through prolonged or repeated exposure	H372: Ccauses damage to the central nervous system and systems for reproduction through prolonged or repeated exposure		5.6.3

*) Justification for (non) classification can be found in the CSR section indicated

- for environmental hazards:

Endpoint	**Hazard category**	**Hazard statement**	**Reason for no classification**	**CSR section*)**
Hazards to the aquatic environment (acute/short-term):			conclusive but not sufficient for classification	7.5
Hazards to the aquatic environment (long-term):	Aquatic Chronic 3	H412: Harmful to aquatic life with long lasting effects.		7.5
Hazardous to the ozone layer:			conclusive but not sufficient for classification	7.5

*) Justification for (non) classification can be found in the CSR section indicated

Labelling

Signal word: Danger

Hazard pictogram:

GHS08: health hazard

Hazard statements:

H351: Suspected of causing cancer via inhalation
H360Df: May damage the unborn child
H372: Cause damage to the central nervous system and systems for reproduction through prolonged or repeated exposure
H412: Toxic to aquatic life with long lasting effects.

Precautionary statements:

P202: Do not handle until all safety precautions have been read and understood.
P260: Do not breathe dust/fume/gas/mist/vapours/spray.
P273: Avoid release to the environment.
P280: Wear protective gloves/protective clothing/eye protectionP308+P313: IF exposed or concerned: Get medical advice/attention.
P501: Dispose of contents/container in accordance with local regulation

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3.2. Classification and labelling according to DSD / DPD

3.2.1. Classification and labelling in Annex I of Directive 67/548/EEC

Chemical name: Diantimony trioxide (Representative sample)

Related composition: Diantimony trioxide (Representative sample)

Legal classification as laid out in Annex 1 of Directive 67/548/EEC.

Classification

The substance is classified as follows:

- for physicochemical properties

Endpoint	**Classification**	**Reason for no classification**	**CSR section*)**
Explosiveness:		conclusive but not sufficient for classification	6.1
Oxidising properties:		conclusive but not sufficient for classification	6.2
Flammability:		conclusive but not sufficient for classification	6.3
Thermal stability:		conclusive but not sufficient for classification	

*) Justification for (non) classification can be found in the CSR section indicated

- for health hazards:

Endpoint	Classification	Reason for no classification	CSR section*)
Acute toxicity:		conclusive but not sufficient for classification	5.2.3
Acute toxicity - irreversible damage after single exposure:		conclusive but not sufficient for classification	5.2.3
Repeated dose toxicity:		conclusive but not sufficient for classification	5.6.3
Irritation / Corrosion:		conclusive but not sufficient for classification	5.3.4 and 5.4.3
Sensitisation:		conclusive but not sufficient for classification	5.5.3
Carcinogenicity:	Carc. Cat. 3; R40 Limited evidence of a carcinogenic effect.		5.8.3
Mutagenicity - Genetic Toxicity:		conclusive but not sufficient for classification	5.7.3
Toxicity to reproduction - fertility:		conclusive but not sufficient for classification	5.9.3
Toxicity to reproduction - development:		conclusive but not sufficient for classification	5.9.3
Toxicity to reproduction - breastfed babies:		conclusive but not sufficient for classification	5.9.3

*) Justification for (non) classification can be found in the CSR section indicated

- for the environment

Endpoint	Classification	Reason for no classification	CSR section*)
Environment:		conclusive but not sufficient for classification	7.5

*) Justification for (non) classification can be found in the CSR section indicated

Labelling

Indication of danger:

Xn - harmful

R-phrases:

R40 - limited evidence of a carcinogenic effect

S-phrases:

S2 - keep out of the reach of children
S22 - do not breathe dust
S36/37 - wear suitable protective clothing and gloves

Chemical name: Diantimony trioxide - Composition medium PbO

Related composition: Diantimony trioxide - Composition medium PbO

Remarks: Classification based on legal classification as laid out in Annex 1 of Directive 67/548/EEC. The higher PbO impurity leads to a different classification than for the representative sample. **Classification**

The substance is classified as follows:

- for physicochemical properties

Endpoint	**Classification**	**Reason for no classification**	**CSR section*)**
Explosiveness:		conclusive but not sufficient for classification	6.1
Oxidising properties:		conclusive but not sufficient for classification	6.2
Flammability:		conclusive but not sufficient for classification	6.3
Thermal stability:		conclusive but not sufficient for classification	

*) Justification for (non) classification can be found in the CSR section indicated

- health hazards:

Endpoint	**Classification**	**Reason for no classification**	**CSR section*)**
Acute toxicity:		conclusive but not sufficient for classification	5.2.3
Acute toxicity - irreversible damage after single exposure:		conclusive but not sufficient for classification	5.2.3
Repeated dose toxicity:		conclusive but not sufficient for classification	5.6.3
Irritation / Corrosion:		conclusive but not sufficient for classification	5.3.4 and 5.4.3
Sensitisation:		conclusive but not sufficient for classification	5.5.3
Carcinogenicity:	Carc. Cat. 3; R40 Limited evidence of a carcinogenic effect.		5.8.3
Mutagenicity -		conclusive but not	5.7.3

Genetic Toxicity:		sufficient for classification	
Toxicity to reproduction - fertility:		conclusive but not sufficient for classification	5.9.3
Toxicity to reproduction - development:		conclusive but not sufficient for classification	5.9.3
Toxicity to reproduction - breastfed babies:		conclusive but not sufficient for classification	5.9.3

*) Justification for (non) classification can be found in the CSR section indicated

- for the environment:

Endpoint	**Classification**	**Reason for no classification**	**CSR section*)**
Environment:	R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.		7.5

*) Justification for (non) classification can be found in the CSR section indicated

Labelling

Indication of danger:

Xn - harmful

R-phrases:

R40 - limited evidence of a carcinogenic effect
R52/53 - harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment

S-phrases:

S2 - keep out of the reach of children
S22 - do not breathe dust
S36/37 - wear suitable protective clothing and gloves
S61 - avoid release to the environment. refer to special instructions/safety data sheets

Chemical name: Diantimony trioxide - Composition high PbO

Related composition: Diantimony trioxide - Composition high PbO

Remarks: Classification based on legal classification as laid out in Annex 1 of Directive 67/548/EEC. The higher PbO impurity leads to a different classification than for the representative sample.

Classification

The substance is classified as follows:

- for physicochemical properties

Endpoint	**Classification**	**Reason for no classification**	**CSR section*)**

Explosiveness:		conclusive but not sufficient for classification	6.1
Oxidising properties:		conclusive but not sufficient for classification	6.2
Flammability:		conclusive but not sufficient for classification	6.3
Thermal stability:		conclusive but not sufficient for classification	

*) Justification for (non) classification can be found in the CSR section indicated

- for health hazards:

Endpoint	**Classification**	**Reason for no classification**	**CSR section*)**
Acute toxicity:		conclusive but not sufficient for classification	5.2.3
Acute toxicity - irreversible damage after single exposure:		conclusive but not sufficient for classification	5.2.3
Repeated dose toxicity:	Xn; R48/20/22 Harmful: danger of serious damage to health by prolonged exposure through inhalation and if swallowed.		5.6.3
Irritation / Corrosion:		conclusive but not sufficient for classification	5.3.4 and 5.4.3
Sensitisation:		conclusive but not sufficient for classification	5.5.3
Carcinogenicity:	Carc. Cat. 3; R40 Limited evidence of a carcinogenic effect.		5.8.3
Mutagenicity - Genetic Toxicity:		conclusive but not sufficient for classification	5.7.3
Toxicity to reproduction - fertility:	Repr. Cat. 1; R60 May impair fertility.		5.9.3
Toxicity to reproduction - development:	Repr. Cat. 1; R61 May cause harm to the unborn child.		5.9.3
Toxicity to reproduction - breastfed babies:		conclusive but not sufficient for classification	5.9.3

*) Justification for (non) classification can be found in the CSR section indicated

- for the environment:

Endpoint	**Classification**	**Reason for no classification**	**CSR section*)**
Environment:	N; R51/53 Dangerous for the environment; Toxic to		7.5

	aquatic organisms, may cause long-term adverse effects in the aquatic environment.		

*) Justification for (non) classification can be found in the CSR section indicated

Labelling

Indication of danger:

T - toxic
N - dangerous for the environment

R-phrases:

R48/20/22 Harmful: danger of serious damage to health by prolonged exposure through inhalation and if swallowed.
R40 - Limited evidence of a carcinogenic effect
R51/53 - Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
R60 May impair fertility
R61 - May cause harm to the unborn child

S-phrases:

S2 - keep out of the reach of children
S22 - do not breathe dust
S36/37 - wear suitable protective clothing and gloves
S53 - avoid exposure - obtain special instructions before use
S61 - avoid release to the environment. refer to special instructions/safety data sheets

3.2.2. Self classification(s)

As ATO is mentioned in Annex I of 67/548/EC and current knowledge does not trigger additional classification there is no need for additional self-classification.

3.2.3. Other classification(s)

None.

4. ENVIRONMENTAL FATE PROPERTIES

General discussion of environmental fate and pathways:

Antimony metal and antimony containing compounds will dissolve and generate antimony ions (Vangheluwe et al., 2001). The environmental fate section will therefore discuss the fate of antimony in general. Antimony, being an elemental substance, cannot be degraded, but may be transformed between different phases, chemical species, and oxidation states.

The speciation and physico-chemical state of antimony are important for its behaviour in the environment and availability to biota. For example, antimony incorporated in mineral lattices is inert and unlikely to be bioavailable. Most analytical methods for antimony do not distinguish between the various forms of antimony. While the total amount of antimony may be known, the nature of the antimony compounds, the importance of adsorption, etc. are not. This information, which is critical in determining the availability of antimony, is likely to be site-specific (ATSDR, 1992).

There are uncertainties surrounding the thermodynamic data for Sb compounds and, as a consequence, the Eh-pH diagrams differ between different sources. Earlier diagrams suggest that antimony is immobile under oxidizing conditions, occurring as solid oxides (Brookins, 1988), but more recent diagrams show that in oxidizing conditions, $Sb(OH)_6^-$ is the most important species, confirming the relatively high mobility of Sb under oxidizing conditions (Filella et al., 2002a; Filella et al., 2002b).

The conclusions that are drawn in the EU Risk Assessment Report (RAR) for antimony trioxide on the fate of antimony in water are:

i) In natural waters antimony exists almost exclusively in the dissolved phase in the two valency states + 3 and + 5. Both Sb(III) and Sb(V) ions hydrolyse easily, and Sb(III) is present as the neutral species $Sb(OH)_3$, and Sb(V) as the anion, $Sb(OH)_6^-$.

ii) According to thermodynamic calculations, antimony should almost exclusively be present as Sb(V) in oxic systems and as Sb(III) in anoxic systems, when they reach equilibrium. Even though the dominant species in oxic waters is Sb(V), Sb(III) has been detected in concentrations much above what is predicted, and the reverse is true for Sb(V) in anoxic systems. It is clear from speciation measurements of well oxygenated antimony solutions (CanMET, 2010) that antimony oxidation processes in freshwaters are slow, with half-lives usually being in the order of months in laboratory solutions. Whilst there is evidence to suggest that factors such as UV light, dissolved organic carbon (DOC), and iron and manganese oxyhydroxide precipitates can all increase the rate of oxidation of Sb(III) to Sb(V), thermodynamic equilibrium is unlikely to be approached in natural waters. This is confirmed by the available monitoring data which include speciation measurements of Sb in the field. Equilibrium predictions of the chemical speciation of antimony in natural waters must therefore be treated with caution.

iii) Reports exist on both conservative behaviour (i. e. the concentration only changes with dilution or evaporation), and a behaviour corresponding to a mildly scavenged element with surface (atmospheric) input.

iv) In addition to the inorganic forms of antimony, there also exist methylated forms of trivalent and pentavalent antimony.

v) Interactions between the antimony species (anionic $Sb(OH)_6^-$ or the neutral $Sb(OH)_3$) present in natural waters and the predominantly negatively charged natural organic matter may occur, but firm conclusions cannot currently be drawn on its overall importance in Sb speciation.

vi) Transformation/dissolution studies indicate that diantimony trioxide solubility is dependent on the pH conditions, being more soluble at pH 8 than at pH 6. The maximum observed dissolution was 0.18 mg l^{-1} from a 1 mg l^{-1} loading after 28 days. Redox and salinity conditions may also affect the rate of dissolution. Antimony metal and $NaSb(OH)_6$ showed greater solubility in transformation/dissolution tests, although 1 mg l^{-1} loadings resulted in concentrations of up to only 0.6 mg l^{-1} after 28 days (CanMET, 2010).

As no information is available about the relative toxicities of the different forms of antimony, and speciation analysis of environmental samples is also extremely uncommon, the PEC is expressed in terms of the dissolved antimony concentration.

The conclusions that are drawn in the EU RAR for antimony trioxide on the fate of antimony in sediment are:

i) The adsorption of antimony in oxic sediments has been correlated with the presence of iron-, manganese-, and aluminium oxides.

ii) The decrease in bioavailable antimony in water by oxic sediments is not a permanent decrease, as the adsorption on the hydrous oxides is dependent on both pH and oxic condition (which may change). This is largely due to the redox cycling of iron (oxy) hydroxide precipitates with which antimony may be associated. In addition, antimony may become bioavailable to organisms inhabiting the sediment through ingestion of the sediment.

iii) In anoxic systems, and in the presence of sulphur, antimony forms soluble or insoluble stibnite, $SbS_2^-$and $Sb_2S_3(s)$, respectively, depending on pH. This may result in a larger decrease in bioavailable antimony, when compared to the oxic part of the sediment.

The conclusions that are drawn in the EU RAR for antimony trioxide on the fate of antimony in soil are:

i) The sorption and precipitation of $Ca[Sb(OH)_6]_2$seems to be a more important process overall in the fate of antimony in the environment than the dissolution processes of Sb_2O_3.

ii) The solubility of antimony compounds depends on the soil conditions (Eh/pH) and the time given to dissolve. The results of transformation/dissolution tests indicate that some antimony substances may be more soluble at higher pH (e. g. pH 8.5) than at low pH (e. g. pH 6).

iii) The most important soil characteristic to influence the mobility of antimony in soil (and sediments), appears to be the presence of hydrous oxides of iron, manganese, and aluminium, to which antimony may adsorb. In addition, these hydrous oxides seem to oxidise dissolved trivalent antimonite ($Sb(OH)_3$) to the pentavalent antimonate ($Sb(OH)_6^-$).

iv) The largest effect of pH on sorption seems to be around pH 3 - 4, with decreasing sorption at higher pH values. The effect of pH as such is probably less important when compared to the effect of the hydrous oxides. The effect of pH on antimony mobility seems to be via the influence of hydrous oxides on the valence of antimony and the solubility of the antimony compound, and also via the increasing negative charge of the soil at increasing pH (and hence, weaker sorption of the negatively charged $Sb(OH)_6^-$).

v) Due to the anionic character of the dissolved species ($Sb(OH)_6^-$), antimony is expected to have a low affinity for organic carbon. However, there are results that indicate that the sorption of Sb(V) by humic acid in acid soils with high proportions of organic matter may be more important than previously suspected, although the strong Sb(V) scavenging potential of $Fe(OH)_3$probably results in a diminished role of organic matter binding in soils with high amounts of amorphous hydroxides.

vi) The cationic exchange reactions, which are the main sorption reactions on clay minerals, are not expected to be important for the anionic antimony.

vii) Initial differences in sorption depending on the type of antimony compound diminish with time.

viii) The influence of the concentration of added antimony on sorption appears to be small.

ix) A higher Sb porewater concentration can be achieved in transformation studies when using Sb_2O_3, when compared to $SbCl_3$. The limiting factor appears to be precipitation of $Ca[Sb(OH)_6]_2$.

The conclusions that are drawn in the EU RAR for antimony trioxide on the fate of antimony in air are:

i) Anthropogenic activities may result in long-range transport of antimony far from its source.

ii) Combustion/incineration processes transform antimony compounds to diantimony trioxide regardless of the pre-incinerated form of antimony.

iii) There are indications that diantimony trioxide may dissolve in the atmosphere and that the trivalent form will oxidise to the pentavalent form.

4.1. Degradation

4.1.1. Abiotic degradation

4.1.1.1. Hydrolysis

Data waiving

Reason: study scientifically unjustified

Justification: In accordance with section 1 of REACH Annex XI the hydrolysis study does not need to be conducted as abiotic degradation rates are not relevant to metals.

4.1.1.2. Phototransformation/photolysis

4.1.1.2.1. Phototransformation in air

This information is not applicable to antimony.

4.1.1.2.2. Phototransformation in water

This information is not applicable to antimony.

4.1.1.2.3. Phototransformation in soil

This information is not applicable to antimony.

4.1.2. Biodegradation

4.1.2.1. Biodegradation in water

4.1.2.1.1. Estimated data

This endpoint has been waived (see explanation below).

4.1.2.1.2. Screening tests

Information requirement: Biodegradation in water: screening test

Data waiving

Reason: other justification

Justification: In accordance with column 2 of REACH Annex VII, the ready biodegradability study does not need to be conducted as the substance is inorganic.

4.1.2.1.3. Simulation tests (water and sediments)

Data waiving

Information requirement: Simulation testing for biodegradation in water and sediment

Reason: other justification

Justification: In accordance with column 2 of REACH Annex VII, the biodegradability study does not need to be conducted as the substance is inorganic.

4.1.2.2 Biodegradation in sediments

This endpoint has been waived(In accordance with column 2 of REACH Annex VII, the biodegradability study does not need to be conducted as the substance is inorganic).

4.1.2.3. Summary and discussion of biodegradation in water and sediment

This endpoint has been waived (see explanation below).

4.1.2.4. Biodegradation in soil

Information requirement: Soil simulation testing

Data waiving

Reason: other justification

Justification: In accordance with column 2 of REACH Annex VII, the biodegradability study does not need to be conducted as the substance is inorganic.

4.1.3. Summary and discussion of degradation

Antimony metal and antimony containing compounds will dissolve and generate antimony ions (Vangheluwe et al*.,* 2001). The environmental fate section will therefore discuss the fate of antimony in general. Antimony, being an elemental substance, cannot be degraded, but may be transformed between different phases, chemical species, and oxidation states.

4.2. Environmental distribution

4.2.1. Adsorption/desorption

The studies on adsorption/desorption are summarised in the following table:

Table 18:Overview of studies on adsorption/desorption

Method	**Results**	**Remarks**	**Reference**
Study type: transformation experiment (soil) Determination of total Sb concentration added and Sb pore water concentration after certain incubation time. The experiment was performed on 2 soils, one sandy soil and one loamy soil over a 24 week period: soils were incubated at 20º C, with a final humidity of 22g/100g dry substance (both soils). The incubation was initiated with 2 drying/rewetting cycles.	Adsorption coefficient: log Kp: 1.91 at 20° C (control sandy soil) log Kp: 2.18 at 20° C (control loam soil) log Kp: 1.32 at 20° C (10 mg Sb/kg sandy soil) log Kp: 1.41 at 20° C (10 mg Sb/kg loam soil) log Kp: 1.48 at 20° C (50 mg Sb/kg sandy soil) log Kp: 1.88 at 20° C (50 mg Sb/kg loam soil)	2 (reliable with restrictions) weight of evidence read-across from supporting substance (structural analogue or surrogate) **Test material: Diantimony trichloride**	Vangheluwe M, Vandenbroele M, Van Sprang P, Smolders E, Degryse F (2001)

Method	Results	Remarks	Reference
Study type: summary study (soil) Total concentrations Sb_2O_3 was mixed with the soil in a mechanical homogenizer. The soils were treated with 32 or 1,000 mg Sb/kg (Sb_2O_3). The evolution of chemical activity of Sb in the soil was studied by extraction with H_2O, NH4-Ac-EDTA, 0.5N HNO_3 and 0.2 N NaOH after different incubation times of Sb in the soils. The solubility of the pure Sb_2O_3 was determined as follows: mixing of 200 mg pure Sb_2O_3 with 50 ml extraction product during 30 min equilibration time followed by filtration. 200 mg Sb_2O_3 was also added to 10g soil; extraction followed immediately.	Adsorption coefficient: log Kp: 1.78 (32 mg Sb/Kg sandy soil) log Kp: 2.34 (1000 mg Sb/kg sandy soil) log Kp: 1.97 (32 mg Sb/kg heavy clay soil) log Kp: 2.21 (1000 mg Sb/kg heavy clay soil)	2 (reliable with restrictions) weight of evidence read-across from supporting substance (structural analogue or surrogate) **Test material: diantimony trioxide**	Pauwels J (1985)
Study type: Sorption and non exchangeability tests (soil) batch equilibrium method 10 g of soil were equilibrated for 6 days with 81 mL of a solution containing 0.19 mol/m3 Sb (40 mg/L of each element). Soil-solution mixtures were contained in weighed, 100 mL centrifuge tubes, which were held in an end-over-end shaker. Suspensions were centrifuged and the supernantant removed for metal analysis by flame atomic absorption spectroscopy. The tube containing the soil and the entrainment solution was weighed and the soil equilibrated with 1M KCl to remove the exchangeable from of the metal. After centrifugation, the supernatant was assayed for metal concentration. The weight and metal concentration of the entrained solution from the first equilibration step were used to correct the measured concentration.	Adsorption coefficient: log Kp: 1.44 (sandy soil) log Kp: 2.35 (loam soil) log Kp: 1.98 (clay soil) log Kp: 2.08 (humous rich soil)	2 (reliable with restrictions) weight of evidence read-across from supporting substance (structural analogue or surrogate) **Test material (element): antimony**	King LD. (1988)
Study type: adsorption/desorption (soil) batch equilibrium method	Adsorption coefficient: Kp: 1 — 2065 (110 Japanese soils) log Kp: 1.79 (geometric mean	2 (reliable with restrictions) weight of evidence	Nakamaru Y, Tagami K & Uchida S. (2006)

Method	Results	Remarks	Reference
Kp was measured for 110 soil samples by the batch technique using 124Sb (half life: 60.2 d) as a tracer. The Kp measurements for all samples were carried out in triplicate. Three grams of each soil sample were placed in a polypropylene bottle (50 mL) and 30 mL of deionized water were added. Prior to adding 124Sb, the suspension was preconditioned by shaking for 24 h at 23 °C in an end-overend shaker (TAITEC, BR-160LF). About 30 kBq of 124Sb including about 0.3 mg of stable Sb carrier were then added as Sb(III) (SbCl3). After 7 d, the sample suspension was separated by centrifugation at 3000 rpm for 20 min, and the supernatant was filtered though a 0.45-mm membrane filter. Gamma rays (0.603 MeV) of 124Sb in the filtrate were measured with a NaI scintillation counter (Aloka, ARC-300) to determine its activity concentration. From preliminary tests, the 7-d shaking time was sufficient to achieve equilibrium of Sb sorption. To specify Sb forms in the batch process, 12 samples were selected as they are typical Japanese soils. This set was also used for the NH4NO3 extraction. The Eh and pH of the soil suspensions were measured. Each filtrate was passed through two ion exchange columns separately charged with cation exchange resin (Powdex, PCH) and anion exchange resin (Powdex, PAO). By measuring the 124Sb in the drainages, the proportions of anion and cation fractions of 124Sb in the soil solution were determined.	excluding outlying value of 2065)	read-across from supporting substance (structural analogue or surrogate) **Test material: antimony trichloride**	
Study type: adsorption/desorption (soil) Measurement of soil solution from spiked soil samples 5 concentrations of SbCl3 were added to soil samples, to give concentrations between 0 - 82 mmol Sb/kg, along with a control	Adsorption coefficient: log Kp: 1.6 at 20° C (Kd 38 L/kg)	2 (reliable with restrictions) weight of evidence read-across from supporting substance (structural analogue or surrogate) **Test material:**	Oorts et al (2008)

Method	Results	Remarks	Reference
sample containing no Sb. Soil solution was sampled in triplicate between 2 and 35 days after amendment.		**antimony trichloride**	
Study type: adsorption/desorption (soil) Added a concentration of 0 - 50 mg Sb/kg dw. Pore water extractions taken after 24 weeks incubation at 22 % water content or after 30 weeks incubation at field capacity	Adsorption coefficient: log Kp: 1.2 — 1.9 (sandy soil) log Kp: 1.3 — 2.2 (loam soil)	2 (reliable with restrictions) weight of evidence read-across from supporting substance (structural analogue or surrogate) **Test material: antimony trichloride**	Vangheluwe M, Vandenbroele M, Van Sprang P, Smolders E, Degryse F (2003)
Study type: adsorption/desorption (soil) batch equilibrium method A batch method was used. Soil, Sb(V) stock and Milli-Q water were added to 50 ml vials with a final volume of 40 ml. 1M HCl or NaOH were added to the vials to give pH ranges between 2.5 and 7. Samples were mixed in a rotating unit for 24 hours, then centrifuged and filtered. Aqueous samples were then analysed using ICP-MS.	Adsorption coefficient: log Kp: 1.9 — 3.1 (loam soil)	2 (reliable with restrictions) weight of evidence read-across from supporting substance (structural analogue or surrogate) **Test material (element): Potassium antimonate**	Tighe M, Lockwood P & Wilson S (2005)
Study type: desorption (soil) Extraction of antimony from soils using deionised water Soils were sampled from an area contaminated from mining and smelting activities, consisting of tilled soils and forest soils. Extraction was carried out using deionised water at a solid: solution ratio of 1:10. Suspensions were prepared in duplicate. Suspensions were agitated on a table shaker (60 rpm) at 23 ± 2° C, centrifuged for 10 minutes at 4000 rpm and filtered through 0.45 um membrane filters. Prior to analysis extracts were diluted in 2 % HNO3. Concentrations were determined using ICP-MS.	Adsorption coefficient: log Kp: 2.8 — 2.9 (forest soil) log Kp: 2.8 — 3.2 (tilled soil)	2 (reliable with restrictions) weight of evidence read-across from supporting substance (structural analogue or surrogate) **Test material (element): antimony**	Ettler V, Mihaljevic M, Sebek O& Nechutny Z (2007)
Study type: desorption (soil) Soil samples were shaken with	Adsorption coefficient: log Kp: 2.4 — 4	2 (reliable with restrictions)	Fuentes E, Pinochet H, De Gregori I & Potin-

Method	Results	Remarks	Reference
water and Sb concentrations measured in soil and solution Aliquots of 1g dry soil were weighed into 50 ml polypropylene vessels with 10 ml H_2O. Vessels were shaken for 24 hours at room temperature at 150 rpm. Slurries were centrifuged at 10° C for 30 minutes at 4000 rpm and the supernatant decanted off. Sb (III) and Sb(V) concentations in the soil and in the solutions were then determined.		weight of evidence read-across from supporting substance (structural analogue or surrogate) **Test material (element): antimony**	Gautier M (2003)
Study type: desorption (soil) Antimony extracted from soil samples using water Aliquots of soil samples were weighed and added to polypropylene vessels with water in a solid: liquid ratio of 1:10. Vessels were shaken at room temperature for 24 hours. Sample solutions were centrifuged at 3500 rev/ min and then 17.000 rev/min to obtain clear solutions. Samples were filtered before HPLC analysis. Extractions were carried out in triplicate. Sample blanks were prepared and concentrations of the extracts were corrected by subtracting the corresponding blank concentration.	Adsorption coefficient: log Kp: 3.8 — 4.1	2 (reliable with restrictions) weight of evidence read-across from supporting substance (structural analogue or surrogate) **Test material (element): antimony**	Lintschinger J, Michalke B, Schulte-Hostede S & Schramel P (1998)
Study type: adsorption (soil) soil and pore water samples were taken in the field and Sb concentrations measured Soil samples were taken from from a woodland area, at different depths down the soil profile. Pore water samples were taken using pairs of 'Rhizon' pore water samplers, at 10 cm intervals to a depth of 50 cm. They were left to equilibriate for four weeks, then sampled. Soil samples were oven dried to constant weight at 40° C then passed through a 2 mm sieve. Samples were analysed using ICP-MS.	Adsorption coefficient: log Koc: 1.8 — 2.4	2 (reliable with restrictions) weight of evidence read-across from supporting substance (structural analogue or surrogate) **Test material (element): antimony**	Clemente R, Dickinson NM & Lepp NW (2008)
Study type: monitoring data (Water and suspended particle	Adsorption coefficient:	2 (reliable with restrictions)	Habib S & Minski MJ (1982)

Method	Results	Remarks	Reference
matter) Total concentrations. Concentrations in water and suspended particle matter were measured to allow calculation of Kp values.	log Kp: 4.5 (River Thames)	weight of evidence read-across from supporting substance (structural analogue or surrogate) **Test material (element): antimony**	
Study type: Monitoring data (water and suspended particulate matter) Sb total, Sb(III) and Sb(V) concentrations. Concentration of antimony in water and suspended particulate matter to allow calculation of Kp values.	Adsorption coefficient: log Kp: 3.3 (Solo River)	2 (reliable with restrictions) weight of evidence read-across from supporting substance (structural analogue or surrogate) **Test material (element): antimony**	Van der Sloot HA, Hoede D & Wijkstra J (1989)
Study type: Monitoring data (filtered and unfiltered water samples.) Total and soluble concentrations. Concentration in water and suspended particles reported to allow calculation of Kp values.	Adsorption coefficient: log Kp: 3.54 (10th percentile of 119 samples) log Kp: 4.14 (50th percentile of 119 samples) log Kp: 4.64 (90th percentile of 119 samples)	2 (reliable with restrictions) weight of evidence read-across from supporting substance (structural analogue or surrogate) **Test material (element): antimony**	Veselý J, Majer V, Kucera J & Havránek V (2001)
Study type: Monitoring study (Water and suspended particulate matter) Total concentrations. Concentration in water and suspended particulate matter reportedto allow calculation of Kp values.	Adsorption coefficient: log Kp: 3.52 log Kp: 3.64	2 (reliable with restrictions) weight of evidence read-across from supporting substance (structural analogue or surrogate) **Test material (element): antimony**	Van der Sloot HA, Hoede D, Wijkstra J, Duinker JC & Nolting RF. (1985)
Study type: monitoring data (water and suspended particles) Total and soluble concentrations. Concentration in water and suspended matter reported to allow calculation of Kp values.	Adsorption coefficient: log Kp: 4.07 (Hudson river) log Kp: 4 (Hudson river mixed with sea water)	2 (reliable with restrictions) weight of evidence read-across from supporting substance (structural analogue or surrogate)	Li X, Burkhardt L & Teraoka H (1984)

Method	Results	Remarks	Reference
		Test material (element): antimony	
Study type: monitoring study (sediment) Total concentrations. Concentration in sediments and water reported to allow calculation of Kp values.	Adsorption coefficient: log Kp: 3.17 (Solo River) log Kp: 3 (Wono Kromo River) log Kp: 3.72 (Porong River)	2 (reliable with restrictions) weight of evidence read-across from supporting substance (structural analogue or surrogate) **Test material (element): antimony**	Hoede D, Wijkstra J & Van der Sloot HA (1987)
Study type: monitoring data (Water and suspended particle matter) Total concentrations. Concentration in sediments and water are reported to allow calculation of Kp values.	Adsorption coefficient: log Kp: 3.4 (world rivers average) log Kp: 3.5 (world oceans average)	4 (not assignable) weight of evidence estimated by calculation **Test material (element): antimony**	Martin J-M & Whitfield M (1983)
Study type: Monitoring data. (sediment) Total concentrations. Concentration in sediments and water reported to allow calculation of Kp values.	Adsorption coefficient: Kp: 41 — 4218 log Kp: 1.6 — 3.63	2 (reliable with restrictions) weight of evidence read-across from supporting substance (structural analogue or surrogate) **Test material (element): antimony**	Brannon JM & Patrick WH. (1985)
Study type: Monitoring data (sediment) Total Sb concentrations in sediments and water. Concentration in sediments and water reported to allow calculation of Kp values.	Adsorption coefficient: log Kp: 3.68 (Katsura river, upstream STP) log Kp: 2.55 (Katsura river, 5km downstream STP) log Kp: 2.51 (Katsura river, close downstream STP) log Kp: 3.95 (Kamo river, upstream STP) log Kp: 2.47 (Uji river, downstream STP)	2 (reliable with restrictions) weight of evidence read-across from supporting substance (structural analogue or surrogate) **Test material (element): antimony**	Kawamoto Y & Morisawa S (2003)
Study type: Monitoring data. (sediment) Total concentrations.	Adsorption coefficient: log Kp: 4.2 (Bravona river, reference site B1) log Kp: 3.3 (Bravona river, reference site B2)	2 (reliable with restrictions) weight of evidence	Mori C, Orsini A & Migon C (1999)

Method	Results	Remarks	Reference
Concentration in sediments and water reported to allow calculation of Kp values.	log Kp: 2.99 (Bravona river, slightly polluted B3) log Kp: 3.05 (Bravona river, slightly polluted B4) log Kp: 3.3 (Bravona river, slightly polluted B5) log Kp: 2.69 (Bravona river, slightly polluted B6) log Kp: 3.51 (Presa river, reference site P1) log Kp: 3.65 (Presa river, polluted P2) log Kp: 2.89 (Presa river, polluted P3) log Kp: 3.12 (Alzillelo river, reference site A1)	read-across from supporting substance (structural analogue or surrogate) **Test material (element): antimony**	
Study type: desorption (sediment) Extraction of antimony from soils using deionised water Soils were sampled from an area contaminated from mining and smelting activities, consisting of tilled soils and forest soils. Extraction was was carried out using deionised water at a solid: solution ratio of 1:10. Suspensions were prepared in duplicate. Suspensions were agitated on a table shaker (60 rpm) at 23 ± 2° C, centrifuged for 10 minutes at 4000 rpm and filtered through 0.45 um membrane filters. Prior to analysis extracts were diluted in 2 % HNO3. Concentrations were determined using ICP-MS.	Adsorption coefficient: log Koc: 3 — 3.7	2 (reliable with restrictions) weight of evidence read-across from supporting substance (structural analogue or surrogate) **Test material (element): antimony**	Ettler V, Mihaljevic M, Sebek O & Nechutny Z (2007)
Study type: desorption (sediment) Water and sediment samples were taken from the same sites and analysed for Sb concentration Water and sediment samples were collected at 4 stations. Water samples were filtered through a 0.45 µm cellulose nitrate filter and acidified to pH 2 with HNO3 within 24 hours of collection. The upper 5 cm of sediment were collected, passed through a 1mm mesh, dried at room temperature and crushed to	Adsorption coefficient: log Koc: 3.2 — 3.8	2 (reliable with restrictions) weight of evidence read-across from supporting substance (structural analogue or surrogate) **Test material (element): antimony**	Sola and Prat (2006)

Method	Results	Remarks	Reference
particles smaller than 150 µm. Three subsamples were digested with HCl and HNO3. Concentrations of Sb were analysed using inductively coupled plasma mass spectrometry.			
Study type: adsorption (sediment) Environmental water and sediment samples taken and analysed for Sb concentrations Sediment and water samples were taken at 27 widely distributed sites in the Famatina Range. Water samples were analysed directly by ICP-MS. For sediment samples 0.1 g of sediment were digested in HNO3:HClO4:HF (2.5:2.5:5, v/v), doubly evaporated to incipient dryness with HNO3 and made up to 100ml in 2 % HNO3 in preparation for ICP-MS analysis.	Adsorption coefficient: log Kp: 1.8 — 3.6	2 (reliable with restrictions) weight of evidence read-across from supporting substance (structural analogue or surrogate) **Test material (element): antimony**	Fernandez-Turiel JL, Lopez-Soler A, Llorens JF, Querol X, Acenolaza (1995)
Study type: adsorption (soil) Nearly 500 soil samples from across Europe were equilibrated with CaCl2 (1:10 m/v). Samples were then spiked with 20 µl of 500 mg Sb(V)/L solution as antimony(V) chloride and mixed for a further 72 h. Samples were centrifuged at 1200 g for 20 min and supernatants filtered to <0.22 µm. The Sb concentrations in filtered solutions were determined by ICPMS.	Adsorption coefficient: log Kp: 1.8 (Median value of 498 soils. Range 0-3.74)	2 (reliable with restrictions) weight of evidence read-across from supporting substance (structural analogue or surrogate) **Test material: Antimony (V) chloride**	Janik L, Forrester S, Kirby JK & McLaughlin MJ (2010)

Discussion

Transport of metals between aqueous phase and soil/sediment/suspended matter should be described on the basis of measured soil/water, sediment/water and suspended matter/water equilibrium partition coefficients (Kp), instead of using common mathematical relationships based on, for example, octanol-water partition coefficients, as is usually done for organic chemicals (TGD, 1996). The use of the median Kd value for environmental risk assessment is stipulated in the ECHA guidance R.7.13-2 section 2.2.2 (2008).

Kp_{soil}

Four reliable studies were identified in the EU RAR for diantimony trioxide which report soil Kp.

Vangheluwe et al. (2001) report the results of a transformation experiment in soil using Sb_2O_3 and $SbCl_3$. The transformation experiment was performed for a duration of 24 weeks, with soils incubated at 20º C, with a final humidity of 22 g/100g dry substance (both soils). The incubation was initiated with 2 drying/rewetting cycles. Calculation of the Kp_{soil}, using a control soil in Vangheluwe et al. (2001), results in a partition coefficient in sandy soils of 81 l/kg (log Kp_{soil}= 1.91) and 150 l/kg (log Kp_{soil}= 2.18) in loamy soils. In the control the concentration was 0.57 mg Sb/kg in sandy soil and 0.45 mg Sb/kg in loamy soil. The corresponding pore water concentrations were 7mg Sb/l and 3mg Sb/l, respectively. The lowest applied Sb dose in this experiment (10 mg Sb/kg; Sb_2O_3), which is higher than normally expected in the environment, resulted in the Kp_{soil}values of 26 l/kg (log Kp_{soil}= 1.41) and 21 l/kg (log Kp_{soil}= 1.32) for sandy and loamy soil, respectively. The distribution coefficient Kd between soil and pore water was calculated to be 30 l/kg (log Kp_{soil} = 1.48) for 50 mg Sb/kg applied as $SbCl_3$ in sandy soil and 75 l/kg (log Kp_{soil}= 1.88) in a loamy soil.

Pauwels (1985) studied the distribution of Sb in soil and the uptake by plants for soils from Belgium and Algeria. The soils were treated with 32 or 1,000 mg Sb/kg (Sb_2O_3). The Kp in sandy soil (pH = 5.7) was 60 (log Kp_{soil}= 1.78) and 128 (log Kp_{soil}= 2.34) for the low and high concentrations, respectively, while in a soil with heavy clay (pH = 7.8) the Kp was 94 (log Kp_{soil}= 1.97) and 161 (log Kp_{soil}= 2.21) for the low and high concentrations, respectively.

King (1988) performed batch experiments with 13 soil series samples (pH: 4.2-6.5, clay 2-63 %) taken from the south east of England). The equilibrium concentration of antimony was <1 to 100 mg/l, which ranges from background levels to much above background levels. As regards the importance of pH, no pH dependence of Kd values of Sb was found in the study of King (1988), but Kd values were correlated with oxide content and with clay content. Since the pH effect on Sb sorption is quite small, this pH effect is probably hidden by the effect of oxide content, when comparing different soils.

Based on the soil classification system developed by USDA (1967) the soil types sand (n = 2), sandy loam (n = 2), sandy loam-loam (n = 1), loam (n = 1), sandy clay loam-clay loam (n = 1), clay (n = 1) and silt loam (n = 1) were identified. In addition one humus-rich soil sample with no data on sand, silt or clay is also available. Two additional humus-rich soil samples were excluded since it was not possible to calculate partition coefficients from the data available. In order not to have a disproportionately large influence of the different soil types in this study (the majority consisting of only one or two values), when compared to data from other studies, it was decided to combine the different loam soils, resulting in one sand soil (n = 2; Lakeland-A, Norfolk-Ap), one loam soil group (n = 7; Cecil-Ap, Davidson-Ap, Mecklenburg-Ap, Wahee-A, Iredell-Ap, White Store-A, Portsmouth-Ap), one clay soil group (n = 1; Hayesville-A), and one humus-rich soil (n=1; Wasada-Ap). The corresponding (median; for the sand and loam soils) log values are 1.44, 2.35, 1.98, and 2.08, respectively.

Nakamura et al. (2006) studied the mobility of antimony in Japanese agricultural soils by radiotracer experiments using^{124}Sb tracer. The Kd values for Sb (0.1 mg Sb/kg added as $SbCl_3$, 7 days equilibration) measured in 110 Japanese soils ranged from 1 to 2065 l/kg, with a geometric mean of 62 l/kg (Log Kp_{soil}= 1.79) excluding one extremely high value of 2065 l/kg. Experimental measurements of Kd showed a decrease with both increasing pH and increasing phosphate concentration. The latter suggested that one aspect of the antimony sorption in Japanese soils was influenced by specific adsorption of anions such as phosphate. However, other aspects could not be explained by this specific adsorption mechanism, because only 20-40 % of soil-sorbed antimony could be extracted by phosphate solution.

Four sources for log Kp_{soil}values for antimony were identified in the EU RAR:

i) The study by Vangheluwe et al. (2001), which contain the log Kp_{soil} for sandy and loamy soils. The corresponding partition coefficients for the two control soils were 1.91 and 2.18; for the 10 mg Sb/kg exposure group it was 1.41 and 1.32. In another experiment using 50 mg Sb/kg the partition coefficients 1.48 and 1.88 were obtained for sandy and loamy soil, respectively.

ii) The study by Pauwels (1985), which resulted in the log Kp_{soil}values of 1.78, 2.34, 1.97, and 2.21, with the first two values coming from a sandy soil and the last two values from a soil with heavy clay.

iii) The study by King (1988), which resulted in the values 1.44, 2.35, 1.98, and 2.08 for the sand, loam, clay and humus-rich soils, respectively.

iv) The study by Nakamura et al. (2006), which resulted in the log Kp_{soil}1.79.

However, in order to try to give equal weight to results from different studies performed in different types of soils at different concentrations only one value for each soil type from each study will be used. Since the “loading dependence” for antimony in soil does not seem to be important (see above) a median value of the partition coefficients will be taken for the different concentrations used for each soil type. This means that the data points (log Kp_{soil}values) resulting from the study by Vangheluwe et al. (2001), will be used in this CSR, and will be 1.48 for sandy soil (median value of 1.91, 1.32, and 1.48), and 1.88 for loamy soil (median value of 2.18, 1.41, and 1.88). The resulting data points from the study by Pauwels (1985) would be 2.06 for sandy soils (median value of 1.78 and 2.34) and 2.09 for the soil with heavy clay (median value of 1.97 and 2.21). The values from King (1988) are 1.44, 2.35, 1.98, and 2.08, and the value from Nakamaru et al. (2006) is 1.79. Thus, the resulting values (log Kp_{soil}) are 1.48, 1.88, 2.06, 2.09, 1.44, 2.35, 1.98, 2.08 and 1.79. Based on these nine data points, it was decided to use the median value in the EU RAR (log Kp_{soil}= 1.98).

A further eight studies have since been identified that report additional log Kp soil values for antimony. Four of these studies (Ettler et al. 2007, Fuentes et al. 2003, Lintschinger et al. 1998 and Clemente, Dickinson and Lepp 2008) investigate how easily antimony in soils is desorbed. All four studies used soils collected from sites which were potentially exposed to antimony either due to mining and smelting operations or industrial use of antimony. Following the approach taken in the EU RAR, log Kp values are calculated for each soil type reported in each study. This results in log Kp values of 2.85 (forest soil) and 3 (tilled soil) (Ettler et al., 2007), 3.2 (Fuentes et al., 2003), 3.95 (Lintschinger et al., 1998) and 2.1 (Clemente et al., 2008).

Oorts et al. (2008) spiked soil from an agricultural field with antimony trichloride at concentrations from 0-1000 mg Sb/kg. The concentration of antimony in the soil solution was monitored from 2-35 days after spiking. A linear relationship between soil solution Sb concentration and dose was observed up to 500 mg Sb/kg, above which the soil solution Sb concentration remained constant. The log Kp was calculated from the linear portion of the graph as 1.6.

Vangheluwe et al. (2003) spiked a sandy soil and a loam soil with antimony trichloride at concentrations from 0-50 mg Sb/kg. The concentration of antimony in the soil solution was monitored after 24 weeks at 22% water content, or after 30 weeks at field capacity. Concentrations in the soil solution ranged from 0.007-3.82 (sandy soil) and 0.003-0.86 (loam soil). The log Kp was calculated as 1.55 for the sandy soil and 1.75 for the loam.

Tighe, Lockwood and Wilson (2005) spiked two floodplain (loam) soils with potassium antimonate at a range of concentrations (0-11.3 mg Sb/l). After 1 day's equilibration the concentration of Sb in the aqueous phase was analysed and Freundlich isotherms constructed. The log Kp values ranged from 1.9-3.1 for both soils. As both soils are classed as loams the median log Kp of 2.5 is used in this assessment.

Based on the nine data points from the EU RAR and the additional nine data points identified here, we have decided to use the median value in the assessment (log Kp_{soil}= 2.07). This value is very similar to the value used in the EU RAR (log Kp_{soil}= 1.98).

New data has recently become available. Janik et al (2010) determined the Log Kp of antimony in nearly 500 soils collected from across Europe. Antimony was applied as antimony (V) chloride (5 mg Sb/kg) and allowed to equilibrate for 72 hours. After this time the solid solution partitioning coefficient for each soil was determined. The measured Log Kp values ranged from 0 -3.74, with a median value of 1.8. The range of Log Kp values reported in this study spans the range reported by other researchers and reported here. As the results from this study cover a wide number of soils, of different types the median value is not used to influence the Log Kp used in the risk assessment, but is used to confirm that the Log Kp of 2.07 used for soil is an appropriate value. The use of the median Kd value for environmental risk assessment is stipulated in the ECHA guidance R.7.13-2 section 2.2.2 (2008).

$Kp_{suspended\ matter}$

Partition coefficients for the distribution of metals between water and suspended matter are used to calculate the dissolved concentrations from total concentrations in surface water. Seven reliable studies were identified in the EU RAR for diantimony trioxide which report suspended matter Kp.

Habib and Minski (1982) reported mean concentrations of antimony in soluble and suspended particulate fractions of 0.27 µg Sb/l and 8.4 mg Sb/kg, respectively, for three stations on the River Thames. The sampling covered a 10-month period, with a sampling frequency of every second week. Each sampling was performed and completed within five hours. The resulting log Kp value is 4.49 l/kg.

Martin and Whitfield (1983) report a log Kp suspended matter of 3.4 representing a world river average.

Van der Sloot et al. (1989) determined metal concentrations of particulate matter in the Solo River (Indonesia). Sampling of the particulate matter involved continuous flow centrifugation of water. Particulate matter was obtained in two size/density fractions. The metal content of the particulate matter was determined using neutron activation analysis (NAA). The metal concentrations of the water samples (0.45 µm filtered) were determined with NAA after a preconcentration procedure. For the calculation of the Kp values the average metal content of the two size fractions was used. The average log Kp value is 3.3 l/kg.

Veselý et al. (2001) derived partition coefficients for 41 elements, among them antimony, from water samples collected from 54 Czech rivers at 119 localities over the whole state territory in the summers of 1997 and 1998 under stable hydrological conditions. The analysed river waters had a mean pH of 7.74 (range 6.9 to 8.8), ionic strength 7.8 mmol/l, specific conductance 538mS/cm at 25º C, alkalinity of 1.9 mmol, and moderate mean contents of suspended particulate matter (SPM) of 9.9 mg/l (range 1.0-124 mg/l). The 10th, 50th and 90thpercentile of the log $Kp_{suspended\ matter}$were 3.54, 4.14 and 4.64, respectively. The values of Kp were calculated by dividing the total concentration of the element in SPM by its concentration in filtered water. There was no statistically significant dependence between log Kp values for antimony and loading (element loading is the sum of element concentration in the "dissolved" fraction and in the SPM).

Van der Sloot et al. (1985) measured several oxy-anionic metals, among them antimony, in water and particulate matter samples from the Dutch Wadden Sea, the North Sea, the estuaries of the Rhine and Scheldt and Lake Yssel. Kp values derived from data for Lake Yssel (the only freshwater samples) are presented above. Sampling of particulate matter involved filtration through 0.45 µm filters. The metal content was determined after leaching for 18 h with 0.1 N HCl.

Li et al. (1984) performed batch experiments with particulate matter from the Hudson River (USA). Unfiltered water samples (freshwater, C_L= 18 mg/l) were spiked with 13 radiotracers, including antimony. The spikes did not greatly change the natural concentration of various trace elements, as most radiotracers were carrier free and the amounts of spikes added were small. The samples were shaken for 20 days at 20° C. The aqueous radioactivity was determined in filtered (< 0.4 µm) subsamples taken at predetermined intervals using a germanium-lithium detector. Kp values for (unfiltered) water and a 4:1 mixture with filtered seawater are presented (equilibration period 20 days).

Hoede et al. (1987) determined metal concentrations of particulate matter in Indonesian river water. Sampling of the particulate matter involved continuous flow centrifugation of water. Particulate matter was obtained in two size/density fractions. The metal content of the particulate matter was determined using neutron activation analysis (NAA). The metal concentrations of the water samples (0.45 µm filtered) were determined with NAA after a preconcentration procedure. For the calculation of the Kp values the average metal content of the two size fractions was used.

Seven sources for log $Kp_{suspended\ matter}$values for antimony were identified in the EU RAR:

i) The study by Habib and Minski (1982) in which the log $Kp_{suspended\ matter}$ for the river Thames in the UK was 4.5.

ii) The study by Martin and Whitfield (1983) including a log $Kp_{suspended\ matter}$ of 3.4, representing a world river average.

iii) The study by Van der Sloot et al. (1989) including a log $Kp_{suspended\ matter}$ of 3. 3 for the river Solo (Indonesia).

iv) The study byVeselý et al. (2001) in which the 50thpercentile of log $Kp_{suspended\ matter}$for Czech rivers was 4.14.

v) The study by van der Sloot et al. (1985) including two log $Kp_{suspended\ matter}$values of 3.52 and 3.64 for the Dutch lake Ysselmeer.

vi) The study by Li et al. (1984) in which the log $Kp_{suspended\ matter}$ for the Hudson river (North America) was 4.07.

vii) The study by Hoede et al. (1987) in which the log $Kp_{suspended\ matter}$ for the Indonesian rivers Solo, Wono Kromo, and Porong were 3.17, 3.00, and 3.72, respectively.

However, in order to try to give equal weight to results from different studies performed in different waters, it was decided to use one value for each water system. This means that the data points (log $Kp_{suspended\ matter}$values) from the River Thames will be 4.5, for the world wide average 3.4, for the River Solo 3.2 (median value of 3. 3 and 3.17), for the Czech rivers 4.14, for Lake Ysselmeer 3.58 (median value of 3.52 and 3.64), for the Hudson River 4.07, for the River Kromo 3.00, and for the River Porong 3.72. Thus, the resulting values (log $Kp_{suspended\ matter}$) are 4.5, 3.4, 3.2, 4.14, 3.58, 4.07, 3.00, and 3.72.

Based on these eight data points, it was decided to use the median value (log $Kp_{suspended\ matter}$= 3.65) in the EU

RAR. No additional studies have been identified since the EU RAR so this value is used here also. The use of the median Kd value for environmental risk assessment is stipulated in the ECHA guidance R.7.13-2 section 2.2.2 (2008).

$Kp_{sediment}$

Partition coefficients for the partitioning of metals between water and suspended matter are used to calculate the concentration in sediment from the dissolved concentration in water on a local scale. When calculating the concentration in sediments on a regional scale the partitioning of metals between water and sediment should be used. Three reliable studies were identified in the EU RAR for diantimony trioxide which report a sediment Kp.

Brannon and Patrick (1985) determined Sb concentrations in the interstitial water phase of 10 North American sediments. Sediments were kept under anoxic conditions. Ten freshwater sediment samples were mixed with cellulose (1% weight: weight basis) to enhance reduction of the sediment. Sb(III) was added (75 mg/kg, sediment dry weight) in the form of an antimony potassium tartrate solution. The containers were sealed and incubated for 45 days under a nitrogen atmosphere at 20˚C. After this period interstitial water from the sediments was collected by centrifugation of the sample under nitrogen atmosphere. All aqueous concentrations for unamended sediments were below the detection limit. Log $Kp_{sediment}$ (l/kg) calculated from the total Sb content of 10 Sb amended freshwater sediments (native Sb-content and added Sb) and the corresponding interstitial concentrations ranged from 2.82 to 3.64. The mean log $Kp_{sediment}$ was 3.32.

Kawamoto and Morisawa (2003) studied the distribution and speciation of antimony in river water, sediment and biota in tributaries of the Yodo River, Japan. Samples were taken both upstream and downstream of municipal sewage treatment plants (STP), accepting wastewater from dye works, which are the main industries in the area. The antimony concentrations in water did not correlate well with the antimony concentration in sediments, as the concentration of antimony in water upstream of the STP in the Katsura River was lower than downstream (0.5 and 3.4 mg Sb/l, respectively) but the opposite was true for the concentration in sediments (2.4 and 1.2 mg Sb/kg dry weight). Concentrations measured in water and sediments downstream from another STP in the Umi River were 3.4 mg Sb/l and 1.0 mg Sb/kg dry weight, which are very similar to those measured downstream of the STP located on the Katsura River. Speciation of antimony revealed that the proportion of dissolved Sb(III) and Sb(V) changed depending on whether or not the sampling site was upstream or downstream of a STP, and how far downstream of the STP the sampling was performed. The proportion of Sb(III) and Sb(V) upstream and far downstream of STP was 20/80 and 30/70, respectively, while at point close downstream of an STP it was 1/99. This difference, which was suggested to be the result of the processes in the STP, thus resulted in a non-typical water for speciation of antimony.

Mori et al. (1999) measured the concentration of antimony in water and sediments in Corsican Rivers upstream and downstream of an abandoned realgar mine. The Bravona River spring is located in central Corsica and after 38 km reaches the Tyrrhenian Sea, on the eastern coast of Corsica. One of its tributaries, the Presa River, crosses an abandoned realgar mine. Ten sampling sites were chosen: six were located on the axial course of the Bravona River, three on the Presa River (1 upstream of the mine and two downstream) and one on a secondary tributary (the Alzillelo). The Presa River connects to the Bravona river between stations B2 and B3.

Three sources for log $Kp_{sediment}$values for antimony were identified in the EU RAR:

i) The study by Brannon and Patrick (1985) resulting in an averaged $Kp_{sediment}$ of 3.32 from 10 North American sediments.

ii) The study by Kawamoto and Morisawa (2003) in which the $Kp_{sediment}$ for Japanese rivers (upstream and downstream of STP connected to Sb-emitting industries) was given: upstream STP – 3.68, 3.95; downstream STP – 2.51, 2.55, 2.47. Since the discharge of antimony, via the STP, changed the proportion of Sb(III) and Sb(V) upstream and downstream from the STP, only the values obtained upstream of the STPs will be used here.

iii) The study by Mori et al. (1999) in which a number of $Kp_{sediment}$ values for Corsican rivers (from reference sites to strongly polluted) were given: reference sites – 4.20, 3.3, 3.51, 3.12; polluted – 2.99, 3.03, 3.30, 2.69; heavily polluted – 3.65, 2.89.

However, in order to try to give equal weight to results from different studies performed in different waters, only one value for each water system will be used. This means that the data points (log $Kp_{sediment}$values) are:

North American sediments = 3.32, River Katsura = 3.68, River Kamo = 3.95, River Bravona = 3.18 (median value of 4.2, 3.3, 2.99, 3.05, 3.3, 2.69), River Presa = 3.51 (median value of 3.51, 3.64, 2.89), and River Alzillelo = 3.12. Thus, the resulting values (log $Kp_{sediment}$) are 3.32, 3.68, 3.95, 3.18, 3.51, and 3.12. Based on these six data points, it was decided to use the median value (log $Kp_{sediment}$= 3.4).

A futher three studies have since been identified that report additional log Kp sediment values for antimony (Ettler et al., 2007, Sola and Prat, 2006; Fernandez-Turiel et al., 1995). All three of these studies report paired monitoring data from water and sediment which allow us to calculate log Kp sediment values. The studies by Ettler et al. and Sola and Prat are located in areas potentially exposed to antimony due to mining and smelting operations. The area sampled by Fernandez-Turiel et al. is relatively uncontaminated. Following the approach used in the EU RAR only a single log Kp is used for each water system. The measurements reported in these studies result in log Kp values of 3.35 (Ettler et al., 2007), 3.5 (Sola and Prat, 2006) and 2.7 (Fernandez-Turiel et al., 1995).

Based on the six data points from the EU RAR and the additional three data points identified here, we have decided to use the median value of these 9 data points in the assessment (log $Kp_{sediment}$= 3.35). This value is very similar to the value used in the EU RAR (log $Kp_{sediment}$= 3.4). The use of the median Kd value for environmental risk assessment is stipulated in the ECHA guidance R.7.13-2 section 2.2.2 (2008).

The following information is taken into account for any environmental exposure assessment:

A weight of evidence approach has been taken to determine the log Kp values for soil, suspended matter and sediment. The log Kp values that will be used in the assessment are: log Kp_{soil} 2.07, log $Kp_{suspended\ matter}$ 3.65, and log $Kp_{sediment}$ 3.35.

In order to run EUSES, partition coefficients are required for soil, suspended matter, sediment, and raw, settled, activated and effluent sewage sludge. All of these are available except for the partition coefficients for sewage sludge. For organic substances EUSES can calculate a default partition coefficient based on the log Kow, but this is not applicable to inorganic substances. Instead, the individual Kp values available for soil, suspended matter and sediment have been used to back-calculate a theoretical log Kow based on the equations given in the TGD (ECB, 2003). The median theoretical log Kow for soil is 5.31, for suspended matter it is 6.98 and for sediment is also 6.98. The median of these three values (log Kow 6.98) has been entered into EUSES to calculate the partition coefficients for sewage sludge.

The calculated log Kp values are 4.13 for raw sewage sludge and settled activated sludge and 4.22 for activated sewage sludge and effluent sewage sludge. The compartment-specific log Kp values listed above have been used for soil, sediment and suspended matter.

4.2.2. Volatilisation

This information is not applicable to antimony.

4.2.3. Distribution modelling

This information is not applicable to antimony.

4.2.4. Summary and discussion of environmental distribution

Experimental data are available on the partitioning on antimony in the environment. These data have been used to determine log Kp_{soil}, log $Kp_{sediment}$ and log $Kp_{suspended\ matter}$ for use in the risk assessment. Volatilization and distribution modelling are not applicable endpoints for antimony.

4.2.5 Calculated and measured concentrations

The concentrations of antimony in the environment can be estimated via calculations or via available measured data.

Based on the available monitoring data, ambient background concentrations in the different compartments can be calculated. The calculated ambient concentrations will consist of the natural background (present only due to natural causes) and the emission of metal from diffuse sources of human origin (present due to anthropogenic activities, both historical and present).

The modelled $PEC_{regional}$ values are steady state concentrations based only on the estimated total emissions of antimony. However, as the time for reaching steady state is not taken into consideration and the natural background concentrations are not included, the modelled $PEC_{regional}$ values do not represent the current situation. In addition, they only include antimony from the compound being considered, and not all potential sources of antimony to the environment. Therefore, the background concentrations based on measured data will be used instead of the calculated $PEC_{regional}$ in the calculations of local PECs.

This approach was used in the EU RAR for ATO and is in accordance with the methods used in risk assessments for other metals (ICMM, 2007). We have therefore also used this approach for the risk assessment of antimony metal and compounds.

4.2.5.1 Reasonable worst case ambient concentration

A reasonable worst case (RWC) ambient concentration to be used in the regional risk characterisation will be calculated as follows:

RWC-ambient $PEC_{country}$: median value of all 90th percentiles that have been derived for different sites, rivers/catchments or regions within a country. The median value from the 90th percentiles has actually been used for PEC regional for environmental risk assessment as stipulated by the ECHA guidance R16.4.2.

In cases where the amount of data for a country are too limited for deriving site/river/catchment-specific 90th percentile values, the 90th percentile of all relevant data are considered as the RWC-ambient PEC. For countries with only one ambient data point, that single value is used as an initial estimate for the RWC-ambient $PEC_{country}$. Measured values coming from polluted sites or mining areas are not included for the derivation of a regional RWC-ambient PEC, since those values are influenced by point sources and are therefore not representative for ambient (i.e., diffuse) contamination on a regional scale.

RWC ambient country-specific data are only available for a limited number of EU countries, when compared to the FOREGS database which includes measurements from the majority of the EU countries + Norway. However, since the FOREGS database is made up of measurements corresponding to low anthropogenic pressure, the use of country-specific measurements from the FOREGS database for those countries lacking RWC ambient data may result in an underestimation of the environmental concentrations intended to represent $PEC_{regional}$. This was investigated in the EU RAR for ATO. The results indicated that for water and sediment the FOREGS data were lower than the 90th percentiles based on other data sources and therefore inclusion of the FOREGS data reduced the $PEC_{regional}$ significantly. For this reason the FOREGS data were not included in the calculation of $PEC_{regional}$ water or sediment. Although the FOREGS soil data were less influential on the $PEC_{regional}$, the same approach to that for water and sediment was followed for consistency.

A literature review has been conducted to identify any literature published since the EU RAR for ATO. Several new monitoring studies were identified. In addition, GEMAS soil monitoring data has become available since the EU RAR. The data from these new sources have been added to the data presented in the RAR and evaluated to conclude that the $PEC_{regional}$ values defined in the RAR are still suitable for use.

4.2.5.2 Measured levels

4.2.5.2.1 Levels in surface water

Baseline background concentrations of antimony in stream waters measured in the FOREGS project result in values that range over about three orders of magnitude, from <0.002 to 1.21 µg Sb/l (excluding two outliers up to 2.91 µg Sb/l), with a median value of 0.07 µg Sb/l (see Table 10 and Figure 1).

Table 19: Concentrations of Sb in European stream water according to FOREGS http://www.gsf.fi/publ/foregsatlas/article.php?id=15

Unit	Number of samples	Min	Median	Mean ± SD	90P	Max
µg Sb/l	807	<0.002	0.07	0.109 ± 0.177	0.21	2.91

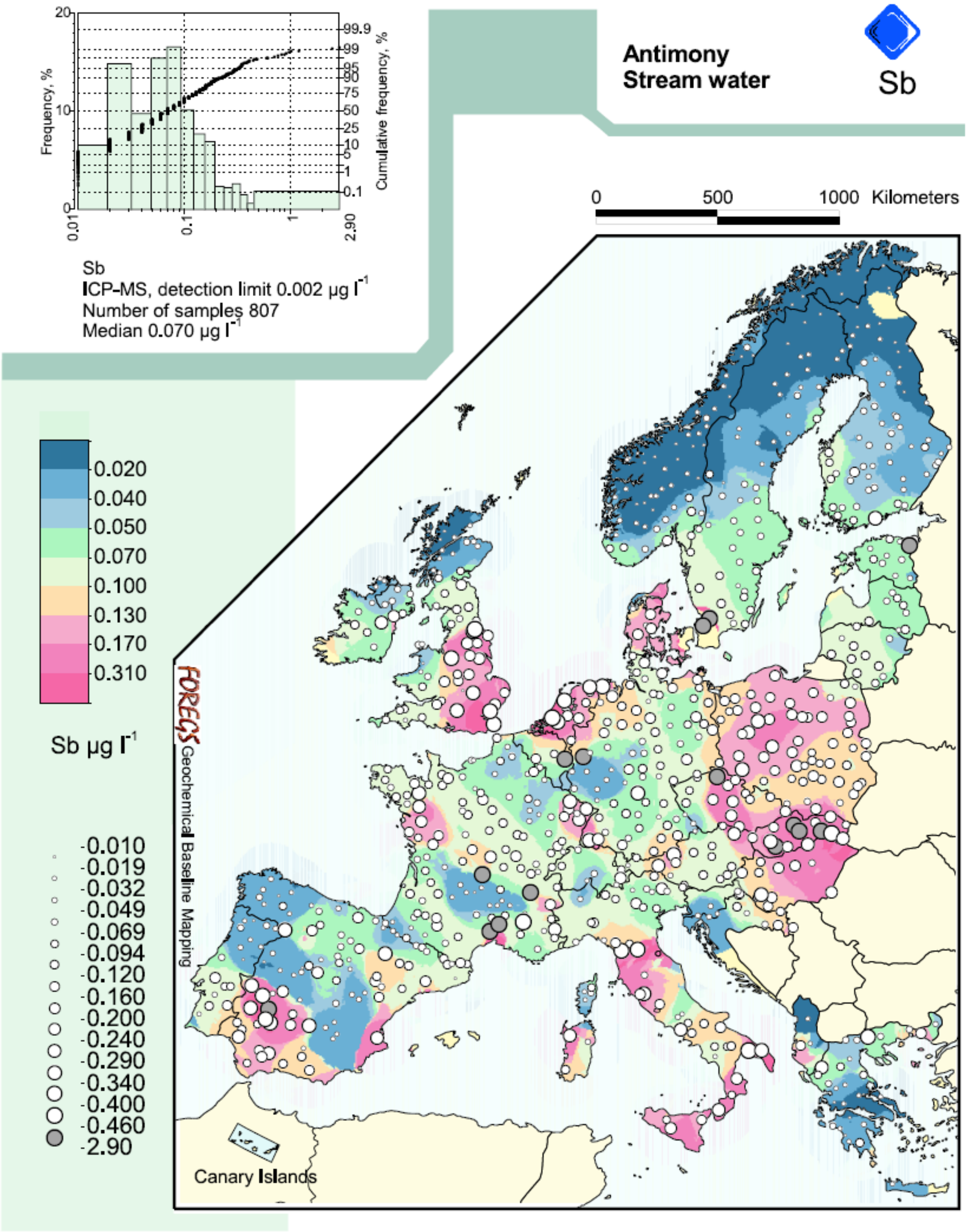

Figure 1: FOREGs map showing measured concentrations of Sb in European stream water (http://www.gsf.fi/publ/foregsatlas/maps/Water/w_icpms_sb_edit.pdf).

Measured antimony concentrations in rivers, lakes, groundwater and precipitation from other sources besides the FOREGs database were reported in the EU RAR and are presented again here in Tables 11-14 together with monitoring data made available since publication of the EU RAR.

Table 20:Measured antimony concentrations in European rivers.

Location	Concentration (Sb µg/l)	Speciation (Total, unless otherwise specified)	Period	Remark	Reference
France Rhône River					Kharkar et al.,

Location	Concentration (Sb µg/l)	Speciation (Total, unless otherwise specified)	Period	Remark	Reference
(Avignon)	1.5 (16 % standard dev. – pooled estimate from dupl. determin.)		1966, June	Precipitation (sulphide) + NAA	1968
Rhône River (Arles) Isère (Domène)	0.34 0.33		05-09-81 02-09-81	HG-AAS	Andreae and Froelich, 1984
Rhône River	0.49			NAA	Guieu et al., 1993
Bournac	1.6-32.2	Sb(V)	2004 February, March, May	HPLC and HG-AFS Polluted by the mining residues from the Sb mine of Bournac	Casiot et al., 2007
Corsica	1-330 (total)		September 1992 - June 1993	HG-GFAAS Sampling along a gradient downstream of a mine	Migon and Mori, 1999
Corsica Alzillelo River Bravona River Presa River	3.0 1.0–41 4.0-385		1990, winter, spring, summer	HG-AAS Unpolluted Upstream-downstream confluence with Presa River Upstream-Downstream Realgar mine	Mori et al., 1999
Germany Iller kanal Donau (Ulm) Donau (Böfingerhalde) Lech (Augsburg) Lech kanal (Gersthofen) Lech kanal (Langweid)	0.050 (±10 %) 0.060 (±10 %) 0.10 (±10 %) 1.0 (±10 %) 5.2 (±10 %) 2.3 (±10 %)			NAA	Schramel et al., 1973
Rhine River (Oppenheim) Main River (Frankfurt)	0.0004 0.23 0.0001.2 n.d. 0.0003 0.31 0.00018 n.d.	Sb(III) Sb(V) MSA DMSA Sb(III) Sb(V) MSA DMSA		HG-AAS	Andreae et al., 1981
Rhine (Bregenz) Rhine	0.080 0.23		12-05-82 02-04-82	HG-AAS	Andreae and Froelich, 1984

Location	Concentration (Sb µg/l)	Speciation (Total, unless otherwise specified)	Period	Remark	Reference
(Oppenheim) Main (Frankfurt) Danube (Neuberg) Elbe (below Hamburg)	0.53 0.31 <0.00037		06-12-82 10-05-82 09-06-81		
Luxembourg Geosdorf	≥ 0.4 ≤ 2200		2004, March – 2009, January	ICP-MS and DPASV (differential pulse anodic stripping voltammetry) Drainage water from a contaminated mining area	Filella et al. 2009
Netherlands Rhine	0.85		1975, February	HG-NAA	Van der Sloot et al., 1985
Rhine River (Lobith) Rhine River (Gorkum)	0.80 0.60			HG-AAS	Haring et al., 1982
Norway 11 rivers	0.35 (weighted mean) <0.16-2.1 (min-max; individual obs.)		1971, May-October	NAA	Salbu et al., 1979
Larsmyrbekken, drainage stream from a shooting range	9 (mean) 20 (max) 6 (mean) 14 (max)		2001 2006	AAS	Strømseng et al., 2009
Poland Vistula River	0.60 ± 0.040			HMDE-DPASV Surface water (non-filtered)	Postupolski and Golimowski, 1991
Portugal Tejo River (Santarem) Tejo River (Vilafranca)	0.10 0.23		30-04-82 06-12-82	HG-AAS	Andreae, 1983
Sao Domingos (ex mining area)	> 2 < 8 Range of 6 samples.			Instrumental Neutron Activation Analysis (INAA) and Compton-Suppression Neutron Activation Analysis	Landsberger et al. 2010

Location	Concentration (Sb µg/l)	Speciation (Total, unless otherwise specified)	Period	Remark	Reference
				(CSNAA). Surface waters from an area impacted by mine waste, dust mobilisation and acid mine drainage from a sulphide-mining complex.	
Spain Guadalquivir (Coria)	0.54		18-12-82	HG-AAS	Andreae, 1983
Manzanares River	n.d. 0.39	Sb(III) Sb(V)		HPLC-HG-ICP-AAS	Smichowski et al., 1995
Guadiamar River	0.4-3.8		July 2001 - July 2003	ICP-MS Polluted by mining activity 1 station at upstream from the mine influence, 4 stations downstream	Sola and Prat, 2006
Guadiamar River	0.2-3.5 (data read from graph)		July 2000	ICP-MS Polluted by mining accident 3 stations upstream and 10 stations downstream from the Aznalcóllar mine and tailing pond (15 km closest to the mine)	Sola et al., 2004
Sweden Skellefte River Ume River Ångerman River	0.050 0.070 0.080	Unfiltered	9-11-64 23-1-64 17-5-64	NAA	Landström and Wenner, 1965
Creek in Gideå, north	<0.0365		1990, September	ICP-MS Measurements were performed on 125Sb	Carbol et al., 1995
Switzerland Canton Geneva	0.08 0.13 0.16		Samples over 12 years	Jura region Alps region Plain region ICPMS	Nirel et al, 2008
United Kingdom Gowny River	0.42 0.13			Precipitation (zirconium	Abu-Hilal and Riley, 1981

Location	Concentration (Sb µg/l)	Speciation (Total, unless otherwise specified)	Period	Remark	Reference
Cowny River				oxide) + colorimetry (ion pair SbCl6 with crystal violet)	
Thames River	0.27 (±57 %) 0.086-0.86 (min-max)		23-10-78 – 17-08-79	NAA 3 stations	Habib and Minski, 1982
Thames River (downstream of Oxford)	0.39 0.35	Total Dissolved	11-04-97 – 01-11-98	ICP-MS Weekly spot sampling	Neal et al., 2000
Glenshanna River (Scotland)	5.3 n.d. 5.3	Total Sb(III) Sb(V)		HG-AAS Disussed mine entrance	Mohammad et al., 1990
	60 2.2 58	Total Sb(III) Sb(V)		Soil heap drainage	
	14 n.d. 14	Total Sb(III) Sb(V)		River (2 m downstream soil heap)	
Trent River (Cromwell Lock)	1.9		1996, February, April, July, and October	ICP-OES and ICP-MS Non-tidal	Jarvie et al., 2000
Trent River (Torksey)	2.0			Freshwater tidal	
Trent River (Gainsborough	2.1			Freshwater tidal	
Czech Republic	0.33 (median)		Summer, 1997 and Summer, 1998	FAAS and GFAAS 119 localities	Vesely et al, 2001

Table 21:Measured antimony concentrations in European lakes.

Location	Concentration (Sb µg/l)	Speciation (Total, unless otherwise specified)	Period	Remark	Reference
France Lake Pavin	0.032 0.016 0.016	Total Sb(III) Sb(V)	1990, August	HG-AAS Small meromictic lake Surface	Takayanagi and Cossa, 1997
	0.043 n.d. 0.043	Total Sb(III) Sb(V)		Oxic (deep)	

Location	**Concentration (Sb µg/l)**	**Speciation (Total, unless otherwise specified)**	**Period**	**Remark**	**Reference**
	<0.0073	Total		Anoxic	
Germany Lake Constance	0.10-0.17		1986-1987	HG-AAS	Stabel et al., 1991
Lake Constance	0.12 0.11 0.12 0.11 0.11	Constant with depth (mean 9, samples 0-140m) surface 20 m 60 m 140 m	03-04-90 14-11-90	FIA-HG-GF-AAS	Sinemus et al., 1992
Bitterfeld Pfälzer Bergland	31 2.0 28 96 9.0 85	Total Sb(III) Sb(V) Total Sb(III) Sb(V)		IC-ICP-AES Polluted by industrial waste Polluted by mining processes	Ulrich, 1998
Netherlands Lake Yssel	0.37-0.48		1978, April	HG-NAA 3 stations	Van der Sloot et al., 1985
Norway 41 lakes	0.032 (mean)		1977	NAA	Allen and Steinnes, 1979
Sweden South North	0.14 0.13		1980, March-April 1980, March-April	In situ dialysis + NAA 20 small acidic lakes, 2.5 m depth 18 small lakes, samples 2 m below the ice	Borg, 1983
242 lakes	0.035 (median) 0.010-0.063 (10-90 perc.)				Naturvårdsverket, 1999b
United Kingdom Lake Celyn	0.080			Precipitation (zirconium oxide) + colorimetry (ion pair SbCl6 with crystal violet)	Abu-Hilal and Riley, 198
Loch Ewe (NW Scotland)	0.16 0.003	Total Sb(III)		HG-AAS Spring diatom bloom, no temporal variation	Apte et al., 1986
Loch Ewe (NW Scotland)	0.17 0.002 0.15 0.003	Total Sb(III) Total Sb(III)	26-03-83 09-04-83	HG-AAS	Apte and Howard, 1986
Poland				HGAAS	Niezielski, 2006

Location	**Concentration (Sb µg/l)**	**Speciation (Total, unless otherwise specified)**	**Period**	**Remark**	**Reference**
Gniezno City	0.05-0.49 0.05-0.43 0.05-0.36 0.04-0.31	Sb(III) Sb(III) Sb(V) Sb(V)		Lakes in Gniezno City Lakes in Gniezno Neighbourhood	
Lake Jarosławieckie (in Wielkopolski National Park)	0.34 (mean), 0.06 (mean). 0.30(mean), 0.05(mean) 0.64(mean), 0.11(mean)	Sb(III) Sb(V) Total	March 2002, July 2002	HG-AAS Incomplete stratification with epilimnion and metalimnion developing in summer	Pelechaty et al. 2004
Sweden L. Stensjön L. Övre Skärsjön L. Tväringen L. Remmarsjön	 0.022 – 0.029 0.060-0.61 0.016 – 0.019 0.018-0.019		 July-August,2002 Winter, 2004	ICP-MS Reference lakes in the Swedish National Environment Monitoring Programme. L. Övre Skärsjön – a small historical mine tailings deposit	 Grahn et al., 2006

Table 22: Measured antimony concentrations in European groundwaters.

Location	**Concentration (Sb µg/l)**	**Speciation (Total, unless otherwise specified)**	**Period**	**Remark**	**Reference**
Sweden Near Skellefteå Brån Sollefteå	 0.010 0.020 0.030 0.20 0.040 0.060 0.50		 11-8-64 7-9-64 23-1-64 23-1-64 17-5-64 17-5-64 17-5-64	 NAA 2 locations 2 locations 3 locations	 Landström and Wenner, 1965
Poland Warsaw	 0.13			 HMDE-DPASV Surface water (non-filtered)	 Postupolski and Golimowski, 1991
Poznań City	0.24-0.71			HG-GFAAS Piątkowo and Winogrady regions	Niezielski and Siepak, 2005

Table 23:Measured antimony concentrations in European snow and rain water.

Location	Concentration (Sb µg/l)	Speciation (Total, unless otherwise specified)	Period	Remark	Reference
Netherlands	0.89			Rain	Stuyfzand, 1991
Poland				HMDE-DPASV Snow	Postupolski and Golimowski, 1991
Warsaw (City)	36	Sb(III)			
Warsaw (suburb)	3.0	Sb(III)			
	5.1	Total			
Szczyrk (S Poland)	0.030	Total			
Sweden					
Gårdsjön	0.066±0.026 (mean±SD) 0.060 (median) 0.044-0.140 (min-max)		990104-000107	ICP-EAS/ICP-SMS Precipitation during one year, monthly sampling	Eriksson, 2001
Arup (South of Sweden)	0.12, 0.095, 0.11 0.13, 0.21, 0.14		010701-010801 011201-020101	ICP-MS detection limit 10 ng Sb/l	Sternbeck et al., 2002a
Gårdsjön (West)	0.041, 0.036, 0.067 <d.l., 0.14, 0.098		010710-010802 011127-020111		
Bredkälen (North)	0.011, 0.011, <d.l. <d.l., 0.032, 0.034		010703-010731 011204-020104		
Mjölsta (East)	0.17, 0.17, 0.12		011127-020114		

A RWC-ambient PEC of 0.72 µg Sb/l was calculated in the EU RAR using ambient data from eight countries (see **Table 9. Manufacture** Table 10). The country-specific FOREGS 90P values range from similar (Sweden) to about 18 times lower (France) when compared to measured ambient concentrations. Vesely et al. (2001) give additional data to that in

Identifiers	Use descriptors	Other information
M-1: Use of antimony metal in the production of diantimony trioxide	**Environmental release category (ERC):** ERC 1: Manufacture of substances **Process category (PROC):** PROC 21: Low energy manipulation of substances bound in materials and/or articles PROC 22: Potentially closed processing operations with minerals/metals at elevated temperature. Industrial setting PROC 23: Open processing and transfer operations with minerals/metals at elevated temperature PROC 26: Handling of solid inorganic substances at ambient temperature	Tonnage of substance: 9000.0 Remarks: : Use of antimony metal in the production of diantimony trioxide

the RAR that could be used to update the RWC-ambient background. Samples were taken from 119 river sites in the Czech Republic, but no range or 90th percentile is reported, only a median value of 0.33 Sb µg/l. INERIS (2009) collated antimony water monitoring data from EU member states. Data was available from the Czech Republic, Germany, Spain, France, Portugal, Greece and the UK. Over 95 % of samples were from rivers, with the remainder from transitional waters, lakes and coastal waters. The 90th percentile of nearly 5000 samples was 0.06 µg Sb/l.

Table 24: Calculation of RWC-ambient PEC for antimony in freshwater. Country-specific 90P FOREGS data are included for comparative purposes only.

Country	**RWC-ambient PEC (90P) µg Sb/l**	**Data used**	**FOREGS -90P µg Sb/l**
Austria			0.25
Belgium			0.66
Bulgaria			-
Cyprus			-
Czech Republic			0.26
Denmark			0.18
Estonia			0.10
Finland			0.07
France	3.3	1.5, 0.34, 0.49, 0.33, 3, 1, 4, 0.032	0.18
Germany	1.52	0.05, 0.06, 0.10, 1.0, 5.2, 2.3, 0.23, 0.08, 0.23, 0.31, 0.53, 0.31, 0.00037, 0.10, 0.17, 0.12, 0.11	0.17
Greece			0.15
Hungary			0.24
Ireland			0.20
Italy			0.27
Latvia			0.08
Lithuania			0.10
Luxembourg			-
Malta			-
Netherlands	0.83	0.85, 0.8, 0.6, 0.37, 0.48	0.39
Poland	0.60	0.60	0.19
Portugal			0.14
Romania			-
Slovakia			0.75
Slovenia			-
Spain	0.53	0.54, 0.39	0.28
Sweden	0.13	0.05, 0.07, 0.08, 0.018 (= 0.0365/2)*, 0.14, 0.13, 0.063	0.09
United Kingdom	2.0	0.42, 0.13, 0.27, 0.35, 1.9, 2, 2.1, 0.08, 0.16, 0.17, 0.15	0.30
Norway	0.32	0.35, 0.032	0.06
Median	0.72		0.19** 0.26***

* Half detection limit
**Median of FOREGS country-specific 90P values
***Median value of RWC values when available and country-specific FOREGS 90P-values for those countries with no RWC-value

The median value from the 90th percentiles has actually been used for PEC regional for environmental risk assessment as stipulated by the ECHA guidance R16.4.2.

The EU RAR for ATO concluded that the RWC-ambient background concentration of antimony in freshwater (dissolved) is 0.72 Sb µg/l. There are no newly available data to suggest that this value should be adjusted. We will therefore also use the 0.72 Sb µg/l RWC-ambient background.

4.2.5.2.2 Levels in marine water

Measured antimony concentrations in marine water are presented in Table16.

Table 25: Measured antimony concentrations in marine waters adjacent to Europe.

Location	Concentration (µg Sb/l)	Speciation (Total, unless otherwise specified)	Period	Remark	Reference
Adriatic Sea (north)	0.19-0.53 (mean 0.31)			Precipitation (MnO_2) + NAA 5 locations	Strohal et al., 1975
Atlantic Ocean (north west)	0.24			Precipitation (sulphide) + NAA	Schutz and Turekian, 1965
Atlantic Ocean, Portuguese coast	0.16		26-04-82	HG-AAS Surface water	Andreae, 1983
Atlantic Ocean (50-70° N)	0.0037-0.023 0.12-0.15 (mean 0.14)	Sb(III) Sb(V)		Preconcentration of hydrides on active carbon + NAA 0-4000 m	Middelburg et al., 1988
Atlantic Ocean, French coast off Nantes Mouth Loir	0.21 0.22 0.003	Total Total Sb(III)		HG-AAS	Takayanagi and Michel, 1996
Atlantic Ocean (54-68° N)	0.23 0.16 n.d. 0.16 n.d. n.d.	Total Sb(III) MSA Total Sb(III) MSA	1993	HG-GC-PID Surface water Deep water	Cutter and Cutter, 1998
Baltic Sea				HG-AAS	Andreae and Froelich, 1984
Station BY5	0.038-0.11 0.0007-0.0097 <0.0007	Total MSA DMSA	11-06-81	10-95 m, 10 samples	
Station BY11	0.039-0.083	Total MSA DMSA	12-06-81	10-210 m, 15 samples	
Station BY15	0.018-0.073 0.0002-0.019 0.020-0.068 0.0016-0.0050 <0.0007	Total Sb(III) Sb(V) MSA DMSA	13-06-81	10-235 m, 19 samples	
Station BY23	0.043-0.095 <0.0006-0.0085 <0.0012-0.0049	Total MSA DMSA	15-06-81	10-65 m, 6 samples	
Station BY26	0.0006-0.0011 0.063-0.083 <0.0006-0.011 <0.0012 0.046-0.067	Total Sb(III) Sb(V) MSA DMSA	14-06-81,	10-90 m, 8 samples	
Dutch Wadden Sea	0.18-0.35		April 1978	HG-NAA 12 stations	Van der Sloot et al., 1985
Irish Sea	0.13-0.40			Precipitation	Portmann and

Location	Concentration (µg Sb/l)	Speciation (Total, unless otherwise specified)	Period	Remark	Reference
	(median 0.22)			(MnO_2) + solvent extraction (CCl_4) + colorimetry (rhodamine B)	Riley, 1966
Irish Sea	0.26			Precipitation (zirconium oxide) + colorimetry (ion pair $SbCl_6$ with crystal violet) Surface water	Abu-Hilal and Riley, 1981
Gullmar fjord, Sweden	<0.50			Spectrophotometry Shallow water	Noddack and Noddack, 1939b
Mediterranean (east) Tyro Basin Bannock Basin	0.20-0.24 0.0073-0.044 0.18-0.21 0.34-0.85 0.11-0.64 0.20-0.32 0.20-0.24 0.023-0.037 0.16-0.21 0.67-0.77 0.39-0.65 0.12-0.28	Total Sb(III) Sb(V) Total Sb(III) Sb(V) Total Sb(III) Sb(V) Total Sb(III) Sb(V)	1987, 21/5-5/6 1987, 21/5-5/6	HG-NAA 10-3347 m (oxic) 3579-3563 m (anoxic) 2-3300 m (oxic) 3320-3470 m (anoxic)	Van der Weijden et al., 1990
Mediterranean, Spanish coast	0.14 n.d.	Total Sb(III)		FIA-HG-AAS Industrial area	De la Calle Guntinas et al., 1991
Mediterranean , Spanish coast Santander Denia	n.d. 0.25 n.d. 0.29	Sb(III) Sb(V) Sb(III) Sb(V)		HPLC-HG-ICP-AAS	Smichowski et al., 1995
Mediterranean (west)	0.16 0.22 0.16	Total Sb(III) Total		HPLC-HG-ICP-AAS	Takayanagi et al., 1996
Mediterranean, Open-ocean	0.16 0.0021	Total Sb(III)		HG-AAS	Takayanagi and Michel, 1996
North Sea	0.30			HG-AAS	Haring et al., 1982
North Sea, Belgian coast	0.30-0.82			HMDE-DPASV 3 m, 5 samples	Gillain et al., 1979)
North Sea, Belgian coast	0.12 0.16			RRDE-ASV HMDE-DPASV 3 m, 5 samples	Brihaye et al., 1983
North Sea, Belgian coast	0.050-0.38 (median 0.12) <0.005-0.039 0.015-0.25	Total Sb(III) Sb(V)	1983, July	RDE-ASV, HMDE-DPASV 19 stations	Gillain and Brihaye, 1985
North Sea, Southern Bight	0.20-0.37		1981, October	HG-NAA 10 stations	Van der Sloot et al., 1985

Location	Concentration (µg Sb/l)	Speciation (Total, unless otherwise specified)	Period	Remark	Reference
and British Channel					
WorldOcean average	0.33			Precipitation (sulphide) + NAA	Schutz and Turekian, 1965

The concentrations measured in marine waters, adjacent to the EU, are normally within the range of 0.20-0.40 µg Sb/l. Filella et al. (2002a) concluded that the concentration of antimony in oceans is about 0.2 µg Sb/l, and that the decrease in antimony concentrations as well as in data scatter with time reflect the parallel improvement of the analytical techniques available. The relatively lower concentrations measured in the brackish waters of the Baltic Sea have been attributed to a higher particle flux and longer water residence time, compared to the oceans (Andreae and Froelich, 1984).

It is reasonable to think that at least some of the Sb in marine waters is due to anthropogenic activity. For the EU RAR for ATO a (high) estimate of 0.2 µg Sb/l was chosen as an ambient background of antimony in marine waters (dissolved). This same value will be used here.

4.2.5.2.3 Levels in sediment

Baseline background concentrations of antimony in stream water sediments measured in the FOREGS project result in values that range over three orders of magnitude from < 0.02 to 34.1 mg Sb/kg dw, with a median value of 0.615 mg Sb/kg dw (see Table 17 and Figure 2).

Table 26: Concentrations of Sb in European stream sediment according to FOREGS (http://www.gsf.fi/publ/foregsatlas/article.php?id=15).

Unit	Number of samples	Min	Median	Mean ± SD	90P	Max
mg Sb/kg dw	848	<0.02	0.615	1.07 ± 1.88	2.10	34.1

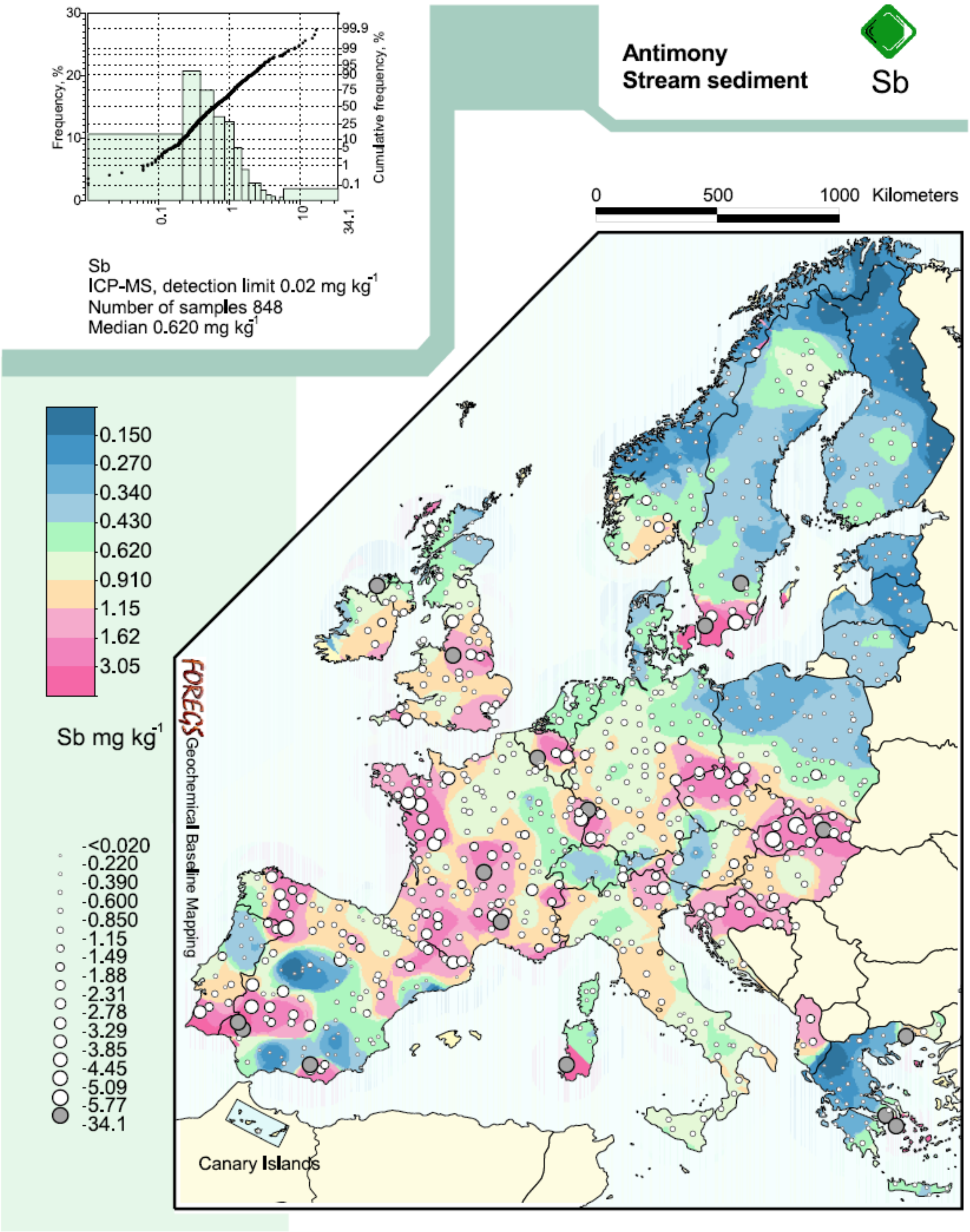

Figure 2: FOREGs map showing measured concentrations of Sb (mg/kg dw) in European stream sediment (http://www.gsf.fi/publ/foregsatlas/maps/StreamSed/s_icpms_sb_edit.pdf).

Measured antimony concentrations in sediments from other sources besides the FOREGs database were reported in the EU RAR for ATO and are presented in Table 27 below together with monitoring data that have been published since the ATO RAR.

Table 27: Measured antimony concentrations in European sediments.

Location	Concentration (Sb mg/kg dw)	Speciation (Total, unless otherwise specified)	Period	Remark	Reference
Austria					

Location	Concentration (Sb mg/kg dw)	Speciation (Total, unless otherwise specified)	Period	Remark	Reference
Danube River and Danube Canal (Vienna)	9.62, 10.01, 12.21, 12.01, 13.37, 16.83 (medians from the stations) 8.22-22.22 (range)		1973, August – 1974, March	NAA 6 stations, no significant variation over time	Rehwoldt et al., 1975
France Bournac Creek	500 ± 2		March 2004	Supelcosil LC-SAX1 (20 mm × 4.6 mm i.d.) column and a 200 lL sample loop. Near mine	Cassiot et al, 2007
Corsica River Bravona and River Presa	4-1108 (min-max)			GFAAS Sampling along a gradient downstream of a mine	Mori et al., 1999, Mignin and Mori 1999
Germany Markt RedwitzFaulschlamm (Großlappen) Bodenschlamm (Inn) Isarwerkkanal (München) Bodenschlamm (Zulauf-Speicher)	0.9 (±10 %) 46.5 (±10 %) 36.5 (±10 %) 4.1 (±10 %) 1.5 (±10 %) 6.0 (±10 %)			NAA Upstream large chemical industry producing Hg Downstream ditto Samples were selected in such a way that contamination could be expected	Schramel et al., 1973
Rhine (Ginsheimer Altrhein)	7.95-96.1 (min-max)			NAA 5 stations, 0-15 cm Polluted	Dissanayake et al., 1983
Rhine	3 38 1	Sb(III) Sb(V) TMSbO		ICP-OES ”surface sediments”, polluted	Hirner et al., 1990
River in West Germany	0.2-9.8 (min-max) 0.1-1.2 0.1-0.9	$SbMeH_2$ $SbMe2_H$ $SbMe_3$		LTGC-ICP-MS	Krupp et al., 1996
Mansfeld region	<2 – 4860			WDRXF & EDXRF Various sites downstream from abandoned mining area	Wennrich et. al 2004

Location	Concentration (Sb mg/kg dw)	Speciation (Total, unless otherwise specified)	Period	Remark	Reference
Italy Arno River Venice Lagoon	 0.2 0.14-0.74			 HG-AFS	 Barghigiani et al., 1995
  Lagoon Sacca di Goro Po River delta	 2.03 1.02		1992, April – 1992, June	NAA Heavy industrialised coast line High water renewal Slow water renewal	Bondavalli et al., 1996
Luxembourg Geosdorf	≥ 0.052 ≤ 1.329 Range of 13 samples.		2006, October – 2008, December	Total aqua regia Sb concentration was performed on all the collected samples. All samples were extracted with oxalate and hydrogen peroxide solutions. Water reservoirs contaminated by drainage from a mining area.	Filella et al. 2009
Norway Norwegian freshwater lakes	 0.29 (median) 0.07-3 (10P-90P) 0.04 (median) 0.009-0.14 (10P-90P)		 1996-1997	 ICP-MS 210 lakes, no significant local source of pollution Upper 0.5 cm 30-50 cm depth	 Rognerud and Fjeld, 2001
Slovakia Ruzin reservoir	34.1 Mean result of 17 samples, SD 14.2		June 2005	Atomic Absorption Spectrometry with a hydride generation system 23 surface sediment samples Contaminated by drainage	Hiller et al., 2010

Location	Concentration (Sb mg/kg dw)	Speciation (Total, unless otherwise specified)	Period	Remark	Reference
				from a mining area	
Slovakia Velke Kozmalovce reservoir	14.8 Mean result of 6 samples, SD 1.16		June 2005	Atomic Absorption Spectrometry with a hydride generation system 23 surface sediment samples Contaminated by drainage from a mining area	Hiller et al., 2010
Spain Guadiamar River	0.69 ± 0.1 3.41 – 4.93			ICP-MS. Control Site Mine Polluted river	Solà and Pratt 2006
Sweden Lake Övre Skärsjön	0.07 ± 0.048			ICP-MS “no identifiable point sources of contaminants were found in their catchments, besides a small historical mine tailings deposit in the catchment of Lake Övre Skärsjön.”	Grahn et al., 2006
Lake Stensjön	0.11 ± 0.211				
Lake Tväringen	0.04 ± 0.060				
Lake Remmarsjön	0.05 ± 0.028				
United Kingdom Southampton Water				NAA	Leatherland and Burton, 1974
Town Quay	0.92			Surface	
	2.3			10 cm	
Woolston	0.88			15 cm	
Hamble	0.71			Surface	
	0.67			10 cm	
Calshot	0.7			Surface	
Mersey River	2.9			Surface	
Thames	1.27 -126.5 (mean: 8.4)		Oct 1978 – Aug 1979	Neutron activation analysis. γ-ray spectroscopy « Suspended Particulates »	Habib and Minski, 1982

Location	Concentration (Sb mg/kg dw)	Speciation (Total, unless otherwise specified)	Period	Remark	Reference
				All sites downstream from human activity.	

A RWC-ambient PEC of 3 mg Sb/kg dw (0.65 mg/kg ww) in freshwater sediments was calculated in the EU RAR using ambient data from five countries (see Table 28). The country-specific FOREGS 90P values range from similar in size (Italy and UK) to eight times smaller (Austria) when compared to measured ambient concentrations. The new data that are not influenced by point sources (Grahn et al., 2006, control site from Solà and Pratt 2006) do not suggest that the RWC-ambient PEC in the EU RAR needs to be altered. INERIS (2009) collated antimony sediment monitoring data from EU member states. Data was available from the Czech Republic, Germany, Spain, France, Portugal, Greece and the UK. The 90th percentile of nearly 500 samples was 2.8 mg Sb/kg dw whole sediment. This data also does not suggest that the RWC-ambient PEC used in the EU RAR needs to be altered.

Table 28: Calculation of RWC-ambient PEC for antimony in freshwater sediments. Country specific 90P FOREGS data are included for comparative purposes only.

Country	RWC-ambient PEC (90P) mg Sb/kg dw	Data used	FOREGS -90th percentile mg Sb/ dw
Austria	15.1	9.62, 10.01, 12.21, 12.01, 13.37, 16.83	1.80
Belgium			7.28
Bulgaria			-
Cyprus			-
Czech Republic			2.88
Denmark			0.64
Estonia			0.45
Finland			0.52
France			2.78
Germany	9.7	0.9, 0.4, 11.9	1.39
Greece			0.73
Hungary			1.34
Ireland			1.72
Italy	1.6	0.2, 0.14, 0.74, 2.03, 1.02	1.35
Latvia			0.39
Lithuania			0.54
Luxembourg			-
Malta			-
Netherlands			0.87
Poland			0.90
Portugal			2.21
Romania			
Slovakia			5.55
Slovenia			2.46
Spain			2.86
Sweden			1.38
United Kingdom	2.3	0.92, 0.71, 0.7, 2.9	2.36
Norway	3	3	1.12
Median	3		1.38* 1.72**

*Median of FOREGS country-specific 90P values
**Median value of RWC values when available and country-specific FOREGS 90P-values for those countries with no RWC-value

The median value from the 90th percentiles has actually been used for PEC regional for environmental risk assessment as stipulated by the ECHA guidance R16.4.2.

In conclusion, the RWC-ambient background concentration of antimony in freshwater sediments used in this risk assessment is 3 mg Sb/kg dw (0.65 mg Sb/kg ww).

4.2.5.2.4 Levels in marine sediments

Measured antimony concentrations in marine sediment were reported in the EU RAR and are presented in Table 20 together with data that has become available since publication of the EU RAR.

Table 29: Measured antimony concentrations in marine sediments.

Location	**Concentration (mg Sb /kg$_{dw}$)**	**Speciation (Total, unless otherwise specified)**	**Period**	**Remark**	**Reference**
Greece Upper Saronikos Gulf	0.16-18 (min-max)		1973	NAA Athens sewage outfall area 20 samples Lower concentrations further away from outfall area ~20 cm maximum penetration	Papakostidis et al., 1975
Upper Saronikos Gulf Elefsis Bay Keratsini Bay Piraeus Harbour	0.4 2 15 65		1975, beginning of	NAA 0-5 cm Background level Industry discharge Athens outfall Fertilizer factory	Grimanis et al., 1977
Sweden Skagerrak and Kattegat	0.68 (mean) 0.66 (median) 0.2-2.14 (range) n=149 0.88 (mean) 0.83 (median) 0.4-2 (range) n=70		1987-1992	ICP-MS Marine sediments 0-2 cm 40-55 cm	Cato, 1997
Baltic Sea	0.8 (median) 0.16-4.7 (min-max)			Taken at 0.55 m depth, brackish water	Naturvårdsverket, 1999a
North Adriatic Sea	20			NAA, Under strong	Strohal et al., 1975

Location	**Concentration (mg Sb /kg_{dw})**	**Speciation (Total, unless otherwise specified)**	**Period**	**Remark**	**Reference**
				influence of the North Italian industrial region, open sea sample taken at 35 m depth	
Spain Oza Harbour mouth Inside the Oza Harbour Oza beach El Burgo estuary El Burgo estuary closest to bridge, Sta. Cristina beach Inside the Ares-Betanzos estuary Inside the Ares-Betanzos estuary Inside the Ares-Betanzos estuary Coast close to Perbes village Coast close Cirro village Coast close Redes village	 1.51 1.35 1.06 0.22 0.66 0.54 0.25 0.26 0.34 0.54 0.47 0.71			USS and ETASS Esuarine sediments. Human influence expected.	Cal-Prieto et al., 2001

The information on antimony concentrations in marine sediments is scarce, which is why the concentration chosen for freshwater sediments was also used for the marine sediments in the EU RAR for ATO. The ambient background concentration of antimony in marine and freshwater sediments used in the RAR for ATO was 3 mg Sb/kg dw, corresponding (with EUSES default conversion factors) to 0.65 mg Sb/kg ww. The newly available marine sediment data (Cal-Prieto et al. 2001) do not suggest that the RWC ambient concentration needs to be adjusted so this value will also be used here.

4.2.5.2.5 WWTP levels

Measured antimony concentrations in STP sludge are presented in Table 30 below. No additional data to those reported in the EU RAR for ATO were identified.

The levels of antimony in 48 municipal wastewater treatment plants have been reported by Eriksson (2001). The levels found were in the range 0.6 mg Sb/kg_{dw} to 18 mg Sb/kg dw, with the median level being 1.3 mg Sb/kg dw, and the 90th percentile 3.4 mg Sb/kg dw. The samples were collected spring-early summer 2000. The sample with the highest concentration of antimony was collected from wastewater treatment plants (Borås) that had a possible contribution from the textile industry.

Sternbeck et al. (2002a) studied 4 municipal wastewater treatment plants that differed substantially in type of loading. The emission of antimony calculated as person equivalents (pe) was similar for the three WWTP, with the lowest concentrations ranging from 0.039 to 0.078 g Sb/pe and year (equivalent to 0.57-3.1 mg Sb/kg dw), while this substantially increased to 1.2 g Sb/pe and year (16 mg Sb/kg dw) for the WWTP connected to the textile industries.

Table 30: Measured antimony concentrations in European wastewater treatment plants.

Location	Concentration (mg Sb/kg dw)	Period	Remark	Reference
Sweden	0.6-18 (mean ± S.D.: 2.4 ± 3.0) (median: 1.3) (P90:3.4	2000, spring-summer	ICP-QMS Values from 48 WWTPs spread across the country.	Eriksson, 2001
Sweden	16 3.1 1.7 0.57	2001	ICP-MS Values from 4 WWTP with different loadings Household, textile industries, graphical Household, surface water, various industries Household, laundry Only household	Sternbeck et al., 2002a

4.2.5.2.6 Levels in soil

Antimony, being a natural element, will naturally occur in soils as a result of weathering parent rock material. The concentrations of antimony in soils are highest in soils from sedimentary rocks such as argillaceous sediments and shale (Fergusson, 1990). The average concentration of antimony in the earth's crust is approximately 0.2 - 0.3 mg/kg (Lisk, 1972; Bowen, 1979; Wedepohl, 1995). The average concentration of antimony in soils is about 0.5 mg/kg (Reiman and Caritat, 1998) to 1 mg/kg (Bowen, 1979), but wide ranges have been reported (see Table 31 below).

Baseline background concentrations of antimony in soil (topsoil and subsoil) measured in the FOREGS project result in values in topsoil that range over three orders of magnitude, from <0.02 to 31.1 μg Sb/kg dw, with a median value of 0.60 mg Sb/kg dw (see Table 31 and Figure 3). The median ratio topsoil/subsoil is 1.15. Concentrations detected in subsoil are presented inTable 24.

Table 31: Concentrations of Sb in European topsoil according to FOREGS http://www.gsf.fi/publ/foregsatlas/article.php?id=15).

Unit	Number of samples	Min	Median	Mean ± SD	90P	Max
mg Sb/kg dw	840	0.02	0.60	1.04 ± 2.04	1.91	31.1

Table 32: Concentrations of Sb in European subsoil according to FOREGS http://www.gsf.fi/publ/foregsatlas/article.php?id=15).

Unit	Number of samples	Min	Median	Mean ± SD	90P	Max
mg Sb/kg dw	783	<0.02	0.47	0.836 ± 1.73	1.53	30.3

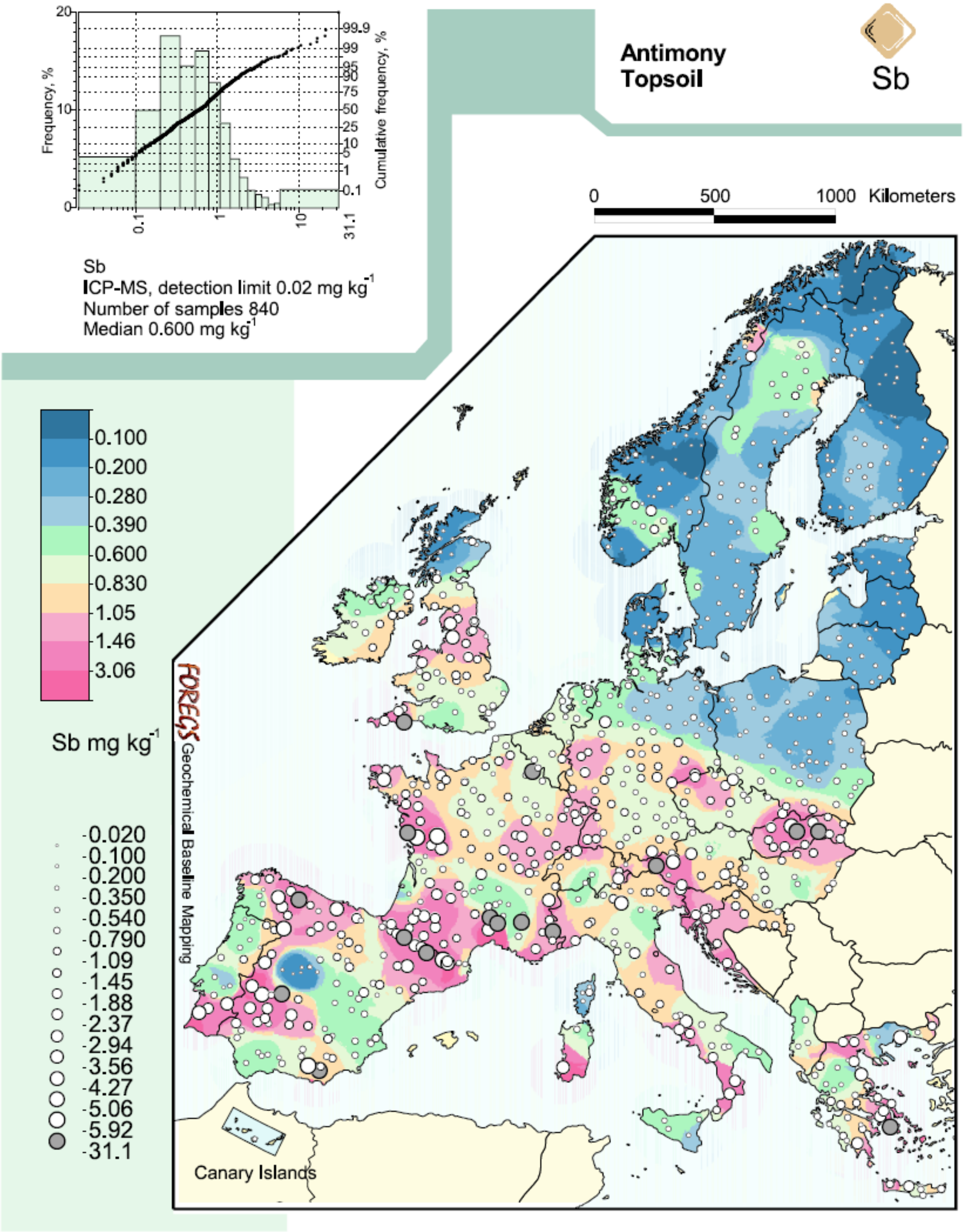

Figure 3: FOREGs map showing measured concentrations of Sb (mg/kg dw) in European top soil (http://www.gsf.fi/publ/foregsatlas/maps/Topsoil/t_icpms_sb_edit.pdf).

Measured antimony concentrations in European soils from other sources besides the FOREGS database were reported in the EU RAR and are presented here in Table 33 together with monitoring data published since the EU RAR.

Table 33: Measured antimony concentrations in European soils.

Location	Concentration (Sb mg/kg dw)	Speciation (Total, unless otherwise specified)	Period	Remark	Reference
Austria					Fritsche, 2003
Liesingtal	1.4, 1.1, 1.1, 1.1, 1.0		2002	FIFU-AAS 31 samples, different soil types and locations near motorways all over Austria	
Knittelfeld	4.8, 2.5, 1.2, 1.1, 0.9				
Rankweil	2.9, 2.6, 1.4, 1.1, 0.8				
Brennersee	3.4, 5.1, 2.3, 1.9, 1.7				
Tangente (SW of)	3.4, 3.3, 3.8, 2.9, 4.0				
	3.7, 4.0				
Wien (Stadtpark)	1.9, 1.9				
Graz (Stadtpark)	0.5, 0.4				
Lungau					
Austria				HPLC-ID-ICP-MS	Amereih et al, 2005
	1.21 – 6.30 1.13 – 8.68	Total Sb Total Sb	2002 2005	Knittlefeld Site near traffic routes	
	0.076 – 0.149 1.13 – 8.68	Extractable Sb (III)	2002 2005		
	0.033 – 0.840 0.048 – 1.52	Extractable Sb (V	2002 2005		
	0.82 – 2.74	Total Sb	2002	Rankweil Site near traffic routes	
	0.052 – 0.138	Extractable Sb (III)	2002		
	0.048 – 0.494	Extractable Sb (V))	2002		
	0.64 – 0.81	Total Sb	2002	Langmuir Reference site	
	0.033 – 0.03	Extractable Sb (III)	2002		
	0.031 – 0.038	Extractable Sb (V))	2002		
Belgium	<0.2-0.5 <0.2-0.5 <0.2-0.5			GF-AAS 130 soil samples from all over Belgium in areas as far away as possible from point sources. Normal levels in top soils (0-10 cm) Quaternarian	De Temmerman et al., 1984

Location	**Concentration (Sb mg/kg dw)**	**Speciation (Total, unless otherwise specified)**	**Period**	**Remark**	**Reference**
	0.1-3.0 <0.2-0.5 <0.2-0.5 1.0			parent material Sand Sandy-loam Loam and clay (polder) Alluvium (clay) Palaeozoic and Mesozoic parent material Sand (woods) Stony loam-heavy clay Upper limit of "normal" concentration in unpolluted soil	
Czech and Slovak republics	7.47 - 3112 1.31 – 10.7			Long term instrumental neutron activation analysis Samples in the vicinity of a lead smelter Clean site	Borovixka et al, 2006
Příbram (Forest soil)	≥ 4.86 ≤ 2058 Mean= 379 mg/kg d.w. (20 samples)			Quadrupole-based ICP-MS Monitoring of topsoils in the vicinity of a lead smelter 8 soil profiles (4 in forested area, 4 in agricultural area) were sampled	Ettler et al., 2010
Příbram (Agricultural soil)	≥ 3.12 ≤ 131			Quadrupole-based ICP-MS Monitoring of topsoils in the vicinity of a lead smelter 8 soil profiles (4 in forested area, 4 in agricultural area) were sampled	Ettler et al., 2010
France	26.1-43.5 1200			Sites contaminated by mine Slag	Denys et al., 2009

Location	Concentration (Sb mg/kg dw)	Speciation (Total, unless otherwise specified)	Period	Remark	Reference
				AAS or ICPOES	
Germany	222-333			GF-AAS + HG-AAS Soil samples associated with gray copper ore	Gebel et al., 1997
	1.0 4.0			AAS Agricultural (unpolluted) soil Luvisol Chernozem	Hammel et al., 1998
Bavaria	232 268			HPLC-ICP-MS Polluted soil, 2 samples	Lintschinger et al., 1997
Bitterfeld	5.8 2.8 2.4 1.3 9.0 4.0 3.6 2.0			PAA Industrial area Loam from flood plain forest around Bitterfeld-Greppin (Accumulation in Ah horizon, decrease with depth but at 1 m depth (Gor-horizon acts as a barrier) PAA 10 cm 50 cm 100 cm 150 cm NAA 10 cm 50 cm 100 cm 150 cm	Schulze et al., 1997
Bitterfeld	$>100^{**}$			IC-ICP-MS Strongly polluted	Ulrich, 1998
Bitterfeld	2487^{***}			FIA-ICP-MS Strongly polluted	Ulrich, 2000
Nordpfälzer Bergland	13 ± 2 82 ± 6 153 ± 14 18 ± 1 1317 ± 508			AAS Soil samples from a historical (1442-1932) mining area Fallow meadow Agriculture used meadow Vineyard Vineyard Former mine dump	Hammel et al., 1998
	0.24 ± 0.01 – 39.5 ± 0.36		January, 2004	GC-EI/MS-ICP-MS	Duester et al, 2005

Location	Concentration (Sb mg/kg dw)	Speciation (Total, unless otherwise specified)	Period	Remark	Reference
				Urban soils	
	8 - 486			Fias-Hydrid-AAS-system Abandoned mining area	Hammel et al, 2000
Bavaria				ICP-MS Area with industrial Sb use	Lintschinger et al, 1998
	118 ± 20			30 – 60 cm depth	
	73.4 ± 2.5			10 – 30 cm depth	
	196 ± 4			10 – 30 cm depth	
Italy Tuscany				ICP/AES Clay pigeon shooting range	Migliorini et al, 2005
	< detection limit – 16.3			7 sites in shot fall area	
	< detection limit			2 control sites	
Tuscany			Autumn 1996, spring and autumn 1997, spring 1998	AAS Abandoned Sb mining area	Baroni et al, 2000
	27.74 ± 4.31	Total Sb		Old field site	
	0.08 ± 0.02	Soluble Sb			
	0.18 ± 0.05	Extractable Sb			
	202.80 ± 39.70; 192.40 ± 31.72	Total Sb		Mine dump site 1	
	0.17 ± 0.05; 0.15 ± 0.04	Soluble Sb			
	2.90 ± 0.48; 3.0 ± 0.64	Extractable Sb			
	2795.53 ± 539.12 – 15,112.94 ± 961.55 0.92 ± 0.12 - 2.04 ± 0.59-	Total Sb Soluble Sb Extractable Sb		Mine dump site 2	
	1.78 ± 0.47 – 14.91 ± 3.05 6529.70 ± 890.65 – 9197.50 ± 1205.36 13.00 ± 2.47 – 31.40 ± 5.71	Total Sb Soluble Sb Extractable Sb		Tailing pond site	

Location	Concentration (Sb mg/kg dw)	Speciation (Total, unless otherwise specified)	Period	Remark	Reference
	02.48 ± 43.65 – 792.60 ± 153.80				
Netherlands Soils, Holland Marsh	1.85, 2.11 1.73 0.66 0.58 0.93 0.75 0.7		1970, June	PAA Market-garden soils Surface 0-7.5 cm 7.5-15.0 cm 15.0-22.5 cm 22.5-30 cm 30.0-37.5 cm 37.5-45 cm	Chattopadhyay and Jervis, 1974
Lekkerkerk	0.24-3.2 0.32-3.2 0.4-3.0			Highly polluted soils Comparison of three techniques Colorimetry HG-AAS GF-AAS	Haring et al., 1982
Norway	2.2 1.26 0.83 0.22 1.09 0.33 0.25 0.41 0.31 0.23 0.17		1977, Summer	NAA Humus layer, Mean values S. Norway (0-60 km from the coast) S. Norway (60-120 km from the coast) E. Norway, central part E. Norway, northern part W. Norway, coast Møre/Trøndelag, coast Møre/Trøndelag, inland Nordland, coast Nordland, inland Troms/Finnmark, coast Troms/Finnmark, inland	Allen and Steinnes, 1979; Steinnes, 1980
South North	2.4 0.22			Surface soil (decrease along a northly gradient)	Steinnes et al., 1997
Poland	0.34 – 2.26			AAS Farming soils – affected by main industrial centre of	Loska et al, 2004

Location	**Concentration (Sb mg/kg dw)**	**Speciation (Total, unless otherwise specified)**	**Period**	**Remark**	**Reference**
				Poland, Czech Republic and a local coal mine	
Portugal	30.5 – 5986.4			Hydride generation Abandoned mine area	Pratas et al, 2005
Sao Domingos (ex mining area)	> 98 < 1100 Range of 5 samples.			Instrumental Neutron Activation Analysis (INAA) and Compton-Suppression Neutron Activation Analysis (CSNAA). Topsoils from an area impacted by mine waste, dust mobilisation and acid mine drainage from a sulphide-mining complex.	Landsberger et al., 2010
Spain Guadiamar valley	0.71-3.31 (mean: 1.80) 0.89-323 (mean: 13.7)			ICP-MS Soils unaffected by acidic mining sludges Soils affected by a toxic flood from acidic mining sludges	Cabrera et al., 1999
Extremadura	Mean = 225.0 Mean = 2.0 Mean = 874.6 Mean = 8.7 Mean = 2443.8 Mean = 1752.0 Mean = 5.5		Spring, 1999	INAA Mari Rosa mining site Mari Rosa reference site Pilar Pilar reference site S. Antonio wastes S. Antonio muds S. Antonio reference sites	Murciego et al, 2007
La Coruna	2.22 – 3.81			(ETAAS Garden soils close to roads A9 highway	Cal-Prieto et al, 2001

Location	Concentration (Sb mg/kg dw)	Speciation (Total, unless otherwise specified)	Period	Remark	Reference
	3.52 – 4.10 0.46 – 8.81 0.53 0.29			Main Avenue Roadside border Uncultivated soil Cultivated soil	
Sweden	0.25±0.08 (mean±stdev) 0.25 (median) 0.07-0.41 (min-max) 0.21±0.10 (mean±stdev) 0.23 (median) 0.02-0.38 (min-max)			ICP-EAS/ICP-QMS Topsoil, n=25 from different regions in Sweden covering different types of soil and parent material Subsoil, n=25 from different regions in Sweden covering different types of soil and parent material	Eriksson, 2001
United Kingdom South East England	0.7			AAS Rural soil (acid sandy soil, pH=4.9)	Cornfield, 1977
Scotland	~1			Arable surface soils	Mitchell and Burridge, 1979
Scottish soils	0.29-1.3 (mean = 0.64)			SSMS 10 samples, different soil types and locations	Ure et al., 1979
Northumberland	6.9 7.6 170-360 90-200 120-180			Rural soils 0-5 cm 10-15 cm Proximity to Sb smelter (concentrations decrease with depth) 100 m from smelter 250 m from smelter 450 m from smelter	Ainsworth et al., 1990a
Derbyshire			1990, May	ICP-AES *Old mining area*	Li and Thornton, 1993

Location	Concentration (Sb mg/kg dw)	Speciation (Total, unless otherwise specified)	Period	Remark	Reference
Shipman Cornwall	23.4 21.8 17.1 1.43 1.11 1.2 103 41.3 17.3 1.1 1.03 0.63 37.9 36.1 28.9 1.01 0.68 ??? 2.21 2.32 1.95 0.65 0.53 0.51 5.49 6.33 3.91		1990, August 1991, December	Winster village and farm A Topsoil (0-15 cm) Subsoil (15-20 cm) Subsoil (30-45 cm) Control site (farm B) Topsoil (0-15 cm) Subsoil (15-20 cm) Subsoil (30-45 cm) Old smelter site (stone Edge) Topsoil (0-15 cm) Subsoil (15-20 cm) Subsoil (30-45 cm) Smelter surrounding area Topsoil (0-15 cm) Subsoil (15-20 cm) Subsoil (30-45 cm) *Old zinc mining area* Shipman mining area Topsoil (0-15 cm) Subsoil (15-20 cm) Subsoil (30-45 cm) Old Red sandstone area Topsoil (0-15 cm) Subsoil (15-20 cm) Subsoil (30-45 cm) *Old mining area* Old mining site Topsoil (0-15 cm) Subsoil (15-20 cm) Subsoil (30-45	

Location	Concentration (Sb mg/kg dw)	Speciation (Total, unless otherwise specified)	Period	Remark	Reference
				cm) Old mining site, Wheal sister Farm Topsoil (0-15 cm) Subsoil (15-20 cm) Subsoil (30-45 cm) *Old As calciner and Sn smelter sites* New Mill Farm Topsoil (0-15 cm) Subsoil (15-20 cm) Subsoil (30-45 cm)	
Thetford Forest	0.0 8.7			ICP-MS 0-10 cm soil horizon Control soil (pH 3.3) Contaminated soil (pH 3.9)	Hartley et al., 1999
3 sites in southwest England, 1 site in Derbyshire, 1 site in Scotland	37.07 0.25 11.89 – 336.20 0.0 – 5.50 15.32 – 63.18 0.01 – 1.22 14.63 – 709.84 0.07 – 2.42 14.04 – 673.39 0.12 – 3.93	Total Sb Water soluble Sb Total Sb Water soluble Sb Total Sb Water soluble Sb Total Sb Water soluble Sb Total Sb Water soluble Sb		Hydride generation FAAS Old mining site Devon Great Consols Old mining site Wheal Betsy Old mining site Trevinnick Old mining site Stone Edge Old mining site Glendinning	Flynn et al, 2003

*Mobile content (NH_4NO_3 extraction)
**Sb(V) (90 %), Sb(III) (10 %), TMSbO (only in small concentrations)
***Concentration in soil extracts, units µg/l. Sb(V), Sb(III), and TMSbO values determined.

Since publication of the EU RAR for ATO data from a Europe wide monitoring programme GEMAS has also become available (Reimann et al, 2009). Over 2000 samples were taken from both agricultural and grazing soils. Pristine sample sites were not selected but point sources were avoided as far as possible. The results are presented in Table 34 and Table 35 and Figure 4 and Figure 5 below. The median values of the 90th percentiles per country are 0.63 Sb mg/kg and 0.70 Sb mg/kg for agricultural and grazing land respectively. The median value from the 90th percentiles has actually been used for PEC regional for environmental risk assessment as stipulated by the ECHA guidance R16.4.2.

Table 34: Monitored concentrations of antimony in agricultural soils

Country	Minimum Sb mg/kg	Maximum Sb mg/kg	Median Sb mg/kg	90th percentile Sb mg/kg
AUS	0.17	9.13	0.61	1.14
BEL	0.16	0.66	0.39	0.55
BOS	0.23	1.69	0.53	1.13
BUL	0.08	0.84	0.28	0.44
CRO	0.14	0.93	0.45	0.58
CYP	0.06	0.82	0.26	0.55
CZR	0.22	1.16	0.46	0.90
DEN	0.08	0.50	0.13	0.17
EST	0.06	0.26	0.07	0.11
FIN	0.01	0.35	0.08	0.17
FOM	0.08	2.93	0.26	1.31
FRA	0.02	2.99	0.34	0.93
GER	0.07	3.19	0.30	0.70
HEL	0.05	1.59	0.28	0.63
HUN	0.10	3.00	0.31	1.02
IRL	0.09	1.27	0.42	0.62
ITA	0.07	4.19	0.32	0.85
LAV	0.05	0.18	0.08	0.14
LIT	0.06	0.13	0.09	0.11
LUX	0.20	0.20	0.20	0.20
MON	0.16	1.35	0.32	0.97
NEL	0.11	2.86	0.26	0.36
NOR	0.01	0.93	0.08	0.22
POL	0.07	1.03	0.14	0.33
PTG	0.03	17.10	0.20	1.25
SIL	0.19	2.47	0.35	0.75
SKA	0.33	2.54	0.73	1.18
SLO	0.21	1.61	0.63	1.02
SPA	0.03	12.94	0.34	1.11
SRB	0.21	3.30	0.44	1.02
SWE	0.03	0.91	0.14	0.25
UKR	0.03	0.80	0.14	0.32
UNK	0.02	8.03	0.35	0.65

Table 35: Monitored concentrations of antimony in grazing soils

Country	Minimum Sb mg/kg	Maximum Sb mg/kg	Median Sb mg/kg	90th percentile Sb mg/kg
AUS	0.15	10.00	0.65	2.20
BEL	0.21	0.72	0.38	0.55
BOS	0.21	1.94	0.58	1.37
BUL	0.07	1.01	0.26	0.49
CRO	0.20	4.28	0.65	1.49
CYP	0.05	0.26	0.19	0.25
CZR	0.26	0.61	0.46	0.60
DEN	0.07	0.32	0.13	0.17
EST	0.04	1.08	0.08	0.31
FIN	0.01	2.08	0.09	0.21
FOM	0.10	1.65	0.27	0.97

Country	**Minimum Sb mg/kg**	**Maximum Sb mg/kg**	**Median Sb mg/kg**	**90th percentile Sb mg/kg**
FRA	0.03	9.80	0.35	0.99
GER	0.06	3.06	0.42	0.88
HEL	0.06	6.99	0.32	0.80
HUN	0.10	2.45	0.38	0.95
IRL	0.11	1.12	0.44	0.67
ITA	0.07	5.92	0.36	0.97
LAV	0.05	0.21	0.09	0.12
LIT	0.05	0.43	0.09	0.12
LUX	0.23	0.23	0.23	0.23
MON	0.24	1.51	0.49	1.20
NEL	0.13	0.72	0.34	0.48
NOR	0.01	1.01	0.10	0.34
POL	0.06	0.71	0.17	0.45
PTG	0.05	1.87	0.15	1.41
SIL	0.13	4.33	0.37	0.92
SKA	0.35	7.96	0.64	1.61
SLO	0.39	1.34	0.63	0.80
SPA	0.04	5.00	0.40	1.24
SRB	0.14	1.53	0.44	0.70
SWE	0.01	24.61	0.15	0.33
UKR	0.02	1.26	0.16	0.32
UNK	0.02	4.25	0.38	0.83

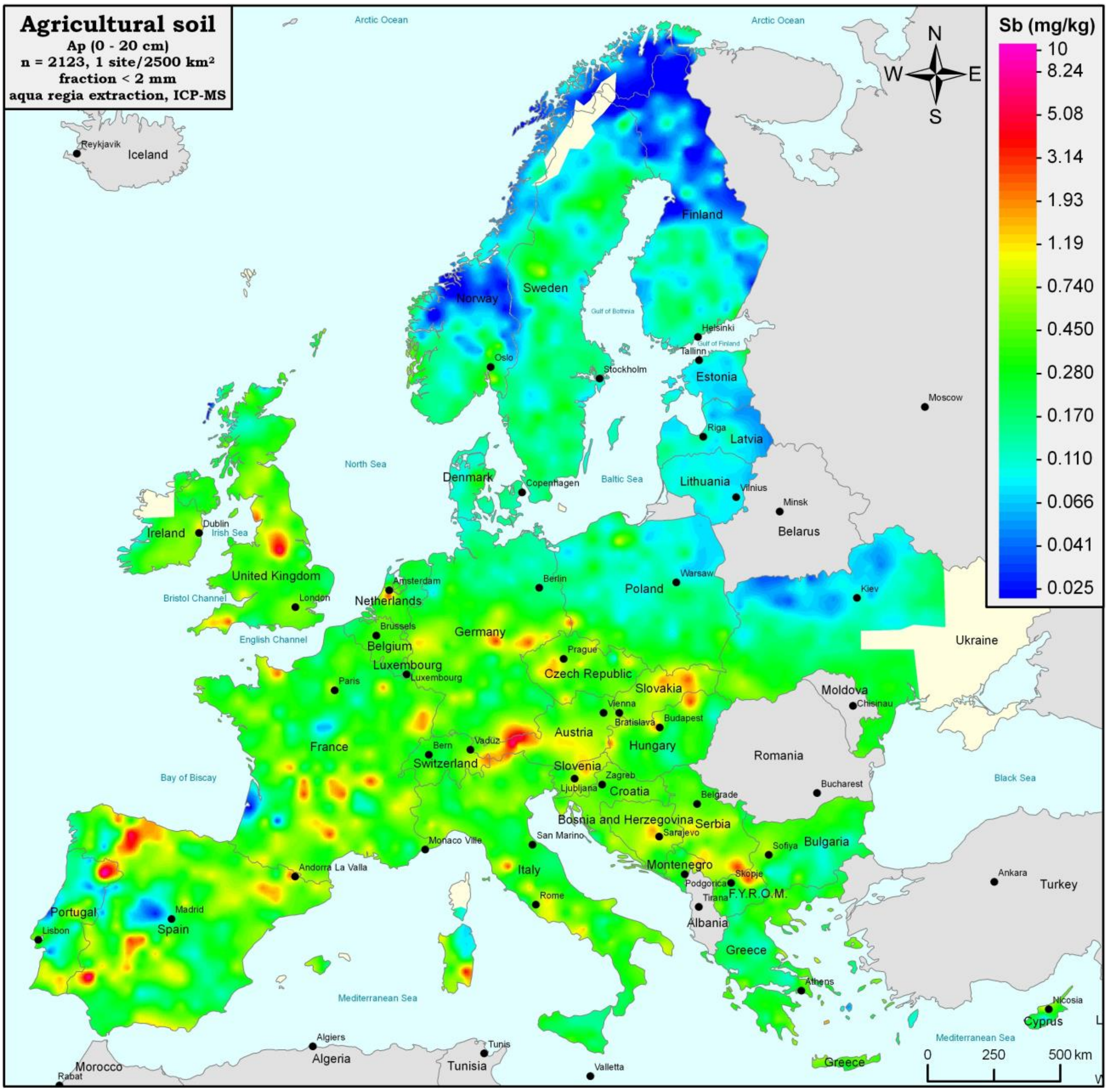

Figure 4: GEMAS map showing measured concentrations of Sb (mg/kg) in European agricultural soil

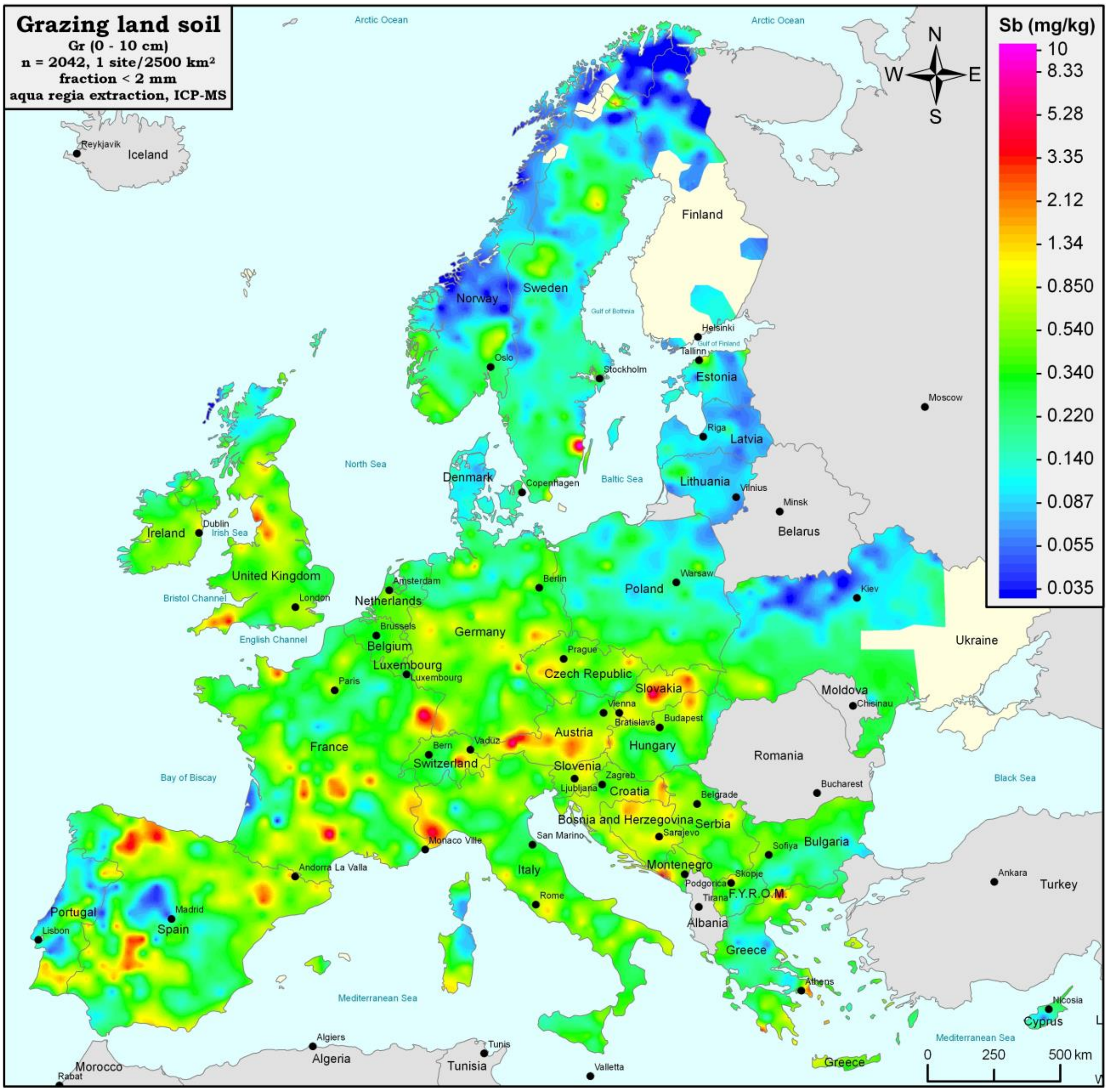

Figure 5: GEMAS map showing measured concentrations of Sb (mg/kg) in European grazing land soil

A RWC-ambient PEC of 1.7 mg Sb/kg dw (1.5 mg/kg ww) in soil is calculated in the EU RAR for ATO using ambient data from 7 countries (see Table 36). The country-specific FOREGS 90P values range from a factor of two larger (Spain and Sweden) to a factor of almost three lower (Germany and UK) when compared to measured ambient concentrations. The newly available monitoring data from sites without point sources are in the same range as those reported in the EU RAR. The GEMAS monitoring data also do not suggest that the RWC-ambient needs to be refined. Therefore, the same RWC ambient used in the EU RAR will be used here.

Table 36: Calculation of RWC-ambient PEC for antimony in soil. Country specific 90P FOREGS data are included for comparative purposes only.

Country	RWC-ambient PEC (90P) mg Sb/kg dw	Data used	FOREGS -90th percentile mg Sb/kg dw
Austria			3.1
Belgium	1.6	0.1, 0.5, 0.1, 0.5, 0.1, 0.5, 0.1, 3, 0.1, 0.5, 0.1, 0.5	0.99
Bulgaria			-

Country	**RWC-ambient PEC (90P) mg Sb/kg dw**	**Data used**	**FOREGS -90th percentile mg Sb/kg dw**
Cyprus			-
Czech Republic			1.91
Denmark			0.17
Estonia			0.42
Finland			0.33
France			2.61
Germany	3.7	1, 4	1.27
Greece			2.71
Hungary			0.98
Ireland			1.03
Italy			2.57
Latvia			0.25
Lithuania			0.30
Luxembourg			-
Malta			-
Netherlands	1.73	1.73	0.95
Poland			0.70
Portugal			3.52
Romania			-
Slovakia			12.2
Slovenia			1.69
Spain	1.8	1.8	3.87
Sweden	0.25	0.25	0.58
United Kingdom	5.13	0.7, 1, 0.64, 6.9	1.76
Norway	1.26	2.2, 1.26, 0.83, 0.22, 1.09, 0.33, 0.25, 0.41, 0.31, 0.23, 0.17	0.58
Median	1.73		1.03* 1.59**

*Median of FOREGS country-specific 90P values
**Median value of RWC values when available and country-specific FOREGS 90th percentile values for those countries with no RWC value

4.2.5.2.7 Levels in air

Measured antimony concentrations in European air were reported in the EU RAR for ATO and are presented here in Table 28. No additional European air monitoring data was identified as being available since the EU RAR.

Table 37: Measured antimony concentrations in European air.

Location	**Concentration (Sb ng/m^3)**	**Speciation (Total, unless otherwise specified)**	**Period**	**Remark**	**Reference**
Austria				FIFU-AAS	Umweltbundesamt, 2004
Illmitz	<0.082 – 2.0 (mean = 1.0)		2004, Jan – Feb	10 samples PM10	
Kittsee	<0.082 – 3.5 (mean = 1.4)			10 samples PM10	
Wörgl	1.2 – 2.4			5 samples	

Location	Concentration (Sb ng/m^3)	Speciation (Total, unless otherwise specified)	Period	Remark	Reference
	(mean = 1.9)		2003, Oct - Nov	PM10	
Vomp	2.5 – 6.1 (mean = 4.3)			6 samples PM10	
Brixlegg	0.19 – 3.2 (mean = 1.2)			4 samples PM10	
Inntal	1.2 – 6.7 (mean = 4.4)			5 samples PM10	
Finland			1996, April – 1997, June	ICP-MS	Pakkanen et al., 2001
Helsinki (central)	0.77 ± 1.4 0.78 ± 0.52			PM$_{2.3}$ PM$_{2.3-15}$	
NW Helsinki (rural)	0.36 ± 0.4 0.036 ± 0.033			PM$_{2.3}$ PM$_{2.3-15}$	
Germany			1994, May-October	ICP-MS PM10-fraction	Dietl et al., 1997
Munich (central)	13.4 (range 9.0-16.7)			High traffic density	
NE Munich (residential district)	3.2 (range 1.69-5.0)			Very light traffic density	
Municipal putrification plant	618-14720 (min-max)	Methylated		GC-ICP-MS Sewage gas	Feldmann and Hirner, 1995
Domestic waste deposit	23900-71600 (min-max)	Methylated		Landfill gas	
Norway Nordmoen			1988, April-May	ICP-MS	Hillamo et al., 1988
	0.07		Atlantic air		
	0.54		UK & Ireland air		
	0.13		Central Europe air		
Oslo	6 ± 0.5[a]		1994, summer	ICP-MS Street dust, unit mg/kg	de Miguel et al., 1997
Sweden				ICP-MS Road tunnels with heavy traffic	Sternbeck et al., 2002b
Gothenburg (Tingstad)	28 ± 10 (range: 17-40)		1999, November	Tunnel inlet	
	75 ± 35 (range: 56-131)			Tunnel outlet	
Gothenburg (Lundby)	34 ± 12 (range: 20-49)		2000, April	Tunnel inlet	

Location	Concentration (Sb ng/m^3)	Speciation (Total, unless otherwise specified)	Period	Remark	Reference
	107 ± 14 (range: 91-127)			Tunnel outlet	
Stockholm (central) S Stockholm	20 ± 12 (range: 5-42) 1.8 ± 1.3 (range: 0.4-3.9)		2003	ICP-MS PM10-fraction Urban air Country side (next to motorway E4)	Sternbeck, 2003
Hornsgatan (densely trafficked street canyon)	15.5 Mean result of 12 samples, SD 12.8		2003, September – 2004, September	ICP sector field mass spectrometry and ICP optical emission spectrometry. Monitoring study of concentrations of particulate heavy metals in urban air.	Johannson et al., 2009
United Kingdom Inland part of England	50 29		1980, Aug.-Oct 1980, Nov-Jan	NAA Industrial area, with ferrous and non-ferrous metal smelting and manufacturing	Pattenden et al., 1982

[a]Mean ± S.E.

The EU RAR for ATO calculated a RWC-ambient background concentration of antimony in air of 2.6 ng Sb/m^3 based on these data. As no additional data were identified this value will also be used here.

4.2.5.3 Summary of the RWC-ambient concentration

RWC-ambient concentrations based on the available measured data are presented in Table 29 below.

Table 38: Ambient background concentrations of antimony in the environment.

Compartment	Concentration
Freshwater	0.72 µg Sb/l
Sediment	0.65 mg Sb/kg ww
Soil	1.5 mg Sb/kg ww
Air	2.6 ng Sb/m^3
Marine water	0.20 µg Sb/l
Marine sediment	0.65 mg Sb/kg ww

4.3. Bioaccumulation

4.3.1. Aquatic bioaccumulation

The studies on aquatic bioaccumulation are summarised in the following table:

Table 39: Overview of studies on aquatic bioaccumulation

Method	Results	Remarks	Reference
Hyalella azteca aqueous (freshwater) field study Total uptake duration: 17 d Details of method: Log relationships between the background corrected Sb concentrations in water and Hyallela were exmained in scatter plots and then tested by Pearsons correlation coefficients. Valid adsorption isotherms were observed. BCF = (metal in Hyalella - background metal in Hyalella)/water concentration. The relationship between concentrations accumulated by specimens of the amphipod Hyalella azteca and concentrations in water for 27 metals (including antimony) in a field deployment were determined in two metal-contaminated rivers in northwestern Québec, Canada. The amphipods were placed along with natural food items in small acrylic cages and left in six riverine sites for 17 days.	BCF: 5.6 L/kg (whole body w.w.) (kinetic)	2 (reliable with restrictions) weight of evidence read-across from supporting substance (structural analogue or surrogate) **Test material (element): antimony**	Coulliard Y, Grapentine LC, Borgmann U, Doyle P & Masson S (2008)
Salmo trutta aqueous (freshwater) field study Total uptake duration: 23 d Caged trout were exposed to antimony downstream of a military area. Concentrations in the water and fish were measured over 23 days.	BCF: 19.4 — 28.6 (gill ww) BCF: 4.5 — 6.7 (liver ww)	2 (reliable with restrictions) weight of evidence read-across from supporting substance (structural analogue or surrogate) **Test material (element): antimony**	Heier LS, Lien IB, Stromseng AE, Ljones M, Rosseland BO, Tollefsen (2009)
Coregonus clupeaformis, Esox lucius, Osmerus mordax and Perca flavescens	BCF: 7 (whole body w.w.) (Species: Coregonus clupeaformis, Location: Moose Lake)	3 (not reliable) supporting study	Uthe JF & Bligh EG (1971)

Method	Results	Remarks	Reference
not determined (freshwater) field study Details of method: based on total Sb concentrations in fish and the average Sb concentration in surface water	BCF: 11 (whole body w.w.) (Species: Esox lucius, Location: Moose Lake) BCF: 10 (whole body w.w.) (Species: Corgegonus clupeaformis, Location: Lake Ontario) BCF: 12 (whole body w.w.) (Species: Esox lucius, Location: Lake St. Pierre) BCF: 14 (whole body w.w.) (Species: Esox lucius, Location: Lake Erie) BCF: 12 (whole body w.w.) (Species: Osmerus mordax, Location: Lake Erie) BCF: 10 (whole body w.w.) (Species: Perca flavescens, Location: Lake Erie)	read-across from supporting substance (structural analogue or surrogate) **Test material (element): antimony**	
Ecklonia radiata, Sargassum lacerifolium, Ulva dp., Mytilus edulis planulatus, Helagrapsus sp., Arripus georgianus, Semir hamphus australis, Sillaginodes punctatus not determined (saltwater) field study Details of method: - results from monitoring data on Sb concentrations in marine organisms and waters used for calculation of BCF - factor of 10 used for conversion of concentrations based on dry weight into concentrations based on wet weight monitoring study on antimony concentrations in aquatic organisms and waters.	BCF: 55 (whole body d.w.) (Species: Ecklonia radiata) BCF: 71 (whole body d.w.) (Species: Sargassum lacerifolium) BCF: 114 (whole body d.w.) (Species: Ulva sp.) BCF: 18 (organ d.w. (mantle)) (Species: Mytilus edulis planulatus) BCF: 28 (organ d.w. (Viceral mass)) (Species: Mytilus edulis planulatus) BCF: 35 (organ d.w. (Abductors)) (Species: Mytilus edulis planulatus) BCF: 11 (organ d.w. (muscle)) (Species: Helgograpsus sp.) BCF: < 5 (organ d.w. (muscle)) (Species: Arripus georgianus) BCF: 6 (organ d.w. (muscle)) (Species: Semir hamphus australis) BCF: < 5 (organ d.w. (muscle)) (Species: Stillaginodes punctatus)	2 (reliable with restrictions) weight of evidence read-across from supporting substance (structural analogue or surrogate) **Test material (element): antimony**	Maher W (1986)
finfish, shellfish	BCF: 5000 — 15000 (whole	3 (not reliable)	Hall RA, Zook EG

Method	Results	Remarks	Reference
not determined (saltwater) field study Details of method: - results from monitoring data on Sb concentrations in marine organisms and waters (data rom Fillella et al, 2002) used for calculation of BCF monitoring study on antimony concentrations in aquatic organisms.	body w.w.) (finfish) BCF: 4000 — 5000 (whole body w.w.) (shellfish)	supporting study read-across from supporting substance (structural analogue or surrogate) **Test material (element): antimony**	& Meaburn GM (1978)
Ostrea sinuate, Pecten novae-zelandiae, Mytilus edulis aoteanus, Squalus acanthias, Ctenolabrus rupestris not determined field study Details of method: - results from monitoring data on Sb concentrations in marine organisms and waters used for calculation of BCF - factor of 10 used for conversion of concentrations based on dry weight into concentrations based on wet weight monitoring study on antimony concentrations in aquatic organisms and waters.	BCF: 16000 (muscle) (Ostrea sinuate) BCF: 0 (muscle) (Pecten novae-zelandiae) BCF: 0 (muscle) (Mytilus edulis aoteanus) BCF: 40 (eviscerated) (Squalus acanthias) BCF: 40 (whole) (Ctenolabrus rupestris)	4 (not assignable) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material (element): antimony**	Chapman WH, Fisher HL & Pratt MW (1968)

4.3.2. Terrestrial bioaccumulation

The results of terrestrial bioaccumulation studies are summarised in the following table:

Table 40: Overview of studies on terrestrial bioaccumulation

Method	Results	Remarks	Reference
Earthworms Monitoring study on antimony concentrations in soils and earthworms. BSAF calculated based on antimony concentration in soils and antimony in earthworms	BSAF: 0.6 — 1.03 dimensionless (whole body d.w.)	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material (element): antimony**	Ainsworth N, Cooke JA & Johnson MS (1990)

Method	Results	Remarks	Reference
Earthworm, L. terrestris and O. cyaneum Soil samples were weighed, dried in an oven, at 30 ± 5 °C, screened through a 2mm sieve and the fraction < 2mm split for grinding to < 150 µm. This sample was analysed using ICP-AES analysis. Earthworms were washed in UHP water, dried and separated into species groups. They were left for a starvation period after which they were freeze dried at -50°C. They were then ground and an aliquot of 0.200g of sample was digested for 10 minutes with 5ml of 65% nitric acid at 175°C. Once cooled, samples were diluted to 25ml with UHP water and analysed using ICP-AES.	BSAF: 0.034 dimensionless (whole body d.w.) (Species: L terrestris) BSAF: 0.063 dimensionless (whole body d.w.) (Species: O cyaneum)	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material (element): antimony**	Gal J, Hursthouse A & Cuthburt S (2007)
Medicago sativa (alfafa plants) Soil and alfalfa samples were collected simultaneously from the same 20 agricultural sites. The above ground parts of the alfafa plants were separated from the roots, then crushed, homogenised and frozen before freeze drying and pulverising to a fine powder. Digestion of the plant material was carried out using HNO3, then digestion with an optimised microwave programme. Sb was extracted from soil samples by weighing 2.0 g of soil and adding 20 ml of 0.05 mol/L EDTA. The vessel was sealed and shaken for 1 hour at 15 rpm at room temperature. The mixture was then centrifuged at 4000 rpm. Concentrations of Sb from both plant material and soil were determined by HG-AFS.	BSAF: 0.006 — 0.31 (edible fraction)	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material (element): antimony**	De Gregori I, Fuentes E, Rojas M, Pinochet H & Potin-Gautier M (2003) De Gregori I, Fuentes E, Olivares D & Pinochet H (2004)
Latuca sativa 20 lettuce seeds were sown in 3 replicate pots of each soil treatment and kept in a growth cabinet. Plants were harvested 24 days after sowing. They were cut just above the soil surface and dried at 70°C for at least 48 hours.	BSAF: > 0.33 — < 1.2 (edible fraction)	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate)	Oorts K, Gasco G & Smolders E (2005a)

Method	Results	Remarks	Reference
In addition, 4 plants were planted in each container with aged soil (control, 10 mg Sb/kg, 50 mg Sb/kg, 250 mg Sb/kg. Lettuce plants were first precultivated for 18 days, then left for an exposure period of 2 months before harvesting. Edible parts of the plant were harvested and dried at 50°C. Dry plant material was ground and Sb concentations determined by boiling nitric acid digestion and analysis with ICP-OES		**Test material (element): antimony**	
Athyrium flexile and grass Soil samples were weighed, dried in an oven at 30 ± 5° C, screened through a 2mm sieve and the fraction < 2mm split for grinding to < 150 µm. This sample was analysed using ICP-AES analysis. Plant samples were cleaned with freshwater, rinsed with UHP water and dried at room temperature. An aliquot of 0.200 g of sample was digested for 10 minutes with 5ml of 65 % nitric acid at 175° C. After cooling, samples were filtered and diluted to 25 ml with UHP water before analysis with ICP-AES. Due to very low Sb concentartions they were determineed using a continuous flow hydride generation ICP-AES system after pre-reduction of the acid digest solutions with a solution of 7.5 % KI, 10 % hydrochloric acid and 7.5 % ascorbic acid.	BSAF: 0.009 dimensionless (fern stem) BSAF: 0.002 dimensionless (fern leaves) BSAF: 0.009 dimensionless (Grass)	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material (element): antimony**	Gal J, Hursthouse A & Cuthbert S (2007)

4.3.3. Summary and discussion of bioaccumulation

The bioaccumulation of substances can pose a risk of chronic toxicity to organisms due to the accumulation of these substances in their tissues or through biomagnification up the food chain. Bioaccumulation potential is typically quantified by determining either a bioconcentration factor (BCF), a bioaccumulation factor (BAF) or, for soil organisms, a Biota to Soil Accumulation Factor (BSAF).

However, although well understood for organic substances, the determination of BCF, BAF or BSAF may be of little use in understanding the hazard of inorganic substances. Unlike organic substances which may be taken up by passive diffusion across cell walls metals are generally taken up by specific active transport mechanisms and so are regulated. Some metals are essential for growth, so may be highly accumulated when present at low concentrations but accumulated at a lower rate when present at higher concentrations.

Aquatic bioaccumulation

There are no standard laboratory studies designed to measure the bioaccumulation of antimony. Tentative bioconcentration factors can be estimated using results from monitoring studies where the concentration of antimony has been measured in different aquatic organisms.

The EU RAR for diantimony trioxide largely relied on studies that compared measured concentrations in sampled organisms with concentrations in water measured by other researchers (Chapman et al., 1968; Hall et al., 1978; Uthe and Bligh, 1971).

Chapman et al. (1968) calculated bioconcentration factors for a number of elements, including antimony, for fish, invertebrates and plants in both marine and freshwater environments based on literature data. The concentration factors were based on the concentration of the elements expressed in ppm (in water) and ppm of wet weight (in aquatic organisms). When elemental concentrations were reported otherwise (i. e. as units of dry or ash weight of an aquatic organism), the value was converted to wet weight with the assumption that wet weight values are 10 percent of values reported as dry weight and one percent of values reported as ash weight. The concentration of the element in seawater was selected from the literature to be representative of the continental shelf or estuarine waters, since the majority of seafood is harvested from these inshore waters. The representative concentration of antimony was chosen to be 0.5 ug/l, based on the following references: Goldberg (1965), Bowen (1966), Robertson (1967) and Schutz and Turekian (1965).

Chapman et al. (1968) calculated a bioconcentration factor for antimony of 16,000 (8/0.0005) in oyster, using the concentration 8 mg Sb/kg ww obtained from Brooks and Rumsby (1965). In the study by Brooks and Rumsby, six samples each of the three species of bivalves, *Ostrea sinuate*, *Pecten novae-zelandiae* and *Mytilus edulis aoteanus,* were sampled 18 km north of Nelson, New Zealand, at a depth of 22 m in the Tasman Bay. The content of trace elements, among them antimony, was determined i) in the whole animal excluding shells, ii) in the shells, iii) in the individual dissected organs and also iv) in sediment. Antimony was below the detection limit of 30 mg Sb/kg dw in all samples, except for the muscle of the oyster*Ostrea sinuate*, where a concentration of 80 mg/kg dw was measured.

For marine fish, Chapman et al. (1968) derived a bioconcentration factor of 40 using a concentration of 0.02 mg Sb/kg ww derived from literature (Vinogradov, 1953). In the report by Vinogradov the chemical composition of marine organisms was reported for a number of species and elements. A value of 0.2 mg Sb/kg dw in this book is given for both the spiny dogfish (*Squalus acanthias*) (eviscerated) and Goldsinny (*Ctenolabrus rupestris*) (whole), both values originating from the article by Noddack and Noddack (1939a).

In a large survey by Hall et al. (1978) trace element levels, including antimony, were determined in tissues of finfish, molluscs and crustaceans taken from 198 sites around the US coast, including Alaska and Hawaii. Muscle was analysed from 159 species of finfish, liver from 82, whole fish from 17, molluscs from 18, and crustaceans from 16 species. The mean levels of antimony in most finfish muscles and livers fell in the range 0.5-0.9 mg/kg. Most species of whole finfish had antimony levels between 1.0 and 3.0 mg Sb/kg. Most shellfish species displayed mean antimony levels between 0.8 and 1.0 mg Sb/kg. The report does not clearly state on what basis (dry weight, wet weight etc.) the reported concentrations are given. It is assumed that they are given on a wet weight basis. Tentative BCF values for whole finfish and shellfish would be in the range of 5000-15000, and 4000-5000, respectively, using a concentration of antimony in marine waters of 0.2 µg Sb/l (Filella et al*.,* 2002a).

Uthe and Bligh (1971) measured the concentration of a number of metals, including antimony, in freshwater fish from a lake free of major industrial development (Moose Lake) and from lakes in a highly industrialised area (Lower Great Lakes basin). All samples were composite samples consisting of at least 2.5 kg or three fish. In the majority of samples the number of fish used was larger than three. Samples were prepared as follows: headless dressed fish (at least three) were ground and thoroughly mixed and stored at -40º C until analysis. Antimony was analysed using Neutron Activation. The concentration of antimony in the water of the lakes was not measured in the study. Tentative BCFs were calculated in the EU RAR using an estimated antimony concentration in surface water of 0.3 µg Sb/l. The resulting BCF values are presented above.

In addition to these studies, the EU RAR also reported two studies which had measured concentrations in both the exposed organisms and the water (Maher, 1986; Couillard et al., 2008).

Maher (1986) measured antimony in marine organisms and waters from South Eastern Australia using HG-AAS. Water was filtered through a 0.45 µm filter. Samples of macroalgae were washed with distilled water to remove salts, freeze dried and ground to pass a 200 µm sieve. Animals were separated into component tissues and composites prepared by combining the tissues of five freeze dried specimens of each sample. The concentration measured in the marine water (140º E, 51.5º S) was 0.17 ± 0.02 µg Sb/l. Tentative bioconcentration factors were calculated using the concentrations in biota and in water measured by Maher (1986), and a conversion factor of 10 between concentrations in dry weight and wet weight. The resulting bioconcentration factors for algae, mollusc tissues, crustacean tissues, and fish muscle are 55 - 114, 18 - 35, 11 and 68, and < 5-6, respectively.

Couillard et al. (2008) evaluated the relationships between concentrations accumulated by specimens of the amphipod *Hyalella azteca* and concentrations in water for 27 metals (including antimony) in a field deployment in two metal-contaminated rivers in northwestern. The amphipods were placed along with natural food items in small acrylic cages and left in six riverine sites for 17 days. Based on the findings by Borgmann et al. (2007), which showed that the dissolved phase was the dominant route of metal accumulation for 24 (including antimony) of the 27 metals, Couillard et al. (2008) concluded that biouptake of metals in nature by *Hyalella* is mainly due to bioconcentration and therefore adequately represents a field BCF. The use of *Hyalella* for deriving a BCF is supported by the findings of Borgmann et al. (2004) who developed a mechanistically based saturation model for bioaccumulation of metals in *Hyalella azteca* in the laboratory. Although this results in a BCF that decreases with increasing concentrations of metal in the water, a background-corrected BCF at low water concentration can be calculated from the slope of the bioaccumulation curve at metal concentrations in water approaching 0 (Norwood et al., 2007). The BCFs in the field study by Couillard et al. (2008) could not be determined using the full bioaccumulation curve because none of the transplant sites had enough metal concentrations to reach the plateau region of bioaccumulation corresponding to maximum uptake.

Presently, no criteria exist for the measurement of BCFs and BAFs in the field (Arnot and Gobas, 2006). However, the approach taken by Couillard et al. (2008) included key characteristics of methodologies for deriving BCF values (OECD, 1993; Borgmann et al*.,* 2004), namely:

- the requirement of at least three low exposure (i. e. substantially below acute toxicity) treatment levels per metal for the test species. Couillard et al. (2008) used three deployments per river.

- for a given metal the requirement to obtain an absorption isotherm with a slope of approximately 1; this isotherm is defined as the log-log relationship between the chemical concentration in the test organism and that in the water (OECD, 1993). This condition is equivalent to reaching steady-state between organism and water “compartments” for the metal studied.

However, for all sites, except one, the measured concentration of antimony in the *Hyalella* or in the water, or both, was below the detection limit. The BCF value calculated for the only remaining site where the mean measured concentration of both the *Hyalella* and the water was above the detection limit, is 5.6. Although not fully reliable, the study indicates that the bioaccumulation of antimony in *Hyalella* is low.

An additional study has since been identified that investigates the bioaccumulation of antimony (Heier et al., 2009). Heier et al. (2009) exposed caged brown trout (*Salmo trutta*) to water contaminated with various metals downstream of a firing range. Fish were exposed for up to 23 days with concentrations in the water and fish gills and liver determined on days 2, 4, 7, 9, 11 and 23. The concentrations of antimony remained relatively stable throughout the exposure period (2.1 -3.1 µg Sb/l). The concentrations of antimony measured in the fish gills and liver were variable over the exposure period. The authors note that the measured concentrations were close to the analytical limit of detection, which makes them subject to greater uncertainty. In addition, the concentrations in the fish are reported in graphical format only. However, the BCF based on data reported in this study ranges from 4.5 - 28.6, indicating a low potential for bioaccumulation.

The following information is taken into account for any hazard / risk / bioaccumulation assessment:

No fully reliable bioaccumulation studies are available, so measured data from different aquatic organisms have been used to calculate tentative BCF values. For those studies which included measured data for both water and organism samples the BCF varies between 2.9 – 28.6 (Couillard et al., 2008; Heier et al., 2009) for freshwater and <5 - 114 (Maher, 1986) for marine water.

The diantimony trioxide risk assessment relied upon studies in which the concentrations measured in aquatic organisms were compared to monitoring data from other studies. The BCF reported varied between 40 and 15000 for marine fish, whereas for freshwater fish the BCF values were lower, with the highest being 14. For invertebrates tentative BCFs in the range of 4000 - 5000 were calculated. These values were also used in OECD (2008).

As there is a considerable uncertainty in these BCF values the risk characterisation for secondary poisoning in the EU RAR for diantimony trioxide was performed using both a BCF of 40 and a BCF of 15000. The BCF of

15000 gave very unrealistic results, whilst the BCF of 40 predicted concentrations similar to those observed in the environment. The EU RAR for diantimony trioxide therefore concluded that a BCF of 40 was appropriate for use in the assessment of both fresh and marine water. A BCF of 40 is very similar to the BCF calculated from studies which monitored concentrations in both the water and exposed organisms so will also be used in this risk assessment. The bioaccumulation potential of antimony in natural ecosystems is considered to be low. It is therefore concluded that antimony does not meet the bioaccumulation criteria (BCF >2000 l/kg) as set out in the definitive criteria for PBT assessment and listed in Annex XIII of REACH.

Terrestrial bioaccumulation

There are no laboratory studies available on bioaccumulation of antimony in earthworms. However, concentrations of antimony in soil and invertebrates at locations close to an antimony smelter have been measured by Ainsworth et al. (1990b). The highest antimony concentrations were found in earthworms (Oligochaeta). The dry weight concentrations (including gut contents) were 398 ± 94 mg/kg, 213 ± 65 mg/kg and 109 ± 28 mg/kg, at 100m, 250 m and 450m downwind of the smelter. The EU RAR for diantimony trioxide used measurements presented in figures in Ainsworth et al. (1990b) to derive the following approximations for the 0-5, 5-10, 10-15 and >15 cm depths for the 100 m, 250 m and 450 m sites: 367, 253, 220 and 171 mg Sb/kg dw, 204, 155, 114 and 94 mg Sb/kg dw, and 180, 180, 163 and 135 mg Sb/kg dw, respectively. Ainsworth et al. gives earthworm body burden: soil ratios, which are 1.03, 1.05 and 0.6 for the100 m, 250 m and 450 m sites, respectively. Based on these data a biota-to-soil accumulation factor (BSAF) of 1 for earthworms was taken forward to the risk characterisation.

An additional study on the accumulation of antimony by two species of earthworms in the field has been identified (Gal et al., 2007). In this study the concentration of antimony in soil and earthworms at a former antimony mining and smelting site were measured. Earthworms were kept in the laboratory for four days before analysis under starvation conditions so that their gut contents were empty. Concentrations in the soil ranged from 4.7 -1200 mg Sb/kg dw. Concentrations in the earthworms ranged from 0.72 -26 mg Sb/kg dw. The BSAF calculated by Gal et al. ranged from 0.002 -0.140 with means of 0.034 for *L. terrestris*and 0.063 for*O. cyaneum*, respectively.

Three studies have been identified that investigate the uptake of antimony by plants. De Gregori et al. (2003 and 2004) measured antimony concentrations in agricultural soils and the alfalfa crops being grown there. The results of these analyses are reported in two separate papers, but the same sites codes are reported allowing the concentrations in soil and plant matter to be paired. Antimony concentrations in soil ranged from 0.4 - 0.6 mg Sb/kg dw and the concentrations in the edible parts of the alfalfa ranged from 0.2 - 0.42 mg Sb/kg dw. The calculated BSAF ranged from 0.006 - 0.31.

Oorts et al. (2005) investigated the concentrations of antimony accumulated by lettuce in soil collected from an agricultural field. Two experiments were conducted: one with a soil sample collected in 2005 and one with a soil sample from the same field but which had been aged for five years outdoors. The concentrations of antimony in the aged and newly collected soils were 0.4 mg Sb/kg and 0.6 mg Sb/kg respectively. After 24 days exposure to the freshly spiked soil and 2 months exposure to the aged soil the concentrations in the edible portions were measured. The concentrations measured in the lettuce are read from a graph in the report, but indicate that the BSAF would be in the range 0.33 - 1.2.

Gal et al. (2007) also measured the concentrations of antimony in ferns and grasses and a former antimony mining and smelting site. Concentrations in the fern stems ranged from <0.001 - 7.5 mg Sb/kg dw, in fern leaf from <0.001 - 0.83 mg Sb/kg dw and in grass from <0.001 - 7.7 mg Sb/kg dw. The BSAF calculated by Gal et al. for plants ranged from <0.001 - 0.038, with means of 0.007 for fern stem, 0.002 for fern leaves and 0.009 for grass respectively.

The following information is taken into account for any hazard / risk / bioaccumulation assessment:

The studies available on terrestrial bioaccumulation of antimony are non-standard but together indicate that accumulation is expected to be low. The BSAF for both earthworms and plants is generally reported to be below 1. Based on these data and the approach used in the EU RAR for diantimony trioxide a BSAF of 1 for earthworms will be used in this assessment.

4.4. Secondary poisoning

The REACH guidance for Section 4.4 calls for a summary of bioaccumulation and biomagnification factors, and interpretation of the potential to bioaccumulate in the food chain. Bioaccumulation in the food chain is interpreted as increasing accumulation in successive trophic levels, which is analogous to biomagnification.

Antimony bioaccumulation in aquatic and terrestrial food chains is presented in Sections 4.3.1 and 4.3.2, respectively and is discussed in Section 4.3.3. Bioaccumulation of antimony by both aquatic and terrestrial organisms is low. A BCF of 40 has been determined for aquatic organisms and a BSAF of 1 for earthworms. As antimony is not bioaccumulative it will also not bioaccumulate in the food chain (biomagnify). This was also the conclusion reached in another recent regulatory review (Environment Canada, 2010). Based on this, an assessment of secondary poisoning is not required.

5. HUMAN HEALTH HAZARD ASSESSMENT

5.1. Toxicokinetics (absorption, metabolism, distribution and elimination)

5.1.1. Non-human information

The results of experimental studies on absorption, metabolism, distribution and elimination are summarised in the following table:

Table 41. Overview of experimental studies on absorption, metabolism, distribution and elimination

Method	Results	Remarks	Reference
in vitro study in vitro (simulated human body fluids) in vitro (simulated human body fluids) Solubility of test item in simulated human fluids. Principle of test is similar to Transformation/Dissolution testing according to OECD Series 29 (2001)	Main ADME results: The in vitro bioaccessibility of antimony metal in various artificial bodyfluids after 2h and 24h at a loading of 100 mg/l can be summarised by the following obtained final test concentrations as follows: PBS (serum surrogate): 20.3-41.3 mg/L; Gamble's Sln (lung interstitial fluid): 16.8-60.3 mg/L; ALF(lysosomal fluid): 37.0-79.6mg/L; GST (gastric juice): 16.5-13.2mg/L; Artificial sweat solution (ASW): 26.1-60.9mg/L Overall, the outcome of this study suggest that antimony is of similarly low solubility in PBS, GMB, ASW and GST as in water, thus supporting the assumption of poor bioaccessibility. The bioaccessibility for antimony metal is in the same order of magnitude compared with diantimony trioxide, corroborated by the analytical verification of an oxide layer on the surface of antimony metal. Evaluation of results: refer to the executive summary	2 (reliable with restrictions) key study read-across from supporting substance (structural analogue or surrogate) **Test material: antimony**	Hedberg,Y.; Jiang,T.; Wallinder,I.O. (2010)
rat (Sprague-Dawley) male/female Intravenous injection, Intraperitoneal, Oral (gavage)	Main ADME results: absorption: absorption of diantimony trioxide after acute oral exposure to diantimony trioxide particle suspension in this study was low; only 0.3 % after	1 (reliable without restriction) key study	deBie A.Th.J., Dr. Salmon-te Rietstap F.G.C. (2005)

Doses/conc.: Dose administration: IV (intravenous) administration: - Intravenous injection of 5 ml/kg BW in the tail vein. IP (intraperitoneal) administration: - Intraperitoneal dose administered by injection in the abdomen at 10 ml/kg BW. PO (oral) administration. - Oral (gavage) dose of 10 ml/kg BW administered by stomach tube. OECD Guideline 417 (Toxicokinetics) EU Method B.36 (Toxicokinetics)	administration of 100 mg/ kg bw and 0.05 % after administration of 1000 mg/ kg bw absorption: absorption of antimony after oral dosing of diantimony trioxide is a slow process, with a Cmax at approximately 24h, followed by an even slower elimination phase from blood distribution: antimony undergoes significant distribution to most tissues as it binds to red blood cells. Highest levels were found in bone marrow and thyroidea, followed by ovaries, spleen, liver, lung, heart, femur and skin excretion: The major part of diantimony trioxide is excreted via faeces but it is also excreted via urine. Details on metabolites: Antimony as an inorganic substance is not metabolised in animals or humans. Evaluation of results: low absorption after oral exposure	experimental result Test material (EC name): diantimony trioxide	
in vitro study in vitro (simulated human body fluids) Solubility of test item in simulated human fluids. Principle of test is similar to Transformation/Dissolutiion testing according to OECD Series 29 (2001)	Main ADME results: The in vitro bioaccessibility of three different antimony trioxide samples in various artificial bodyfluids after 2h and 24h at a loading of 100 mg/l can be summarised by the following obtained final test concentrations as follows: PBS (serum surrogate): 0.2-9.0 mg/l Gamble's Sln (lung interstitial fluid): 0.7-6.1 ALF(lysosomal fluid): 27.0-76.3 GST (gastric juice): 1.6-4.3 The solubility in neutral media such as PBS and Gamble's solution as well as in acidic gastric juice are in good agreement with the range of reported water solubility data for antimony trioxide (i.e, 2-10 mg/l). The value in artificial lysosomal fluid is implausibly high and likely affected by the known affinity of antimony to form strong complexes with multifunctional organic acid anions like tartrate and citrate, for example. Overall, the outcome of this study suggest that diantimony trioxide is of similarly low solubility in PBS, GMB and GST as in water, thus supporting the assumption of poor bioaccessibility	2 (reliable with restrictions) supporting study **Test material: dioxodistiboxane**	Midander, K.; Wallinder, I.O.; Leygraf, C. (2007)
hamster (Syrian gold	Main ADME results:	2 (reliable with	Leffler P:,

hamster) male intratracheal Exposure regime: Each animal received one single dose (0.2 ml or 0.1 ml) via intratracheal instillation of a suspension containing either Sb2O3 or antimony dust. Doses/conc.: The calculated instilled doses were for antimony trioxide 1.52 mg/kg of body weight and for antimony (dust) 0.04 mg/kg of body weight. In the experiment with different size fractions of antimony trioxide particles the doses used were 0.23 mg/kg of body weight and for antimony 0.33 mg/kg of body weight. no guideline specified equivalent or similar to OECD Guideline 417 (Toxicokinetics)	lung retention: Two phases can be distinguished in the elimination of antimony trioxide and antimony dust. In an initial phase around 20% of the antimony dust was eliminated during the first 20 hours. Evaluation of results: Lung retention: Two phases can be distinguished in the elimination of antimony trioxide and antimony dust. In an initial phase around 20% of the instilled antimony trioxide and approx. 35% of the antimony metal powder were eliminated during the first 20 hours. The corresponding half-lives are 40h for antimony trioxide and 30h for antimony metal powder. The second (slow) elimination phase was characterised by half-lives of 20-40 days for both forms of antimony. The authors also instilled various particle sizes of antimony trioxide and found that, although there was a somewhat lower lung retention of antimony at larger particle sizes, the solubility of the particles was more influential in determining lung retention.	restrictions) supporting study **Test material: dioxodistiboxane**	Gerhardsson L., Brune D. and Nordberg G.F. (1984)
rat (Fischer 344) male/female inhalation Exposure regime: Subchronic study: Animals were exposed 6 hours/day and 5 days/week for 13 weeks. Chronic study: Animals were exposed 6 hours/day and 5 days/week for 52 weeks. Doses/conc.: Subchronic study: The target exposure	Main ADME results: content in red blood cells: as observed in other studies also, there was a dose-dependent increase of antimony bound to red blood cells, whereas there was essentially no Sb in plasma. lung clearance: in lungs containing app. 2 mg of ATO, the pulmonary clearance decreased by 80% compared to a lung containing 0.01-0.02 mg ATO, coinciding with an increase in clearance half-life from 2 mo at lung burden of 0.01-0.02 mg ATO per lung to 10 mo at a lung burden of 2 mg Overall, clearance half-times of 2.3, 3.6, and 9.5 months for the low-, mid-, and high-concentration groups can be estimated, suggesting that clearance is dependent on lung burden. Substantial amounts of antimony were found in the lungs of these animals after 1	2 (reliable with restrictions) supporting study experimental result Test material (EC name): diantimony trioxide	Newton P.E., Bolte H.F., Daly I.W., Pillsbury B.D., Terrill J.B., (1994)

levels were 0, 0.25, 1, 5 and 25 mg/m*3. Chronic study: The target exposure levels were 0, 0.05, 0.5 and 5 mg/m*3. no guideline specified equivalent or similar to OECD Guideline 417 (Toxicokinetics)	year of exposure (10.6, 120, and 1460 micrograms/g lung tissue in the three exposure groups, respectively). It must however be noted that all (!) animals of this study suffered from a high level of interstitial inflammation (even 70% of controls affected); the likely cause of this was a viral infection stated by the authors themselves as having affected all animals in this study. As a result, it cannot be excluded that the lung health of the animal in this study and their clearance capacity was severely compromised.		
rat administration by stomach tube Doses/conc.: A single oral dose of 200 mg antimony trioxide. no guideline specified equivalent or similar to OECD Guideline 417 (Toxicokinetics)	Main ADME results: excretion: rapid decline in the faecal content of antimony that lasted for about 7 days was followed by a more gradual diminution of antimony excretion that continued for more than 30 days excretion: urinary antimony excretion was similarly biphasic, with a rapid decrease in the excretory rate during the first five to six days followed by a more gradual decline	3 (not reliable) supporting study experimental result Test material (EC name): diantimony trioxide	Gross P, Brown JHU, Westrick ML, Srsic RP, Butler NL and Hatch TF (1955a)
rat (Wistar) male oral: gavage Exposure regime: not stated Doses/conc.: diet containing: - 0.1 % (w/w) of metal antimony - 1.0 % (w/w) of antimony and - 1.0 % (w/w) of antimony trioxide. no guideline specified	Main ADME results: distribution: At the time of removal of antimony containing diet the highest concentrations of antimony were found in the blood, spleen, lungs, kidney, hair and bone distribution: 4 weeks after removal of antimony trioxide containing diet, the antimony concentrations in the organs were almost the same as immediately after 12 weeks of exposure	4 (not assignable) supporting study experimental result Test material (EC name): diantimony trioxide	Hiraoka N. (1986)
rat (Wistar) male oral: feed Exposure regime: up to 24 weeks / daily Doses/conc.: - diet containing 1.0 or 2.0 % (corresponding approximately to 500 mg/kg/day or 1000 mg/kg/day) antimony trioxide In the study performed on Wistar rats, sex and number not stated, the animals were fed with diet containing 1.0 or 2.0 % (corresponding approximately to 500 mg/kg/day or 1000 mg/kg/day) antimony trioxide for 24 weeks.	Main ADME results: distribution: Antimony was detected in liver, kidney, spleen, heart, brain, lung, stomach, testis and blood distribution: the highest contents were found in blood, spleen, lung, kidney liver and stomach distribution: average antimony content of organs were at the level of ppb, and the highest concentration of blood among the organs were 59.64ppb	2 (reliable with restrictions) supporting study experimental result Test material (EC name): diantimony trioxide	Sunagawa S (1981)

mouse (CF-1) female oral: unspecified Exposure regime: - single dose (single oral dose study) - once daily for 2, 4, 6, 8 or 10 days (multiple daily doses study) Doses/conc.: - concentrations = 8, 16, and 32 mg Sb-124/kg bw - volume = 10 ml oil suspension/kg bw (single oral dose study) - 16 mg/kg bw at 5/10 groups (multiple daily doses study); (the other 5 groups were additionally administered with TAC) No guideline specified at the time of conduct.	Main ADME results: excretion: Excretion after 25 h: (1) 8 mg Sb/kg bw group: 7.9 % (2) 16 mg Sb/kg bw group: 5.3 % (3) 32 mg Sb/kg bw group: 4.6 %	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) Test material (Common name): tartar emetic (antimony potassium tartrate)	Waitz JA, Ober RE, Meisenhelder JE and Thompson PE (1965a)
dog (Beagle) female oral: capsule Exposure regime: The analyses were continued until very low levels were reached; approximately 5 days. Doses/conc.: 2.79 g debris/capsule amount of antimony not stated no guideline specified	Main ADME results: excretion: Approx. 3 % of the oral 122Sb dose was found in the urine within 3 days after exposure, representing only the fraction excreted via the kidneys after intestinal absorption. Most of it was excreted on the first day.	4 (not assignable) supporting study read-across from supporting substance (structural analogue or surrogate) Test material (mixture): debris containing antimony	Chertok R.J. and Lake S. (1970)
mouse (Balb/c) female oral: gavage Exposure regime: see above "Detail on exposure" Doses/conc.: 18.5 megaBq/kg of 125Sb in diet and for intraperitoneal injection 20kBq. Daily food intake about 3g. Analysis by gamma spectroscopy no guideline specified	Main ADME results: distribution: Organ radioactivity per gram related to daily intake. Concentrations ranged from 0.085% of dietary dose in lung, 0.14% in bone and 0.1-0.2% in ovaries and uterus, respectively. absorption: Equilibrium for Sb radioactivity in the body is attained after 4 days. Intestinal absorption can be roughly assessed from the equilibrium level to about 1.7% of the daily food intake in non-pregnant mice and 15% in pregnant mice, based on whole body counting by deduction of intestinal content. Total radioactivity in litter during the feeding period ranged from approx. 0.1-max. 0.4% of the entire feeding dose. (Results after i.p. injection not summarised here for lack of relevance).	4 (not assignable) supporting study read-across from supporting substance (structural analogue or surrogate) no description of actual (mass) dose, no mass balance given, radioactivity determination not considered adequately precise **Test material (common name): [125]Sb-antimony chloride**	Gerber G.B., Maes J. and Eykens B. (1982)
rat (albino)	Main ADME results:	3 (not reliable)	Moskalev YI

intravenous and oral Doses/conc.: intravenous: 4.9 mg/kg bw; each rat was given 3µCi 124-Sb and 3.5 mg tartrate; volume/rat = 0.5 ml No guideline specified at the time of conduct.	distribution: i.v. admin: relatively low 124-Sb content in all organs; highest levels in the liver and skeleton; 1 day after administration 11 % in liver, 2 % in skeleton, 1 % in blood and 0,7 % in muscles; after 8 days the figures were 8, 0.6, 0.4, 0.3 %, respectively distribution: p.o. administration: the highest antimony levels are found in the skeleton (0.3 %) and the blood (0.17 %) absorption: Absorption from the gastrointestinal tract: the ratio of urinary excretion after intravenous vs. oral administration (4.2 *100/83) yields 5.05 %.	supporting study read-across from supporting substance (structural analogue or surrogate) Test material (Common name): tartar emetic (antimony potassium tartrate)	(1964)
rat oral: gavage Exposure regime: not stated Doses/conc.: not stated no guideline specified	Main ADME results: distribution: Study revealed that 125Sb distributed mainly in blood, especially in red blood cell. excretion: 125Sb dosed intravenously was also very rapidly excreted mainly via urine. For both cases, the excretions rate of 125Sb after the rapid excretion phase was extremely slow. The biological half-life at the slowly decreasing phase was 150-200 days. The conclusions of this study for suckling animals are in contradiction to Gerber et al (1982), see above.	4 (not assignable) supporting study read-across from supporting substance (structural analogue or surrogate) this study has severe shortcomings in that neither the dose nor the dosing regime are stated and conclusions are based on whole body retention only **Test material (common name): antimony chloride**	Inaba J. Nishimura Y. and Ichikawa R. (1983)
cattle ("Pie Noir") female oral: gavage Exposure regime: Cows were fed daily 5 kg of concentrated pellets. Doses/conc.: see above "Details on exposure" no guideline specified	Main ADME results: secretion in milk: Secretion of Sb in milk was small, 0.008 % and 0.05 % of the dose after oral and intravenous application. The transfer of antimony into milk would be about 2.5 x 10*-5 day/litre. distribution: 0.024 % of oral dose was recovered at sacrifice. Approx. 16 % present after injection, large percentage was found in the heart and was presumably deposited there on the endothelial surface immediately after injection distribution: After oral administration, activities per kg of tissue were highest in spleen, liver, bone and skin. Contribution to the body burden was highest in bone followed by skin, muscle, liver, lung and spleen. distribution: After i.v., most Sb remained near the injection site or in liver. excretion: About 82 % of the p.o. Sb and about 2.4 % of the i.v. Sb were recovered in the feces. - After intravenous injection, a large amount of antimony was excreted on day 1 and 2 with a very short turnover time of about 0.4 days	3 (not reliable) disregarded study read-across from supporting substance (structural analogue or surrogate) **Test material (common name): antimony chloride**	van Bruwaene R., Gerber G.B., Kirchmann R. and Colard J. (1982)

hamster (Syrian) inhalation Exposure regime: Duration of the exposure is up to 32 days. There are no information about the frequency of the treatment. Doses/conc.: not stated equivalent or similar to OECD Guideline 417 (Toxicokinetics)	Main ADME results: clearance: Whole-body clearance of both aerosols occurred in two phases. Initial clearance was very rapid, resulting in elimination of 90 % of the day 1 body burden by day 7 postexposure. clearance: The average body burdens at day 1 postexposure for the trivalent and pentavalent groups were 65 % and 60 % of the activity found in the day 0 sacrifice animals, an indication of the rapid clearance within the first 24 hours. clearance: Early rapid clearance was followed by a slower clearance phase during which the remaining antimony was eliminated with a biological half-life of about 16 days. excretion: No statistically significant differences in excretion patterns observed between two aerosol groups. In the early collections, more excreta activity was present in the feces than in the urine. excretion: Fecal antimony was probably due in part to lung clearance via the mucociliary apparatus.	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material (common name): tartar emetic (antimony potassium tartrate)**	Felicetti S.A., Thomas R.G. and McCellan R.O. (1974)
rat (Sprague-Dawley) male intraperitoneal or intravenous Exposure regime: Rats given a single intraperitoneal or intravenous dose of SbCl3. Doses/conc.: - intravenous 800 µg Sb/kg - intraperitoneal 200, 400 and 800 µg Sb/kg no guideline specified equivalent or similar to OECD Guideline 417 (Toxicokinetics)	Main ADME results: excretion: Around 45 to 55 % of the amount of Sb administered was excreted within four days, most being eliminated during the first day. excretion: After intravenous administration of Sb about the same percentage of the administered dose was excreted in the urine and faeces whereas after intraperitoneal administration, about four times more Sb was excreted in the faeces than in the urine.	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) Test material (Common name): antimony trichloride	Bailly R., Lauwerys R., Buchet J.P., Mahieu P. and Konings J. (1991)
rat oral: gavage Exposure regime: Animals received antimony trioxide for eight months. Doses/conc.: 2 % antimony trioxide in diet no guideline specified equivalent or similar to OECD Guideline 417 (Toxicokinetics)	Main ADME results: excretion: after single dose administration: The average daily excretion of antimony increased until the fifth day after which it decreased again. excretion: after sub-chronic administration: A rapid decline in the faecal content of antimony that lasted for about 7 days was followed by a more gradual diminution of antimony excretion that continued for more than 30 days. excretion: after sub-chronic administration: The urinary antimony excretion was similarly biphasic, with a rapid decrease in the excretory rate during the first five to six days followed by a more gradual decline.	3 (not reliable) supporting study experimental result Test material (EC name): diantimony trioxide	Gross P, Brown JHU, Westrick ML, Srsic RP, Butler NL and Hatch TF (1955b)

monkey (rhesus) female 1. oral / 2. intravenously Exposure regime: - probably single dose/ six days observation (oral) - probably single dose / 24 h observation (intravenously) Doses/conc.: - concentration = 8 mg Sb/kg bw (oral) - concentration = 1.28 mg Sb /kg bw (intravenously) No guideline specified at the time of conduct.	Main ADME results: distribution: oral: levels found in blood were between 0.013 - 0.180 µg Sb/ml, peak blood levels were obtained 6 -8 h after dosing, low detectable blood levels of Sb 96 -144 hours after dosing distribution: intravenous: in all monkeys blood antimony dropped rapidly from high of 1.25 - 1.9 µg/ml at 0.25 h to 0.25 µg/ml at 8 h, and to 0.10 µg/ml at 24 h	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) Test material (Common name): tartar emetic (antimony potassium tartrate)	Waitz JA, Ober RE, Meisenhelder JE and Thompson PE (1965b)
rat (Holtzman) male intravenous Exposure regime: - single dose Doses/conc.: - 2.2 mg Sb per dose (approx. 11 mg Sb/kg bw) No guideline specified at the time of conduct.	Main ADME results: distribution: Distribution in tissues: Antimony was found in blood (7 µg Sb/g at 0.5 and 0.5 µg Sb/g at 72 h), liver (3.5 µg Sb/g at 0.5 h and 0.5 µg Sb/g at 72 h) and kidney (between approx. 55 µg Sb/g at 0.5 h and 0.5 µg Sb/g at 72 h) distribution: Excretion: urinary excretion was more than 70 % of the dose within 24 h after administration faecal throughput was 5.9 % in 72 h, with less than 1 % excreted in any of the time period between 0 - 24 hours	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) Test material (mixture): tartar emetic (antimony potassium tartrate)	Waitz JA, Ober RE, Meisenhelder JE and Thompson PE (1965c)
oral: unspecified Model calculation based on a comparison of (i) human dietary intake and (ii) human tissue levels/body burdens	Main ADME results: absorption: Caughtrey calculated an oral absorption of 1% for Sb compounds, based on comparison of daily dietary intake of Sb, & the total Sb body burdens of stable Sb isotopes. It has high relevance, since it reflects absorption at normal dietary (low) intake levels	4 (not assignable) supporting study model calculation **Test material (common name): antimony and its compounds**	Caughtrey, P.J. et al. (1983) Bailly, R. et al. (1991) Moskalev, Y.I. (1964) Rose, E. & Jacobs, H. (1969)b
dog (male) intravenous Exposure regime: 0.8 mg Sb/kg bw/d, for 2 x 6 days (except Sundays) 36h after the last dosing, the dog was sacrificed, and samples of 35 tissue were excised, dried and homogenised. Analysis by “Geiger-Müller counter”.	16h p.a. the following tissue distribution was obtained in a single dog: - by far the highest tissue levels were in thyroid (ca. 19 ug/g wwt) and liver (ca. 13 ug/g wwt); - radioactivity in other tissues was generally an order of magnitude lower, or even less; - testes level was very low at ca. 1 ug/g wwt. For comparison, the total cumulative Sb dose amounts to 9.6 mg.	4 (not assignable) supporting study read-across from supporting substance read-across from supporting substance (structural analogue or surrogate) only briefly documented, without tabulated raw data, and a lack of mass	Cowie, D.B. et al. (1945)

No guideline specified at the time of conduct.		balance **Test material (common name): [124]Sb-sodium antimonyl xylitol (See endpoint summary for justification of read-across)** whereas it may be assumed that 124Sb was employed because of the neutron activation, this is not stated explicitly	
Dermal absorption study in vitro human Coverage (dermal absorption study): open Doses/conc.: The resultant application rates of Diantimony Trioxide were, by mass, 95.27 µg/cm^2, 286.51 µg/cm^2 and 0 µg/cm^2. SKIN PREPARATION - Source of skin: Ten samples of full-thickness human skin were obtained from patients. Nine of the samples were obtained from patients attending the Plastic Surgery Unit, St Johns Hospital, West Lothian NHS Trust, Livingston, UK - Ethical approval if human skin: The patients gave informed consent for their skin to be taken for scientific purposes. - Type of skin: 3 abdomen and 7 breast - Preparative technique: The skin was cleaned of subcutaneous fat and connective tissue using a scalpel blade. The skins were washed in	Based on the occurrence of antimony levels in skin as “natural background”, the corrected percutaneous absorption rates obtained in this study are as follows: (i) total absorbed dose (amount penetrating to receptor medium) at 24h p.a. was 0.01% (at 100 ug/cm$_2$ application rate) and 0.02% of dose (at 1,000 ug/cm$_2$), respectively. (ii) dermal delivery (i.e, total absorbed dose plus amount retained in or on skin after exposure/washing) at 24h amounted to 0.07% (at 100 ug/cm$_2$ application rate) and 0.10% of dose (at 1,000 ug/cm$_2$), respectively. Overall, the percutaneous absorption of antimony trioxide through human skin is very low to negligible.	1 (reliable without restriction) key study experimental result Test material (EC name): diantimony trioxide	Roper C.S. and Stupart L (2006)

cold running water and dried. When required, the human skin samples were removed from ca-20°C storage and allowed to thaw at ambient temperature. Split-thickness membranes were prepared by pinning the full-thickness skin, stratum corneum uppermost, onto a raised cork board and cutting at a setting equivalent to 200-400 µm depth using a Zimmer electric dermatome. Split-thickness skin membranes were divided into 36 pieces (ca 1.5 x 1.5 cm). The stratum corneum was removed from each skin sample by tape stripping with 20 successive tape strips. The skin samples were then placed into labelled vials (Skin 1-36). The corresponding tape strips were transferred into labelled vials (TS 1-36). Each sample was weighed to determine a sample weight. An additional four blank tape strip samples were also prepared. - Thickness of skin (in mm): The thickness of the uncut skin membranes was measured using a micrometer. - Storage conditions: The skin was transferred to Charles River Laboratories on ice. The sample was cut into smaller pieces (where appropriate), wrapped in aluminium foil, put into self sealing plastic bags and stored at ca -20°C until required. One of the skin			

samples (donor 0115) was obtained from Transkin under similar conditions as above. This was transferred to Charles River Laboratories on dry ice and stored at ca -20 °C on arrival. - Justification of species, anatomical site and preparative technique: - no other details on in vitro test system reported OECD Guideline 428 (Skin Absorption: In Vitro Method) OECD Environmental Health and Safety Publications Series on Testing and Assessment No.28. Guidance Document for the Conduct of Skin Absorption Studies			

5.1.2. Human information

The exposure-related observations in humans are summarised in the following table:

Table 42. Overview of exposure-related observations on basic toxicokinetics and/or dermal absorption in humans

Method	**Results**	**Remarks**	**Reference**
Study type: cohort study (retrospective) Type of population: occupational Details on study design: HYPOTHESIS TESTED (if cohort or case control study): - different concentrations of antimony in diverse organs of smelter workers who died (compared with control subjects/ no smelter workers) METHOD OF DATA COLLECTION - Type: Work history / Clinical tests - Details: STUDY POPULATION	EXPOSURE - Mean exposure times in the different groups showed no difference between workers dead from malignancies in comparison to other diseases: · 30.9 ± 7.1 years in the malignancy group · 32.5 ± 8.2 years in the cardiovascular diseases group · 28.9 ± 10 years in the group exposed workers with other diagnosis FINDINGS - the antimony concentration in lung tissue of exposed workers was 12-fold higher than that of the reference group (315 µg/kg wet weight compared to 26 µg/kg wet weight as mean values), but they don't differ much between the different groups:	human study, reliability rating not applicable **Test material (as reported): antimony and its compounds**	Gerhardsson L, Brune D and Nord (1982)

- Total population (Total no. of persons in cohort from which the subjects were drawn): - Selection criteria: · exposed test group: worker at a smelter and refinery, who died during the period 1976 - 1978 - Total number of subjects participating in study: · exposed test group: 40 deceased worker - Sex/age/race: male/average age of 66.6 years/swedish - Smoker/non-smoker: information was collected but not published COMPARISON POPULATION - Type: Control or reference group - Details: · control group: age-matched men from rural area, approx. 50 km from the factory · control group:11 age-matched men (average age of 67.5 years) - no other details on study design are reported Endpoint addressed: basic toxicokinetics	- median lung concentration different groups: 330 µg Sb/kg bw (died from malignancies) 220 µg Sb/kg bw (died from cardiovascular diseases) 360 µg Sb/kf bw (died from other causes) - mean antimony concentration in liver and kidney cortex of smelter workers did not differ from that of the reference group (workers:12 µg Sb/kg and 6 µg Sb/kg - reference group:7 µg Sb/kg and 5 µg Sb/kg - the time from the last exposure to date of death varied between 0 and 23 years - no significant differences of antimony concentration in lung tissue were found when death occurred <1, 1-5, 6-10 or 11-23 years after the cessation of exposure, indicating a long biological half-life in lung tissue - highest level of Sb in lung was 5,480 µg Sb/kg bw at an man who worked for 13 a at the roasters (in addition he had worked 29 a in arsenic and selenium departments under high exposure) INCIDENCE / CASES - In the group of smelter workers: 15 died from malignancies a total of 17 workers died from cardiovascular diseases (6 from respiratory cancer) 8 died from other causes - In the reference group: 7 died from myocardial infarction 3 from cerebrovascular diseases - Other: - among the 6 cases of lung cancer there were 3 smokers and 2 exsmokers; among the referents there were 1 smoker, 8 nonsmokers and 2 cases with information lacking - the median value of Sb in the lung tissue of workers did not differ significantly between smokers, exsmokers and nonsmokers - no other observations are reported		
Study type: health record from industry Type of population: occupational Details on study design:	Blood: Because most antimony and lead in blood is bound to the erythrocytes the analyses were done from whole blood. The resulting Sb-blood values were found between 0.4 and 3.1 µg/l (median: 1.0 µg/l). The Sb-blood values of the glass	2 (reliable with restrictions) supporting study **Test material (EC name):**	Lüdersdorf R. Fuchs A. Mayer P. Skulsuksai G. and Schäcke G. (1987)

METHOD OF DATA COLLECTION - Type: Clinical tests - Details: Investigations took place on days when antimony-containing glass was being produced. Blood and urine samples were collected at the end of the shift. After ashing the biological samples with sulfuric acid/nitric acid, antimony was determined by means of HY-AAS. Urine samples are usually available in larger quantities (>20 ml) than blood samples (mostly less than 10 ml). Thus, a lower relative detection limit, which depends, by a given absolute detection limit of 1.6 ng SB, mainly on the sample size, can be achieved in urine analyses. The content of lead was analysed through ET-AAS directly from diluted samples. STUDY POPULATION - Total population (Total no. of persons in cohort from which the subjects were drawn): A group of male workers from two glass-producing factories were examined. - Selection criteria: According to their specific activities, the entire group was divided into four subgroups: melter, batch mixer, glass washer and craftsman. - Total number of subjects participating in study: 109 workers - Sex/age/race: male/ age: see table 1 - Smoker/nonsmoker: see table 1 - no other details on study desingn are stated Endpoint addressed: basic toxicokinetics	washers and batch mixers are significant higher than those of the craftsmen. In this respect, the melters occupy a middle position with no statistically significant differences to the other groups. Investigations on 51 unexposed control persons resulted in SbB-values ranging from 0.3 to 1.7 µg/l (median: 0.6 µg/l). There was no statistically significant difference compared to the melters and craftsmen. Urine: The concentrations of antimony in urine were between 0.2 and 15.7 µg/l (median: 1.9 µg/l). Parts of these data are clearly elevated compared with those specified in the literature for unexposed people, with a median below 1 µg/l. The values of antimony in the urine of eight unexposed persons ranging from 0.2 to 0.7 µg/l (median: 0.4 µg/l). Comparing this control group and the subgroups with their different fields of activities, higher Sb-urine values were found almost exclusively by those working in the batch bunker. These values are statistically different compared to each one of the other subgroups.	**diantimony trioxide**	
Study type: health record from industry Type of population: occupational	Resorption and elimination kinetics: The workload of the persons occupied in the two examined areas was equivalent. Higher Sb-B and Sb-U levels in the formation area can be largely ascribed to higher external Sb-A levels at the	2 (reliable with restrictions) supporting study **Test material**	Kentner M., Leinemann M., Schaller K-H., Weltle D. and Lehnert G. (1995)

Details on study design: METHOD OF DATA COLLECTION - Type: Clinical tests - Details: The collection of the urine samples was conducted after at least 3 work days at the beginning (U1) and the end (U2) of the fourth or fifth work day (duration of the shift: 7.2 hours). During U2 venous blood samples were also collected. During the same shift personal air sampling was carried out. After the following weekend without Sb exposure the third urine sample was collected at the beginning of the first shift (U3). According to the change in shifts worked (early, normal or late), 54-104 hours lay between samples U2 and U3. STUDY POPULATION A group of workers from the casting area and from the formation was examined. The two groups showed no substantial differences with respect to age, occupational duration or smoking habits. - Total population (Total no. of persons in cohort from which the subjects were drawn): - Total number of subjects participating in study: 21 workers - Sex/age/race: see table 1 - Smoker/nonsmoker: see table 1 - no other details on study design Endpoint addressed: basic toxicokinetics	workplace and not to higher respiratory volume. With respect to Sb-A as well as Sb-B and Sb-U, the values of the formers were generally between 3 and 4 times higher than those of the casters. Resorption coefficients (Sb-A/Sb-B) could be calculated. For the casters this factor amounted to 1.74 and for the formers to 1.22. The elimination coefficient (Sb-B/Sb-U) showed even better agreement, with 0.68 for the casters and 0.66 for the formers. This study shows a correlation between Sb concentrations in air and in blood/urine.	**(EC name): diantimony trioxide**	
Study type: cohort study (prospective) Type of population: occupational Details on study design: METHOD OF DATA COLLECTION - Type: Work history / Clinical	FINDINGS - the amount of antimony in the lungs of these men ranged from nil to just over 11 mg/cm2 - the amount of antimony tended to rise as the period of employment in the antimony work increased - individual levels were very scattered, as men who worked in the plant for many	2 (reliable with restrictions) supporting study **Test material (EC name): diantimony trioxide**	McCallum RI, Day MJ, Underhill J and Aird EGA (1971)

tests : - Details: - monochromatic X-ray spectrophotometry of the workers to determine the antimony content of the lungs - postero-anterior radiograph of the lungs (for pneumoconiosis study) categorised according to the international classification from 1958; each site (of lung) six 10-second counts were taken - the x-ray measurement of antimony has been further developed since McCallum (1967) SETTING: Examination of workers in an antimony plant STUDY POPULATION - Total population (Total no. of persons in cohort from which the subjects were drawn): - Selection criteria: workers employed in the antimony process for 6 month or more - Total number of subjects participating in study: 113 (72 for pneumoconiosis study)men - no other details on study design are stated Endpoint addressed: basic toxicokinetics	years, have not been exposed continuously to high antimony level - a significant association between length of employment and lung antimony was found (r= + 0.552), for the first 20 years it is r= +0.703 - a small number of foreman and baghouse workers have higher median levels than the furnace workers; labourers and other workers have less lung antimony levels - no other findings are reported		
Study type: clinical case study Type of population: occupational Subjects: - Number of subjects exposed: Seven subjects were designated as A, B, C, D, E, F and G. - Sex: male - Age: The age of the workers ranged from 33 to 45 years. - Known diseases: No known history of chronic lung diseases. - Other: Four from the workers were non-smokers, two were smokers and one is a heavy-smoker. - no other details on subjects are given Endpoint addressed: basic toxicokinetics	The results of measurements of total body radioactivity of 125Sb shows that most of the radioactivity was found confined to the lungs only. Practically no radioactivity was detectable over the liver and the other parts of the body. The initial rapid clearance after inhalation exposure is considered to be mainly from the upper thorax/gastrointestinal tract and is referred to as the fast clearance/rapid phase. Material not cleared during the rapid phase is considered to be mainly in the alveolar interstitial (AI) region, which is considered to be the main long-term retention site in the lung. Therefore, in this study the retained activity at 7 days after exposure was taken as initial alveolar deposition (IAD). It was seen that the biological elimination half times for the long-term	2 (reliable with restrictions) supporting study **Test material (EC name): diantimony trioxide**	Garg S.P., Singh I.S. and Sharma R.C. (2003)

	component are more than 600 days in all cases. The reported data shows a considerable inter-subject variation, which arises due to natural biological variability among individuals exposed under similar conditions. It also shows that the retention in all the smokers is considerably greater than that in all the non-smokers. This study indicates a slow elimination half-life from the lung, ranging from 600 to 1,100 days for non-smokers and 1,700 to 3,700 days for smokers. The retention in the lungs after 180 days was found to be more than 51% of the estimated IAD in all the seven cases.		
Study type: clinical study Type of population: human volunteer (male), n=25 Details on study design: comparative i.v. (75-100 mg/kg bw) and i.m (75 -125 mg/kg bw) administration (single), monitoring of excretion pattern over time basic toxicokinetics	In the study involving 25 male volunteers being given 124Sb-DMSA by i.m. or i.v. injection, the following excretion pattern was reported: - following i.m. administration, cumulative excretion accounted for about 25% of 124Sb after 1 d, 50% after 15 d, and 68% after 32 d. - following i.v. injection, cumulative excretion accounted for about 35% of 124Sb after 1 day, and 63% after 4 days. Extracorporal radioactivity counting indicated relatively high accumulation of activity in the thyroid and liver, peaking about 2 days after injection. Elimination occurred in two phases: - approximately 80-85% of the peak content was removed with a half-time of a few days, and the remaining 15-20% had a much longer retention time that could not be quantified over the relatively short observation period	human study, reliability rating not applicable supporting study **Test material (common name): [124]Sb-sodium antimony dimercaptosuccinate** Form: powder	Abdallah A. & Saif, M. (1962)
Study type: Survey data of workers in a textile plant Details on study design: - the aim of this study was to monitor Sb2O3 exposure by measuring airborne and urinary concentrations in workers of textile industry exposed to low levels of Sb2O3 Endpoint addressed: basic toxicokinetics	- no significant correlation was found between personal exposures and the difference between the urinary levels at the beginning and the end of the shift - the mean personal exposure level of "higher exposure worker" over the week was significantly higher than that of jet operators and controls - the mean personal exposure level of jet operators was significantly higher than for the controls - the urine levels of Sb measured at the beginning and end of the shift did not vary significantly in any worker, no	2 (reliable with restrictions) supporting study **Test material (mixture): flame retardant formulation**	Iavicoli I, Caroli S, Alimonti A, Petrucci F and Carelli G (2002)

	correlation personal exposure levels and urine levels found - all urinary levels in all workers were higher than in the control group		

5.1.3. Summary and discussion of toxicokinetics

Overview and quality of the database:

The majority of published data on toxicokinetics of trivalent antimony substances summarised in this dossier were generated several decades before the establishment of standardised test guidelines, and thus obviously do not correspond to current requirements. However, they nevertheless represent supportive data, from which the following conclusions can be drawn:

- for highly water-soluble antimony substances such as tartar emetic (potassium antimony tartrate), exact figures for oral absorption are difficult to derive. This is related to several experimental shortcomings, such as lack of a mass balance, inadequate description of dose and test item, and mostly indirect conclusions based on urinary excretion, for example. Therefore, these data at best allow rough estimates of absorbed/excreted amounts as supportive data. Nevertheless, the available published data support the assumption that absorption via the oral route is in the range of 1-5% of the dose for highly water soluble trivalent antimony substances, whereby it is not clear whether the upper range is not biased due to the circumstance that some data may refer to pentavalent antimony substances (which are all of high water solubility) instead of the less soluble trivalent species.

- calculations based on a comparison of daily dietary intake of Sb, and the total Sb body burdens of stable Sb isotopes in humans (such as Caughtrey et al. 1983) suggest an oral absorption of up to 1% for Sb compounds, regardless of their origin and speciation; however, since Sb(V) is the predominant stable valence state under ambient environmental conditions and therefore the most predominant species in drinking water and diet, this calculation is likely to be biased on the grounds that the much more soluble Sb(V) is likely to be more bioavailable than the poorly soluble Sb(III) species.

- for poorly water-soluble substances such as diantimony trioxide (approx. 5-6 orders of magnitude lower in water solubility than antimony trichloride, for example), published data are not available; for this reason, reference is made to a relative bioavailability study specifically with diantimony trioxide in rats (de Bie et al., 2005), which was conducted under GLP and in full OECD guideline compliance. This study is also of highest relevance to any rat study, since it covers the entire dose range (100-1,000 mg/kb bw) for any animal oral studies likely to be conducted, yielding oral absorption rates of 0.3% (at 100 mg/kg bw) and 0.05% (at 1,000 mg/kg bw), respectively.

Dermal absorption:

A percutaneous absorption study on antimony trioxide (Roper and Stupart, 2006) was conducted in vitro with human skin, in full compliance with OECD test guideline 428 and OECD guidance no. 28 for the conduct of skin absorption studies (2004), and under GLP. The study was performed with unlabelled test material (including background correction for endogenous antimony), and analytical verification was by inductively coupled plasma-mass spectroscopy (ICP-MS). Diantimony trioxide was applied as a suspension in aqueous HPMC (1%) at two application rates (100 µg/cm^2 and 300 µg/cm^2). The total absorbed doses (receptor medium) were at 0.01-0.02% of dose, when counting the amount retained in and on the skin as potentially absorbable, a conservative value for dermal delivery of 0.07-0.10% of dose can be derived. Overall, the dermal absorption of antimony trioxide can be assessed as very low to negligible. For risk assessment purposes, a conservative value of 0.1% from liquid media, and 0.01% from dry/dust media (1710th of the level from liquid media) can be taken forward, in accordance with metal-specific guidance (HERAG).

Inhalation absorption:

Biomonitoring and autopsy data indicate that antimony is retained in the lungs for long periods of time (based on limited data from a study of seven men (Garg et al.,2003), the biological elimination half-times have been estimated to 600-1100 days for nonsmokers and 1700-3700 days for smokers), and that antimony may accumulate in lung tissue after repeated exposure to diantimony trioxide in the air. It has also been shown that the excretion of antimony from the lung occurs in two phases, one rapid initial phase followed by a slower second phase:

The retention and distribution of diantimony trioxide following intratracheal instillation or inhalation exposure has been studied in hamsters (Leffler et al.,1984) and rats (Newton et al.,1994), respectively. The results demonstrate that the extent of deposition and subsequent clearance of antimony from the lung is primarily dependant on solubility and particle size. Larger and more soluble trivalent antimony particles are cleared more rapidly than small and less soluble particles that tend to remain in the lungs for extended periods. The elimination of diantimony trioxide from lung seems to consist of two phases, one early rapid clearance followed by a slower clearance phase. In hamsters the calculated biological half times (t1/2) for the initial phase (0-20 h) was 40 hours, and for the second (20-200 h) phase approximately 20-40 days. The rapid initial phase of elimination from the lungs is considered to be mediated by mucociliary transport.

In the intratracheal instillation study by Leffler and coworkers (1984) in hamsters, it was shown that the retention of diantimony trioxide 190 h after exposure was 44-60 % for the lung and 7.2-12.6 % for the liver. In this study, neither the retention of diantimony trioxide was measured in e. g. bone marrow or thyroid which are known to contain relatively high amounts of antimony after exposure, nor was the excretion in urine or faeces determined.

Overall, it seems appropriate for inhaled material to assume the following:

(i) any antimony trioxide inhaled (by rats or humans) will be subject to particle-size dependant deposition in the respiratory tract; such particle size distributions are available not only for all key inhalation studies in this dossier, but also for all antimony trioxide workplaces; based on these data, fractional deposition can be predicted with the aid of the MPPD model both for rats and humans.

(ii) any antimony trioxide deposited in the extrathoracic (head) and tracheobronchial regions of rats and humans can be assumed to be rapidly translocated to the GI tract within minutes of deposition, and will therefore be subject to oral absorption rates.

(iii) material deposited in the alveolar fraction of rats and humans will partly also be escalated by mucociliary processes to the GI tract but at a very slow rate, whereas the remainder may be subject to a minor degree to some dissolution, with uncleared antimony having half-lives of approx. one month.

For the sake of simplicity, material predicted to be deposited in the ET and TB fractions of the respiratory tract are assumed to be cleared to the GI tract and subject to oral absorption at a rate of 0.05% (reflective of high doses/exposures typical for example of toxicity testing conditions for such an “inert” material). Conversely, based on the data summarised further above, material deposited in the alveolar fraction is assumed to be (I) cleared to 50% by rapid mucociliary escalation, subject to 0.05% oral absorption. In contrast, (II) the remaining 50% are cleared very slowly by dissolution and other processes (resulting in only a minor portion being systemically available) with a half-life of approx. 30 days (conservative assumption), but overall contributing only to a minor extent to overall absorption - for calculation details and corresponding MPPD model predictions, please refer to the attached report by Vetter (2014, IUCLID endpoint summary for Toxicokinetics). From this orientating model calculation considering particle-size dependant deposition and clearance, it can be estimated that for inhaled antimony trioxide, the overall absorption rate is << 1%.

For the sake of completeness, it is noted here that based on data on physical particle size and density for 8 different samples of diantimony trioxide and with the use of the MPPD model and using unrealistic, conservative absorption values of 1.0% for the gastrointestinal tract (reflective of low dietary intake of various forms of antimony) and 100% for pulmonary deposition (thereby disregarding the slow clearance of this poorly soluble material), a default inhalation absorption value of 6.82 % was previously derived in the EU Risk Assessment for antimony trioxide, for precautionary risk assessment purposes. However, when considering dosing/exposure levels as typical of animal laboratory safety toxicity studies with antimony trioxide, more realistic experimentally verified values for oral absorption and lung clearance can be applied, as outlined above.

Oral:

Soluble antimony substances

Published data on oral absorption largely pertain to potassium antimony tartrate (also known as tartar emetic) and/to antimony trichloride. Both substances are highly water soluble, and in particular complexes of antimony with tartaric or citric acid are known to be stable and highly soluble, and thus have been used in the past in attempts to enhance the solubility/bioavailability of antimony, for example in pharmaceutical preparations. These data are therefore cited here only for comparison, since they represent a worst case for the assessment of the oral bioavailability of poorly soluble trivalent antimony substances, such as antimony trioxide:

species / test system	**dose / test substance**	**oral absorption**	**comments**	**reliability score**	**references**
mice/ rats/ monkeys oral (gavage) and i. v dosing	8-32 mg/kg bw ^{124}Sb Tartar emetic(1)	oral absorption mice (single dosing 4.6-7.9%, rep. dosing 5%. (assessment for rats/monkeys incomplete)	Oral absorption assessment based on cumulative urinary excretion; Mass balance 80% (mice)	RL=2	Waitz et al. (1965)
rat	Sb Tartar emetic(1)	absorption~ 5%	(2)	RL=3	Moskalev (1964), sec. citation from Coughtrey et al. (1983), and ICRP (1996)
mouse oral dosing (gavage)	not specified	Absorption max. 1-2% ICRP states “much less than 10%)	Sec. lit (2) No further data available		Walker (1970), sec. citation from Thomas et al. (1973)
hamster oral dosing (gavage)	2 µCi (not further specified) ^{124}Sb tartrate	Absorption < 1% estimated by ICRP based on fractional retention in GI tract	Exact dose not given, but very low since carrier-free tracer used	RL=2	Felicetti et al. (1974)
human route not stated	^{124}Sb tartrate	Absorption ~ 1% ICRP states “much less than 10%)	Sec. lit (2) No further data available		Rose & Jacobs (1969) sec. citation from Coughtrey et al. (1983)
human (f) ingestion	dose unknown/ Sb sulphide	Absorption < 5% value not stated in the publication, but estimated as an upper limit by ICRP based on blood and urine levels	attempted suicide with unknown amount of Sb_2S_3	RL=2	Bailly et al. (1991): sec. citation from Coughtrey et al. (1983)

species / test system	**dose / test substance**	**oral absorption**	**comments**	**reliability score**	**references**
rats oral dosing (gavage)	dose unknown$^{125}SbCl_3$	Whole body retention: ~ 1% for adults and 25d weanlings 40% for 5d sucklings	Exact dose not given, but very low since carrier-free tracer used	RL=4	Inaba et al. (1984)
mouse via diet	18.5 MBq/kg$^{125}SbCl_3$	1.7% calculated for suckling mice	Exact dose not given, but very low since carrier-free tracer was used	RL=4	Gerber et al. (1982)
dog oral dosing (capsules)	Nuclear debris (undefined)	> 4%	dose not given	RL=4	Chertok & Lake (1970)

(1): tartar emetic: potassium antimony tartrate; (2): cited from secondary literature (review)

Poorly soluble antimony substances:

Toxicokinetic data on poorly soluble antimony substances are scarce, which is why a fully guideline-compliant toxicokinetic study with antimony trioxide in rats was commissioned by industry. This study is considered the key study for the assessment of oral bioavailability in this dossier: in this relative bioavailability and tissue distribution study (De Bie and Salmon-te Rietstap, 2005), the absorption of diantimony trioxide after oral exposure to an diantimony trioxide particle suspension as studied by comparison to intravenous administration of antimony trichloride as a “reference” substance. Overall, absorption after oral dosing was low; only 0.3 % after administration of 100 mg/ kg bw and 0.05 % after administration of 1000 mg/ kg bw. Whereas in the EU Risk Assessment on antimony trioxide a conservative default oral absorption of 1% was taken forward to account for all possible forms of antimony, the values derived by de Bie et al. (2005) are more relevant to toxicity testing in laboratory animals (rats) because of the dose ranges applied (i. e., 100-1,000 mg/kg bw/d), anticipated to be required for testing of such a poorly bioavailable substance.

Tissue distribution and elimination:

From published data on soluble antimony substances, it is known that any antimony that becomes systemically available is in blood is strongly associated with erythrocytes. In the few available published studies addressing the aspect of tissue distribution, the highest levels were reported in thyroid, livers, kidney and spleen – other organs are in most cases not comprehensively studied. One very old study (Cowie, 1945) reports levels of 13 and 19 ug/g tissue wet weight for thyroid and liver, respectively, but the analytical procedure casts some doubt on the precision of these values.

The key study for the assessment of tissue distribution and elimination characteristics is a fully guideline-compliant study by de Bie et al. (2005). In this study, 72 hours after a single oral dose of 1,000 mg/kg bw/d to male and female rats, ca. 0.008% of the dose were excreted via urine, with the balance (98.7-100%) representing material excreted via faeces; total tissue levels and residual carcass levels were 0.0003-0.0004% and 0.0017-0.0023%, respectively. The detailed tissue analysis yielded (among other tissues with general lower levels, in ng/g of tissue): bone marrow 1192-1996, thyroid 1507-2103, spleen 197-113, livers 41-64 and lungs 41-61 (male-female, respectively). With respect to organs of reproductive function, the following data can be summarised: testes 2.8 ng/g, prostrate 8.5 ng/g; uterus, 11.4 ng/g, ovaries 262 ng/g. In consideration of the very low total amount of antimony (0.0003-0.0004%) in organs altogether, the above values allow the reasonable assumption that organs of male and female reproduction do not represent target organs for antimony trioxide.

The following information is taken into account for any hazard / risk assessment:

Value used for CSA:

Bioaccumulation potential: no bioaccumulation potential
Absorption rate - oral (%): 0.05-0.3
Absorption rate - dermal (%): 0.01-0.1
Absorption rate - inhalation (%): <<1%

5.2. Acute toxicity

5.2.1. Non-human information

5.2.1.1. Acute toxicity: oral

The results of experimental studies are summarised in the following table:

Table 43. Overview of experimental studies on acute toxicity after oral administration

Method	Results	Remarks	Reference
rat oral: gavage No guideline specified at the time of conduct	LD50: > 16000 mg/kg bw	3 (not reliable) weight of evidence experimental result Test material (EC name): diantimony trioxide	Gross P, Brown JHU, Westrick ML, Srsic RP, Butler NL and Hatch TF (1955c)
rat oral: unspecified No guideline specified at the time of conduct.	LD50: > 600 mg/kg bw	3 (not reliable) weight of evidence experimental result Test material (EC name): diantimony trioxide	Fleming AJ (1938)
rat oral: feed No guideline specified at the time of conduct.	: (Study documentation is insufficient for assessment e.g. number of animals not stated.)	3 (not reliable) weight of evidence experimental result Test material (EC name): diantimony trioxide	Smyth, H.R.; Thompson, W.L. (1945a)
rat (Sherman) not stated No guideline specified at the time of conduct.	LD50: > 20000 mg/kg bw	4 (not assignable) weight of evidence experimental result Test material (EC name): diantimony trioxide	Smyth HF and Carpenter CPJ (1948a)
rat stomach intubation no guideline specified	LD50: > 20000 mg/kg bw	3 (not reliable) weight of evidence experimental result Test material (EC name): diantimony trioxide	Weil, C.S. (1978a)
rat oral: feed No guideline specified at the time of conduct.	fatal dose: > 7500 mg/kg bw (experiment (2))	3 (not reliable) supporting study experimental result Test material (mixture): Flame	Foulger, J. H. (1950)

		Resistant Polythene Composition	
guinea pig oral: feed No guideline specified at the time of conduct.	: (Study documentation is insufficient for assessment e.g. number of animals not stated.)	3 (not reliable) supporting study experimental result Test material (mixture): Flame Resistant Polythene Composition	Foulger, J. H. (1950)

5.2.1.2. Acute toxicity: inhalation

The results of experimental studies are summarised in the following table:

Table 44. Overview of experimental studies on acute toxicity after inhalation exposure

Method	Results	Remarks	Reference
rat (Charles-River rat (strain:CD)) male/female inhalation: aerosol (nose only) OECD Guideline 403 (Acute Inhalation Toxicity) EU Method B.2 (Acute Toxicity (Inhalation)) (92/69/EEC) additional examinations performed: clinical signs, gross pathology, histopathological examination of nose, larynx, trachea and lungs (five levels) 24 hours and 14 days after cessation of exposure	LC50 (4 h): > 5.2 mg/L air (male/female) (LC50 was assigned to a level greater than the limit concentration (5.20 mg/L air) tested since no mortality occurred.) There were no signs of respiratory irritation, based on an absence of test item-related clinical signs and histopathological effects in the nose, larynx and trachea 24 hours and 14 days after exposure.	1 (reliable without restriction) key study experimental result Test material (EC name): diantimony trioxide	Leuschner, J. (2006)
rat injection intratracheally (intratracheal) No guideline specified at the time of conduct.	: (No conclusions on acute toxicity properties of diantimony trioxide are drawn from this study.)	3 (not reliable) supporting study experimental result Test material (as reported): Titanium Dioxide pigments (doped with Sb2O3)	anonymous (1963)
rat inhalation No guideline specified at the time of conduct.	concentration causing death (4 h): > 20.1 mg/L air (nominal)	3 (not reliable) supporting study experimental result Test material (as reported): Mica flake pigments	anonymous (1962)
rat (ChR-CD) male inhalation No guideline specified at the time of conduct.	: (Toxicological relevance cannot be judged due to significant methodical and reporting deficiencies.)	3 (not reliable) supporting study experimental result Test material (mixture): self-extinguishing nylon and GR -PE	Tayfun, F.O. (1972)
rat (ChR-CD) male inhalation No guideline specified at the time of conduct.	: (Toxicological relevance cannot be judged due to significant methodical and reporting deficiencies.)	3 (not reliable) supporting study experimental result Test material (as reported): fibreglass reinforced 4 GT	Sarver, J.W. (1974)

		polyester	
rat (ChR-CD) male inhalation No guideline specified at the time of conduct.	: (No effect levels can be concluded.)	3 (not reliable) supporting study experimental result Test material (Composition): Mixture of Antimony trioxide	Tayfun, F.O. (1970)
rat (ChR-CD) male inhalation (whole body) No guideline specified at the time of conduct.	: (Toxicological relevance cannot be judged due to significant methodical and reporting deficiencies.)	3 (not reliable) supporting study experimental result Test material (composition): Antimony oxide mixture	Tayfun, F.O. (a)
rat (ChR-CD) male inhalation No guideline specified at the time of conduct.	: (Toxicological relevance cannot be judged due to significant methodical and reporting deficiencies.)	3 (not reliable) supporting study experimental result Test material (composition): mixture of pyrolysis products	Tayfun, F.O. (b)
rat injection intratracheal (directly into the lung) no guideline specified	: (Toxicological relevance cannot be judged due to significant methodical and reporting deficiencies.)	3 (not reliable) supporting study experimental result Test material (EC name): diantimony trioxide	Clayton, J.W. (1963)
other: rats and guinea pigs inhalation No guideline specified at the time of conduct.	: (Toxicological relevance cannot be judged due to significant methodical and reporting deficiencies.)	3 (not reliable) supporting study experimental result Test material (mixture): Flame Resistant Polythene Composition	Foulger, J. H. (1950)

5.2.1.3. Acute toxicity: dermal

The results of experimental studies are summarised in the following table:

Table 45. Overview of experimental studies on acute toxicity after dermal administration

Method	Results	Remarks	Reference
rabbit Coverage: occlusive No guideline specified at the time of conduct.	LD50: > 8300 mg/kg bw (According to the TGD a body weight of 3.0 kg should be applied for the rabbits which gives a dose of 8.3 g/kg bw.)	2 (reliable with restrictions) key study experimental result Test material (EC name): diantimony trioxide	Gross P, Brown JHU, Westrick ML, Srsic RP, Butler NL and Hatch TF (1955d)
rabbit no guideline specified	LD50: > 8 g/kg bw	3 (not reliable) supporting study experimental result Test material (EC name): diantimony trioxide	Weil, C.S. (1978b)

5.2.1.4. Acute toxicity: other routes

There are no reliable reports whatsoever on acute toxicity via other routes in the public domain.

5.2.2. Human information

The exposure-related observations in humans are summarised in the following table:

Table 46. Overview of exposure-related observations on acute toxicity in humans

Method	Results	Remarks	Reference
Study type: cohort study (prospective) Type of population: fetuses Details on study design: SETTING: - dry human foetal livers were supplied as powders by Dr. E.M. Widdowson, Dunn National Laboratory, University of Cambridge - Al-powder mixed with In2O3 and Yb2O3 was used as conducting medium and internal standard for SSMS analysis - the livers were prepared for analysis by ashing test portions, weighting and mixing with the Al-mixture STUDY POPULATION - Total number of subjects participating in study: 70 foetal livers - Age: 12 - 40 weeks COMPARISON POPULATION - Details: standard reference bovine liver (SRM 1577) - no other details on study design are reported Endpoint addressed: acute toxicity: oral	FINDINGS - the mean antimony concentration in fetal livers was 0.02 mg/g dry weight, ranging between 0.01 and 0.06 mg/g dry weight (literature values for adult livers range from 0.01 to 0.42 µg/g dry weight) - no other findings are reported. This study indicates an in utero exposure of human fetuses to antimony.	4 (not assignable) supporting study Test material (Trace Element Composition): Antimony in human foetal liver	Shand CA, Aggett PJ and Ure AM (1985)
Study type: poisoning incident Type of population: occupational Subjects: - Number of subjects exposed: >60 humans - Demographic information: in Newcastle - no other details on subjects are given Endpoint addressed: acute toxicity: oral	Toxicological relevance cannot be judged due to significant methodical and reporting deficiencies.	3 (not reliable) supporting study Test material (formulation): fruit lemonade out of enamelled buckets	Dunn JT (1928)

5.2.3. Summary and discussion of acute toxicity

For acute inhalation toxicity there is one animal study (Leuschner, 2006) which has been performed according to OECD TG 403 and which shows no signs of acute toxicity after inhalation exposure to diantimony trioxide, indicating a LC50 > 5.20 mg/ L (5200 mg/ m^3). The animal studies on acute oral exposure are all old (Fleming, 1938; Gross *et al.*, 1955; Myers *et al.*, 1978), they do not comply with today standards and in most of them mortality was the only parameter investigated as they were designed to determine at what dose level death occured. Still, they indicate that oral LD50 is in excess of 20000 mg/kg bw in rats. There is one valid study on dermal exposure (Gross *et al.*, 1955), which indicates that the LD50 for dermal exposure is higher than 8300 mg/kg bw. In conclusion, diantimony trioxide is of low acute inhalation, oral and dermal toxicity.

The following information is taken into account for any hazard / risk assessment:

LD50 (oral): >20000 mg/kg bw/day
LD50 (dermal): >8300 mg/kg bw

LC50 (inhalation): >5200 mg/m³

Value used for CSA:

Acute oral toxicity: No adverse effect observed

Acute dermal toxicity: No adverse effect observed

Acute inhalation toxicity: No adverse effect observed

Justification for classification or non-classification

Acute oral toxicity

The animal studies on acute oral exposure are all old, they do not comply with today standards and in most of them mortality was the only parameter investigated as they were designed to determine at what dose level death occured. Still, they indicate that oral LD50 is in excess of 20,000 mg/kg bw in rats which will be used for classification purposes.

LD50 oral, rat > 20,000 mg/kg bw

The classification criteria according to regulation (EC) 1272/2008 as acutely toxic are not met since the ATE is above 2,000 mg/kg body-weight, hence no classification required.

Specific target organ toxicant (STOT) – single exposure: oral

The classification criteria according to regulation (EC) 1272/2008 as specific target organ toxicant (STOT) – single exposure, oral are not met since no reversible or irreversible adverse health effects were observed immediately or delayed after exposure and no effects were observed at the guidance value, oral for a Category 1 classification of 300 mg/kg bw and at the guidance value, oral for a Category 2 classification of 2000 mg/kg bw. No classification required.

Acute inhalation toxicity

The reference Leuschner (2006) is considered as the key study for acute inhalation toxicity and will be used for classification. Rats were nose only exposed towards diantimony trioxide dust for 4 hours at 5.2 mg/L air. During the conduct of the study no mortalities occurred.

LC50 inhalation, rat > 5.2 mg/L air

The classification criteria according to regulation (EC) 1272/2008 as acutely toxic are not met since the ATE for dusts and mists is above 5.0 mg/L, hence no classification required.

Specific target organ toxicant (STOT) – single exposure: inhalation

The classification criteria according to regulation (EC) 1272/2008 as specific target organ toxicant (STOT) – single exposure, inhalation dust/mist/fume are not met since no reversible or irreversible adverse health effects were observed immediately or delayed after exposure and no effects were observed at the guidance values, inhalation dust/mist/fume for a Category 1 classification of 1.0 mg/L/4 h and at the guidance value or inhalation dust/mist/fume for a Category 2 classification of 5.0 mg/L/4 h. Therefore, no classification is required. However, such classification is also not warranted, since observations on respiratory irritation in test animals were not observed at the highest inhalation exposure level. No relevant pulmonary changes were observed in the 5 localisations of the lung neither in the rats sacrificed 24 hours after exposure nor the rats sacrificed 14 days after exposure.

5.3. Irritation

5.3.1. Skin

5.3.1.1. Non-human information

The results of experimental studies on skin irritation are summarised in the following table:

Table 47: Overview of experimental studies on skin irritation

Method	Results	Remarks	Reference
albino rabbits Coverage: occlusive (clipped over the entire trunk without cutting the skin) No guideline specified at the time of conduct	not irritating	2 (reliable with restrictions) key study experimental result Test material (EC name): diantimony trioxide	Gross P, Brown JHU, Westrick ML, Srsic RP, Butler NL and Hatch TF (1955e)
guinea pig Coverage: It is not stated whether the application was occlusive or non-occlusive. (clipped intact shoulder skin) no guideline specified	Toxicological relevance cannot be judged due to significant methodical and reporting deficiencies.	3 (not reliable) supporting study experimental result Test material (mixture): antimony (III) oxide	Dion, L.A. (1970a)
albino guinea pig Coverage: It is not stated whether the application was occlusive or non-occlusive. (shaved) no guideline specified	Toxicological relevance cannot be judged due to significant methodical and reporting deficiencies.	3 (not reliable) supporting study experimental result Test material (composition): mixture of antimony oxide	Frank, K.M. (1970a)
rabbit Coverage: Uncovered no guideline specified	Toxicological relevance cannot be judged due to significant methodical and reporting deficiencies.	3 (not reliable) supporting study experimental result Test material (EC name): diantimony trioxide	Weil, C.S. (1978a)

5.3.1.2. Human information

The exposure-related observations in humans are summarised in the following table:

Table 48. Overview of exposure-related observations on skin irritation in humans

Method	Results	Remarks	Reference
Study type: health record from industry (three cases of dermatitis in workers at a brazing rod manufacturing plant) Type of population: occupational Endpoint addressed: skin irritation / corrosion	Shortly after the exposure the workers noted the onset of skin lesions. Crusted follicular papules and pustels of the arms (accentuated in the antecubital fossae), trunk and forehead in two of the three workers were examined. One of these workers also had a dry eczematous patch on the left trunk. In the third worker erythematous follicular	2 (reliable with restrictions) key study Test material (EC name): diantimony trioxide	White GP., Mathias CGT., Davin JS. (1993)

	papules were noted on the ventral and dorsal aspects of both forearmes and on the posterior legs and back. The urine antimony level, which was measured in one worker, was 53.2 µg/L (level in unexposed persons are less than 1.0 µg/l). In all three workers the dermatitis resolved with the avoidance of antimony-related work.		
Study type: health record from industry Type of population: occupational Endpoint addressed: skin irritation / corrosion	The occurrence of the skin eruptions in 23 workers has been reported. Intense itching preceded the skin eruption. A diffuse blotchy erythema may occur but most commonly the early lesions are small erythematous papules and may be associated with much excoriation. The papules enlarge and in some cases become frankly pustular. The sites most commonly involved in the 23 cases were antecubital area, shins, back of neck, forearmes, trunk, back of knees and face. Two furnacemen who presented one side of their body to heat when working had lesions only on the limbs of that side. The rash subsides in form 3 to 4 days when the worker is transferred to a cooler part of the factory. The eruption occurs in the warm summer month and is rarely seen in the winter. Histologically, the early lesion showed epidermal cellular necrosis with associated acute dermal inflammatory cellular reaction. The lesion is closely related to sweating ducts. The absence of any evidence of an eczematous reaction is striking and would accord with the lack of clinical evidence of an allergic mechanism for the rash.	2 (reliable with restrictions) key study Test material (EC name): diantimony trioxide	Stevenson C.J. (1965)
Study type: health record from industry Type of population: occupational Details on study design: - examination of workers and retired workers especially x-ray of the lungs Endpoint addressed: skin irritation / corrosion	The rash consisted of papules and pustules around sweat and sebacous glands. It affected particularly the fore arms and thighs and the flexures and did not appear on the face, hands or feet. The spots disappeared rapidly over a weekend or public holiday, but reappeared	2 (reliable with restrictions) key study Test material (EC name): diantimony trioxide	McCallum R.I. (1963)

	on return to work. Over hundred men were employed but the frequency of dermatitis was not stated.		
Study type: health record from industry Type of population: occupational Details on study design: - examination of 51 male workers over 25 years - over the 25-year period, subjects were examined 2 - 5 times - evaluation included a physical examination, laboratory analysis, chest X-ray and pulmonary function studies - general clinical examinations were performed on each subject; specialist consultations were obtained when appropriate - workers employed in an antimony smelting plant - age between 31 and 54 years (mean 45.23) - workers were exposed to dust containing predominantly antimony oxide (38.73 - 88.86 %) Endpoint addressed: skin irritation / corrosion	"Antimony dermatosis", characterised by vesicular or pustular lesions with residual hyperpigmentation, were present in 32 of 51 exposed workers (63 %), especially during the summer season and when working near the furnace where temperatures were excessively high.	2 (reliable with restrictions) supporting study Test material (EC name): diantimony trioxide	Potkonjak V., Pavlovich M. (1983a)
Type of population: general Details on study design: 1. - tested at 10 men and 10 women - fibre treated with a mix of antimony oxide and a substance of which the identity was deleted from the report - fibre contained 1% antimony oxide (by weight) - one-inch squares of the test fabric were applied to the arms of ten men and to the arms or legs of ten women - fibre squares held in place with adhesive tape for six days - two weeks after removal, new patches were applied for 48 hours - skin under the patches was examined at two and six days and on final day at patch removal 2. - fibre treated with a mix of antimony oxide and a substance of which the identity was deleted from the report - fibre contained 1 % antimony oxide (by weight) - one-inch squares of the test material were applied to the arms of 46 men and to the arms or legs of 127 women - fibre squares held in place with adhesive tape for six days	1. No skin reactions were seen at any of the examinations. 2. After six days of occluded wear one subject had paplues along the edge of patch area, however, similar paplues were also seen under the tape area. Subjects had small indented areas under patch that appeared as red spots that coincided with the crimed pattern of this fibre.	3 (not reliable) supporting study Test material (fibre): treated with antimony trioxide	anonymous (1970a)

- two weeks after removal, new patches were applied as a challenge for the skin sensitisation and were removed after 48 hours - skin under the patches was examined at two and six days and on final day at patch removal Endpoint addressed: skin irritation / corrosion			
Study type: health record from industry Type of population: occupational Details on study design: - 5 months evaluation of the illness among workers of a mining company engaged in the mining, concentrating and smelting of an antimony sulphide ore - examination of 78 men who had worked for 2 weeks or longer in the smelter building Endpoint addressed: respiratory irritation Endpoint addressed: skin irritation / corrosion Endpoint addressed: eye irritation	- the illnesses which were observed resemble industrial antimony poisoning as described in literature in respect to upper respiratory irritations, pulmonary inflammation, systematic reactions and skin lesions - as symptoms of antimony poisoning are said to be similar to those caused by arsenic, no clear differentiation can be made for the results of this observation - antinomy in the urine of some workers was indicative for antimony absorption - in animal studies kidney and liver damage and pulmonary inflammation were found caused by antimony	3 (not reliable) supporting study Test material (EC name): diantimony trioxide	Renes L.E. (1953)
Study type: cohort study (prospective) Type of population: occupational Details on study design: METHOD OF DATA COLLECTION - Details: Examinations, including lung radiography (on 62 workers) SETTING: Systematic examinations were performed at a work place (antimony sulphide ore smelting plant) STUDY POPULATION - Selection criteria: workers employed for at least 3 years in an antimony sulphide ore smelting plant - Total number of subjects participating in study: 101 - Sex: male - Other: 20 of the workers who showed pneumoconiotic symptoms were detailed clinical examined - no other details on study design Endpoint addressed: skin irritation / corrosion	FINDINGS - light respiratory difficulty, tiredness, myalgia, light coughing, and light dyspepsia without pain or diarrhoea INCIDENCE / CASES Incidence/ Number of cases for each disease: - 2 workers gave suspicion to pneumoconiosis by X-ray pulmonary changes (spent all their working time in smelting plants) - 31 of 62 workers were found to have lung changes (radiography) - 22 cases of emphysema with bronchitis - 51 cases of catarrh in the upper respiratory tract - 16 cases of deviation of the nasal septum - 12 cases of conjunctivitis - 16 cases of antimony dermatosis (characterised by vesicular or pustular lesions with residual scars and hyperpigmentation, especially during the	4 (not assignable) supporting study Test material (Antimony Smelting Plant): antimony sulphide ore	Karajovic D (1957)

	summer season and 13 of the cases were working near the furnace where temperatures were high) OTHER OBSERVATIONS: - No effects were observed on the gastrointestinal tracts, the liver, the cardiovascular system or the central or peripheral nervous system, which according to the authors indicated that there were no systemic toxic effects - no other findings are reported		

5.3.2. Eye

5.3.2.1. Non-human information

The results of experimental studies on eye irritation are summarised in the following table:

Table 49. Overview of experimental studies on eye irritation

Method	Results	Remarks	Reference
rabbit (Himalayan) OECD Guideline 405 (Acute Eye Irritation / Corrosion) EU Method B.5 (Acute Toxicity: Eye Irritation / Corrosion)	not irritating Cornea score: 0 of max. 0 (mean) (Time point: 24,48 and 72 hours) (the test did not reveal any corneal lesions) Iris score: 0 of max. 0 (mean) (Time point: 24, 48 and 72 hours) (the iris was not affected by instillation of the item) Conjunctivae score: 0.44 of max. 1 (mean) (Time point: 24,48 and 72 hours) Chemosis score: 0 of max. 0 (mean) (Time point: 24,48 and 72 hours)	1 (reliable without restriction) key study experimental result Test material (EC name): diantimony trioxide	Leuschner J. (2005)
rabbit (New Zealand White) In this study the eye irritation potential of antimony oxide was investigated in 5 male and 5 female New Zealand albino rabbits.	Toxicological relevance cannot be judged due to significant methodical and reporting deficiencies.	2 (reliable with restrictions) supporting study experimental result Test material (EC name): diantimony trioxide	anonymous (1979)
rabbit no guideline specified	Toxicological relevance cannot be judged due to significant methodical and reporting deficiencies.	3 (not reliable) supporting study experimental result Test material (EC name): diantimony trioxide	Smyth HF and Carpenter CPJ (1948b)
rabbit	Toxicological relevance cannot be judged due to significant methodical and reporting deficiencies.	4 (not assignable) supporting study experimental result Test material (EC	Webb, G.A. (1978)

		name): diantimony trioxide	

5.3.2.2. Human information

The exposure-related observations in humans are summarised in the following table:

Table 50. Overview of exposure-related observations on eye irritation in humans

Method	Results	Remarks	Reference
Study type: health record from industry Type of population: occupational Endpoint addressed: eye irritation	Conjunctivitis was seen in 14 cases (27.5 %). Conjunctivitis was observed in workers employed in an antimony smelting plant. However, since the exposure contained not only diantimony trioxide it is unclear what caused the conjunctivitis and consequently whether diantimony trioxide has eye irritation potential or not.	2 (reliable with restrictions) supporting study Test material (EC name): diantimony trioxide	Potkonjak V., Pavlovich M. (1983a)
Study type: health record from industry Type of population: occupational Details on study design: - 5 months evaluation of the illness among workers of a mining company engaged in the mining, concentrating and smelting of an antimony sulphide ore - examination of 78 men who had worked for 2 weeks or longer in the smelter building Endpoint addressed: respiratory irritation Endpoint addressed: skin irritation / corrosion Endpoint addressed: eye irritation	- the illnesses which were observed resemble industrial antimony poisoning as described in literature in respect to upper respiratory irritations, pulmonary inflammation, systematic reactions and skin lesions - antinomy in the urine of some workers was indicative for antimony absorption - the exposure situations are not very well described. Consequently, it is unclear what caused the conjunctivitis and whether diantimony trioxide has an eye irritation potential or not.	3 (not reliable) supporting study Test material (EC name): diantimony trioxide	Renes L.E. (1953)

5.3.3. Respiratory tract

5.3.3.1. Non-human information

In an OECD 403 study, five male and five female rats were exposed nose-only to diantimony trioxide (5.20 mg/L) for a single 4-hour period. In addition, three male and three female satellite animals were subjected to the same exposure conditions for additional histopathological examinations.

All animals revealed an activation of macrophages in the lungs (five levels) 24 hours and 14 days after exposure. The alveolar lumen contained aggregations of foamy alveolar macrophages and macrophages with and without phagocytic material. In addition, inflammatory reactions were noted with granulocytic infiltrations and secretion. The changes observed can be explained with physiological clearance mechanisms to be expected after inhalation exposure to such a high concentration of poorly soluble dust material. The findings were minimal to mild in severity, and clearly subsided to a large extent after the 14-day observation period. No test item-related changes were noted in the nose (five levels), larynx and trachea 24 hours and 14 days after exposure. In conclusion, no signs of acute toxicity or respiratory irritation were observed in rats exposed to a single, nose only dose of diantimony trioxide.

For further details please refer to the entry Leuschner, J. (2006) under section 5.2.1.2. Acute toxicity: inhalation

5.3.3.2. Human information

The exposure-related observations in humans are summarised in the following table:

Table 51. Overview of exposure-related observations on respiratory irritation in humans

Method	Results	Remarks	Reference
Study type: health record from industry Type of population: occupational Details on study design: - 5 months evaluation of the illness among workers of a mining company engaged in the mining, concentrating and smelting of an antimony sulphide ore - examination of 78 men who had worked for 2 weeks or longer in the smelter building Endpoint addressed: respiratory irritation Endpoint addressed: skin irritation / corrosion Endpoint addressed: eye irritation	- the illnesses which were observed resemble industrial antimony poisoning as described in literature in respect to upper respiratory irritations, pulmonary inflammation, systematic reactions and skin lesions - antinomy in the urine of some workers was indicative for antimony absorption - the exposure situations are not very well described. Consequently, it is unclear what caused the conjunctivitis and whether diantimony trioxide has an eye irritation potential or not.	3 (not reliable) supporting study Test material (EC name): diantimony trioxide	Renes L.E. (1953)

5.3.4. Summary and discussion of irritation

Skin:

The Committee for Risk Assessment (RAC) of the European Chemicals Agency (ECHA) concluded that a harmonised classification of irritating to skin was not supported, since special conditions, namely substantial heat and sweat, were required in addition to high chemical dermal exposure in all the cases where skin effects had been described in the workplace. Furthermore, it was unclear whether diantimony trioxide was the only chemical substance to which these workers had been exposed (ECHA/PR/09/09, Helsinki, 06 July 2009).

Eye:

In a recent (Leuschner, 2005) very well-conducted and reported acute eye irritation/corrosion test with highly pure diantimony trioxide, performed according to OECD guideline 405 and in compliance with GLP regulations, the only observation was conjunctival redness (grade 1) observed in 2 animals at 24 and 24 to 72 hours after installation, respectively. There were no corneal lesions, the iris was not affected by instillation of the item, and there were no systemic intolerance reactions.

In contrast, in a rather dated study (1979) conducted in the early stages of GLP implementation and prior to the establishment of OECD test guidelines, “antimony oxide” (without further specification) of unknown purity and composition was tested. The designated source (“PPG Industries”) is a company that nowadays fabricates coatings; it may therefore be speculated that the powder that was tested may not have been only an “antimony oxide” of sorts, but perhaps a flame retardant or other preparation. Given the poor hygiene of eye irritant testing facilities at the time and in particular a lack of “specific pathogen free” conditions, it may be questioned whether the good health in which the animals were claimed to be could really be established beyond doubt. Because of the poorly defined test substance and the questionable health status of the test animals in this study, it was concluded in a weight-of-evidence approach to assign higher reliability to the more recent GLP- and guideline-conform study.

Respiratory tract

In an acute inhalation study with antimony trioxide in rats (Leuschner, 2006), in which irritation of the respiratory tract was also evaluated, no signs of respiratory tract irritation were found. In five case report studies on workers occupationally exposed to antimony trioxide, effects that could indicate irritation in the respiratory tract have been described. However, there is very little information concerning exposure in these studies and it is unclear whether antimony trioxide was the causative agent. Based on the available data antimony trioxide can be concluded not to be irritating to the respiratory system.

The following information is taken into account for any hazard / risk assessment:

Diantimony trioxide elicits skin irritation potential only under conditions of high chemical dermal exposure and severe sweating.

Diantimony trioxide is not eye irritating.

Value used for CSA:

Skin irritation / corrosion: No adverse effect observed (not irritating)

Eye irritation / corrosion: No adverse effect observed (not irritating)

Respiratory irritation / corrosion: No adverse effect observed (not irritating)

Justification for classification or non classification

Skin irritation:

The Committee for Risk Assessment (RAC) of the European Chemicals Agency (ECHA) concluded that a harmonised classification of irritating to skin was not supported, since special conditions, namely, substantial heat and sweat, were required in addition to high chemical dermal exposure, in all the cases where skin effects had been described in the workplace. Furthermore, it was unclear whether diantimony trioxide was the only chemical substance to which these workers had been exposed (ECHA/PR/09/09, Helsinki, 06 July 2009).

Eye irritation:

Reference Leuschner (2005) is considered as the key study for eye irritation and will be used for classification. The overall irritation results are as follows:

The classification criteria according to regulation (EC) 1272/2008 as irritating to eyes are not met since the mean score for corneal opacity, iritis, conjunctival oedema after 24, 48 and 72 h was each time 0.0 and the mean score for conjunctival redness was 0.44, hence no classification required. The classification criteria according to regulation (EC) 1272/2008 as irritating to eyes are not met since the mean score after 24 h was 0.4, hence no classification required.

Respiratory irritation:
The justification for non classification as respiratory irritant is covered under the endpoint specific target organ toxicity- single exposure as given in the acute toxicity section.

No data available that concluded respiratory irritation is present after repeated inhalation exposure. However, due to the fact that an acute inhalation toxicity test at the an exposure of 5.2mg/L revealed no relevant pulmonary changes in the 5 localisations of the lung, neither in the rats sacrificed at 24 hours after exposure nor of rats sacrificed 14 days after exposure, one may safely conclude that diantimony trioxide is void of any irritating potential towards the respiratory tract.

5.4. Corrosivity

Since diantimony trioxide is not irritating to the skin, eyes or the respiratory tract, corrosive properties can be excluded.

5.4.1 Non-human information

Since diantimony trioxide is not irritating to the skin, eyes or the respiratory tract, corrosive properties can be excluded.

5.4.2 Human information

Since diantimony trioxide is not irritating to the skin, eyes or the respiratory tract, corrosive properties can be excluded.

5.4.3 Summary and discussion of corrosion

Since diantimony trioxide is not irritating to the skin, eyes or the respiratory tract, corrosive properties can be excluded.

5.5. Sensitisation

5.5.1. Skin

5.5.1.1. Non-human information

The results of experimental studies on skin sensitisation are summarised in the following table:

Table 52. Overview of experimental studies on skin sensitisation

Method	Results	Remarks	Reference
guinea pig (Dunkin-Hartley) female Guinea pig maximisation test Induction: intradermal and epicutaneous Challenge: epicutaneous, occlusive OECD Guideline 406 (Skin Sensitisation) (, EC Guideline B.6. (96/54/EC))	not sensitising No. with positive reactions: 1st reading: 0 out of 10 (negative control); 48 h after chall.; dose: vehicle only (0 %) 2nd reading: 0 out of 10 (negative control); 72 h after chall.; dose: vehicle only (0 %) 1st reading: 0 out of 20 (test group); 48 h after chall.; dose: 2 ml of a 50 % (w/w) suspension in vehicle 2nd reading: 0 out of 20 (test group); 72 h after chall.; dose: 2 ml of a 50 % (w/w) suspension in vehicle 1st reading: 20 out of 20 (positive control); 48 h after chall.; dose: 5 % (w/v) benzocaine in 40 % ethanolic 0.9 % NaCl solution 2nd reading: 20 out of 20 (positive control); 72 h after chall.; dose: 5 % (w/v) benzocaine in 40 % ethanolic 0.9 % NaCl solution	1 (reliable without restriction) key study experimental result Test material (EC name): diantimony trioxide	Chevalier F. (2005)
guinea pig male	no interpretation possible	3 (not reliable)	Dion, L.A.

similar to todays standard Buehler test, but not meeting the criteria Induction: intradermal and epicutaneous Challenge: epicutaneous no guideline specified	No. with positive reactions: 1 out of 10 (test group - intact skin); 24 h after chall.; dose: 25 % mixture in f.a.d. 2 out of 10 (test group - intact skin); 24 h after chall.; dose: 50 % mixture of f.a.d. 0 out of 10 (test group - abraded skin); 24 h after chall.; dose: 25 % mixture of f.a.d.	supporting study experimental result Test material (composition): 1:8 mixture of antimony oxide and perbromophenyl ether	(1970b)
guinea pig similar to todays standard Buehler test, but does not meet the criteria Induction: intradermal and epicutaneous Challenge: epicutaneous no guideline specified	interpretation is not possible No. with positive reactions: 1st reading: 4 out of 10 (test group); 24 h after chall.; dose: 50 % mixture on intact skin 1st reading: 6 out of 10 (test group); 24 h after chall.; dose: 50 % mixture on abraded skin 2nd reading: 0 out of 10 (test group); 48 h after chall.; dose: 50 % mixture 1st reading: 2 out of 10 (test group); 24 h after chall.; dose: 25 % mixture on intact skin 1st reading: 4 out of 10 (test group); 24 h after chall.; dose: 25 % mixture on abraded skin 2nd reading: 0 out of 10 (test group); 48 h after chall.; dose: 25 % mixture	3 (not reliable) supporting study experimental result Test material (composition): 1:6 mixture of antimony oxide and hexabromobenzene	Frank, K.M. (1970b)

5.5.1.2. Human information

The exposure-related observations in humans are summarised in the following table:

Table 53. Overview of exposure-related observations on skin sensitisation in humans

Method	Results	Remarks	Reference
Study type: medical monitoring Type of population: occupational and volunteers Details on study design: - patch tests with pure powder of antimony trioxide - applied with Finn Chambers on Scanpor tape to healthy skin of the back - exposure period: 2 days; evaluation: 3 days after exposure start	- 2 subjects from ceramics industry (1 enmaller, 1 decorator) show ed positive responses to antimony trioxide (stated in the result part) - no volunteer showed a positive reaction	3 (not reliable) supporting study Test material (EC name): diantimony trioxide	Motolese A, Truzzi M, Giannini A and Seidenari S (1993)
Study type: medical monitoring Type of population: occupational Details on study design: - patch tests with: dry antimony powder and a suspension of the powder in water in 20 control subjects 50 % mixture of the powder in soft yellow paraffin in 10 subjects - tests in these cases were carried out with trioxide in 3 grades of refinement (commonly encountered in the process)	- no positive reaction was obtained	4 (not assignable) supporting study Test material (EC name): diantimony trioxide	Stevenson CJ (1969)
Study type: medical monitoring	- after six days of occluded wear	3 (not reliable)	Edwards, D.F.

Type of population: not specified Details on study design: - one-inch squares of the test material were applied to the arms of 46 men and to the arms or legs of 127 women - Patch fixed with adhesive tape - exposure time: six days - 2 weeks after removal, new patches were applied as a challenge for skin sensitisation - exposure time: 48 hours	one subject had papules along the edge of patch area and similar papules were under the tape area. - subjects had small indented areas under patch that appeared as red spots that coincided with the crimped pattern of this. - There is no information on the distribution of diantimony trioxide from the fibre to the skin so the conclusion which can be drawn from this study is that 1 % diantimony trioxide in the fibre is not sensitising. However, no conclusions on the sensitising potential of diantimony trioxide can be drawn from this study.	supporting study Test material (Dacron fibre): containing 1 % Sb_2O_3 and 6 % octabromobiphenyl	(1970b)

5.5.2. Respiratory system

5.5.2.1. Non-human information

There are no reports whatsoever on non-human respiratory sensitisation in the public domain.

5.5.2.2. Human information

There are no reports indicating reliable information on human respiratory sensitisation in the public domain.

5.5.3. Summary and discussion of sensitisation

Skin sensitisation

There is a complete absence of any human studies of adequate quality that can be used for assessing the sensitising potential of diantimony trioxide. However, there is one reliable animal study (Chevalier, 2005), performed according to TG 406 and GLP, which shows that diantimony trioxide has no sensitising properties.

The following information is taken into account for any hazard / risk assessment:
Diantimony trioxide is not a skin sensitiser.

Value used for CSA: No adverse effect observed (not sensitising)

Respiratory sensitisation

Based on an industry survey, during many years of industrial practice no cases of hypersensitivity were observed till now by workers exposed exclusively to diantimony trioxide.

The following information is taken into account for any hazard / risk assessment:

Diantimony trioxide is not a respiratory sensitiser.

Value used for CSA: No adverse effect observed (not sensitising)

Justification for classification or non-classification

Sensitisation:

The reference Chevalier F. (2005), is considered as the key study on skin sensitisation and will be used for classification. The overall sensitisation results are as follows:

Moore, G.E.(1994) – Buehler method in guinea pigs
The incidence of sensitisation after the challenge application was 0/20. Thus, the classification criteria according to regulation (EC) 1272/2008 as skin sensitizer are not met since 0 % of the test animals responded.

Respiratory sensitisation:

Based on an industry survey, during many years of industrial practice no cases of hypersensitivity were observed till now by workers exposed exclusively to diantimony trioxide. Thus, no classification as respiratory sensitiser according to regulation (EC) 1272/2008 is required.

5.6. Repeated dose toxicity

5.6.1. Non-human information

5.6.1.1. Repeated dose toxicity: oral

The results of experimental studies are summarised in the following table:

Table 54. Overview of experimental studies on repeated dose toxicity after oral administration

Method	Results	Remarks	Reference
rat (Wistar) male/female subchronic (oral: feed) 0 ppm (nominal in diet) 1000 ppm (nominal in diet) 5000 ppm (nominal in diet) 20000 ppm (nominal in diet) Exposure: a 90-day duration study no guideline specified, but conducted according to OECD 408.	NOAEL: 1686 mg/kg bw/day (male) NOAEL: 1879 mg/kg bw/day (female)	1 (reliable without restriction) key study experimental result Test material (EC name): diantimony trioxide	Hext P.M., Pinot P.J. and Rimmel B.A. (1999)
rat (Wistar) male subchronic (oral: feed) 500 mg/kg/day or 1000 mg/kg/day (nominal in diet) Exposure: 24 weeks (daily, no post exposure period) no guideline specified	No LOAEL identified (This study indicates that repeated exposure to antimony trioxide via the oral route might have an adverse effect on RBC in Wistar rats.) Slight disorder and cloudy swellings of the hepatic cords was observed in the liver and a significant increase in ASAT and ALP, which indicate hepatic cell lesion and cholestasis, respectively, suggests that diantimony trioxide is toxic to the liver. However, the changes in the biochemistry parameters must be compared with normal ranges, for examples with historical control data of the laboratory in question, and	4 (not assignable) supporting study experimental result Test material (EC name): diantimony trioxide	Sunagawa S. (1981)

	also evaluated in context of other findings (clinical and histopathological) supporting the biochemistry findings. Since information on historical controls and adverse histological liver findings are lacking a LOAEL will not be derived from this study. This study supports what other studies have shown; that there is a high distribution of antimony to blood, spleen, lung, liver and kidney after oral exposure, but also to testes and brain.		
rat subchronic (oral: feed) 2 % (corresponding approximately to a daily intake of 1000 mg/ kg bw) Exposure: Basal diet was given for 8 months. no guideline specified	Toxicological relevance cannot be judged due to significant methodical and reporting deficiencies.	3 (not reliable) supporting study experimental result Test material (EC name): diantimony trioxide	Gross P, Brown JHU, Westrick ML, Srsic RP, Butler NL and Hatch TF (1955f)
rat (albino) male subchronic (oral: unspecified) 60 mg/kg*d 270 mg/kg*d 1070 mg/kg*d Exposure: - 30 days No guideline specified at the time of conduct.	Toxicological relevance cannot be judged due to significant methodical and reporting deficiencies.	3 (not reliable) supporting study experimental result Test material (EC name): diantimony trioxide	Smyth, H.R.; Thompson, W.L. (1945b)
rat (Sherman) male/female subacute (oral: feed) 3-4 dose levels ranging from 60-1070 mg/ kg bw/ day Exposure: 30 days no guideline specified	Toxicological relevance cannot be judged due to significant methodical and reporting deficiencies.	3 (not reliable) supporting study experimental result Test material (EC name): diantimony trioxide	Smyth HF and Carpenter CPJ (1948b)
rat (Wistar) male chronic (oral: feed) 1 % (w/w) antimony trioxide (corresponding approximately to 500 mg/ kg bw/ day) no guideline specified	Toxicological relevance cannot be judged due to significant methodical and reporting deficiencies.	3 (not reliable) supporting study experimental result Test material (EC name): diantimony trioxide	Hiraoka N. (1986)
rat (oral: unspecified) Exposure: 20 treatments No guideline specified at time of conduct.	Toxicological relevance cannot be judged due to significant methodical and reporting deficiencies.	3 (not reliable) supporting study experimental result Test material (EC name): diantimony trioxide	Fleming, A.J. (1938)
dog subchronic (oral: gavage) 1 g (nominal in water) 20 cc (in 4 % citric acid) Exposure: 21 daily treatments with water antimony mixture, followed by 11 daily treatments with 20cc. of a saturated solution of antimony trioxide in 4 % citric acid (daily)	Toxicological relevance cannot be judged due to significant methodical and reporting deficiencies.	3 (not reliable) supporting study experimental result Test material (EC name): diantimony trioxide	Fleming, A.J. (1938)

No guideline specified at the time of conduct.			
rabbit (oral: gavage) No guideline specified at the time of conduct.	Toxicological relevance cannot be judged due to significant methodical and reporting deficiencies.	3 (not reliable) supporting study experimental result Test material (EC name): diantimony trioxide	Fleming, A.J. (1938)

5.6.1.2. Repeated dose toxicity: inhalation

The results of experimental studies are summarised in the following table:

Table 55. Overview of experimental studies on repeated dose toxicity after inhalation exposure

Method	Results	Remarks	Reference
rat (Fischer 344) male/female chronic (inhalation: dust) (whole body) 0.055 mg/m³ (analytical conc.) 0.511 mg/m³ (analytical conc.) 4.50 mg/m³ (analytical conc.) Vehicle: air Exposure: exposure for 1 year (daily, 6 hours per day, 5 days per week) equivalent or similar to OECD Guideline 452 (Chronic Toxicity Studies)	NOAEC: >= 0.51 mg/m³ air (male/female) based on: test mat. LOAEC: >= 4.5 mg/m³ air (male/female) based on: test mat. (impaired lung clearance)	2 (reliable with restrictions) key study experimental result Test material (EC name): diantimony trioxide	Newton P.E. and Daly I.W. (1990a) Newton P.E., Bolte H.F., Daly I.W., Pillsbury B.D., Terrill J.B., (1994)
rat (Fischer 344) male/female subchronic (inhalation: dust) (whole body) 0.000 mg/m³ (analytical conc.) 0.25 mg/m³ (analytical conc.) 1.08 mg/m³ (analytical conc.) 4.92 mg/m³ (analytical conc.) 23.46 mg/m³ (analytical conc.) Exposure: - 13 weeks followed by a 27-week observation period (- exposure for 6 hours/day, 5 days/week for) no guideline specified	A reliable LOAEC or NOAEC cannot be derived from this study, since this study can be regarded inconclusive for the local lung effects as the incidence of interstitial chronic pneumonia and interstitial fibrosis in controls is higher than or equal to exposed animals.	2 (reliable with restrictions) supporting study experimental result Test material (EC name): diantimony trioxide	Newton P.E., Bolte H.F., Daly I.W., Pillsbury B.D., Terrill J.B., (1994) Newton P.E. and Daly I.W. (1990b)
rat (Wistar) male/female chronic (inhalation: aerosol) (whole body) 50 mg/m³ (target concentration) 36.0 mg/m³ (analytical conc. 2E: Sb ore) 40.1 mg/m³ (analytical conc. 2W: Sb ore) 45.0 mg/m³ (analytical conc. 3E: Sb2O3) 46.0 mg/m³ (analytical conc. 3W: Sb2O3) Exposure: The animals were exposed for 52 weeks. (The animals were scheduled to be exposed for 7 hours per day and 5 days per week.)	LOAEC: 45 mg/m³ air	3 (not reliable) supporting study experimental result Test material (EC name): diantimony trioxide	Groth D.H., Stettler L.E. and Burg J.R. (1986)

no guideline specified			
rat (Sprague-Dawley) male/female chronic (inhalation: aerosol) (nose only) 2000 mg/m³ Exposure: 66 to 311 days (All animals received from 1 to 6 exposures of 1 hour each, every 2 months.) no guideline specified	Toxicological relevance cannot be judged due to significant methodical and reporting deficiencies.	4 (not assignable) supporting study experimental result Test material (EC name): diantimony trioxide	Cooper D.A:, Pendergrass E.P., Vorwald A.J., Mayock R.L. and Brieger H. (1968)
rat (Sprague-Dawley) male/female subchronic (inhalation: dust) (nose only) 0 mg/m³ (analytical conc.) 2.6 mg/m³ (analytical conc.) 4.4 mg/m³ (analytical conc.) 6.3 mg/m³ (analytical conc.) Exposure: Animals were treated from fertilisation to day 19, one day prior to scheduled euthanasia. (6 hours per day) draft guideline published in the United States Environmental Protection Agency Health Effects Test Guidelines, Inhalation Developmental Toxicity Study, OPPTS 870.3600 OECD Guideline No. 414, Prenatal Developmental Toxicity Study	LOAEC: 2.6 mg/m³ air (female) (The LOAEC for local toxicity in the lungs was based on acute pneumonia with significantly increased lung weight, 24.2 and 20.3 % higher than control for absolute and relative weights, respectively.) It could be discussed whether effects caused by pulmonary overload in the rat is also relevant for humans.	2 (reliable with restrictions) supporting study experimental result Test material (EC name): diantimony trioxide	Schroeder R.E. (2003a)
other: rats and miniature swine (CDF rats, Fisher rats and Sinclair S-1 miniature swine) female chronic (inhalation: dust) (whole body) 4.2 ± 3.2 mg Sb/m³ (analytical conc., corresponding to 5.0 ± 3.8 mg Sb2O3/m3) 1.6 ± 1.5 mg Sb/m³ (analytical conc., corresponding to 1.9 ± 1.8 mg Sb2O3/m3) Exposure: The exposure lasted approx. one year. (The exposure lasted 6 hours per day, 5 days per week.) no guideline specified	NOAEC: 1.9 mg/m³ air (based on findings indicative of endogenous lipoid pneumonia (focal fibrosis, presence of giant cells and cholesterol clefts) observed in animals in this dose group. This LOAEC should however be considered unreliable predominantly because of the inadequate verification of test atmospheres and particle size determinations.) It is noted that the female survival rate was significantly higher than that of the male counterparts in the study by Groth et al. (1986). The differences in incidence between the studies might be explained by the longer observation period (12 months vs 20 weeks) and the use of older animals (8 months vs 14 weeks) in the study by Watt (1983).	3 (not reliable) supporting study experimental result Test material (EC name): diantimony trioxide	Watt W.D. (1983)
guinea pig subchronic (inhalation: dust) (whole body)	:Toxicological relevance cannot be judged due to significant methodical and	3 (not reliable) supporting study experimental result	Dernehl C.U., Nau C.A. and Sweets H.H. (1945)

45.4 mg/m^3 (analytical conc.) Exposure: exposure for 27 weeks (During the first three weeks the animals were exposed for two hours daily, seven days a week. After three weeks, the exposure time was increased to three hours a day.) no guideline specified	reporting deficiencies.	Test material (EC name): diantimony trioxide	
other: rats and rabbits subchronic (inhalation: dust) (whole body) 100-125 mg/m^3 (rats) 89 mg/m^3 (rabbits) Exposure: Rats were exposed for 14.5 months (100 hours/month). Rabbits were exposed for 10 months (100 hours/month). no guideline specified	Toxicological relevance cannot be judged due to significant methodical and reporting deficiencies.	3 (not reliable) supporting study experimental result Test material (EC name): diantimony trioxide	Gross P, Westrick M.L., Brown J.H.U., Srsic R.P., Schrenk H.H. and (1955)
other: miniature swine (sinclair S-1) female (inhalation: dust) (whole body) 4.2 ± 3.2 mg Sb/m^3 (high dose chamber) (analytical conc., corresponding to 5.0 ± 3.8 mg Sb2O3/m3) 1.6 ± 1.5 mg Sb/m^3 (low dose chamber) (analytical conc., corresponding to 1.9 ± 1.8 mg Sb2O3/m3) Vehicle: unchanged (no vehicle) Exposure: approx. 1 year exposure period (6 hours per day, 5 days per week) no guideline specified	- the results show evidence of antimony trioxide related toxicity - in addition to the lung parameters only blood urea nitrogen and body weights show exposure related alteration - the lung is the main target organ of antimony trioxide inhalation toxicity. No exposure related histopathologic changes were observed in the swine.)	2 (reliable with restrictions) supporting study experimental result Test material (EC name): diantimony trioxide	Watt, W.D. (1983)

5.6.1.3. Repeated dose toxicity: dermal

Data waiving

Information requirement (Test type): Repeated dose toxicity after dermal administration

Reason: other justification

Justification: Repeated dose toxicity study via dermal route does not need to be performed since a Repeated dose toxicity study via inhalation is available.

According to the data requirements as outlined in Annexes VIII-IX, 8.6 of Regulation (EC) 1907/2006 a repeated dose toxicity study shall be via the most appropriate route of administration, having regard to the likely route of human exposure. The inhalation route is considered as the most appropriate route of exposure.

5.6.1.4 Repeated dose toxicity: other routes

There are no reliable reports whatsoever on repeated dose toxicity via other routes in humans in the public domain.

5.6.2. Human information

The exposure-related observations in humans are summarised in the following table:

Table 56. Overview of exposure-related observations on repeated dose toxicity in humans

Method	Results	Remarks	Reference
Type of population: occupational Details on study design: The subjects were 51 males between the age of 31 and 54 who worked in the smelting plant where they were exposed to dust containing predominantly antimony oxide and had definitive experienced pneumoconiotic changes. They had worked in the factory from 9-31 years, exclusive as smelters. Endpoint addressed: repeated dose toxicity: inhalation	Roentgenological findings: The X-rays showed sporadic and singly disseminated small, dense, roundish or polygonal opacities of pinhead type, diameter usually less than 1.0 mm, in 34 workers (67 %); numerous small, pinhead type opacities densely distributed in the mid-lung regions of 7 workers (14 %); a markedly high profusion of pinhead type opacities in the entire lung field of 9 workers (17 %) and a markedly high profusion of larger (1-3 mm), often irregular, opacities in the entire lung field of one worker (2 %). No case of confluent massive fibrosis was observed. Other findings included enlarged, dense hilar shadows and emphysematous changes in the upper and lower regions (34.5 %); active tuberculous lesions (i.e. non-calcified) were seen in one case and their identity was confirmed by laboratory examination; inactive tuberculosis in 18.2 %; peribronchial changes were noted in 17 workers (33 %). The pneumoconiotic changes were only seen in smelters who were exposed to the antimony oxide dust for more than 9 years (data not shown). Clinical findings: Clinical respiratory symptoms and signs observed were permanent breathlessness in effort in 7 cases (16 %), periodical breathlessness in effort in 26 cases (50 %), coughing with expectoration (chronic bronchitis) in 19 cases (37 %), coughing without expectoration in 12 cases (24 %), wheezing in 12 cases (24 %), generalised weakness in 13 cases (26 %), chest tightness or pains in 13 cases (26 %), whistling bronchi in 12 (24 %) and snoring, coarse bronchi in 14 (27 %). According to the authors the	2 (reliable with restrictions) supporting study Test material (EC name): diantimony trioxide	Potkonjak V., Pavlovich M. (1983b)

	prevalence of chronic coughing was markedly high whereas the other pulmonary symptoms and signs showed no particularity - they were found as often in patients with other simple pneumoconioses. Pulmonary function tests showed obstructive changes of the forced expiration volume in 17.6 %, light abnormality of airway resistance in 17.2 % and moderate to severe airway resistance in 9.1 %. Small airway obstruction as manifested by forced expiratory flow rates was recorded in 16.7 %, bronchospasms was seen in 4.4 % and hyperinflation was noted in 34.5 %. Arterial blood gases were normal during rest and after exercise; hypoxia was noted in 2 subjects only. Expired gases had normal O2 and CO2 concentrations. Non-homogenous alveolar ventilation was found in 31 %. Abnormal CO transfer was observed in two cases. Conjunctivitis was seen in 14 cases (27.5 %) and upper airway inflammation in 18 cases (35.3 %). It is not clear from the report if the group with upper airway inflammation was included in the group with chronic bronchitis. “Antimony dermatosis” characterised by vesicular or pustular lesions with residual hyperpigmentation were present in 32 workers (63 %), especially during the summer season and when working near the furnace where temperatures were excessively high. No systemic toxicity with regard to the cardiovascular, hepatic, hematopoietic, renal or central or peripheral nervous system was noted, except for musculo-skeletal complaints which were noted without any objective signs of pathology. This study shows that pneumoconiotic changes (the frequency was not stated) in smelters can be observed after 9 years of exposure and more		

	frequently after 10 or more years. The pneumoconiosis, which was called antimoniosis, was characterised by numerous small opacities of pinhead type, densely distributed in the middle and lower lungfields. Emphysema was observed in 34.5 % but massive fibrosis was not seen in any case. Changes in lung function were observed, however, no consistent pattern could be ascertained. Chronic coughing, chronic bronchitis, conjunctivitis and dermatitis were clinical signs but no systemic toxicity was observed.		
Study type: cohort study (prospective) Type of population: occupational Details on study design: METHOD OF DATA COLLECTION - Details: Examinations, including lung radiography (on 62 workers) SETTING: Examinations were performed at a work place (antimony sulphide ore smelting plant). The working conditions were reported to be “not at all ideal”. STUDY POPULATION - Total population (Total no. of persons in cohort from which the subjects were drawn): - Selection criteria: workers employed for at least 3 years in an antimony sulphide ore smelting plant - Total number of subjects participating in study: 101 - Sex: male - Other: 20 of the workers who showed pneumoconiotic symptoms were detailed clinical examined - no other details on study design are reported Endpoint addressed: repeated dose toxicity: inhalation	FINDINGS - light respiratory difficulty, tiredness, myalgia, light coughing, and light dyspepsia without pain or diarrhoea INCIDENCE / CASES Incidence/ Number of cases for each disease: - 2 workers gave suspicion to pneumoconiosis by X-ray pulmonary changes (spent all their working time in smelting plants) - 31 of 62 workers were found to have lung changes (radiography) - 22 cases of emphysema with bronchitis - 51 cases of catarrh in the upper respiratory tract - 16 cases of deviation of the nasal septum - 12 cases of conjunctivitis - 16 cases of antimony dermatosis (characterised by vesicular or pustular lesions with residual scars and hyperpigmentation, especially during the summer season and 13 of the cases were working near the furnace where temperatures were high) OTHER OBSERVATIONS: - No effects were observed on the gastrointestinal tracts, the liver, the cardiovascular system or the central or peripheral nervous system, which according to the authors indicated that there were no	4 (not assignable) supporting study Test material (Antimony Smelting Plant): antimony sulphide ore	Karajovic D (1957)

	systemic toxic effects - no other findings are reported This study indicates that exposure to diantimony trioxide may cause pneumoconiosis, emphysema, irritation to the eye, respiratory tract and the skin. However, data on exposure are lacking and no control group was included in the study. Therefore, this study cannot be used for quantitative risk assessment.		
Study type: cohort study (prospective) Type of population: occupational Details on study design: METHOD OF DATA COLLECTION - Details: lung changes were radiographed SETTING: - examination of men working with the production of antimony oxide and the pure metal from sulphide ore by various smelting processes, especially x-ray of the lungs STUDY POPULATION - Total population (Total no. of persons in cohort from which the subjects were drawn):>100 men were employed - Selection criteria: men working with the production of antimony oxide and the pure metal from sulphide ore - Total number of subjects participating in study: not specified - Sex: male - no other details on study design are reported Endpoint addressed: repeated dose toxicity: inhalation	FINDINGS - skin irritation in warm weather : the rash consisted of papules and pustules around sweat and sebaccous glands and was compared in appearance to the lesions of chickenpox or smallpox - the rash affected particularly the fore arms and thighs and the flexures and did not appear on the face, hands or feet. - the spots disappeared rapidly over a weekend or public holiday, but reappeared on return to work - a number of men working on this antimony plant at present have symptomless lung changes on radiographic examination (first noticed in another investigation) - Observation did not show any alteration in the radiological opacities, but: 2 men developed tuberculosis lesions (which responded promptly to chemotherapy) - one man with pneumoconiosis who had respiratory symptoms had chronic bronchitis with respiratory obstruction - men exposed to antimony excrete it in their urine - examination of urine sample of 3 men with lung changes showed: 425, 480 and 680 µg/l - in a men with pneumoconiosis who retired at the age of 65 years urine level was 55 µg/l 7 month later and 28 µg/l 4 years later (there was no detectable diminution in the lung changes over this period)	2 (reliable with restrictions) supporting study Test material (ore): antimony oxide and the pure metal from sulphide ore	McCallum RI (1963)

	- no other findings are reported This study supports that lung changes resembling pneumoconiosis occurs in humans occupationally exposed to diantimony trioxide. However, due to lack of specific exposure data this study cannot be used for quantitative risk assessment.		
Study type: cohort study (prospective) Type of population: occupational Details on study design: HYPOTHESIS TESTED (if cohort or case control study): - Appearance of radiological abnormalities in the lungs of workers METHOD OF DATA COLLECTION - Type: Clinical tests - Details: radiological investigation (using macro-radiographs), direct measurement of amount of antimony in the lungs with differential x-ray method and lung function test SETTING: antimony process workers in a plant STUDY POPULATION - Total number of subjects participating in study: 274 men - Sex: male - no other details on study design are stated Endpoint addressed: repeated dose toxicity: inhalation	FINDINGS, see table 1 - all the antimony pneumoconiosis was of the simple type (category 1-3 in the international classification) - 177 workers were found to have normal lungs (after initial testing or further check at Department of Health) - 26 new cases of antimony pneumoconiosis were discovered (since investigation in 1962, where 9 % of the workers were found to have changes in the lungs) - another 18 men with antimony pneumoconiosis were already under clinical observation - abnormal shadows in the radiograph of the lungs of 8 men were thought to result from inhalation of mixed dust of antimony, zirconium, coal or furnace brick - histological examination of lungs: suggested that there was little or no reaction to antimony dust (number not stated, but probably few since it was indicated that such material was scarce) - differential x-ray method showed that 2 men with antimony pneumoconiosis, who were only exposed to antimony dust, had antimony deposit in their lungs; 3 men who had been exposed to a mixture of antimony and zirconium had negative results CLINICLA INVESTIGATIONS: - irritant effects of antimony on the skin - no harmful effects of antimony trioxide were found clinically or	2 (reliable with restrictions) supporting study Test material (natural substance and industrial products): Antimony sulphide ore, antimony fume, antimony slag, antimony trioxide, antimony regulus	McCallum RI (1967)

	with lung function test INCIDENCE / CASES - Incidence/ Number of cases for each disease / parameter under consideration: - Other: Histological sections of the lungs of an antimony worker who died from carcinoma of the lung showed an accumulation of dust particles and dust laden macrophages lying in alveolar septa and in perivascular tissues without fibrosis or an inflammatory reaction. - no other findings are reported This study supports that lung changes resembling pneumoconiosis occurs in humans occupationally exposed to diantimony trioxide. However, no exposure data were reported and no control group was included, therefore this study cannot be used for quantitative risk assessment.		
Type of population: occupational Details on study design: The mortality and the underlying causes were investigated in workers employed in an antimony plant. The population studied was recruited from an antimony works in the north east of England. At the start of the study all people in the company's employed on 1 January 1961 were recruited into the survey. The workers were subdivided into four occupational groups: a) antimony workers, b) maintenance workers, c) zircon workers and d) others (including office workers and management staff). An antimony worker is defined here as any person who worked in the antimony plant for at least three month regardless of his present or last occupation. Two sets of expected figures were worked out: the first based on national rates for England and Wales and the second based on local rates. Endpoint addressed: repeated dose toxicity: inhalation	Except for increase in mortality from lung cancer no effects were observed in mortality from other causes. No effect on mortality from circulatory disease, ischaemic heart disease, respiratory disease, genitourinary disease, accident and suicides and others was observed in this study. However, there were no exposure data reported and thus this study cannot be used for any quantitative risk assessment.	2 (reliable with restrictions) supporting study Test material (EC name): diantimony trioxide	Jones, R.D. (1994)
Study type: In a case study, illness among workers of a mining company engaged in the mining, concentrating and smelting of an antimony sulphide ore was reported.	The illness was found among workers engaged in the smelting operations and among maintenance workers who spent a substantial part of their time in	3 (not reliable) supporting study Test material (EC name): diantimony	Renes L.E. (1953)

The smelter was divided into two zones, the electric furnace area and the cupel area. The average zone concentration of antimony was 10.07 and 11.81 mg per m^3 of air, respectively for the two zones. The average zone concentration of arsenic was 1.10 and 0.36 mg per m^3 of air, respectively for the two zones. From the nature of the operations in which the air-borne contaminants were evolved, it seemed logical to assume that the antimony and arsenic existed as oxides. Endpoint addressed: repeated dose toxicity: inhalation	the smelter building. Sixty-nine of 78 workers made 218 visits to the plant physician for reasons of occupational illness. The frequency of various types of injuries observed each month was relatively constant. With increasing length of employment in the smelter, there was a progressive increase in the number of severe injuries, like nasal septal perforations, laryngitis, tracheitis and pneumonitis. The following percentage distribution of the diagnoses made during the first five months was: bronchitis (7 %), conjunctivitis (4 %), dermatitis (20 %), gastritis (3 %), gastroenteritis (5.5 %), laryngitis (11 %), neuritis (1 %), pharyngitis (8 %), pneumonotis (5.5 %), rhinitis (20 %), secondary sinusitis (1.5 %), septal perforations (8.5 %) and tracheitis (10 %). Chest x-rays taken of six men who were acutely ill from heavy exposures to smelter fumes showed definite pneumonitis extending fanwise from each hilus. Among workers who had heavy exposures to smelter fumes seemingly systemic toxic effects, such as abdominal cramps, diarrhea, vomiting, dizziness, nerve tenderness and tingling, severe headaches and prostration. Antimony was detected in urine in seven out of nine workers and arsenic was found in the urine of one worker (the number of urine samples taken were not stated). Laryngitis, with voice changes among affected workers, ranged from hoarseness to aphonia. The dermatitis that developed among the workers was observed in sweaty, hairy, friction areas, such as axillae, groin and back of the neck. These were nodular ulcerative lesions. The occurrence of dermatitis was sporadic and most of the cases occurred during one week in the second month of operation, presumably	trioxide	

	after the workers had been very heavily exposed to fumes. Of the subjective symptoms reported by the workers, soreness and bleeding of the nose were experienced by more than 70 % of the workers. Sore throat, hoarseness, burning or redness of the eyes, metallic taste in the mouth, pain in the chest, headache and shortness of breath were the second most frequent complaints and were noted by about 25 % of the workers. About 10 % of the workers complained about weight loss, nausea, vomiting, diarrhoea, inability to smell properly and tightness in the chest. Less frequent complaints were spitting of blood, abnormal urination, abdominal cramps, muscle soreness, insomnia and blurred vision. This case study indicates that occupational exposure to antimony may result in upper respiratory irritations, pulmonary inflammation, skin lesions and systemic reactions. Due to the operations of antimony it can be assumed that the antimony existed as oxides. However, the precense of diantimony trioxide was not analysed. Although exposure to arsenic trioxide also occurred, no early signs of arsenic intoxication, such as increased pigmentation of certain skin areas, keratoses of the palms and soles, loss of hair and nails, garlic odour of the breath and perspiration or swelling of ankles were observed. No detailed exposure data were presented, therefore this study is inconclusive and cannot be used for quantitative risk assessment.		
Study type: Lesions of the respiratory tract and the lungs caused by antimony trioxide have been reported in workers involved in antimony processing metallurgical works. Endpoint addressed: repeated dose toxicity: inhalation	Rhinitis (54.3 %), perforation of the septa (33.2 %), pharyngitis (76.5 %), bronchitis (54.3 %), pneumoconiosis (20.8 %) and symptoms of emphysema (41.9 %) was observed. The development of pneumoconiosis stopped at the micronodular size, the nodules	3 (not reliable) supporting study Test material (EC name): diantimony trioxide	Klucik I., Juck A. and Gruberova J. (1962)

	did not tend to confluence. As analysis of the dust did not show any content of free SiO2, the authors presumed that pneumoconiosis was caused by antimony trioxide. Due to unclear exposure conditions of the workers, this study is considered inconclusive and will not be used for risk characterisation.		

5.6.3. Summary and discussion of repeated dose toxicity

Discussion

Inhalation:

The majority of the repeated dose studies in animals cited above is considered inconclusive because they do not comply with current test guidelines, they lack essential information regarding exposure conditions and statistical evaluations of the results or both control and exposed animals showing signs of non-treatment related illness. Still, there are inhalation studies indicating that diantimony trioxide can contribute to what is described as impairment of lung clearance (Newton et al., 1994; Watt, 1983; Groth et al., 1986a; MPI, 2003). A NOAEC of 0.51 mg/m^3 is derived from the study by Newton et al., 1994 and brought forward to the risk characterisation. The NOAEC is based on impaired lung clearance that was observed at 4.50 mg/m^3.

Oral:

Two repeated dose oral studies (Sunagawa, 1981; Hext *et al.,* 1999) suggest that diantimony trioxide may be toxic to the liver. This being based on a 10 % increase in liver weight. In addition, one study (Hext et al., 1999) exhibitedsignificantly elevated ASAT values and significantly decreased ALP values. The other study(Sunagawa, 1981) revealed both ASAT and ALP levels to besignificantly elevated. However, in the absence of histological change or any clinical signs of antimony intoxication to support liver adversity, the differences are regarded as adaptive or incidental to treatment with diantimony trioxide. A NOAEL of 1686 mg/kg/d for liver toxicity is suggested.

Dermal:

Studies on repeated dermal exposure are not available. Given the experimentally verified negligible percutaneous absorption, this route of entry into the body is not considered relevant for risk assessment.

The following information is taken into account for any hazard / risk assessment:

repeated dose toxicity via oral application: NOAEL=1686mg/kg bw/day

Value used for CSA (via oral route - systemic effects):

No adverse effect observed (NOAEL: 1686 mg/kg bw/day) (subchronic; rat)

Value used for CSA (dermal - systemic effects):

No study available

Value used for CSA (dermal - local effects):

No study available

Value used for CSA (inhalation - systemic effects):

No adverse effect observed

Value used for CSA (inhalation - local effects):

No adverse effect observed (NOAEC: 0.51 mg/m³) (subchronic; rat)

Justification for classification or non-classification

Repeated dose toxicity, oral:

The reference Hext P.M., Pinot P.J. and Rimmel B.A. (1999) is considered as the key study for repeated dose toxicity via oral application and will be used for classification. Rats were dosed at 20,000 ppm/day orally via feed for 90 days. Based on the lack of any adverse effects, the no observed adverse effect level (NOAEL) via oral application for diantimony trioxide was established at 1686 mg/kg bw/day.

The classification criteria according to regulation (EC) 1272/2008 as specific target organ toxicant (STOT) – repeated exposure, oral are not met since no reversible or irreversible adverse health effects were observed immediately or delayed after exposure and the no observed adverse effect level (NOAEL) via oral application is above the guidance value for a Category 1 classification of 10 mg/kg bw/day and above the guidance value for a Category 2 classification of 100 mg/kg bw/day. For the reasons presented above, no classification for specific target organ toxicant (STOT) – repeated exposure, oral is required.

Repeated dose toxicity, dermal:

Diantimony trioxide was tested in a percutaneous absorption test indicating that absorption does not occur. The toxicological profile of this material does not give rise to concern in human use, since the substance is not absorbed through the skin. In view, also, of the lack of percutaneous absorption, a calculation of the margin of safety has not been carried out.

For the reasons presented above, no classification for specific target organ toxicant (STOT) – repeated exposure, dermal is required.

Repeated dose toxicity, inhalation:

The rat is uniquely sensitive to changes within the lung when exposed under conditions of particle overload to poorly soluble low-toxicity particles such as diantimony trioxide. Although particle overload is observed in other experimental species such as the mouse, it is only in the rat that a sequence of events is initiated that leads to fibroproliferative disease, septal fibrosis, hyperplasia and eventually lung tumours. However, similar pathological changes are not observed in other common laboratory rodents, non-human primates or in exposed humans. Detailed epidemiological investigations have shown no causative link between titanium dioxide (stated as a surrogate for poorly soluble particles such as diantimony trioxide) exposure and the risk of non-malignant respiratory disease in humans.

According to regulation (EC) 1272/2008, a classification for specific target organ toxicity – repeated exposure shall be taken into account only when reliable evidence associating repeated exposure to the substance with a consistent and identifiable toxic effect demonstrates support for the classification. These adverse health effects include consistent and identifiable toxic effects in humans, or, in experimental animals, toxicologically significant changes which have affected the function or morphology of a tissue/organ, or have produced serious changes to the biochemistry or haematology of the organism and these changes are relevant for human health.

The following observations have been made in experimental animals and in human epidemiological studies:

(i) No systemic toxicity was shown to result from chronic inhalation exposure in rats to high concentrations of diantimony trioxide

(ii) Particle overload is observed for insoluble particles such as diantimony trioxide, whereby the rat is the most sensitive species studied, and species-specific differences are demonstrated in various mechanistic animal studies (Oberdörster, 1996). It has been demonstrated with reasonable certainty that lung overload conditions are not relevant for human health and, therefore, results based on these data do not justify classification.

The high level of fibrotic changes in control rats clearly suggests that the test system/species is of rather limited value for the desired study objective. It is important to note that granuloma or granulomatous inflammation are not reported either by Watt (at exposures roughly equivalent to the Newton study) or by Groth (at exposure sup to 45 mg/m^3). By weight-of-evidence, the indications of granulomatous changes suggested by Newton in particular because of the "high background" are hardly convincing. Out of the extensive catalogue of effects that trigger STOT classification, only the issue of granuloma remains. However, in the light of our comments above, by applying a weight-of-evidence approach, there is no consistent reporting of these effects. In accordance with guidance for STOT classification, there is an absence of consistent identifiable toxic effects other than the non-specific PSP overload, which is an adaptive response not triggering a STOT classification.

5.7. Mutagenicity

5.7.1. Non-human information

5.7.1.1. In vitro data

The results of experimental studies are summarised in the following table:

Table 57. Overview of experimental in vitro genotoxicity studies

Method	Results	Remarks	Reference
bacterial reverse mutation assay (e.g. Ames test) (gene mutation) S. typhimurium TA 1535, TA 1537, TA 98 and TA 100 (met. act.: with and without) E. coli WP2 uvr A (met. act.: with and without) E. coli WP2 (met. act.: with and without) Doses: The doses tested were 100, 200, 500, 1000, 2500 and 5000 µg/plate. OECD Guideline 471 (Bacterial Reverse Mutation Assay)	Evaluation of results: negative Test results: negative for S. typhimurium TA 1535, TA 1537, TA 98 and TA 100(all strains/cell types tested); met. act.: with and without; cytotoxicity: no	1 (reliable without restriction) key study experimental result Test material (EC name): diantimony trioxide	Elliot b.M., Mackay J.M., Clay P. and Ashby J. (1998a)
mammalian cell gene mutation assay (gene mutation) mouse lymphoma L5178Y cells (met. act.: with and without) Doses: The highest dose tested was limited by the solubility of antimony trioxide to 50 µg/ml (172 µM), where precipitation of the test substance could be seen. OECD Guideline 476 (In vitro Mammalian Cell Gene Mutation Test)	Evaluation of results: negative Test results: negative for mouse lymphoma L5178Y cells (all strains/cell types tested); met. act.: with and without; cytotoxicity: no	1 (reliable without restriction) key study experimental result Test material (EC name): diantimony trioxide	Elliot b.M., Mackay J.M., Clay P. and Ashby J. (1998a)
bacterial reverse mutation assay (e.g. Ames test) (gene mutation) S. typhimurium TA 1535, TA 1537, TA 98 and TA 100 S. typhimurium TA 1538 E. coli WP2 E. coli WP2 Doses: The antimony trioxide was dissolved in distilled water at a concentration of 0.05 M.	Evaluation of results: negative (Antimony trioxide did not show any mutagenicity in the reverse mutation assay. Only qualitative results given by the authors, no quantitative results such as number of revertants.)	3 (not reliable) supporting study experimental result Test material (EC name): diantimony trioxide	Kanematsu N., Hara M. and Kada T. (1980)

2.5 µmol (729 µg)/disk no guideline specified			
in vitro mammalian chromosome aberration test (chromosome aberration) lymphocytes: human (met. act.: with and without) Doses: 10, 50, and 100 µg/ml (final concentrations) was added to duplicate cultures of cells. The highest dose was limited to the solubility of the test compound. OECD Guideline 473 (In vitro Mammalian Chromosome Aberration Test)	Evaluation of results: Positive Chromosomal aberrations as well as polyploidy and endoreduplication were recorded. There was no evidence of cytotoxicity measured by the mean mitotic index for the cultures treated with antimony trioxide compared to control. No increase in the number of polyploidy and endoreduplicated cells was noted. At the 92 hour sampling time, a statistically significant increase was seen at 100 µg/ml of antimony trioxide without S9-mix ($p < 0.05$). Test results: positive for lymphocytes: human (all strains/cell types tested); met. act.: with and without; cytotoxicity: no	1 (reliable without restriction) key study experimental result Test material (EC name): diantimony trioxide	Elliot b.M., Mackay J.M., Clay P. and Ashby J. (1998a)
sister chromatid exchange assay in mammalian cells (DNA damage and/or repair) Chinese hamster cells Doses: Diantimony trioxide final concentrations were 0.09, 0.17 or 0.34 µg/ml. equivalent or similar to OECD Guideline 479 (Genetic Toxicology: In Vitro Sister Chromatid Exchange Assay in Mammalian Cells)	Evaluation of results: A statistically significant increase in the number of SCEs/metaphase was obtained. The significant increase could be seen from the concentration of 0.09 µg/ml. No cytotoxicity was reported at the final concentration of 0.34 µg/ml.	2 (reliable with restrictions) supporting study experimental result Test material (EC name): diantimony trioxide	Kuroda K., Endo G., Okamoto A., Yoo Y.S. and Horiguchi S. (1991)
Bacillus subtilis recombination assay (DNA damage and/or repair) bacteria, other: Bacillus subtilis M45(rec-) and H17(rec+) S. typhimurium TA 100 S. typhimurium TA 98 Doses: 50 mg antimony oxide was dissolved in 1 ml of distilled water and the solution was diluted serially 2-fold and used for the assay. The oxide was not completely dissolved . The concentration of the compound in the fluid was determined by ICP (inductively coupled plasma emission spectrometer). DNA damage test in the B. subtilits rec-assay	Test results: negative for S. typhimurium, other: TA100 and TA98	2 (reliable with restrictions) supporting study experimental result Test material (EC name): diantimony trioxide	Kuroda K., Endo G., Okamoto A., Yoo Y.S. and Horiguchi S. (1991)
sister chromatid exchange assay	Evaluation of results:	3 (not reliable)	Gebel T.,

in mammalian cells (DNA damage and/or repair) lymphocytes: human Doses: Cultures were treated with antimony trioxide at final concentrations of 0, 0.1, 0.5, 1, 2 and 5 µM, corresponding to 0, 0.03, 0.15, 0.29, 0.58 and 1.5 µg/ml. equivalent or similar to OECD Guideline 479 (Genetic Toxicology: In Vitro Sister Chromatid Exchange Assay in Mammalian Cells)	positive Test results: positive for lymphocytes: human It is difficult to draw conclusions on the reliability of this result on the basis of the details provided.	supporting study experimental result Test material (EC name): diantimony trioxide	Christensen S. and Dunkelberg H. (1997)
Bacillus subtilis recombination assay (DNA damage and/or repair) bacteria, other: Bacillus subtillis H17 (Rec+, arg- try-) and M45 (Rec-, arg- try-) Doses: The antimony trioxide was dissolved in distilled water at a concentration of 0.001-10 M. 2.5 µmol (729 µg)/disk no guideline specified	Evaluation of results: positive	2 (reliable with restrictions) supporting study experimental result Test material (EC name): diantimony trioxide	Kanematsu N., Hara M. and Kada T. (1980)

5.7.1.2. In vivo data

The results of experimental studies are summarised in the following table:

Table 58. Overview of experimental in vivo genotoxicity studies

Method	Results	Remarks	Reference
chromosome aberration assay (chromosome aberration) rat (Sprague-Dawley) male/female oral: gavage 250 mg/kg (nominal conc.) 500 mg/kg (nominal conc.) 1000 mg/kg (nominal conc.) OECD Guideline 475 (Mammalian Bone Marrow Chromosome Aberration Test) ICH Tripartite Harmonised Guideline on Genotoxicity: Specific Aspects of Regulatory Tests, 1995	Evaluation of results: negative Test results: Genotoxicity: negative (male/female); toxicity: no effects	1 (reliable without restriction) key study experimental result Test material (EC name): diantimony trioxide	Whitwell J. (2006)
micronucleus assay (chromosome aberration) rat (Sprague-Dawley) male/female oral: gavage 250 mg/kg (nominal conc.) 500 mg/kg (nominal conc.) 1000 mg/kg (nominal conc.) OECD Guideline 474 (Mammalian Erythrocyte	Evaluation of results: negative Test results: Genotoxicity: negative (male/female); toxicity: no effects	1 (reliable without restriction) key study experimental result Test material (EC name): diantimony trioxide	Whitwell J. (2006)

Micronucleus Test) ICH Tripartite Harmonised Guideline on Genotoxicity: Specific Aspects of Regulatory Tests, 1995			
micronucleus assay (chromosome aberration) mouse (CD-1) male/female oral: gavage 400 mg/kg (nominal conc.) 667 mg/kg (nominal conc.) 1000 mg/kg (nominal conc.) OECD Guideline 474 (Mammalian Erythrocyte Micronucleus Test)	Evaluation of results: negative Test results: Genotoxicity: negative (male/female); toxicity: no effects	1 (reliable without restriction) key study experimental result Test material (EC name): diantimony trioxide	Elliot b.M., Mackay J.M., Clay P. and Ashby J. (1998b)
micronucleus assay (chromosome aberration) mouse (CD-1) male/female oral: gavage 400 mg/kg (nominal conc.) 667 mg/kg (nominal conc.) 1000 mg/kg (nominal conc.) OECD Guideline 474 (Mammalian Erythrocyte Micronucleus Test)	Evaluation of results: negative Test results: Genotoxicity: negative (male/female); toxicity: no effects	1 (reliable without restriction) key study experimental result Test material (EC name): diantimony trioxide	Elliot b.M., Mackay J.M., Clay P. and Ashby J. (1998b)
chromosome aberration assay (chromosome aberration) mouse (Swiss) male oral: gavage 400 mg/kg body mass 666.67 mg/kg body mass 1000 mg/kg body mass equivalent or similar to OECD Guideline 475 (Mammalian Bone Marrow Chromosome Aberration Test) no guideline specified	Evaluation of results: ambiguous The same data was also published elsewhere (Gurnani et al., 1993). Strangely, the animals in the high-dose group which died on day 20 were evaluated for aberrations after sacrifice on day 21 in the 1993 publication. Due to the unexplained lethality in the high-dose group and the discrepancy between the two publications, the Gurnani study results are considered questionable and will not be used for risk assessment. Test results: Genotoxicity: ambiguous (male); toxicity: yes	3 (not reliable) supporting study experimental result Test material (EC name): diantimony trioxide	Gurnani N., Sharma A. and Talukder G. (1992)
(chromosome aberration) mouse (Swiss) male oral: gavage 400 mg/kg body mass 666.67 mg/kg body mass 1000 mg/kg body mass equivalent or similar to OECD Guideline 475 (Mammalian Bone Marrow Chromosome Aberration Test) no guideline specified	Evaluation of results: ambiguous The same data was also published elsewhere (Gurnani et al., 1992). Strangely, the animals in the high-dose group which died on day 20 were evaluated for aberrations after sacrifice on day 21 in the 1992 publication. Due to the unexplained lethality in the high-dose group and the discrepancy between the two publications, the Gurnani study results are considered questionable and will not be used	3 (not reliable) supporting study experimental result Test material (EC name): diantimony trioxide	Gurnani N., Sharmar A. and Talukder G. (1993)

	for risk assessment. Test results: Genotoxicity: ambiguous (male); toxicity: yes		
unscheduled DNA synthesis (DNA damage and/or repair) rat (Alderley Park AlPk: ApfSD) male oral: gavage 3200 mg/kg (nominal conc.) 5000 mg/kg (nominal conc.) OECD Guideline 486 (Unscheduled DNA Synthesis (UDS) Test with Mammalian Liver Cells in vivo)	Evaluation of results: negative Test results: Genotoxicity: negative (male); toxicity: no effects	1 (reliable without restriction) key study experimental result Test material (EC name): diantimony trioxide	Elliot b.M., Mackay J.M., Clay P. and Ashby J. (1998b)

5.7.2. Human information

The exposure-related observations in humans are summarised in the following table:

Table 59. Overview of exposure-related observations on genotoxicity in humans

Method	Results	Remarks	Reference
Study type: human data Endpoint addressed: genetic toxicity	The mean SCE and MN did not differ significantly between the three groups (A, B and control), analysed by one-way ANOVA and Dunnett´s test. In the high dose (Group A), 11 subjects had significant levels of oxidative damage versus 5.5 expected. After adjustment of confounding factors the measure of risk for Group A subjects compared to controls was 14.2 (P=0.002). No other significant findings could be seen. In this study the “high exposure group” is exposed to air concentrations that is almost equivalent to ambient air concentrations and no monitoring of the non-exposed control workers were performed for comparison. In addition, the workers are likely exposed to a series of chemicals which had not been identified.	2 (reliable with restrictions) supporting study Test material (EC name): diantimony trioxide	Cavallo D., Iavicoli I., Setini A., Marinaccio A., Perniconi B., Carelli (2002)

5.7.3. Summary and discussion of mutagenicity

Discussion

In vitro/In vivo
Considering the available genotoxicity data, antimony trioxide does not induce gene mutations in vitro, but has been shown to induce structural chromosome aberrations in cultured mammalian cells in vitro. However, negative in vivo results on induction of chromosome aberrations and/or micronuclei were obtained in two different species – mouse (Elliot et al., 1998) and rat (Whitwell, 2006), (Kirkland et al., 2007). An in vivo UDS assay in rats was also negative (Elliot et al., 1998). These tests were performed according to GLP and using OECD test guideline protocols and oral administration. According to a recent guideline-conform toxicokinetic study (De Bie, 2005) conducted under GLP at a dose of 1000 mg/kg as used in these mutagenicity studies, tissue distribution data confirmed that the bone marrow was exposed. It can therefore be concluded that diantimony trioxide does not cause systemic mutagenicity in vivo after oral administration.

Human data
In the human study the genotoxicity of antimony trioxide in lymphocytes from occupationally exposed workers was assessed. No induction of micronuclei or sister chromatid exchanges could be seen between the two exposed groups and the unexposed control. In an enzyme-modified comet assay a significantly higher proportion of the workers in the “high exposure group” showed oxidative DNA damage in their lymphocytes compared to control. However, the workers were exposed to diverse chemicals and no monitoring was performed on the control group, therefore a correlation between the oxidative DNA damage and air concentration of antimony trioxide is uncertain.

The following information is taken into account for any hazard / risk assessment:

Based on the information obtained in highly reliable guideline studies it is concluded that diantimony trioxide does not induce genetic toxicity.

Value used for CSA: Genetic toxicity: No adverse effect observed (negative)

Justification for classification or non-classification

Genetic toxicity, in vivo:
Negative in vivo results on chromosome aberrations and micronuclei were obtained in two different species via oral application – mouse (Elliot et al., 1998) and rat (Whitwell, 2006), (Kirkland et al., 2007). An in vivo UDS assay in rats was also negative (Elliot et al., 1998).

Genetic toxicity, in vitro:
Based on the outcome of numerous in vitro genetic toxicity studies it can be concluded that diantimony trioxide does not induce gene mutations in vitro. The induction of structural chromosome aberrations in cultured mammalian cells in vitro is overruled by negative in vivo studies in rats and mice.

The classification criteria according to regulation (EC) 1272/2008 as germ cell mutagen are also not met.

5.8. Carcinogenicity

5.8.1. Non-human information

5.8.1.1. Carcinogenicity: oral

It has been shown that the systemic availability of diantimony trioxide following oral application is below 1%. No adverse health effects were observed in 90-day repeated dose oral toxicity studies at the limit dose, indicating an absence of systemic toxicity. Furthermore, diantimony trioxide is void of genetic toxicity. Therefore, the conduct of a carcinogenicity study via the oral route is considered dispensable.

5.8.1.2. Carcinogenicity: inhalation

The results of experimental studies are summarised in the following table:

Table 60. Overview of experimental studies on carcinogenicity after inhalation exposure

Method	Results	Remarks	Reference
rat (Fischer 344) male/female inhalation: dust (whole body) 0 mg/m³ (analytical conc.) 0.06 ± 0.04 (mean ± SD) mg/m³ (analytical conc.) 0.51 ± 0.13 (mean ± SD) mg/m³ (analytical conc.) 4.50 ± 1.33 (mean ± SD) mg/m³ (analytical conc.) Exposure: 52 weeks (6 hr/day and 5 days / week) equivalent or similar to OECD Guideline 451 (Carcinogenicity Studies)	NOAEC (carcinogenicity): > 4.5 mg/m³ air (analytical) (male/female) Neoplastic effects: no effects	2 (reliable with restrictions) key study experimental result Test material (EC name): diantimony trioxide	Newton PE, Bolte HF, Daly IW, Pillsbury BD, Terrill JB, Drew RT, Ben-Dyke (1994) Newton P.E. and Daly I.W. (1990b)
rat (Fischer 344) female inhalation: dust (whole body) 4.2 ± 3.2 mg Sb/m³ (high dose chamber) (analytical conc. (averaged dose; corresponding to 5.0 ± 3.8 mg Sb2O3/m³)) 1.6 ± 1.5 mg Sb/m³ (low dose chamber) (analytical conc. (averaged dose, corresponding to 1.9 ± 1.8 mg Sb2O3/m³)) Exposure: approx. 1 year exposure period (6 hours per day, 5 days per week) no guideline specified	LOAEC (carcinogenicity): 5 mg/m³ air (female) (A LOAEC of 5.0 mg/m3 is suggested based on the development of scirrhous carcinomas and the NOAEC is set to 1.9 mg/m3. However, this level is considered unreliable because of inadequate concentration verification.) NOAEC (carcinogenicity): 1.9 mg/m³ air (female) Neoplastic effects: yes	3 (not reliable) supporting study experimental result Test material (EC name): diantimony trioxide	Watt WD (1983)
rat (Wistar) male/female inhalation: dust (whole body) 45.0 mg/m³ mean daily TWA Sb2O3 (analytical conc. (in chamber 3E; Range of TWAs: 0-118.5 mg/m³)) 46.0 mg/m³ mean daily TWA Sb2O3 (analytical conc. (in chamber 3W; Range of TWAs: 0-191.1 mg/m³)) 36.0 mg/m³ mean daily TWA Sb ore (analytical conc. (in chamber 2E; Range of TWAs: 0-83.2 mg/m³)) 40.1 mg/m³ mean daily TWA Sb ore (analytical conc. (in chamber 2W; Range of TWAs: 0-91.1 mg/m³)) Exposure: up to 52 weeks / 12 months (7 h/d and 5 d/wk) no guideline specified	LOAEC (carcinogenicity): 45 mg/m³ air (female) (neoplasms) Neoplastic effects: yes	2 (reliable with restrictions) supporting study experimental result Test material (EC name): diantimony trioxide	Groth DH, Stettler LE, Burg JR, Busey WM, Grant GC and Wong L (1986)

5.8.1.3. Carcinogenicity: dermal

It has been shown that the systemic availability of diantimony trioxide following dermal exposure is below 1 %. No adverse health effects were observed in 90-day repeated dose oral toxicity studies at the limit dose, indicating an absence of systemic toxicity. Furthermore, diantimony trioxide is void of genetic toxicity.

Therefore, the conduct of a carcinogenicity study via the dermal route is considered dispensable.

5.8.1.4. Carcinogenicity: other routes

There are no reliable reports whatsoever on carcinogenicity via other routes in the public domain.

5.8.2. Human information

The exposure-related observations in humans are summarised in the following table:

Table 61. Overview of exposure-related observations on carcinogenicity in humans

Method	Results	Remarks	Reference
Study type: longitudinal study Type of population: occupational Details on study design: HYPOTHESIS TESTED (if cohort or case control study): - the original hypothesis was that an excess of lung cancer was being experienced by antimony workers at this plant. METHOD OF DATA COLLECTION - Type:- information about the deaths and reason for the death of workers were received from the Office of Population, Censuses and Surveys (OPCS) SETTING: comparison of the mortality of a census population and a prospective cohort of men employed on an antimony smelter (from 1961-92) STUDY POPULATION - Total population (Total no. of persons in cohort from which the subjects were drawn): 2508 - Selection criteria: all men employed between 1961 and 1992 with at least 3 months of employment - Total number of subjects participating in study: 1452 - no other details on study design are stated Endpoint addressed: carcinogenicity	FINDINGS - 1420 men were traced by OPCS: - 357 men had died by the end of 1992 - 29 men emigrated by the end of 1992 INCIDENCE / CASES total results: - Incidence/ Number of cases for each disease / parameter under consideration: - a) antimony workers: significant increase in mortality from lung cancer (37 v. 23.9, p= 0.016) no difference in mortality from stomach cancer or other neoplasms - b) maintenance men: significant increase in mortality from lung cancer (15 v. 8.1, p= 0.038) and other neoplasms (18 v. 8.4, p = 0.006), but no difference in mortality from stomach cancer - c) + d) zircon workers and others: no increased death rates result differences between the "the before 1961 groups" and "the after 1960 groups" for lung cancer: - for antimony workers before 1961 there is a significant excess of lung cancer (32 v. 14.7, p = 0.001) - for the maintenance workers before 1961 there is a significant excess of lung cancer (12 v. 5.3, p = 0.016) - no evidence for excess of lung cancer was found in the zircon and miscellaneous groups and in all groups recruited after 1960	2 (reliable with restrictions) supporting study Test material (pure substance and formulations): Antimony ore	Jones RD (1994)

	- 60 % of the expected mortality from lung cancer is in the antimony + maintenance groups before 1961 - no other observations are reported Over the year's antimony metal, antimony alloys and diantimony trioxide were produced in the plant. Until the early 1970s considerable quantities of lead alloys were made, containing as much as 80 % lead and 10 % arsenic. All production of antimony metal and its alloys stopped in 1973 and after that only diantimony trioxide was manufactured. Since the 1960s the bulk of ore used was a sulphide ore containing about 60 % of antimony and up to 0.5 % of arsenic. Arsenic metal and its trioxide were also brought into the plant to make arsenic alloys.		

5.8.3. Summary and discussion of carcinogenicity

Discussion

Three chronic inhalation studies in rats are available for carcinogenicity assessment of diantimony trioxide (Watt, 1983; Groth et al., 1986a, Newton et al., 1994). Two animal studies indicate neoplastic properties of diantimony trioxide, whereas one animal study showed negative results. There is also one human study available (Jones, 1994). However, due to lack of exposure data the human study is regarded inconclusive. The exposure duration in all three animal studies is 12 months and thus all studies deviates from the OECD guideline on chronic toxicity/carcinogenicity, which prescribes an exposure period of 24 months for rats. In the first animal study (Watt, 1983) inhalation of 5.0 mg Sb2O3/m3 for 12 months produced lung neoplasms in 44% of the animals tested (only females were exposed). In the second study, (Groth et al.,1986a) a 9 times higher dose (45 mg Sb2O3/m3) produced pulmonary neoplasms in 32% of the female rats exposed under similar conditions, but none in male rats. It is noted that the female survival rate was significantly higher than the male counterparts in the study by Groth et al., (1986a). The differences in incidence between the studies might be explained by a longer observation period (12 months vs 20 weeks) and by the use of older animals (8 months vs 14 weeks) in the study by Watt (1983). The study by Newton et al., (1994) showed no diantimony trioxide-related lung tumours, neither in males nor females, at any dose level up to 4.5 mg/m3. This is in contrast with the data reported by Watt and Groth and the cause to the difference is not entirely clear. However, the histopathology slides from the negative study were re-evaluated by the pathologist who evaluated the slides from the Groth and of the Watt studies. The re-examination confirmed a lack of antimony trioxide-related neoplastic changes in the study. In addition, the comparison of the Watt and the Newton studies, which were conducted at similar exposure levels, showed that the exposed rats had more lung damage and appeared to have considerably more antimony deposited in the lungs in the Watt study than in the Newton *et al.* study. This may suggest that the exposure levels in the Watt study may have been above those reported. Given that the dose level in the study by Groth is 10 times higher and also the dose levels in the study by Watt were likely higher than 1.9 and 5.0 mg/m3 the dose levels in the study most probably fit in the dose range where no tumours were observed. However, the difference could also be due to different particle generation techniques or different strains of rats. The particle size, which will affect lung deposition, clearance and retention and hence target organ dose, was similar among the studies although they were all measured using different techniques. In the study by Newton and co-workers it was shown that diantimony trioxide reduced the pulmonary clearance rate in a dose dependent manner, interpreted by the authors as a toxic effect of diantimony trioxide rather than a general effect due to pulmonary overload. However, it is well known that reduced lung clearance rate at chronic exposure of rats to poorly soluble particles (PSPs) can result in pulmonary overload, subsequently followed by an inflammatory response, epithelial cell hypertrophy and/or hyperplasia and squamous metaplasia. The persistence of these tissue responses over chronic time periods can lead to secondary development of lung tumours (Hext, 1994). Thus, it could be speculated that the neoplastic effects seen in the Watt and Groth studies is a result of pulmonary overload and an inflammatory response to particulate diantimony trioxide. The tumour development as a consequence of pulmonary overload is an inflammatory-driven process which usually takes over a year (15-18 months) of PSP exposure via inhalation (Driscollet al., 1997). In the present studies on antimony trioxide, development of lung tumours occurred earlier – already at 12 months of antimony inhalation.

Due to the deviations from the OECD guidelines and the critical shortcoming in all three studies, US NTP (National Toxicology Program) has embarked on a testing programme leading to a new, full 2-year bioassay. A 14d range-finder on rats and mice was already conducted at the end of 2007 and preliminary reporting was already conducted and will be further evaluated for inclusion into the REACH dataset for ATO. The chronic toxicity studies in both rats and mice have already started; finalisation expected end 2010 and reporting 2013-2015.

The overall expert judgement by TC NES is that the most likely mechanism for carcinogenicity appears to be impaired lung clearance and particle overload followed by an inflammatory response, fibrosis and tumours. Consequently, diantimony trioxide can be regarded as a threshold carcinogen and as a starting point for a quantitative risk characterisation the NOAEC of 0.51mg/m^3 derived for local repeated dose toxicity is also used for carcinogenicity. However, in this context, it is questionable whether effects caused by pulmonary overload in the rat are also relevant for humans. Positive (Hext, 1994), (Oberdorster, 1995) and negative (Tran and Buchanan, 2000; Kuempel et al., 2001) findings of particle overload in human lungs are reported. Macrophage transport of particles into the alveolar interstitium is the major clearance mechanism in humans but of minor importance to the rat. These species differences are related to morphological features of the lung, i. e. to the relative short pathway length from the alveoli to the ciliated terminal bronchioles in rats (Bailey et al., 1989; Kreyling, 1990; Kreyling et al., 1991). In the absence of mechanistic data to the contrary, it must be assumed that the rat model of tumorigenicity can identify potential carcinogenic hazards to humans and the rat presently remains the appropriate model for both neoplastic and non-neoplastic responses to PSP exposure (ILSI Risk Science Institute Workshop Participants., 2000).

Value used for CSA (route: oral):

No study available

Value used for CSA (route: dermal):

No study available

Value used for CSA (route: inhalation):

Adverse effect observed NOAEC: 0.51 mg/m^3 (chronic; rat)

Target organs: respiratory: lung

Justification for classification or non-classification

Diantimony trioxide is already classified as inhalation carcinogen category 2 (according to regulation (EC) 1272/2008).

5.9. Toxicity for reproduction

5.9.1. Effects on fertility

5.9.1.1. Non-human information

The results of experimental studies are summarised in the following table:

Table 62. Overview of experimental studies on fertility

Method	Results	Remarks	Reference
rat (Wistar) male fertility oral: gavage 27.4 mg APT/kg bw = 10 mg antimony/kg bw (nominal conc.) 12.0 mg ATO/kg bw = 10 mg antimony/kg bw (nominal conc.) 1200 mg ATO/kg bw = 1000 mg antimony/kg bw (nominal conc.) Exposure: 4 weeks of administration (- administration by gavage: 3 days per week - daily doses of the compounds were 27.4 (APT) , 12.0 (ATO) and 1200 (ATO) mg/kg bw (corresponding daily doses of antimony were 10, 10 and 1000 mg/kg bw)) Guidelines for Animals Experiments in the Faculty of Medicine, Kyushu University Law No. 105 of the Government of Japan Notification No. 6 of the Government of Japan	NOAEL (for testicular toxicity) : > 1200 mg/kg bw/day (male)	2 (reliable with restrictions) supporting study experimental result Test material (EC name): diantimony trioxide	Omura M, Tanaka A, Hirata M and Inoue N (2002)
rat female fertility inhalation: dust 250 mg /m3 (nominal conc. (for chronic poisoning)) Exposure: - 1.5 - 2 months before mating - continuing through mating and gestation until 3-5 days prior to delivery (daily for 4 h/day)	The reported effects on pregnancy rate and average litter size in this study would at first glance indicate that antimony trioxide may have an adverse effect on fertility on rats. However, the study suffers from several severe shortcomings: - test item identity and purity - analytical controls Finally, the reported exposure level is approx.. 50-fold above the level known in sub-chronic inhalation studies to be associated with inert particle lung overload. Given the particular sensitivity of rats for this phenomenon, it is therefore plausible to assume that at this excessive exposure level, the animals were adversely affected in their lung function, so that the effects on other organs functions are likely to be secondary to this massive impairment.	3 (not reliable) supporting study experimental result Test material (commercial antimony compounds): antimony trioxide	Belyaeva AP (1967a)
rat (Wistar) male/female oral: feed 84 (males) / 97 (females) mg/kg	NOAEL: 1879 mg/kg bw/day (nominal) (female) based on: test mat. (Based on the	1 (reliable without restriction) supporting study	Hext PM, Pinto PJ and Rimmel BA (1999)

bw*day (nominal in diet (calculated mean daily dose of Sb2O3)) 412 (males) / 494 (females) mg/kg bw*day (nominal in diet (calculated mean daily dose of Sb2O3)) 1686 (males) / 1879 (females) mg/kg bw*day (nominal in diet (calculated mean daily dose of Sb2O3)) Exposure: 90 days (continuously) - use of a protocol that conforms to modern guidelines	complete absence of effects on organs of reproduction in female animals.) NOAEL: 1686 mg/kg bw/day (nominal) (male) based on: test mat. (Based on the complete absence of effects on organs of reproduction in male animals	experimental result Test material (EC name): diantimony trioxide	
rat female fertility intraperitoneal 50 mg of substance/kg bw (nominal conc. (suspended in 1 ml of sterile oil)) Vehicle: oil	The reported effects on pregnancy rate and average litter size in this study would at first glance indicate that antimony trioxide may have an adverse effect on fertility on rats. However, the study suffers from several severe shortcomings: - identitiy and purity of the substance is not stated - exposure levels not analytically verified - not reported how pregnancy was determined - no data presented on incidence of resorptions or foetal deaths - no statistical calculations presented - no control data for morphological changes Finally, the reported exposure level is approx.. 50-fold above the level known in sub-chronic inhalation studies to be associated with inert particle lung overload. Given the particular sensitivity of rats for this phenomenon, it is therefore plausible to assume that at this excessive exposure level, the animals were adversely affected in their lung function, so that the effects on other organs functions are likely to be secondary to this massive impairment.)	3 (not reliable) supporting study experimental result Test material (commercial antimony compounds): metallic antimony	Belyaeva AP (1967b)
mouse (CD-1) male fertility oral: gavage 27.4 mg APT/kg bw = 10 mg antimony/kg bw (nominal conc.) 12.0 mg ATO/kg bw = 10 mg antimony/kg bw (nominal conc.) 1200 mg ATO/kg bw = 1000 mg	NOAEL (for testicular toxicity) : > 1200 mg/kg bw/day (male)	2 (reliable with restrictions) supporting study experimental result Test material (EC name): diantimony trioxide	Omura M, Tanaka A, Hirata M and Inoue N (2002)

antimony/kg bw (nominal conc.) Exposure: 4 weeks of administration (- administration by gavage: 5 days per week - daily doses of the compounds were 27.4 (APT) , 12.0 (ATO) and 1200 (ATO) mg/kg bw (corresponding daily doses of antimony were 10, 10 and 1000 mg/kg bw)) Guidelines for Animals Experiments in the Faculty of Medicine, Kyushu University Law No. 105 of the Government of Japan Notification No. 6 of the Government of Japan			
mouse (Swiss) male fertility oral: gavage 400 mg/kg bw/day (nominal in water) 667 mg/kg bw/day (nominal in water) 1000 mg/kg bw/day (nominal in water) Vehicle: water Exposure: 21 days (daily) sperm quality was monitored after 21 days of daily oral exposure with diantimony trioxide in an in vivo chromosome aberration test in germ cells	Within an in vivo chromosome aberration test, sperm abnormalities were monitored and compared with the control. The frequency of abnormal sperms did not differ significantly between treated and control mice at the P=0.05 level, indicating that diantimony trioxide did not exert a marked effect on testes even after prolonged treatment.)	3 (not reliable) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material: >>>??? Read-across is indicated in field "Study result type" although test material ID is same as in section 1.1<<<** Form: suspension	Gurnani, N.; et al. (1993) Gurnani, N.; et al. (1992)

Data waiving

Information requirement: Toxicity for reproduction / fertility

Reason: study scientifically unjustified

Justification: In accordance with regulation (EC) 1907/2006, Annex IX in conjunction with Annex X, Section 8.7, Column 2, in conjunction with the Guidance on information requirements and Chemical Safety Assessment Chapter R.7a (Version 2.3, December 2013): Endpoint specific guidance, Section R.7.6 studies for reproductive toxicity do not need to be conducted if

1. the substance is of low toxicological activity (no evidence of toxicity seen in any of the tests available)

2. it can be proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure (e. g. plasma/blood concentrations below detection limit using a sensitive method and absence of the substance and of metabolites of the substance in urine, bile or exhaled air) and

3. there is no or no significant human exposure.

Based on the weight of evidence from the available short- and long-term toxicity/fertility studies in rodents and the relevant information on the toxicokinetic behaviour in rats it is concluded that diantimony trioxide does not present a reproductive toxicity hazard, as follows:

(re. 1)

- available oral 90-day studies in rats showed no signs of systemic toxicity whatsoever up to the highest dose tested (i. e, 1686 and 1879 mg/kg bw/d for male and female animals respectively), including a complete absence of effects (neither on macroscopic or histopathological observations, nor on organ weights) on organs of reproduction in male and female animals (Hext, 1999);

- in an oral (gavage) 28-day repeated dose toxicity study in male rats and mice with diantimony trioxide (ATO) and antimony potassium tartrate (APT), the effects on testes, epididymides, ventral prostate and seminal vesicle and sperm quality were investigated. No apparent effects of the antimony compounds on sperm parameters, histopathological parameters or weights of reproduction organs or accessory sex organs were observed after treatment with 12, 1200 mg ATO/kg bw/day and 27.4 mg APT/kg /day (Omura, 2002);

- Gurnani et al. (1992, 1993) assessed morphological alterations in the sperm of male Swiss albino mice orally treated for 21 days with doses of 0, 400, 667, 1000 mg/kg bw/day with diantimony trioxide. There were no indications of increased abnormal sperm between treated and control mice. In view of the limited reliability of the concurrent genotoxicity investigations, these findings may be considered primarily as supporting information.

- chronic inhalation studies in rats with diantimony trioxide (Newton et al. 1994) did not show any exposure related systemic effects at concentrations which however were associated with local effects in the respiratory tract, up to conditions at which lung overload was observed in the test animals. This shows that even at high inhalation exposure concentrations, local effects are the sole effect of toxicological concern, whereas organs of reproduction in male and female animals were not adversely affected;

- further, there were no signs of acute toxicity via oral, dermal or inhalation route in any of the studies reported in this dossier;

- diantimony trioxide is neither a dermal nor a respiratory sensitiser;

- diantimony trioxide is void of any genotoxic potential whatsoever as verified both in in vitro and in vivo tests;

- in a rat inhalation developmental toxicity study with diantimony trioxide, the no-observed-effect-concentration (NOEC) for development toxicity was at the highest exposure level evaluated at 6.3 mg/m^3, due to an absence of any developmental effects whatsoever.

(re.2)

- detailed toxicokinetic investigations specifically with antimony trioxide and, where appropriate, estimations based thereon have documented the poor bioavailability of diantimony trioxide via oral (0.05-0.3%), dermal (0.01-0.1%) and inhalation (<<1%) routes at doses expected to be used for any reproduction toxicity study (i. e., 100-1,000 mg/kg bw/d); corresponding tissue distribution data clearly indicate that organs of reproduction do not represent likely target organs for antimony (de Bie et al., 2005); the documented poor bioavailability in-vivo is corroborated by the very poor water solubility and the very low bioaccessibility in simulated biological media

(re.3)

- diantimony trioxide is used either in industrial settings with good industrial hygiene practices in place and with process conditions that effectively minimise worker exposure; human exposure via the environment as assessed by environmental monitoring data (EU RAR, 2008) has been shown to be negligible; likewise, the potential for release of antimony from consumer articles has been assessed in detail (EU RAR, 2008) and similarly been shown to be negligible.

- exposure scenarios were generated for all relevant industrial, professional and consumer uses as well as for service life of diantimony trioxide containing articles. All uses report a risk characterisation ratio of ≤ 0.75, thus demonstrate safe use for all routes of exposure.

- in accordance with regulation (EC) 1907/2006, Annex I, Section 1.1.4 the study giving rise to the highest concern shall be used to establish the DNEL. Local effects in the chronic inhalation studies with rats were observed at lower exposure concentrations than those in the prenatal developmental toxicity study which were similarly not associated with any systemic effects whatsoever, thus the NOAEC obtained in the chronic inhalation study was used as point of departure for risk assessment purposes. This supports the conclusion that maintaining conditions of controlled risk for local effects via inhalation will ensure that the probability of adverse systemic effects is negligible.

In conclusion, the conduct of experimental studies on reproductive toxicity is not considered to be required.

Toxicity to reproduction: other studies

No relevant information available

5.9.1.2. Human information

There are no reliable reports whatsoever on the impairment of human fertility in the public domain.

5.9.2. Developmental toxicity

5.9.2.1. Non-human information

The results of experimental studies are summarised in the following table:

Table 63. Overview of experimental studies on developmental toxicity

Method	Results	Remarks	Reference
rat (Sprague-Dawley) dust aerosol atmosphere (nose only) 2.6 mg/m³ 4.4 mg/m³ 6.3 mg/m³ Exposure: Animals were treated from fertilization (day 0 of gestation) to day 19. (6 hours per day) OECD Guideline 414 (Prenatal Developmental Toxicity Study)	LOAEC (maternal toxicity): 2.6 mg/m³ air (analytical) based on: test mat. (This LOAEC was based on an increase in lung weights both absolute and relative to brain weights at all exposure levels evaluated (2.6, 4.4, and 6.3 mg/m³).) NOEC (developmental toxicity): 6.3 mg/m³ air (analytical) based on: test mat.	2 (reliable with restrictions) key study experimental result Test material (EC name): diantimony trioxide Form: powder	Schroeder R.E. (2003b)
rat (Sprague-Dawley) inhalation: dust (nose only) 0.39 ± 0.455 mg/m³ (analytical conc.) 0.73 ± 1.017 mg/m³ (analytical conc.) 1.48 ± 1.986 mg/m³ (analytical conc.) 6.07 ± 6.479 mg/m³ (analytical conc.)	NOEC (maternal toxicity): 6.07 mg/L air (analytical) based on: test mat. NOEC (developmental toxicity): > 6.07 mg/L air (analytical) based on: test mat.	dose range finding experiment for a pre-natal developmental toxicity study supporting study read-across from supporting substance (structural analogue or surrogate) **Test material:** antimony trioxide	Schroeder, R.E. (2003)

Vehicle: clean air Exposure: Day 0 to day 19 of gestation (approximately six hours/day) OECD Guideline 414 (Prenatal Developmental Toxicity Study) (adopted 2001-01-22)		Form: powder	
female albino rats inhalation: aerosol 0.27 ± 0.42 mg/m3 0.082 ± 0.0047 mg/m3 0.027 ± 0.0038 mg/m3 Exposure: 21-day around-the-clock exposure (around-the-clock aerosol exposure) no guideline specified	The study suffers from several severe shortcomings: - it is not reported how the antimony oxide aerosol was generated - no details on analytical method for verification of exposure levels, purity and particle size of the test compound was not stated - few or no statistical calculations are available, since the evaluation is based on a translation from the russian original it is not clear whether the studied substance is antimony trioxide or antimony pentoxide - no information on how the animals were actually exposed (ventilation rate, etc); study considered inconclusive and not useful for risk assessment purposes	3 (not reliable) disregarded study supporting study experimental result Test material (EC name): diantimony trioxide	Grin N.V., Govorunova N.N., Bessemrnyy A.N. and Pavlovich L.V. (1987)

Data waiving

Information requirement: Developmental toxicity / teratogenicity

Reason: study scientifically unjustified

Justification: In accordance with regulation (EC) 1907/2006, Annex IX in conjunction with Annex X, Section 8.7, Column 2, in conjunction with the Guidance on information requirements and Chemical Safety Assessment Chapter R.7a (Version 2.3, December 2013): Endpoint specific guidance, Section R.7.6 studies for reproductive toxicity do not need to be conducted if

1. the substance is of low toxicological activity (no evidence of toxicity seen in any of the tests available)

2. it can be proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure (e. g. plasma/blood concentrations below detection limit using a sensitive method and absence of the substance and of metabolites of the substance in urine, bile or exhaled air) and

3. there is no or no significant human exposure.

Based on the weight of evidence from the available short- and long-term toxicity/fertility studies in rodents and the relevant information on the toxicokinetic behaviour in rats it is concluded that diantimony trioxide does not present a reproductive toxicity hazard, as follows:

(re. 1)

- available oral 90-day studies in rats showed no signs of systemic toxicity whatsoever up to the highest dose tested (i. e, 1686 and 1879 mg/kg bw/d for male and female animals respectively), including a complete absence of effects (neither on macroscopic or histopathological observations, nor on organ weights) on organs of reproduction in male and female animals (Hext, 1999);

- in an oral (gavage) 28-day repeated dose toxicity study in male rats and mice with diantimony trioxide (ATO) and antimony potassium tartrate (APT), the effects on testes, epididymides, ventral prostate and seminal vesicle and sperm quality were investigated. No apparent effects of the antimony compounds on sperm parameters, histopathological parameters or weights of reproduction organs or accessory sex organs were observed after treatment with 12, 1200 mg ATO/kg bw/day and 27.4 mg APT/kg /day (Omura, 2002);

- Gurnani et al. (1992, 1993) assessed morphological alterations in the sperm of male Swiss albino mice orally treated for 21 days with doses of 0, 400, 667, 1000 mg/kg bw/day with diantimony trioxide. There were no indications of increased abnormal sperm between treated and control mice. In view of the limited reliability of the concurrent genotoxicity investigations, these findings may be considered primarily as supporting information.

- chronic inhalation studies in rats with diantimony trioxide (Newton et al. 1994) did not show any exposure related systemic effects at concentrations which however were associated with local effects in the respiratory tract, up to conditions at which lung overload was observed in the test animals. This shows that even at high inhalation exposure concentrations, local effects are the sole effect of toxicological concern, whereas organs of reproduction in male and female animals were not adversely affected;

- further, there were no signs of acute toxicity via oral, dermal or inhalation route in any of the studies reported in this dossier;

- diantimony trioxide is neither a dermal nor a respiratory sensitiser;

- diantimony trioxide is void of any genotoxic potential whatsoever as verified both in in vitro and in vivo tests;

- in a rat inhalation developmental toxicity study with diantimony trioxide, the no-observed-effect-concentration (NOEC) for development toxicity was at the highest exposure level evaluated at 6.3 mg/m³, due to an absence of any developmental effects whatsoever.

(re.2)

- detailed toxicokinetic investigations specifically with antimony trioxide and, where appropriate, estimations based thereon have documented the poor bioavailability of diantimony trioxide via oral (0.05-0.3%), dermal (0.01-0.1%) and inhalation (<<1%) routes at doses expected to be used for any reproduction toxicity study (i. e., 100-1,000 mg/kg bw/d); corresponding tissue distribution data clearly indicate that organs of reproduction do not represent likely target organs for antimony (de Bie et al., 2005); the documented poor bioavailability in-vivo is corroborated by the very poor water solubility and the very low bioaccessibility in simulated biological media

(re.3)

- diantimony trioxide is used either in industrial settings with good industrial hygiene practices in place and with process conditions that effectively minimise worker exposure; human exposure via the environment as assessed by environmental monitoring data (EU RAR, 2008) has been shown to be negligible; likewise, the potential for release of antimony from consumer articles has been assessed in detail (EU RAR, 2008) and similarly been shown to be negligible.

- exposure scenarios were generated for all relevant industrial, professional and consumer uses as well as for service life of diantimony trioxide containing articles. All uses report a risk characterisation ratio of ≤ 0.75, thus demonstrate safe use for all routes of exposure.

- in accordance with regulation (EC) 1907/2006, Annex I, Section 1.1.4 the study giving rise to the highest concern shall be used to establish the DNEL. Local effects in the chronic inhalation studies with rats were observed at lower exposure concentrations than those in the prenatal developmental toxicity study which were similarly not associated with any systemic effects whatsoever, thus the NOAEC obtained in the chronic inhalation study was used as point of departure for risk assessment purposes. This supports the conclusion that maintaining conditions of controlled risk for local effects via inhalation will ensure that the probability of adverse systemic effects is negligible.

In conclusion, the conduct of experimental studies on reproductive toxicity is not considered to be required.

5.9.2.2. Human information

There are no reliable reports whatsoever on the developmental toxicity of diantimony trioxide in humans in the public domain.

5.9.3. Summary and discussion of reproductive toxicity

Effects on fertility

For fertility there are three non-standard fertility studies in animals, one on female rats (Belyaeva, 1967) and one on male rats and mice (Omura et al., 2002), and one human occupational report study (Belyaeva, 1967). At a first glance, the inhalation study in female rats by Belyaeva (1967) appears to suggest that diantimony trioxide might have an adverse effect on fertility after repeated exposure to 250 mg/ m³. However, the results must be regarded as inconclusive and cannot be used for risk assessment, since the study report does not provide a valid description of the overall experimental conditions and the purity of the test substance. Furthermore, since it is well-established that rats are particularly sensitive to inert particle overload (in contrast to humans) which occurs in sub-chronic studies at levels approx. 50-fold below the level in Belyaeva (1967), it can reasonably be assumed that the rats in this study suffered from a massive, non-substance-specific impairment of their respirator system by overload of lung macrophages and breakdown of their lung clearance, so that any adverse effects can easily be explained as of secondary nature.

The gavage study on male rats and mice (Omura, 2002) showed no testicular toxicity after 4 weeks repeated exposure up to 1200 mg/ kg bw. The human case report study on women occupationally exposed to diantimony trioxide indicates that diantimony trioxide might affect the fertility of female workers. However, this study is inconclusive due to the lack of information on the control group, the exposure situation and the overall workplace environment. Based on these fertility studies in animals and humans, no conclusion on female fertility can be derived. However, a 90-day oral feeding study in male and female rats, of diantimony trioxide reported no effects on reproductive organs up to a dose of 1686 mg/kg in males and 1879 mg/kg in females.

Value used for CSA (route: oral):

No adverse effect observed

Value used for CSA (route: dermal):

No study available

Value used for CSA (route: inhalation):

No study available

Developmental toxicity

For developmental toxicity there is one acceptable animal study available (Schroeder, 2003), albeit with dose intervals which were not strictly according to guidelines. Whereas the high dose did not give rise to any relevant systemic maternal toxicity, there were in fact signs of local inflammatory effects in the lung at mid and high dose groups, which is in line with other studies on diantimony trioxide showing an absence of systemic effects even at very high oral doses contrasting with adverse local lung effects via inhalation. With respect to developmental toxicity, this rat inhalation study with exposure 6 h/day throughout gestation showed no statistically significant effect whatsoever at 2.6, 4.4 or 6.3 mg diantimony trioxide /m³. Although a slight increase of resorptions and postimplantation loss was observed in the highest dose group, these values did not differ statistically from controls ($p = 0.11$) and were within the range of recent historical control data (4-8 %, mean 6 %). This study therefore allows derivation of an NOEC for developmental toxicity of > 6.3 mg diantimony trioxide/m³. Based on these studies there is no concern for reproductive toxicity and thus no quantitative risk characterisation will be made for the fertility or developmental toxicity.

<u>The following information is taken into account for any hazard / risk assessment:</u>

A prenatal developmental toxicity study in rat via inhalation, with exposure 6h/day throughout gestation, showed no statistically significant developmental toxicity at 2.6, 4.4 or 6.3 mg antimony trioxide /m³, suggesting that the NOEC for developmental toxicity is >6.3 mg antimony trioxide/ m³.

Value used for CSA (route: oral)

No study available

Value used for CSA (route: dermal):

No study available

Value used for CSA (route: inhalation):

No adverse effect observed NOAEC: 6.3 mg/m³ (subacute; rat)

Justification for classification or non classification

Justification for classification or non-classification (effects on fertility)

Based on the weight of evidence from the available long-term toxicity studies in rodents and the relevant information on the toxicokinetic behaviour in rats, it is concluded that diantimony trioxide does not present a reproductive toxicity hazard. There were no associated adverse effects on reproductive organs of rats and mice from chronic toxicity studies whereby exposures were either oral to high levels or inhalation to high concentrations of diantimony trioxide.

For the reasons presented above, conducting a developmental toxicity study or a two-generation reproduction toxicity study would therefore not provide any further insights in the toxicity of diantimony trioxide. Because of the lack of absorption and systemic distribution, any quantitatively relevant exposure of reproductive organs in male and female mammalian species to diantimony trioxide is unlikely, so that any specific effects on reproduction are not to be expected. Therefore, it is scientifically not justified to conduct either a developmental toxicity study or a two-generation reproduction study in rats which complies with the 3R-rules and the principles of animal welfare.

For the reasons presented above, no classification for reproductive toxicity is required.

Justification for classification or non-classification (developmental toxicity)

The reference Schroeder R. E. (2003) was identified as key study for this endpoint and will be used for classification and labelling. This rat inhalation study, with exposure 6h/day throughout gestation, showed no statistically significant developmental toxicity at 2.6, 4.4 or 6.3 mg antimony trioxide/m³. This study suggests that the NOAEC for developmental toxicity is > 6.3 mg antimony trioxide/m³.

Thus, no classification as developmental toxicant according to regulation (EC) 1272/2008 is required.

5.10. Other effects

5.10.1. Non-human information

5.10.1.1. Neurotoxicity

There are no reliable reports whatsoever on neurotoxic effects in animals in the public domain.

5.10.1.2. Immunotoxicity

There are no reliable reports whatsoever on immunotoxic effects in animals in the public domain.

5.10.1.3. Specific investigations: other studies

There are no reliable reports whatsoever on other effects in animals in the public domain.

5.10.2. Human information

Table 64. Overview of exposure-related observations: endpoint not specified

Method	Results	Remarks	Reference
Study type: medical monitoring Details on study design: - 1 inch squares of test material were applied to arms or legs of ten women - fixed with adhesive tape - first exposure time: 6 days -14 days after end of exposure new patches were applied - second exposure time: 48 h - examination of skin: at 2 and 6 days and on final day at patch removal Endpoint addressed: not specified	- no skin reactions were seen at any of the examinations	3 (not reliable) supporting study Test material (solid fibre): Dacron fibre treated with a mixture of antimony oxide (Sb_2O_3) and perbromophenyl ether	Edwards, D. F. (1970)
Study type: cohort study (prospective) Type of population: occupational Details on study design: METHOD OF DATA COLLECTION - Type: clinical examination STUDY PERIOD: - examination during 1962 - 1964 (2 years period) SETTING: - Gynaecological examinations on women occupationally exposed to dust containing metallic antimony, antimony trioxide and antimony pentasulfide - antimony measured in blood, urine, mother's milk, placenta, amniotic fluid and umbilical cord blood STUDY POPULATION - Total population (Total no. of persons in cohort from which the subjects were drawn): - Selection criteria: female workers engaged in an antimony plant - Total number of subjects participating in study: 161 women with high exposure 157 women with lower exposure 115 control women - no other details on study design are reported Endpoint addressed: not specified	FINDINGS - disturbances of the menstrual cycle in 61.2 % of the exposed women compared with 35.7 % of the controls - infections in the sex organs in 30.4 % of the exposed women compared with 55.3 % of the controls - other ailments of the sexual organs in 8.4 % of the exposed workers - mean values (mg %) of antimony = 5.3±0.6 (blood) and 2.9±0.5 (urine), in high exposure group = 4.0 ±0.5 (blood) and 2.1±0.4 (urine) in low exposure group = 0.33±0.06 (blood) in the control group - in the workers antimony was also detected in breast milk (3.3±2.2 mg/l), placenta (3.2-12.6 mg %), amniotic fluid (6.2 ± 2.8 mg %) and umbilical cord blood INCIDENCE / CASES - incidence of late spontaneous abortions was 12.5 % in the exposed women as compared with 4.1 % in the controls - incidence of premature births was 3.4 % in the exposed	3 (not reliable) supporting study Test material (dust): containing metallic antimony, antimony trioxide and antimony pentasulfide	Belyaeva AP (1967c)

	compared with 1.2 % in the controls - birth weights of children born to the exposed women were comparable to those of children born to the controls, but the body weight of the children of exposed women began to lag already after 3 months and continued to do so also after six and 12 months - Other: - no other findings are reported		

5.11. Derivation of DNEL(s)

5.11.1. Overview of typical dose descriptors for all endpoints

Table 65. Available dose-descriptor(s) per endpoint for the submission substance as a result of its hazard assessment

Endpoint		Dose descriptor	Qualitative assessment	Remarks on study
Acute toxicity	oral	LD50: >20000mg/kg bw/day		LD50 (oral): >20000mg/kg bw/day LD50 (dermal): >8300mg/kg bw LC50 (inhalation): >5200mg/m³
Acute toxicity	dermal	LD50: >8300mg/kg bw		
Acute toxicity	inhalation	LC50: >5200mg/m³		
Irritation / Corrosivity	skin		not irritating	Antimony elicits skin irritation potential only under conditions of high chemical dermal exposure and severe sweating. Antimony is not eye irritating.
Irritation / Corrosivity	eye		not irritating	
Irritation / Corrosivity	respiratory tract		not irritating	
Sensitisation	skin		not sensitising	Antimony is not a skin sensitiser.
Repeated dose toxicity: sub-acute / sub-chronic / chronic	oral	NOAEL: 1686 mg/kg bw/day (subchronic; rat)		repeated dose toxicity via oral application: NOAEL=1686mg/kg bw/day
Repeated dose toxicity: sub-acute / sub-chronic / chronic	dermal			
Repeated dose toxicity: sub-acute / sub-chronic / chronic	inhalation	NOAEC: 0.51 mg/m³ (subchronic; rat) Target organs: respiratory: lung		Only relevant for exposure to antimony in powder form.
Mutagenicity	in vitro / in vivo		Genetic toxicity: negative	see section 5.7.1 / 5.7.2

Carcinogenicity	inhalation	NOAEC: 0.51 mg/m³ Target organs for carcinogenicity: respiratory: lung		Only relevant for exposure to antimony in powder form.
Reproductive toxicity: developmental toxicity	oral			A prenatal developmental toxicity study in rat via inhalation, with exposure 6h/day throughout gestation, showed no statistically significant developmental toxicity at 2.6, 4.4 or 6.3 mg antimony trioxide/m³, suggesting that the NOAEC for developmental toxicity is >6.3 mg antimony trioxide/m³.
Reproductive toxicity: developmental toxicity	dermal			
Reproductive toxicity: developmental toxicity	inhalation	NOAEC: 6.3 mg/m³		

5.11.2. Selection of the critical DNEL(s)

Table 66. DNELs for workers

Exposure pattern	**Route**	**Descriptor**	**DNEL / DMEL**	**(Corrected) Dose descriptor *)**	**Most sensitive endpoint**	**Justification**
Acute - systemic effects	Dermal					Not derived, due to lack of acute systemic toxicity.
Acute - systemic effects	Inhalation					Not derived, due to lack of acute local toxicity.
Acute - local effects	Dermal					Qualitative approach; irritation potential only relevant under conditions of high chemical dermal exposure and severe sweating.
Acute - local effects	Inhalation					Not derived, due to lack of acute local toxicity.

Long-term - systemic effects	Dermal	DNEL (Derived No Effect Level)	281 mg/kg bw/day	NOAEL: 1,686 mg/kg bw/day (based on AF of 6)	repeated dose toxicity	Derived, because route of exposure relevant for workers. The DNEL derivation for antimony trioxide is based on state-of-the-art approaches and using substance-specific information.
Long-term - systemic effects	Inhalation					Not derived, due to lack of systemic toxicity after repeated inhalation exposure in a 12 month toxicity study in rats.
Long-term - local effects	Dermal					Qualitative approach; irritation potential only relevant under conditions of high chemical dermal exposure and severe sweating.
Long-term - local effects	Inhalation	DNEL (Derived No Effect Level)	0.5 mg/m³	NOAEC: 1.5 mg/m³ (based on AF of 3)	repeated dose toxicity	Derived because route of exposure relevant and local effects observed in inhalation toxicity and carcinogenicity studies. The DNEL derivation for antimony trioxide is based on a combination of (i) state-of-the–art recalculation of the point of departure from a rat inhalation bioassay, (ii) detailed morphometric and toxicodynamic remodeling to reflect differences between laboratory animals (rats) and humans, and (iii) consideration of real workplace particle-size distribution monitoring data; the subsequent selection of assessment factors for the modification of this point of departure is based on an analysis of the antimony metal-specific mechanism of action for the selected human health endpoint.
*) The (corrected) dose descriptor starting points have been automatically calculated by multiplying the values of the fields "D(N)MEL" and "Assessment factor" provided in the Endpoint summary of IUCLID section 7. Toxicological information. It reflects the value after any corrections, e.g. route-to-route extrapolation. See column "Justification" for the rationale behind such modifications and the use of assessment factors.						

Discussion

Since only local effects in the respiratory tract were seen in animal studies and no systemic effects could be observed, long-term DNELs were derived for local effects only. The same applies for the carcinogenic potential of diantimony trioxide. Because it can be assumed that particle deposition followed by macrophage infiltration, pulmonary inflammation and impaired clearance are pivotal initial steps in the carcinogenic process, diantimony trioxide can be regarded as a threshold carcinogen and thus no DMEL was derived.

Table 67. DNELs for the general population

Exposure pattern	**Route**	**Descriptor**	**DNEL**	**(Corrected) Dose descriptor *)**	**Most sensitive endpoint**	**Justification**
Acute - systemic effects	Dermal					Not derived, due to lack of acute systemic toxicity.
Acute - systemic effects	Inhalation					Not derived, due to lack of acute systemic toxicity.
Acute - systemic effects	Oral					Not derived, due to lack of acute systemic toxicity.
Acute - local effects	Dermal					Not relevant for general population, because irritation potential occurs only under conditions of high chemical dermal exposure and severe sweating.
Acute - local effects	Inhalation					Not derived, due to lack of acute local toxicity.
Long-term - systemic effects	Dermal	DNEL (Derived No Effect Level)	168.6 mg/kg bw/day	NOAEL: 1,686.0 mg/kg bw/day (based on AF of 10)	repeated dose toxicity	Derived, because route of exposure relevant for consumers and humans exposed via environment. The DNEL derivation for antimony metal is based on state-of-the-art approaches and using substance-specific information.
Long-term - systemic effects	Inhalation					Not derived, due to lack of systemic toxicity after repeated inhalation exposure in a 12 month toxicity study in rats.
Long-term - systemic effects	Oral	DNEL (Derived No Effect Level)	168.6 mg/kg bw/day	NOAEL: 1,686.0 mg/kg bw/day (based on AF of 10)	repeated dose toxicity	Derived, because route of exposure relevant for consumers and humans exposed via environment. The DNEL derivation for antimony metal is based on state-of-the-art approaches and using substance-specific information.
Long-term - local effects	Dermal					Not relevant for general population, because irritation potential occurs only under conditions of high chemical dermal exposure and severe sweating.
Long-term - local effects	Inhalation	DNEL (Derived No Effect Level)	0.1 mg/m³	NOAEC: 0.5 mg/m³ (based on AF of 5)	repeated dose toxicity	Derived, because route of exposure relevant for consumers and humans exposed via environment. The DNEL derivation for antimony metal is based on a combination of (i) state-of-the–art recalculation of

						the point of departure from a rat inhalation bioassay, (ii) detailed morphometric and toxicodynamic remodeling to reflect differences between laboratory animals (rats) and humans, and (iii) consideration of real workplace particle-size distribution monitoring data; the subsequent selection of assessment factors for the modification of this point of departure is based on an analysis of the antimony metal-specific mechanism of action for the selected human health endpoint.
*) The (corrected) dose descriptor starting points have been automatically calculated by multiplying the values of the fields "D(N)MEL" and "Assessment factor" provided in the Endpoint summary of IUCLID section 7. Toxicological information. It reflects the value after any corrections, e.g. route-to-route extrapolation. See column "Justification" for the rationale behind such modifications and the use of assessment factors.						

Discussion

Long-term exposure - systemic effects oral DNEL, children = 16.86 mg/kg bw/day (AF=100)

Long-term exposure - systemic effects dermal DNEL, children = 16.86 mg/kg bw/day (AF=100)

Long-term exposure - local effects inhalation DNEL, consumer = 0.1 mg/m^3 (AF=5)

Since only local effects in the respiratory tract were seen in animal studies and no systemic effects could be observed, long-term DNELs were derived for local effects only. The same applies for the carcinogenic potential of diantimony trioxide. Because it can be assumed that particle deposition followed by macrophage infiltration, pulmonary inflammation and impaired clearance are pivotal initial steps in the carcinogenic process, diantimony trioxide can be regarded as a threshold carcinogen and thus no DMEL was derived.

6. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

6.1. Explosivity

Data waiving: see CSR section 1.3 Physico-chemical properties.

Classification according to GHS and DSD / DPD

Name: diantimony trioxide
Related composition: Diantimony trioxide (Representative sample)
State/form of the substance: powder
Reason for no classification: conclusive but not sufficient for classification

Name: diantimony trioxide
Related composition: Diantimony trioxide - Composition medium PbO
State/form of the substance: powder
Reason for no classification: conclusive but not sufficient for classification

Name: diantimony trioxide
Related composition: Diantimony trioxide - Composition high PbO
State/form of the substance: powder
Reason for no classification: conclusive but not sufficient for classification

6.2. Flammability

Data waiving: see CSR section 1.3 Physico-chemical properties.

Classification according to GHS and DSD / DPD

Name: diantimony trioxide
Related composition: Diantimony trioxide (Representative sample)
State/form of the substance: powder
Reason for no classification (Flammable gases): conclusive but not sufficient for classification
Reason for no classification (Flammable aerosols): conclusive but not sufficient for classification

Reason for no classification (Flammable liquids): conclusive but not sufficient for classification
Reason for no classification (Flammable solids): conclusive but not sufficient for classification

Name: diantimony trioxide
Related composition: Diantimony trioxide - Composition medium PbO
State/form of the substance: powder
Reason for no classification (Flammable gases): conclusive but not sufficient for classification
Reason for no classification (Flammable aerosols): conclusive but not sufficient for classification
Reason for no classification (Flammable liquids): conclusive but not sufficient for classification
Reason for no classification (Flammable solids): conclusive but not sufficient for classification

Name: diantimony trioxide
Related composition: Diantimony trioxide - Composition high PbO
State/form of the substance: powder
Reason for no classification (Flammable gases): conclusive but not sufficient for classification
Reason for no classification (Flammable aerosols): conclusive but not sufficient for classification
Reason for no classification (Flammable liquids): conclusive but not sufficient for classification
Reason for no classification (Flammable solids): conclusive but not sufficient for classification

6.3. Oxidising potential

Data waiving: see CSR section 1.3 Physico-chemical properties.

Classification according to GHS and DSD / DPD

Name: diantimony trioxide
Related composition: Diantimony trioxide (Representative sample)
State/form of the substance: powder
Reason for no classification (Oxidising gases): conclusive but not sufficient for classification
Reason for no classification (Oxidising liquids): conclusive but not sufficient for classification
Reason for no classification (Oxidising solids): conclusive but not sufficient for classification

Name: diantimony trioxide
Related composition: Diantimony trioxide - Composition medium PbO
State/form of the substance: powder
Reason for no classification (Oxidising gases): conclusive but not sufficient for classification
Reason for no classification (Oxidising liquids): conclusive but not sufficient for classification
Reason for no classification (Oxidising solids): conclusive but not sufficient for classification

Name: diantimony trioxide
Related composition: Diantimony trioxide - Composition high PbO
State/form of the substance: powder
Reason for no classification (Oxidising gases): conclusive but not sufficient for classification
Reason for no classification (Oxidising liquids): conclusive but not sufficient for classification
Reason for no classification (Oxidising solids): conclusive but not sufficient for classification

7. ENVIRONMENTAL HAZARD ASSESSMENT

7.1. Aquatic compartment (including sediment)

7.1.1. Toxicity test results

It has been reported that the use of high concentrations of $SbCl_3$ dissolved in water have resulted in precipitation of antimony (Brooke et al., 1986). What is most likely being observed is an initial formation of chloroantimonate (III) species, which in aqueous solutions are weak, and which then hydrolyse to oxychloride (SbOCl), which has low solubility in water, and is further hydrolysed to Sb_2O_3 (Filella et al., 2002b; Filella and May, 2003). The percentage of Sb lost from solution by precipitation in the study by Brooke et al. (1986) during a 96-h test ranged from a low 6% for the lowest exposure concentration (nominally 25 mg Sb/L) to 76 % for the highest concentration (nominally 50 mg Sb/L). The apparent trend was to lose a greater percentage of antimony from solution with increasing nominal concentration. The authors improved the methods by introducing mixing and filtering to remove the precipitate from the solution. The maximum concentration maintained in a solution without organisms for 96 h was 35.0 mg Sb/L, using a nominal concentration of 250 mg Sb/L. Nominal bioassay concentrations at 50 mg Sb/L and 100 mg Sb/L using Sb_2O_3 resulted in measured soluble concentrations of 3.4 and 5.0 mg Sb/L, respectively. Solutions of Sb_2O_3 in laboratory water at nominal concentrations of 28, 58, and 110 mg Sb/L had measured dissolved concentrations during the 96 h experiment period of 1.9, 2.6, and 3.3 mg Sb/L, respectively.

Similar observations of the removal of some antimony species from solution over time have been observed in transformation/dissolution tests on antimony compounds in some cases (CanMET, 2010).

Nominal concentrations will therefore be very misleading guides to the actual amount of dissolved antimony. At equal nominal concentrations, readily soluble compounds like $SbCl_3$ result in more dissolved antimony during the exposure periods used in toxicity experiments than less soluble compounds like Sb_2O_3. However, even the readily soluble compound $SbCl_3$ may at high nominal concentrations result in lower amounts of soluble antimony.

Filella and May (2003) conducted a critical review of all available thermodynamic data on antimony and developed a computer speciation model of antimony in multi-component solutions, representative of different environmental conditions. Based on the limited data set and the subsequent speciation calculations it was shown that antimony is exclusively present as the pentavalent $Sb(OH)_6^-$ in oxic freshwater systems and as the trivalent $Sb(OH)_3$ in anoxic conditions, at all pH values of environmental relevance for aquatic systems. The formation of chloride-antimony species does not appear to be of importance under environmentally relevant conditions, as no Sb(III) -chloride was observed under seawater conditions, and the concentration of possible Sb(V)-chloride could not be calculated due to a lack of data. The very few studies available on Sb(V)-chloride binding had been performed under extremely acidic conditions to prevent hydrolysis and could thus not be used, as it was difficult to establish the strength of such interactions under dilute conditions relative to other antimony species. Therefore no thermodynamic relationship of this kind has been published.

Based on the available information on antimony there is nothing that indicates that the difference observed in toxicity in aquatic systems between different inorganic antimony compounds of the same valence, such as for instance $SbCl_3$ and Sb_2O_3, would be due to different antimony species exerting different degrees/kinds of toxicity. Instead, an observed difference in toxicity at equal nominal doses of antimony is most probably a reflection of differences in solubility, which means that a more soluble antimony compound will result in more dissolved antimony capable of exerting toxicity. However, it may be that higher concentrations of Sb compounds also reflect an increased presence of counter ions and/or protons.

Toxicity studies in the aquatic compartment in which only nominal antimony concentrations are reported will therefore not be considered to be reliable in this report. However, studies will not be rejected based solely on which antimony compound was used in the test, or whether or not a tri- or a pentavalent compound was used, as long as the results are considered reliable and relevant. All effect and no-effect concentrations are reported as a concentration of the antimony ion.

The results from six studies, i. e. Brooke et al. (1986), Kimbal (1978), TAI (1990), Heijerick and Vangheluwe (2003), Heijerick and Vangheluwe (2004), and LISEC (2001), all provide valid EC50s and NOECs for fish, invertebrates and algae.

Toxicity results for marine species are scarce. Only the results from Takayanagi (2001) are considered reliable.

None of the NOECs used to derive the PNECs in the aquatic compartment are considered to be confounded by the additions of counter ions (i. e. chloride) and/or protons resulting from the use of $SbCl_3$.

7.1.1.1. Fish

7.1.1.1.1. Short-term toxicity to fish

The results are summarised in the following table:

Table 68: Overview of short-term effects on fish

Method	**Results**	**Remarks**	**Reference**
Pimephales promelas freshwater static Static acute exposure of Pimephales promelas to Sb (III) (as SbCl3). Tests were conducted in 2L beakers containing 2L of solution with 10 fish per test chamber. The exposures were checked every 24 h for death and/or effect.	LC50 (96 h): 14.4 mg/L element (meas. (not specified)) LC50 (48 h): 17.4 mg/L element (meas. (not specified)) LC50 (24 h): 20.8 mg/L element (meas. (not specified))	2 (reliable with restrictions) key study read-across from supporting substance (structural analogue or surrogate) **Test material: Diantimony trichloride**	Brooke LT, Call DJ, Poirier SH, Lindberg CA & Markee TP (1986a)
Salmo gairdneri (new name: Oncorhynchus mykiss) freshwater static Static acute exposure of Salmo gairdneri juveniles to Sb (III) (as SbCl3). Tests were conducted in 30x30x30 cm tanks containing 24L of solution. Rainbow trout, amphipods, caddisflies and annelids were tested together. The exposures were checked every 24 h for death and/or effect.	LC50 (96 h): > 25.7 mg/L element (meas. (not specified))	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material: Diantimony trichloride**	Brooke LT, Call DJ, Poirier SH, Lindberg CA & Markee TP (1986a)
Ictalurus punctatus freshwater static Static acute toxicity test on Ictalurus punctatus using 5 concentrations of SbCl3. 96 h exposure duration.	LC50 (96 h): 24.6 mg/L element (meas. (geom. mean))	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material: Diantimony trichloride**	TAI (1990)
Pimephales promelas freshwater	LC50 (96 h): 21.9 mg/L dissolved (meas. (not specified))	2 (reliable with restrictions)	Kimball G (1978a)

Method	**Results**	**Remarks**	**Reference**
flow-through A flow-through acute toxicity test was performed in glass aquaria approximately 5.1 litres in volume with a stainless steel screen restricting the test minnows to a 4.1 litre volume.	LC50 (192 h): 20.2 mg/L dissolved (meas. (not specified))	supporting study read-across from supporting substance (structural analogue or surrogate) **Test material: Diantimony trichloride**	
Pimephales promelas freshwater static	LC50 (96 h): > 696 element (meas. (geom. mean))	3 (not reliable) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material: diantimony trioxide**	Curtis MW & Ward CH (1981)
Oncorhynchus mykiss freshwater semi-static Tests were performed at 15 °C with rainbow trout fingerlings of mean weight 1.2 g. Ten fish were tested in 40 L of solution	LC50 (96 h): 37 mg/L element (meas. (geom. mean))	3 (not reliable) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material: Antimony potassium tartrate**	Doe KG, Parker WR, Ponsford SJ & Vaughan JDA (1987a)
Lepomis macrochirus freshwater static	LC50 : > 25.8 mg/L element (Sb) (meas. (not specified))	4 (not assignable) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material: Diantimony trichloride**	U.S. EPA (1988a)
Pargus major (red seabream) saltwater static American Society for Testing and Materials (1998). Standard practice for conducting acute toxicity tests with fishes, macroinvertebrates, and amphibians. E-729-96, In: Annual Book of ASTM Standards, Vol 11.05	LC50 (24 h): 6.9 mg/L dissolved (meas. (not specified)) LC50 (48 h): 6.9 mg/L dissolved (meas. (not specified)) LC50 (72 h): 6.9 mg/L dissolved (meas. (not specified))	2 (reliable with restrictions) key study read-across from supporting substance (structural analogue or surrogate) **Test material: potassium**	Takayanagi K (2001)

Method	Results	Remarks	Reference
	LC50 (96 h): 6.9 mg/L dissolved (meas. (not specified))	**hexahydroxyantimonate**	
Pargus major (red seabream) saltwater static American Society for Testing and Materials (1998). Standard practice for conducting acute toxicity tests with fishes, macroinvertebrates, and amphibians. E-729-96, In: Annual Book of ASTM Standards, Vol 11.05	LC50 (24 h): 15.5 mg/L dissolved (Sb) (meas. (not specified)) LC50 (48 h): 15.5 mg/L dissolved (Sb) (meas. (not specified)) LC50 (72 h): 15.2 mg/L dissolved (Sb) (meas. (not specified)) LC50 (96 h): 12.4 mg/L dissolved (Sb) (meas. (not specified))	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material: Antimony trichloride**	Takayanagi K (2001)
Pargus major (red seabream) saltwater static American Society for Testing and Materials (1998). Standard practice for conducting acute toxicity tests with fishes, macroinvertebrates, and amphibians. E-729-96, In: Annual Book of ASTM Standards, Vol 11.05	LC50 (24 h): 0.93 mg/L dissolved (meas. (not specified)) LC50 (48 h): 0.93 mg/L dissolved (meas. (not specified)) LC50 (72 h): 0.93 mg/L dissolved (meas. (not specified)) LC50 (96 h): 0.93 mg/L dissolved (meas. (not specified))	3 (not reliable) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material: Antimony pentachloride**	Takayanagi K (2001)

Discussion

Freshwater

Three studies of acute toxicity to freshwater fish that are considered valid are available (Kimball, 1978; Brooke et al., 1986; TAI, 1990).

In the study by Kimball (1978), 8 week-old juvenile *Pimephales promelas* were exposed to trivalent antimony ($SbCl_3$) in a flow-through system, performed in duplicates with six concentrations (range: 1.0 - 27.6 mg Sb/L) and a control, with each group comprising 10 fishes. The tests were performed with hard well water. The resulting LC50s for the 4 and 8 d exposures were 21.9 and 20.2 mg Sb/L, respectively.

In the study by Brooke et al. (1986) juvenile *Oncorhynchus mykiss* were exposed in a static test design to trivalent antimony ($SbCl_3$) for 4 days, and the LC50 was determined. The tests were performed in duplicates with two concentrations (11.4 and 25.7 mg Sb/l) and a control, with each group comprising 10 fishes. The mortality in the highest of the two dose groups was 45 %, so no LC50 could be determined other than ”greater-than” values. This study also contained the results of static tests performed on *Pimephales promelas*, which resulted in LC50 values of 20.8 mg Sb/L, 17.4 mg Sb/L, and 14.4 mg Sb/L for the time periods 24 h, 48 h, and 96 h, respectively. These results are considered reliable even though no dose-response relationship was reported, since the methodology used is well described, the antimony concentrations were measured, the water characteristics remained within the tolerance limits of the test species, the estimated LC50 values were within the range of the test concentrations used, and the effect values presented were very similar to those reported by Kimbal (1978) using the same fish species.

In the study by TAI (1990) juvenile *Ictalurus punctatus* were exposed to trivalent antimony ($SbCl_3$) in a static test design for 4 days, in moderately-hard reconstituted culture water. The tests were performed in duplicates with five measured concentrations (nominal concentrations within brackets) of 8.5 (15.6), 15.4 (31.25), 19.8 (62.6), 24.6 (125), and 21.2 (250) mg Sb/L, and a control with 0 mg Sb/L (measured concentration), with each group comprising 10 fishes. The resulting LC50 was 24.6 ± 2.6 mg Sb/L.

The reason that Curtis and Ward (1981) is considered unreliable, even though it included analytical monitoring of the test concentrations, is that the reported effect concentration is not considered to represent a dissolved antimony concentration. This conclusion is based on the fact that (i) the reported “greater than” concentration far exceeds the water solubility of diantimony trioxide, (ii) the concentrations used are not presented, (iii) the test substances in the study were added either directly or in the form of a stock solution in deionized water and the solutions were briefly stirred with a glass rod before a water sample was removed for analysis (i. e. there was no initial pretreatment of the diantimony trioxide to ensure that it was properly dissolved before it was added to the test solution), (iv) initially water samples were not filtered before analysis; filtering through 0.45 µm filters before analysis was performed at a later stage (but it is unclear when and for which chemicals), and (v) it is specifically mentioned that the results of the analysis primarily were used for information about the physicochemical behaviour of the toxicants rather than for computing LC50s (which casts some doubt on whether the nominal or measured concentrations were used).

The reasons why the results reported by Doe et al. (1987) for *Oncorhyncus mykiss* are considered to be unreliable, even though the exposure concentration was measured, are that there is no information presented on (i) the number of concentrations and which concentrations were used, (ii) the dose-response curves (no raw data are reported), (iii) the number of replicates (if any), and (iv) the statistics that were used to calculate the LC50 values.

USEPA (1988) reports results from Spehar (1987) for an acute study with *Lepomis macrochirus* with measured exposure values. Although we have not been able to obtain a copy of Spehar (1987) the value reported is higher than that from Brooke et al. (1986) so would not change the assessment.

Saltwater

Only a single study on the acute toxicity to marine fish was considered valid (Takayanagi, 2001).

In the study by Takayanagi (2001) 3 month-old *Pargus major* were exposed to trivalent ($SbCl_3$) or pentavalent antimony ($SbCl_5$or $K[Sb(OH)_6]$) under static conditions with a control and an unknown number of concentrations (range: $SbCl_3$7.8-25.7 mg Sb/L; $SbCl_5$0.40-1.06 mg Sb/L; $K[Sb(OH)_6]$ 2.8-10.3 mg Sb/L), with each group comprising eight fishes. The tests were performed using natural seawater, with a salinity of 33.7 ppt, passed through sand and activated-charcoal filters. Each aquarium was aerated. The pH was determined every day and the reported ranges were 4.9-7.8, 7.8-8.1, and 7.8-8.1, for $SbCl_3$, $SbCl_5$, and $K[Sb(OH)_6]$, respectively. For the $SbCl_3$test, a decrease in the pH of the test solution was observed. Therefore, a low pH seawater was prepared with HCl for use as control for the $SbCl_3$test in order to assess pH effects. All test fishes survived in the HCl-adjusted seawater, and therefore pH was considered to be a negligible factor, and the mortality found in the $SbCl_3$dilution waters was considered to have been caused by the $SbCl_3$. The concentrations of antimony were measured at the beginning and end of the experiments using the hydride-generation atomic absorption method. The resulting EC50 values for 24 h, 48 h, 72 h, and 96 h exposure were 15.5, 15.5, 15.2, 12.4; 0.93, 0.93, 0.93, 0.93; and 6.9, 6.9, 6.9, 6.9, for $SbCl_3$, $SbCl_5$, and $K[Sb(OH)_6]$, respectively (all concentrations in mg Sb/L). However, the results from using the pentavalent $SbCl_5$ appear to be questionable and will therefore not be used.

The following information is taken into account for acute fish toxicity for the derivation of PNEC:

The lowest valid value for acute toxicity to freshwater fish is 14.4 mg Sb/L for Pimephales promelas (Brooke et al. 1986).

The lowest valid value for acute toxicity to marine fish is 6.9 mg Sb/L for Pargus major (Takayanagi, 2001).

7.1.1.1.2. Long-term toxicity to fish

The results are summarised in the following table:

Table 69: Overview of long-term effects on fish

Method	Results	Remarks	Reference
Pimephales promelas	NOEC (28 d): 4.5 mg/L	2 (reliable with	Kimball G (1978b)

Method	Results	Remarks	Reference
freshwater embryo and sac-fry stage: (sub)lethal effects flow-through Test was initiated with viable fathead minnow eggs that were 16-40 hours old, and were exposed to the test substance upon placing in hatching baskets. Hatching, normal development, survival and length/weight at day 28 were monitored.	dissolved (Sb) (meas. (not specified)) based on: post-hatch survival NOEC (28 d): 1.13 mg/L dissolved (Sb) (meas. (not specified)) based on: length NOEC (28 d): 2.31 mg/L dissolved (Sb) (meas. (not specified)) based on: weight LOEC (28 d): 9.31 mg/L dissolved (Sb) (meas. (not specified)) based on: post-hatch survival LOEC (28 d): 2.31 mg/L dissolved (Sb) (meas. (not specified)) based on: length LOEC (28 d): 4.5 mg/L dissolved (Sb) (meas. (not specified)) based on: weight	restrictions) key study read-across from supporting substance (structural analogue or surrogate) **Test material: Antimony trichloride**	
Pimephales promelas freshwater embryo and sac-fry stage: (sub)lethal effects flow-through US EPA, 1972: Proposed recommended bioassay procedures for egg and fry stages of freshwater fish. Duluth, MN	NOEC (30 d): > 7.5 µg/L element (meas. (not specified)) based on: post-hatch survival NOEC (30 d): > 7.5 µg/L element (meas. (not specified)) based on: length NOEC (30 d): > 7.5 µg/L element (meas. (not specified)) based on: weight	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material: diantimony trioxide**	LeBlanc GA & Dean JW (1984)
Salmo gairdneri (new name: Oncorhynchus mykiss) freshwater embryo and sac-fry stage: (sub) lethal effects semi-static According to Birge et al (1978).	LC10 (28 d): 157 µg/L dissolved (Sb) (meas. (not specified)) based on: mortality	3 (not reliable) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material: Antimony trichloride**	Birge WJ, Black JA, Westerman AG & Hudson JE (1980)
Salmo gairdneri (new name: Oncorhynchus mykiss) freshwater embryo and sac-fry stage: (sub)lethal effects semi-static	LC50 (28 d): 0.58 mg/L dissolved (Sb) (meas. (not specified)) based on: mortality LC1 (28 d): 28.6 µg/L dissolved (Sb) (meas. (not specified)) based on: mortality	3 (not reliable) supporting study read-across from supporting substance (structural analogue or surrogate)	Birge WJ (1978)

Method	Results	Remarks	Reference
Eggs are exposed to antimony from ferilization through 4 days posthatching.		**Test material: Antimony trichloride**	
Carassius auratus freshwater embryo and sac-fry stage: (sub) lethal effects semi-static Eggs are exposed to antimony from ferilization through 4 days posthatching.	LC50 (28 d): 11.3 mg/L dissolved (Sb) (meas. (not specified)) based on: mortality LC1 (28 d): 111 µg/L dissolved (Sb) (meas. (not specified)) based on: mortality	3 (not reliable) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material: Antimony trichloride**	Birge WJ (1978)
Oncorhynchus mykiss freshwater adult fish: (sub)lethal effects semi-static Tests were performed at 15° C with rainbow trout fingerling of mean weight 1.2 g. Ten fish were tested in 40 L of solution	LC50 (30 d): 16 mg/L element (meas. (geom. mean)) based on: mortality	3 (not reliable) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material: Antimony potassium tartrate**	Doe KG, Parker WR, Ponsford SJ & Vaughan JDA (1987b)

<u>**Discussion**</u>

Only two studies are considered to be valid (Kimball, 1978 and LeBlanc and Dean, 1984). However, only Kimball can be used to derive a PNEC since the NOECs reported by LeBlanc and Dean are unbounded.

LeBlanc and Dean (1984) exposed eggs from *Pimephales promelas* in a flow-through system, using two replicates, with five concentrations (range: 0.6 - 7.5 µg Sb/L) and two controls (one regular and one vehicle control (HCl)), with each replicate comprising 55 eggs. The tests were performed in well water with a hardness of 28-40 mg $CaCO_3$/L. Since there were no statistically different effects (endpoints: mortality, larvae lengths and weights) when compared to the control, even at the highest concentration used (7.5 µg Sb/L), the resulting unbounded NOEC value was > 7.5 µg Sb/L.

A chronic test performed by Kimball (1978), used embryo-larvae of *Pimephales promelas* in a flow-through system, with four replicates and six concentrations (range: 0.52 – 19.11 mg Sb/L) and a control, with each group comprising 20 eggs. The tests were performed with hard well water. The lowest resulting NOEC from this study, using reduction of length as an indicator of toxicity, is 1.13 mg Sb/L. This value is also the lowest valid NOEC for freshwater fish from long-term toxicity tests.

There are studies by Birge and co-workers (Birge, 1978; Birge et al., 1980), which report NOECs below 1.13 mg Sb/l. However, even though these studies are well performed, with measured test concentrations etc., neither of them are considered to be valid. The reason for this is that the test concentrations used are never reported, which makes it impossible to determine whether the calculated NOEC values are included in the tested concentration range.

The reasons why the result by Doe et al. (1987) on *Oncorhynchus mykiss* is not considered reliable are presented in the section on acute toxicity above.

<u>The following information is taken into account for long-term fish toxicity for the derivation of PNEC:</u>

The lowest valid NOEC for chronic toxicity to freshwater fish is 1.13 mg Sb/L for Pimephales promelas. (Kimball, 1978).

There are no valid chronic studies with marine fish.

7.1.1.2. Aquatic invertebrates

7.1.1.2.1. Short-term toxicity to aquatic invertebrates

The results are summarised in the following table:

Table 70: Overview of short-term effects on aquatic invertebrates

Method	**Results**	**Remarks**	**Reference**
Chlorohydra viridissimus freshwater static Static acute toxicity test on Chlorohydra viridissimus using 5 concentrations of SbCl3. 96h exposure duration.	LC50 (96 h): 1.77 mg/L element (meas. (not specified)) based on: mortality	2 (reliable with restrictions) key study read-across from supporting substance (structural analogue or surrogate) **Test material: antimony trichloride**	TAI (1990)
other aquatic crustacea: Hyalella azteca freshwater static Static acute toxicity test on Hyalella azteca using 5 concentrations of SbCl3. 96h exposure duration.	LC50 (96 h): 21.6 mg/L element (meas. (not specified)) based on: mortality	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material: antimony trichloride**	TAI (1990)
other aquatic arthropod: Chironomus tentans freshwater static Static acute toxicity test on Chironomus tentans using 5 concentrations of SbCl3. 96h exposure duration.	LC50 (96 h): 4.1 mg/L element (meas. (not specified)) based on: mortality	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material: antimony trichloride**	TAI (1990)
other aquatic mollusc: Physa heterostropha freshwater static Static acute toxicity test on Physa heterostropha using 5 concentrations of	LC50 (96 h): 14.2 mg/L element (meas. (not specified)) based on: mortality	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate)	TAI (1990)

Method	Results	Remarks	Reference
SbCl3. 96h exposure duration.		**Test material: antimony trichloride**	
Hydra oligactis freshwater static Static acute toxicity test on Hydra oligactis using 5 concentrations of SbCl3. 96 h exposure duration.	LC50 (96 h): 1.95 mg/L element (meas. (not specified)) based on: mortality	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material: antimony trichloride**	TAI (1990)
Daphnia magna freshwater static Static tests in a constant temperature water bath using 250 mL beakers containing 200 mL of test solution	LC50 (48 h): 18.8 mg/L dissolved (meas. (not specified)) based on: mortality LC50 (48 h): 12.1 mg/L dissolved (meas. (not specified)) based on: mortality LC50 (96 h): 12.1 mg/L dissolved (meas. (not specified)) based on: mortality	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material: Antimony trichloride**	Kimball G (1978c)
Gammarus sp. freshwater static Static acute exposure of test organisms to Sb (III) (as SbCl3). Tests were conducted in 30x30x30 cm tanks containing 24L of solution. Rainbow trout, amphipods, caddisflies and annelids were tested together. The exposures were checked every 24 h for death and/or effect.	LC50 (96 h): > 25.7 mg/L element (meas. (not specified)) based on: mortality	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material: antimony trichloride**	Brooke LT, Call DJ, Poirier SH, Lindberg CA & Markee TP (1986b)
other aquatic worm: Lumbriculus variegatus freshwater static Static acute exposure of test organisms to Sb (III) (as SbCl3). Tests were conducted in 30x30x30 cm tanks containing 24L of solution. Rainbow trout, amphipods, caddisflies and annelids were tested together. The	LC50 (96 h): > 25.7 mg/L element (meas. (not specified)) based on: mortality	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material: antimony trichloride**	Brooke LT, Call DJ, Poirier SH, Lindberg CA & Markee TP (1986b)

Method	Results	Remarks	Reference
exposures were checked every 24h for death and/or effect.			
other aquatic arthropod: Pycnopsyche sp. freshwater static Static acute exposure of test organisms to Sb (III) (as SbCl3). Tests were conducted in 30x30x30 cm tanks containing 24L of solution. Rainbow trout, amphipods, caddisflies and annelids were tested together. The exposures were checked every 24h for death and/or effect.	LC50 (96 h): > 25.7 mg/L element (meas. (not specified)) based on: mortality	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material: antimony trichloride**	Brooke LT, Call DJ, Poirier SH, Lindberg CA & Markee TP (1986b)
Hydra freshwater static Static acute exposure of test organisms to Sb (III) (as SbCl3). Tests were conducted in 30x30x30 cm tanks containing 24L of solution. Rainbow trout, amphipods, caddisflies and annelids were tested together. The exposures were checked every 24h for death and/or effect.	EC50 (96 h): 0.5 mg/L element (meas. (not specified)) based on: morphology (formation of clubbed tentacles and/or shortened body column and tentacles.) EC50 (48 h): 1 mg/L element (meas. (not specified)) based on: morphology (formation of clubbed tentacles and/or shortened body column and tentacles) EC50 (24 h): 2 mg/L element (meas. (not specified)) based on: morphology (formation of clubbed tentacles and/or shortened body column and tentacles)	3 (not reliable) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material: antimony trichloride**	Brooke LT, Call DJ, Poirier SH, Lindberg CA & Markee TP (1986b)
Daphnia magna freshwater static Tests were performed with D. magna that were less than 24 hours old, which were tested at 20°C. Acute tests used 10 animals per 100 mL test solution.	LC50 (48 h): 6.7 mg/L element (meas. (not specified)) based on: mortality LC50 (48 h): 5 mg/L element (meas. (not specified)) based on: mortality LC50 (48 h): 6.7 mg/L element (meas. (not specified)) based on: mortality	3 (not reliable) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material: antimony potassium tartrate**	Doe KG, Parker WR, Ponsford S J & Vaughan JDA (1987)
other aquatic crustacea: hyalella azteca	LC50 (1 wk): 576 µg/L element (Sb) (nominal) based on: mortality	3 (not reliable) supporting study	Borgmann U, Couillard Y, Doyle P & Dixon DG

Method	Results	Remarks	Reference
freshwater static Basic experimental design was modified from the classical toxicity test: A large number of substances were tested simultaneously at only one concentration in the first experiment. The concentration of each substance was then either increased or decreased in the next experiment. The number of concentrations tested was reduced: 10, 32, and 100 (instead of 10, 18, 32, 56, and 100).	LC50 (1 wk): > 3150 µg/L element (Sb) (nominal) based on: mortality LC50 (1 wk): 687 µg/L element (Sb) (meas. (not specified)) based on: mortality	read-across from supporting substance (structural analogue or surrogate) **Test material (element): antimony**	(2005)
Ceriodaphnia dubia freshwater static	EC50: 3.47 mg/L element (Sb) (meas. (not specified)) based on: mobility	4 (not assignable) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material: antimony trichloride**	U.S. EPA (1988b)
Daphnia magna	EC50 (2 d): 22 mg/kg element (Sb) (meas. (not specified)) based on: mobility EC50 (2 d): 5 mg/kg element (Sb) (meas. (not specified)) based on: mobility	3 (not reliable) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material: antimony (V) chloride**	Fjällborg B & Dave G (2004a)

Discussion

Three studies of acute toxicity to freshwater invertebrates that are considered valid are available (Kimball, 1978; TAI, 1990; Brooke et al., 1986). There is also an additional study by Brooke et al. (1986) which, although not considered reliable, does support the finding of Anon (1990) that the coelenterate hydra is the most sensitive invertebrate tested to date.

In the study by Kimball (1978), <1 d old daphnids were exposed in a static test design to trivalent antimony ($SbCl_3$) for 2 or 4 days. This study was performed with six concentrations (range: 1.65 – 44.15 mg Sb/L) and a control, using four replicates with ten neonates for each concentration. Mortality was the endpoint. In the 2-day exposure regime, the daphnids were exposed to antimony ($SbCl_3$) either with or without feeding. The resulting LC50 values were 12.2 and 18.8 mg Sb/L, respectively. In the 4-day exposure regime, the antimony exposure was only performed together with feeding, and the resulting LC50 was 12.1 mg Sb/L.

In the study by TAI (1990) two hydra species (*Hydra oligogactis*, and *Chlorohydra viridissima*), one snail (*Physa heterostropha*), one midge (*Chironomus tentans*) and an amphipod (*Hyalella azteca*) were tested in a static test design with trivalent antimony ($SbCl_3$) for 4 days. All tests were performed with five concentrations and a control, using duplicate replicates with five individuals for each test chamber. The measured concentrations used (nominal concentration within brackets) were 8.5 (15.6), 15.4 (31.25), 19.8 (62.6), 24.6 (125), and 21.22 (250) mg Sb/L, and a control with 0 mg Sb/L (measured concentration) for *Physa heterostropha*, *Chironomus tentans*, and *Hyalella azteca*. The measured concentrations used (nominal concentration within brackets) for the two hydra species *Hydra oligogactis* and *Chlorohydra viridissima* were 1.18 (0.5), 1.52 (1.0), 2.56 (2.5), 4.48 (5.0), and 5.42 (6.25), and a control with 0 mg Sb/L (measured concentration). Using mortality as the endpoint the resulting LC50s were 1.95, 1.77, 14.2, 4.1, and 21.6 mg Sb/L for *Hydra oligogactis*, *Chlorohydra viridissima*, *Physa heterostropha* and *Chironomus tentans* respectively. Therefore, the hydras were the most sensitive invertebrates.

This observation is further supported by the study by Brooke et al. (1986), in which hydra were also found to be the most sensitive of several tested invertebrates out of *Hydra*sp*.,* amphipods (*Gammarus pseudolimnaeus*), annelids (*Lumbriculus variegatus*), and caddisflies (*Pycnopsyche* sp.). Adult hydroids (*Hydra* sp.) were exposed in a static test design to trivalent antimony ($SbCl_3$) for 4 days, and an EC50 (tentacles clubbed and/or shortened body column and tentacles) was determined. These tests were performed in quadruplicate with five concentrations (range: 0.3 - 3.3 mg Sb/L) and a control, with each replicate consisting of ten hydroids. The resulting EC50 (24 h) was 2 mg Sb/L (1.8 - 2.2 = 95 % confidence interval), the EC50 (48 h) was 1.0 mg Sb/L (confidence limits not reliable, according to authors), and the EC50 (96 h) was 0.5 mg Sb/L (0.5 - 0.6 = 95 % confidence interval). The tests on amphipods (*Gammarus pseudolimnaeus*), annelids (*Lumbriculus variegatus*), and caddisflies (*Pycnopsyche* sp.) were performed in duplicate with two concentrations (11.4 ± 3.9 and 25.7 ± 2.2 mg Sb/L) and a control, with each replicate consisting of ten individuals. The EC50 calculations for these three species all resulted in “greater than” values (> 25.7 mg Sb/L). However, the result of the hydra study is not considered reliable but only indicative, since the endpoint used (tentacles clubbed and/or shortened body column and tentacles) is subjective, and no information is provided on whether a dose-response relationship existed.

The hydra results from the study by Brooke et al. (1986) are only slightly lower then those reported by TAI (1990), i. e. an EC50 (96 h) of 0.5 mg Sb/L (*Hydra* sp.), compared to 1.77 mg Sb/L (*Chlorohydra viridissimus*) and 1.95 mg Sb/L (*Hydra oligactis*). This slight difference may be due to several reasons such as interlaboratory differences, different sensitivities between the different hydra species tested, or the fact that the criteria used for defining the endpoints differ in sensitivity. The criteria for hydra effects in the TAI study were the beginning of the break down of tissue integrity and an associated bacterial growth enveloping the animals, while in the study by Brooke et al. (1986) it was clubbed tentacles and/or shortened body column and tentacles.

Thus, the most sensitive of the aquatic invertebrates is the hydra, and the lowest valid EC50 (96 h) for acute toxicity is 1.77 mg Sb/L.

The reasons why the study by Doe et al. (1987) on the acute toxicity of *Daphnia magna* is considered unreliable, even though exposure concentrations were measured, is that there is no information presented on (i) the number of concentrations and which concentrations were used, (ii) dose-response curves (no raw data are available), (iii) the number of replicates (if any), and (iv) what statistics have been used to calculate the LC50 values.

Borgmann et al. (2005) reported a seven-day acute LC50 value of 0.687 mg Sb/L for *Hyalella azteca*, which is not considered to be reliable. Because of the objective of the study (large-scale screening of metal toxicity for categorization of substances on the Canadian Domestic Substances List) several modifications have been made to the standard experimental design. The main reason why the result from this study cannot be considered reliable is because antimony was clearly not the only toxicity-inducing factor in the test medium. This study used metal standards for toxicity testing. For antimony, a metal standard containing 20% HCl was used. The acid in the metal standards was neutralized by adding a solution of 1M $NaHCO_3$and 1M KOH in a 19:1 ratio. Along with a control treatment (containing normal test medium), an acid control was used (containing acid and neutralizing solution additions equal to the amount added in the tests with acidified metal standards). For metal standards supplied in 20% HCl, survival in the acid controls for the 1,000 µg/L treatment dropped to 32%, indicating that the organisms were adversely affected by the blank test medium. Therefore, toxicity in the metal treatments was most likely overestimated in this study. The LC50 values derived for antimony in the tests using the metal standards is not considered reliable. Toxicity tests were also conducted using sodium antimonate ($NaSbO_3$). However, no toxicity was observed at the highest exposure concentrations tested (1 mg Sb/L nominal, 0.197 mg Sb/L measured).

Fjallborg and Dave (2004) spiked sewage sludge with $SbCl_5$and after 60 days of equilibration grew radish, oats or lettuce. After 14 days’ cultivation the toxicity of the elutriate to *Daphnia magna* was tested. The authors report an EC50 based on the nominal concentrations spiked into the sewage sludge, for which a dose response was observed. For the elutriate after radish cultivation the EC50 was 22 mg Sb/kg, and after oat cultivation the EC50 was 5 mg

Sb/kg. This study included analytical monitoring of the elutriate. These measured concentrations are only reported in graphical format. When the effects data are compared with the measured concentrations in the elutriate a dose reponse is not observed. For this reason, this non-standard study is not considered reliable for use in the assessment.

This is the only study to have tested the toxicity of an Sb(V) compound, and the study is not considered to be valid because no dose response in relation to antimony concentrations was observed. There is therefore no information on the toxicity of exposures which contain a very high proportion of Sb(V), as only relatively limited oxidation of Sb(III) to Sb(V) would be expected within the time frame of an acute toxicity test (or the renewal period of a semi-static chronic test). Sb(V) is expected to be the dominant species in oxygenated natural waters, although the rate of oxidation of Sb(III) to Sb(V) is very slow, with a half-life in laboratory solutions expected to be in the order of months (CanMET, 2010). PNEC values for antimony are expressed in terms of dissolved antimony concentrations.

USEPA (1988) report results from Spehar (1987) of an acute study with *Ceriodaphnia dubia* with measured exposure values. Although we have not been able to obtain a copy of Spehar (1987) the value reported is higher than that from TAI (1990) so would not change the assessment.

The following information is taken into account for short-term toxicity to aquatic invertebrates for the derivation of PNEC:

The lowest valid value for acute toxicity to freshwater invertebrates is 1.77 mg Sb/L for Chlorohydra viridissimus (TAI, 1990).

There are no valid acute studies with marine invertebrates.

7.1.1.2.2. Long-term toxicity to aquatic invertebrates

The results are summarised in the following table:

Table 71: Overview of long-term effects on aquatic invertebrates

Method	Results	Remarks	Reference
Daphnia magna freshwater semi-static OECD Guideline 211 (Daphnia magna Reproduction Test)	NOEC (21 d): 1.74 mg/L dissolved (Sb) (meas. (initial)) based on: reproduction (R: reproduction rate) NOEC (21 d): 3.13 mg/L dissolved (Sb) (meas. (initial)) based on: reproduction (rm= intrinsic rate of natural increase) LOEC (21 d): 3.13 mg/L dissolved (Sb) (meas. (initial)) based on: reproduction (R: reproduction rate) LOEC (21 d): 5.86 mg/L dissolved (Sb) (meas. (initial)) based on: reproduction (rm: intrinsic rate of natural increase)	1 (reliable without restriction) key study read-across from supporting substance (structural analogue or surrogate) **Test material: antimony trichloride**	Heijerick G & Vangheluwe M (2003)
Daphnia magna freshwater semi-static	NOEC (7 d): 3.9 mg/L dissolved (Sb) (meas. (not specified)) based on: reproduction LOEC (7 d): 7.8 mg/L	2 (reliable with restrictions) supporting study read-across from	Kimball G (1978d)

Method	Results	Remarks	Reference
Two week old organisms were placed individually in test beakers (50 mL of solution), and were transferred three times per week to a renewal solution. Test duration was one week with all chemistries and reproductive data counted three times during that week	dissolved (Sb) (meas. (not specified)) based on: reproduction	supporting substance (structural analogue or surrogate) **Test material: Antimony trichloride**	
Daphnia magna freshwater semi-static Neonates (12 h ± 12h) were placed individually in test beakers (50 mL of solution), and were transferred three times per week to a renewal solution. Test duration was 28 days.	NOEC (28 d): 4.16 mg/L dissolved (Sb) (meas. (not specified)) based on: reproduction LOEC (28 d): 7.05 mg/L dissolved (Sb) (meas. (not specified)) based on: reproduction	3 (not reliable) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material: Antimony trichloride**	Kimball G (1978d)
Daphnia magna freshwater semi-static Chronic tests used 1 animal per 50mL (<24h old) and media were renewed and test organisms fed three times/week: food was Chlorella vulgaris supplemented with a suspension of Tetramin. Survival and reproduction were measured to day 30, while survivors at day 33 were measured for length (growth effects).	NOEC (30 d): 1.7 mg/L element (meas. (not specified)) based on: reproduction NOEC (33 d): 0.8 mg/L element (meas. (not specified)) based on: growth	3 (not reliable) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material: antimony potassium tartrate**	Doe KG, Parker WR, Ponsford SJ & Vaughan JDA. (1987)

Discussion

There is one study available providing reliable long term data for aquatic invertebrates (Heijerick and Vangheluwe, 2003).

Heijerick and Vangheluwe (2003) performed a 21-d chronic toxicity test with *Daphnia magna* using $SbCl_3$as the test substance. This study, which is in accordance with the OECD 211 guideline, was conducted as a semi-static test, with full renewal of the test medium three times/week. The test was performed with five measured concentrations (range: 0.056 – 9.96 mg Sb/L) and a control, with ten test chambers per concentration, using one juvenile (<24 h-old) daphnid in each chamber. Mortality of adult organisms was noted and newborn neonates were counted and removed when the exposure medium was renewed. Two endpoints, based on survival and reproduction (net reproduction rate, R, and the intrinsic rate of natural increase, rm) were determined. The resulting 21-d NOEC for reproduction of *Daphnia magna* was 1.74 mg Sb/L, with a LOEC of 3.13 mg Sb/L. The LC50 (21-d) was 4.77 mg/L, the EC50, R (21-d) was 3.82 mg/L, and the EC50, rm (21-d) was 4.86 mg/L.

The study by Kimball (1978) only contains reliable results for a 7-d screening test on *Daphnia magna*. The 7-d screening test was conducted as a static renewal test with exposure to trivalent antimony ($SbCl_3$). The test was performed with four replicates, six concentrations (range: 1.9 – 52.2 mg Sb/L) and a control, with ten test chambers per replicate, using one 2-week old adult daphnid in each chamber. Once the daphnids began reproducing, the neonates and the moults of the adults were counted. Survival was recorded at each renewal period (three times weekly). The resulting 7-d NOEC for reproduction of *Daphnia magna* was 3.9 mg Sb/L. The LC50 for the 7-d screening study was 14.5 mg/L. The set-up for the 28-d test was identical to the screening test, except that neonate daphnids, instead of two week old adults, were placed into the beakers and the concentration range used was 0.52-7.05 mg Sb/L. However, the results from the 28-d exposure period could not be used due to the high control mortality (30 %).

The reasons why the study by Doe et al. (1987) on chronic toxicity of *Daphnia magna* is considered unreliable, even though the exposure concentrations were measured, are that there is no information presented on (i) the size of the groups (the only information given is that there was 1 animal/50 ml), (ii) the number and concentrations that were used, (iii) dose-response curves (no raw data are available), (iv) the number of replicates (if any), and (v) what statistics have been used to calculate the LC50 value and NOECs. The 30 day LC50 is 2.7 mg Sb/L and NOECs for reproduction (30d) and growth (33d) are 1.7 mg Sb/L and 0.8 mg Sb/L, respectively. However, the only information on concentrations is a legend in a figure indicating that one control and two doses of 1.7 mg Sb/L and 3.7 mg Sb/L have been used.

No information is available on the speciation of antimony in ecotoxicity tests, and the PNEC for antimony is therefore expressed in terms of the dissolved antimony concentration.

The following information is taken into account for long-term toxicity to aquatic invertebrates for the derivation of PNEC:

The lowest valid NOEC for chronic toxicity to freshwater invertebrates is 1.74 mg Sb/L for Daphnia magna (Heijerick and Vangheluwe, 2003).

There are no valid chronic studies with marine invertebrates.

7.1.1.3. Algae and aquatic plants

The results are summarised in the following table:

Table 72: Overview of effects on algae and aquatic plants

Method	Results	Remarks	Reference
Pseudokirchnerella subcapitata (algae) freshwater static OECD Guideline 201 (Alga, Growth Inhibition Test) ISO 8692 (Water Quality - Fresh Water Algal Growth Inhibition Test with Scenedesmus subspicatus and Selenastrum capricornutum) (2002)	EC50 (72 h): > 36.6 mg/L dissolved (Sb) (meas. (initial)) based on: biomass EC50 (72 h): > 36.6 mg/L dissolved (Sb) (meas. (initial)) based on: growth rate NOEC (72 h): 2.11 mg/L dissolved (Sb) (meas. (initial)) based on: biomass NOEC (72 h): 2.11 mg/L dissolved (Sb) (meas. (initial)) based on: growth rate LOEC (72 h): 4 mg/L dissolved (Sb) (meas. (initial)) based on: biomass LOEC (72 h): 4 mg/L dissolved (Sb) (meas. (initial)) based on: growth rate	1 (reliable without restriction) key study read-across from supporting substance (structural analogue or surrogate) **Test material: Antimony trichloride**	Heijerick D & Vangheluwe M (2004)
Selenastrum capricornutum (new	EC50 (72 h): 34 mg/L act.	3 (not reliable)	LISEC (1994)

Method	Results	Remarks	Reference
name: Pseudokirchnerella subcapitata) (algae) freshwater static OECD Guideline 201 (Alga, Growth Inhibition Test) Annex to directive 92/69/EEC (1992). Part C3: Methods for the determination of Ecotoxicity: Algal inhibition test.	ingr. (whole media (dissolved + dispersed)) (nominal) based on: biomass EC50 (72 h): 67 mg/L act. ingr. (whole media (dissolved + dispersed)) (nominal) based on: growth rate EC50 (72 h): 28.4 mg/L element (whole media (dissolved + dispersed)) (meas. (not specified)) based on: biomass EC50 (72 h): 55.8 mg/L element (whole media (dissolved + dispersed)) (meas. (not specified)) based on: growth rate NOEC (72 h): 10 mg/L act. ingr. (whole media (dissolved + dispersed)) (nominal) based on: biomass NOEC (72 h): 10 mg/L act. ingr. (whole media (dissolved + dispersed)) (nominal) based on: growth rate NOEC (72 h): 8.3 mg/L element (whole media (dissolved + dispersed)) (meas. (not specified)) based on: biomass NOEC (72 h): 8.3 mg/L element (whole media (dissolved + dispersed)) (meas. (not specified)) based on: growth rate	weight of evidence read-across from supporting substance (structural analogue or surrogate) **Test material: diantimony trioxide**	
Raphidocelis subcapitata (new name: Pseudokirchnerella subcapitata) (algae) freshwater static OECD Guideline 201 (Alga, Growth Inhibition Test) Annex to directive 92/69/EEC, 1992.	EC50 (3 d): > 2.4 mg/L dissolved (Sb) (meas. (arithm. mean)) based on: biomass EC50 (3 d): > 2.4 mg/L dissolved (Sb) (meas. (arithm. mean)) based on: growth rate	1 (reliable without restriction) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material: diantimony trioxide**	LISEC (2001)

Method	Results	Remarks	Reference
Methods for the determination of ecotoxicity: algal inhibition test	NOEC (3 d): 0.323 mg/L dissolved (Sb) (meas. (arithm. mean)) based on: biomass NOEC (3 d): 0.396 mg/L dissolved (Sb) (meas. (arithm. mean)) based on: growth rate LOEC (3 d): 0.396 mg/L dissolved (Sb) (meas. (arithm. mean)) based on: biomass LOEC (3 d): 1.32 mg/L dissolved (Sb) (meas. (arithm. mean)) based on: growth rate		
Lemna minor (aquatic plants) freshwater static Exposures were made with Sb (III) as SbCl3 to Lemna minor. The tests were conducted in 250 mL beakers using 200 mL of solution. Twenty fronds per test chamber were used.	EC50 (96 h): > 25.5 mg/L element (meas. (not specified)) based on: frond number NOEC (96 h): 12.5 mg/L element (meas. (not specified)) based on: frond number LOEC (96 h): 25.5 mg/L element (meas. (not specified)) based on: frond number	2 (reliable with restrictions) key study read-across from supporting substance (structural analogue or surrogate) **Test material: antimony trichloride**	Brooke LT, Call DJ, Poirier SH, Lindberg CA & Markee TP (1986b)
Lemna minor (aquatic plants) freshwater	LOEC (7 d): > 0.22 mg/L element (Sb) (meas. (not specified)) based on: dry matter yield	3 (not reliable) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material: antimony (V) chloride**	Fjällborg B & Dave G (2004b)

Discussion

Effects on algae / cyanobacteria

There are two reliable studies in which the effect of antimony on algal growth was studied (Heijerick and Vangheluwe, 2004; LISEC, 2001).

In the study by Heijerick and Vangheluwe (2004) exponentially growing cultures of the unicellular green alga *Pseudokirchneriella subcapitata* were exposed to various concentrations of trivalent antimony ($SbCl_3$) for a period of 72 h. This study was performed with three replicates, seven concentrations (range: 1.22 – 36.6 mg Sb/L) and a control (<0.002 mg Sb/L), using growth as an endpoint, resulting in the same NOEC value, 2.11 mg Sb/L, for both biomass growth (EbCx) and growth rate (ErCx), with the latter being the preferred parameter according to the revised ISO 8692 guideline. The resulting NOEC for algae is thus 2.11 mg Sb/L, with a corresponding LOEC of 4.00 mg Sb/L.

In the study by LISEC (2001) exponentially growing cultures of the unicellular green algae *Pseudokirchneriella subcapitata* were exposed to various concentrations of trivalent antimony (Sb_2O_3) for a period of 72 h. This study was performed with three replicates, six concentrations (range: 0.074 – 2.4 mg Sb/L) and a control, using growth as an endpoint, and resulted in two NOEC values, 0.323 and 0.396 mg Sb/L. The former was calculated for growth (biomass), and the latter was calculated for growth rate, which is the preferred parameter according to the revised ISO 8692 guideline. The resulting NOEC for algae is thus 0.396 mg Sb/L, with a corresponding LOEC of 1.32 mg Sb/L. However, this NOEC value will not be taken forward as the key endpoint from this study. Instead the highest concentration tested, with an inhibition of growth rate of 3 % will be used. The reason for using the highest tested concentration of 2.4 mg Sb/L, instead of the reported NOEC or the LOEC (EC_3), is that it is not totally clear whether the true beginning of a real dose-response curve is observed, since the highest concentration tested only resulted in an inhibition of 3 % using the recommended endpoint of growth rate. This study has an unusually low variation between the replicates, and a very low effect, even at the highest concentration tested, as shown in the table below.

Table 73: Inhibition of the growth rate of *Pseudokirchneriella subcapitata* due to exposure to Sb_2O_3(LISEC, 2001).

Measured conc. (mg Sb/L)	**0**	**0.074**	**0.156**	**0.323**	**0.396**	**1.32**	**2.4**
Inhibition growth rate (%)	-	0.8	0.8	0.1	1	2.3	3
Relative standard deviation (%)	2.1	2.2	1.8	1.1	1.8	3.5	1.2

A confirmatory test would most likely result in a higher NOEC due to the normally much larger variation. A review of data from 41 algal tests indicates that the E_rC_{10}on average corresponds reasonably well with the NOEC (Heitmann and Staveley, 2003). The choice of the highest concentration tested as the key concentration from this study may therefore still be considered as protective, since the inhibition at this concentration is only 3 %. As a result of the low effect at the highest concentration, i. e. 3 %, no EC50 could be determined.

The study by LISEC (1994) on *Selenastrum capricornutum* (now known as *Pseudokirchneriella subcapitata*) is considered unreliable, despite measured concentrations being reported. The reasons are that (i) the reported effect concentrations were not based on the dissolved concentrations but on nominal concentrations, as the total measured concentrations, which consisted of "whole media" (dissolved and dispersed amount of test material) were within 10% of the nominal concentrations, (ii) the measured concentrations in the filtrate differed substantially between the samples taken at the start (0 h) and the end (72 h) of the experiment (with higher concentrations at the end of the experiment). In addition, the EC50 based on growth rate is extrapolated since only a 16 % inhibition in growth rate was observed in the highest test concentration, which exceeds the maximum solubility of Sb_2O_3.

The following information is taken into account for effects on algae / cyanobacteria for the derivation of PNEC:

The lowest valid value for acute and chronic toxicity to freshwater algae is >36.6 and 2.11 mg Sb/L for Pseudokirchneriella subcapitata (Heijerick and Vangheluwe, 2004).

There are no valid studies with marine algae.

Effects on aquatic plants other than algae

In the study by Brooke et al. (1986), *Lemna minor* was exposed in a static test design to trivalent antimony ($SbCl_3$) for 4 days. The endpoint studied was reduction in frond production. The test was performed in quadruplicate with five concentrations (range: 1.6 - 25.5 mg Sb/L) and a control, with 20 fronds in each test chamber. No EC50 could be obtained. However, in the highest exposure group, i. e. 25.5 mg Sb/l, a significant reduction in frond production occurred (32 %). The resulting NOEC from this study was 12.5 mg Sb/L, with the corresponding LOEC 25.5 mg

Sb/L.

Fjallborg and Dave (2004) spiked sewage sludge with $SbCl_5$and after 60 days equilibration grew radish, oats or lettuce. After 14 days cultivation the toxicity of the elutriate to *Lemna minor* was tested. The authors report that the dry weight of *Lemna minor* was not consistently affected by Sb concentration up to a maximum test concentration of 0.22 mg Sb/L. Although this study included analytical monitoring of the elutriate, its non-standard design and unbounded LOEC make it unsuitable for use in the assessment.

The following information is taken into account for effects on aquatic plants other than algae for the derivation of PNEC:

The only valid value for acute toxicity to freshwater plants is a 4-day EC50 >25.5 mg Sb/L for Lemna minor (Brooke et al, 1986).

7.1.1.4. Sediment organisms

The results are summarised in the following table:

Table 74: Overview of long-term effects on sediment organisms

Method	**Results**	**Remarks**	**Reference**
Chironomus riparius freshwater long-term toxicity (laboratory study) semi-static OECD Guideline 218 (Sediment-Water Chironomid Toxicity Test Using Spiked Sediment)	NOEC (14 d): >= 445 mg Sb/kg fresh wt. element (meas. (not specified)) based on: mortality NOEC (14 d): >= 636 mg Sb/kg dw element (meas. (not specified)) based on: mortality NOEC (14 d): 78 mg Sb/kg fresh wt. element (meas. (not specified)) based on: growth (weight) NOEC (14 d): 112 mg Sb/kg dw element (meas. (not specified)) based on: growth(weight) NOEC (28 d): >= 445 mg Sb/kg fresh wt. element (meas. (not specified)) based on: emergence NOEC (28 d): >= 636 mg Sb/kg dw element (meas. (not specified)) based on: emergence LOEC (14 d): > 445 mg Sb/kg fresh weight element (meas. (not specified)) based on: mortality LOEC (14 d): > 636 mg Sb/kg dw element (meas. (not specified)) based on:	1 (reliable without restriction) key study read-across from supporting substance (structural analogue or surrogate) **Test material: Antimony trichloride**	Heijerick D & Vangheluwe M (2005a)

Method	Results	Remarks	Reference
	mortality LOEC (14 d): 120 mg Sb/kg fresh wt. element (meas. (not specified)) based on: growth (weight) LOEC (14 d): 172 mg Sb/kg dw element (meas. (not specified)) based on: growth (weight) LOEC (28 d): > 445 mg Sb/kg fresh weight element (meas. (not specified)) based on: emergence LOEC (28 d): > 636 mg Sb/kg dw element (meas. (not specified)) based on: emergence		
Lumbriculus variegatus freshwater long-term toxicity (laboratory study) semi-static OECD Draft "Bioaccumulation; Sediment test using benthic oligochaetes", January 2000 (3th revised draft) EPA Guideline 600/R-99/064 "Methods for measuring the toxicity and bioaccumulation of sediment-associated contaminants with freshwater invertebrates", Section 13, Test Method 100.3 "Lumbriculus variegatus bioaccumulation test for sediments"	NOEC (28 d): 120 mg Sb/kg fresh wt. element (meas. (not specified)) based on: mortality NOEC (28 d): 120 mg Sb/kg fresh wt. element (meas. (not specified)) based on: reproduction NOEC (28 d): 78 mg Sb/kg fresh wt. element (meas. (not specified)) based on: dry weight (growth) NOEC (28 d): 172 mg/kg sediment dw element (meas. (not specified)) based on: mortality NOEC (28 d): 172 mg/kg sediment dw element (meas. (not specified)) based on: reproduction NOEC (28 d): 112 mg/kg sediment dw element (meas. (not specified)) based on: dry weight (growth) LOEC (28 d): 244 mg Sb/kg fresh wt element (meas. (not specified)) based on: mortality LOEC (28 d): 244 mg	1 (reliable without restriction) key study read-across from supporting substance (structural analogue or surrogate) **Test material: Antimony trichloride**	Heijerick D & Vangheluwe M (2005b)

Method	Results	Remarks	Reference
	Sb/kg fresh wt element (meas. (not specified)) based on: reproduction LOEC (28 d): 120 mg Sb/kg fresh wt element (meas. (not specified)) based on: dry weight (growth) LOEC (28 d): 348 mg/kg sediment dw element (meas. (not specified)) based on: mortality LOEC (28 d): 348 mg/kg sediment dw element (meas. (not specified)) based on: reproduction LOEC (28 d): 172 mg/kg sediment dw element (meas. (not specified)) based on: dry weight (growth)		
Hyalella azteca freshwater long-term toxicity (laboratory study) semi-static EPA 600/R-99/064, 2000. Section 14: Test Method 100.4, Hyalella azteca 42d Test for Measuring the Effects of Sediment-associated Contaminants on Survival, Growth, and Reproduction. p 72-83.	NOEC (28 d): >= 355 mg/kg sediment dw element (meas. (not specified)) based on: mortality NOEC (28 d): >= 248.5 mg Sb/kg ww element (meas. (not specified)) based on: mortality NOEC (28 d): 124 mg/kg sediment dw element (meas. (not specified)) based on: growth - weight NOEC (28 d): 124 mg/kg sediment dw element (meas. (not specified)) based on: growth - length NOEC (28 d): 87 mg Sb/kg ww element (meas. (not specified)) based on: growth - weight/length NOEC (42 d): 272 mg/kg sediment dw element (meas. (not specified)) based on: mortality NOEC (42 d): 190 mg Sb/kg ww element (meas. (not specified)) based on:	1 (reliable without restriction) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material: Antimony trichloride**	Heijerick D & Vangheluwe M (2003a)

Method	Results	Remarks	Reference
	mortality NOEC (42 d): 272 mg/kg sediment dw element (meas. (not specified)) based on: growth - weight NOEC (42 d): 272 mg/kg sediment dw element (meas. (not specified)) based on: growth - length NOEC (42 d): 272 mg/kg sediment dw element (meas. (not specified)) based on: reproduction NOEC (42 d): 190 mg Sb/kg ww element (meas. (not specified)) based on: growth (weight/length) and reproduction LOEC (28 d): 272 mg/kg sediment dw element (meas. (not specified)) based on: growth - weight LOEC (28 d): 272 mg/kg sediment dw element (meas. (not specified)) based on: growth - length LOEC (28 d): 190 mg Sb/kg ww element (meas. (not specified)) based on: growth - weight/length LOEC (42 d): 355 mg/kg sediment dw element (meas. (not specified)) based on: mortality LOEC (42 d): 248.5 mg Sb/kg ww element (meas. (not specified)) based on: mortality LOEC (42 d): 355 mg/kg sediment dw element (meas. (not specified)) based on: growth - weight LOEC (42 d): 355 mg/kg sediment dw element (meas. (not specified)) based on: growth - length LOEC (42 d): 355 mg/kg		

Method	Results	Remarks	Reference
	sediment dw element (meas. (not specified)) based on: reproduction LOEC (42 d): 248.5 mg Sb/kg ww element (meas. (not specified)) based on: growth (weight/length) and reproduction		

Discussion

Three reliable and relevant chronic sediment toxicity tests with different species are available. The test species all have different exposure routes, feeding habits and ecological niches: (1) the bottom-dwelling *Hyalella azteca* (crustacean) is a surface deposit and filter feeder, (2) *Chironomus riparius* (insect) burrows within the sediment with a combined surface and subsurface feeding behaviour, and (3) *Lumbriculus variegatus* (oligochaete) is a head-down deposit feeder that feeds well below the sediment-water interface.

In Heijerick and Vangheluwe (2003) the amphipod *Hyalella azteca* was exposed to various concentrations of trivalent antimony ($SbCl_3$) in a sediment-water system. The amphipods were exposed for 28 days. After this period, they were separated from the sediment and placed in sediment-free chambers for another 14 days. During this period, survival (day 28, 35, 42), growth (day 28, 42) and reproduction (number of young per female produced from day 28 to 42) were measured. This study was performed with 13 replicates, five concentrations (range: 30.8-249 mg Sb/kg ww) and a control, with each replicate consisting of 10 amphipods. The 13 replicates were used as follows: four replicates were used for the 28-day growth and survival endpoints and eight for the measurements of survival and reproduction on day 35 and 42 (incl. growth). The remaining replicate was used for the performance of chemical measurements. The overlying water was renewed at least three times a week (±75 %). The most sensitive endpoint was growth (both weight and length) after 28 days of exposure, which resulted in a NOEC of 87 mg Sb/kg ww (124 mg Sb/kg dry wt).

Larvae of the midge *Chironomus riparius* were exposed to a concentration range of $SbCl_3$in a sediment-water system (Heijerick and Vangheluwe, 2005). The test procedure was based on the OECD draft proposal for a new guideline 218 “Sediment-Water Chironomid Toxicity Test Using Spiked Sediment” (Draft February 2001, adopted April 2004). Two-day old larvae were exposed to spiked sediment until the larvae transformed to the adult phase. Mortality and growth of the larvae, and emergence to midges were determined after 14 and 28 days of exposure. The study was performed with six concentrations (23- 445 mg Sb/kg ww) and a control (<1.4 mg Sb/kg ww), and 11 replicates per concentration, of which five replicates were used to determine survival and growth after 14 days of exposure, five to determine emergence after 28 days of exposure, and the remaining replicate to perform chemical analyses. The overlying water was renewed at least three times a week (±75 % renewal). The most sensitive endpoint was growth (weight), which resulted in a NOEC of 78 mg Sb/kg ww.

Adults of the oligochaete *Lumbriculus variegatus* were exposed to a concentration range of $SbCl_3$ in a sediment-water system (Heijerick and Vangheluwe, 2005). The test procedure was based on the OECD draft “Bioaccumulation; Sediment test using benthic oligochaetes” (January 2000; 3rd revised draft) and the EPA Guideline 600/R-99/064 “Methods for measuring the toxicity and bioaccumulation of sediment-associated contaminants with freshwater invertebrates”, Section 13, Test Method 100.3 “*Lumbriculus variegatus* bioaccumulation test for sediments”. The test organisms were exposed for 28 days to the spiked sediment. At the end of the exposure period survival, reproduction and growth were monitored. The study was performed with six concentrations (23 - 445 mg Sb/kg ww) and a control (<1.4 mg Sb/kg ww), and 7 replicates per concentration, of which six replicates were used to determine survival, reproduction and growth after 28 days of exposure, and the remaining replicate to perform chemical analyses. The overlying water was renewed at least three times a week (±75 % renewal). The most sensitive endpoint was growth (weight), which resulted in a NOEC of 78 mg Sb/kg ww.

The following information is taken into account for sediment toxicity for the derivation of PNEC:

The lowest valid value for chronic toxicity to sediment organisms is a NOEC of 78 mg Sb/kg ww or 112 mg Sb/kg dw for Chironomus riparius (Heijerick and Vangheluwe, 2005).

7.1.1.5. Other aquatic organisms

No studies were identified on other aquatic organisms which included analytical confirmation of the exposure concentrations.

7.1.2. Calculation of Predicted No Effect Concentration (PNEC)

7.1.2.1. PNEC water

The derivation of the PNEC is described in the table below. There are no ecotoxicity studies which have considered the possible effect of water quality parameters on antimony toxicity. As antimony typically exists as either neutral or negatively charged species (i.e. Sb(OH)3, or Sb(OH)6-) in the environment its behaviour is quite different from that of divalent cationic metals for which biotic ligand models have been developed, such as Cu, Ni and Zn. Sb(III) may form complexes with naturally occurring organic ligands, although because this is not the only form of Sb in the environment any effect that such complexation may have on potential toxicity modification is reduced. There is therefore no evidence to suggest that antimony toxicity is likely to vary widely between different regions.

Table 75: PNEC water

PNEC	Assessment factor	Remarks/Justification
PNEC aqua (freshwater): 0.113 mg/L	10	Extrapolation method: assessment factor There are reliable and relevant short-term toxicity data available for a number of species including fish, Daphnia and algae. However, the most sensitive species in the acute toxicity tests was the green hydra Chlorohydra viridissimus, with an LC50 value of 1.77 mg Sb/L. Relevant and reliable long–term toxicity studies are available for fish, Daphnia and algae. The most sensitive organisms in the long-term toxicity tests are fish. The lowest NOEC (1.13 mg Sb/L) has been derived in a study on the fish Pimephales promelas. According to the ECHA R10 guidance, an assessment factor of 10 shall be applied on the lowest NOEC when NOECs from three trophic levels are available. However, according to footnote c in the ECHA R10 guidance, when deriving a PNECaquatic, an assessment factor of 50 should be used on the lowest of three NOECs covering three trophic levels when the lowest NOEC has not been generated from that trophic level showing the lowest L(E)C50 in the short term test. According to Appendix IV in the TGD, fish (lowest NOEC) and hydra (lowest L(E)C50) both belong to the trophic level “Secondary consumers”. As a consequence, this footnote does not apply for this dataset, and an assessment factor of 10 should be used. Using the assessment factor of 10 on the lowest NOEC results in the following PNECaquatic = 0.113 mg Sb/L. This matches the PNEC derived in the EU RAR for diantimony trioxide of 0.113 mg Sb/L.
PNEC aqua (marine water): 0.0113 mg/L	100	Extrapolation method: assessment factor The only reliable and relevant toxicity study of antimony available for the marine environment is an acute toxicity study on the marine fish Pagrus major, which resulted in a LC50 (96 h) of 6.9 mg Sb/L. Therefore, toxicity data from tests on freshwater organisms are used to derive a PNECmarine water. Relevant and reliable long–term toxicity studies are available from three trophic levels. The lowest NOEC (28d; 1.13 mg Sb/L) has been derived in a study on the fish Pimephales promelas. According to the ECHA R10 guidance, an assessment factor of 100 should be applied to the lowest of three long-term NOECs from three freshwater or saltwater species (normally algae and/or crustaceans and/or fish) representing three trophic levels. However, according to

PNEC	Assessment factor	Remarks/Justification
		footnote c in the ECHA R10 guidance, when deriving a PNECmarine water, an assessment factor of 500 should be applied to the lowest of three NOECs when the lowest NOEC has not been derived from the trophic level with the lowest EC50. According to Appendix IV in the TGD, fish (lowest NOEC) and hydra (lowest L(E)C50) both belong to the trophic level "Secondary consumers". As a consequence, this footnote does not apply for this dataset, and an assessment factor of 100 should be used. Using an assessment factor of 100 on the lowest of the three available freshwater NOECs results in the following PNECmarine water = 11.3 µg Sb/L. This matches the PNEC derived in the EU RAR for diantimony trioxide of 11.3 µg Sb/L.
		The PNECintermittent is intended to indicate a concentration higher than the PNECaquatic which can be tolerated by aquatic communities for short exposure periods. It is therefore based on the most sensitive acute effect. For antimony the most sensitive acute endpoint is an LC50 of 1.77 mg Sb/L for the hydra Chlorohydra viridissimus. An assessment factor of 100 is applied, which results in a PNECintermittent of 0.0177 mg Sb/L. Due to the very small difference in exposure concentrations reported to result in acute and chronic effects this PNEC is actually lower than the PNECaquatic. It is therefore not taken forward in the risk assessment as it is assumed that the PNECaquatic, which is based on a larger dataset of more sensitive endpoints, will also protect against short term exposure.

7.1.2.2. PNEC sediment

The derivation of the PNEC is described in the table below.

Table 76: PNEC sediment

PNEC	Assessment factor	Remarks/Justification
PNEC sediment (freshwater): 11.2 mg/kg sediment dw	10	Extrapolation method: assessment factor Reliable and relevant chronic NOEC values are available for three species with different living and feeding conditions. According to the ECHA R10 guidance the PNECsediment shall be derived from the lowest NOEC divided by an assessment factor of 10. The lowest NOEC (78 mg Sb/kg ww or 112 mg Sb/kg dw) has been derived for the midge Chironomus riparius and the oligochaete Lumbriculus variegatus. This results in the following PNECsediment = 11.2 mg Sb/kg dw (7.8 mg Sb/kg ww). This matches the PNEC derived in the EU RAR for diantimony trioxide.
PNEC sediment (marine water): 2.24 mg/kg sediment dw	50	Extrapolation method: assessment factor No additional studies on the toxicity of antimony to marine sediment organisms were available. Therefore the PNEC sediment (marine) is based on the freshwater data. According to the ECHA R10 guidance the PNECsediment marine shall be derived from the lowest NOEC divided by an assessment factor of 50. The lowest NOEC (78 mg Sb/kg ww or 112 mg Sb/kg dw) has been derived for the midge Chironomus riparius and the oligochaete Lumbriculus variegatus. This results in the following PNECsediment = 2.24 mg Sb/kg dw (1.56 mg Sb/kg ww). This matches the PNEC derived in the EU RAR for diantimony trioxide.

7.2. Terrestrial compartment

7.2.1. Toxicity test results

During the slow transformation of Sb_2O_3 in soil into soluble Sb, the bioavailable Sb concentration (i. e. Sb in soil solution) will gradually increase and there will, as a consequence, not be a constant “toxic pressure” during the exposure period. As long as full equilibrium is not reached, the total Sb toxicity will be underestimated. However, the use of soluble Sb salts for toxicity testing introduces other changes in soil chemistry, besides increasing the concentration of Sb, such as increased concentrations of counter ions (e. g. chloride, sulphate) and protons. These changes in soil chemistry also have the potential to affect the observed toxic response.

At TC NES I ´07 it was concluded that the preferred exposure regime for terrestrial toxicity studies is sufficiently aged soil spiked with Sb_2O_3. This would ensure i) a constant Sb pore water concentration (i. e. constant toxic pressure) during the entire test period and ii) avoids toxic effects due to increased concentrations of counter ions and/or protons.

TC NES I ´07 decided that both the critical NOECs on plants (Oorts et al., 2005; 5.8 mg Sb/kg dw) and invertebrates (Kuperman et al., 2002; Phillips et al., 2002; both 58 mg Sb/kg dw) would be overruled by the results of new plant and invertebrate tests, if the latter were considered valid. Two new toxicity studies, which are both considered valid and were performed in the same Sb_2O_3-spiked and sufficiently aged soil, generated the toxicity data for invertebrates, plants and microrganisms that are used to derive the $PNEC_{soil}$(and thereby overrule the results by Oorts et al. (2005), Kuperman et al. (2002), and Phillips et al. (2002)).

The first of these two studies was performed by Smolders et al. (2007) and reported on the endpoints of lettuce emergence and growth (ISO 11269-2), barley root elongation (ISO 11269-1), and nitrification rate (ISO 14238). The second study was performed by Moser (2007) and reported on the endpoints of mortality and reproduction of *Folsomia candida* (ISO 11267).

7.2.1.1. Toxicity to soil macro-organisms

The results are summarised in the following table:

Table 77: Overview of effects on soil macro-organisms

Method	Results	Remarks	Reference
Eisenia fetida (annelids) long-term toxicity (laboratory study) Substrate: natural soil ISO 11268-2 (Effects of Pollutants on Earthworms. 2. Determination of Effects on Reproduction) Greene et al. 1988. Protocol for short-term toxicity screening of hazardous waste sites. EPA/600/3-88/029. US EPA, Corvallis, OR. 102 p.	NOEC (21 d): 60 mg/kg soil dw element (Sb) (nominal) based on: reproduction NOEC (14 d): 617 mg/kg soil dw element (Sb) (nominal) based on: mortality LOEC (21 d): 86 mg/kg soil dw element (Sb) (nominal) based on: reproduction LOEC (14 d): 697 mg/kg soil dw element (Sb) (nominal) based on: mortality EC50 (21 d): 70 mg/kg soil dw element (Sb) (nominal) based on: reproduction	3 (not reliable) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material: antimony sulphate**	Simini M, Checkai RT, Kuperman RG, Philips CT, Speicher JA & Barclift DJ (2002) Kuperman, RG, Checkai, RT, Simini M, Phillips CT, Speicher JA & Barclift DJ (2006)

Method	**Results**	**Remarks**	**Reference**
Enchytraeus albidus (annelids) long-term toxicity (laboratory study) Substrate: artificial soil OECD Guideline 207 (Earthworm, Acute Toxicity Tests)	NOEC (21 d): 760 mg/kg soil dw element (Sb) (meas. (not specified)) based on: mortality NOEC (42 d): 760 mg/kg soil dw element (Sb) (meas. (not specified)) based on: mortality NOEC (42 d): 760 mg/kg soil dw element (Sb) (meas. (not specified)) based on: reproduction LOEC (21 d): 2012 mg/kg soil dw element (Sb) (meas. (not specified)) based on: mortality LOEC (42 d): 2012 mg/kg soil dw element (Sb) (meas. (not specified)) based on: mortality LOEC (42 d): 2012 mg/kg soil dw element (Sb) (meas. (not specified)) based on: reproduction	3 (not reliable) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material: antimony trichloride**	Heijerick D & Vangheluwe M (2003b)
Enchytraeus sp. (annelids) long-term toxicity (laboratory study) Substrate: natural soil ISO/CD 16387 (draft) Soil quality-effects of pollutants on Enchytraeidae (Enchytraeus sp.)-Determination of effects on reproduction and survival (January 2001)	NOEC (28 d): 100 mg/kg soil dw element (Sb) (nominal) based on: reproduction NOEC (14 d): 384 mg/kg soil dw element (Sb) (nominal) based on: mortality LOEC (28 d): 140 mg/kg soil dw element (Sb) (nominal) based on: reproduction LOEC (14 d): 538 mg/kg soil dw element (Sb) (nominal) based on: mortality EC50 (28 d): 316 mg/kg soil dw element (Sb) (nominal) based on: reproduction	3 (not reliable) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material: antimony sulphate**	Kuperman RG, Checkai RT, Philips CT, Simini M, Speicher JA & Barclift DJ (2002) Kuperman, RG, Checkai, RT, Simini M, Phillips CT, Speicher JA & Barclift DJ (2006)
Folsomia candida (Collembola (soil-dwelling springtail)) long-term toxicity (laboratory study)	NOEC (28 d): ≥ 10119 mg/kg soil dwelement (Sb) (meas. (initial)) based on: mortality	1 (reliable without restriction) key study	Moser TH (2007)

Method	Results	Remarks	Reference
ISO 11267 (Inhibition of Reproduction of Collembola by Soil Pollutants)	NOEC (28 d): 999 mg/kg soil dwelement (Sb) (meas. (initial)) based on: reproduction NOEC (28 d): 9.7 mg Sb/L dissolved (Sb dissolved in pore water) (meas. (not specified)) based on: reproduction NOEC (28 d): 320 mg/kg soil dw element (total Sb in soil, corrected for complete dissolution of Sb2O3 in soil) (estimated) based on: reproduction LOEC (28 d): 2930 mg/kg soil dw element (Sb) (meas. (initial)) based on: reproduction LOEC (28 d): 18.7 mg Sb/L dissolved (Sb dissolved in pore water) (meas. (not specified)) based on: reproduction LOEC (28 d): 710 mg/kg soil dw element (total Sb in soil, corrected for complete dissolution of Sb2O3 in soil) (estimated) based on: reproduction EC50 (28 d): ≥ 10119 mg/kg soil dw element (Sb) (meas. (initial)) based on: reproduction	read-across from supporting substance (structural analogue or surrogate) **Test material: diantimony trioxide**	
Folsomia candida (Collembola (soil-dwelling springtail)) long-term toxicity (laboratory study) ISO 11267 (Inhibition of Reproduction of Collembola by Soil Pollutants)	NOEC (28 d): ≥ 1804 mg/kg soil dw element (Sb) (meas. (initial)) based on: reproduction NOEC (28 d): ≥ 1804 mg/kg soil dw element (Sb) (meas. (initial)) based on: mortality NOEC (28 d): ≥ 13.8 mg Sb/lSb dissolved in pore water (meas. (not specified)) based on: reproduction NOEC (28 d): 13.8 mg Sb/l	3 (not reliable) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material: diantimony trioxide**	Oorts K, Gasco G & Smolders E (2005b)

Method	Results	Remarks	Reference
	Sb dissolved in pore water (meas. (not specified)) based on: mortality		
Folsomia candida (Collembola (soil-dwelling springtail)) long-term toxicity (laboratory study) ISO 11267 (Inhibition of Reproduction of Collembola by Soil Pollutants)	NOEC (28 d): 28 mg/kg soil dw element (Sb) (meas. (initial)) based on: reproduction NOEC (28 d): 28 mg/kg soil dw element (Sb) (meas. (initial)) based on: mortality NOEC (28 d): 0.75 mg Sb/l Sb dissolved in pore water (meas. (not specified)) based on: reproduction NOEC (28 d): 0.75 mg Sb/l Sb dissolved in pore water (meas. (not specified)) based on: mortality LOEC (28 d): 72 mg/kg soil dw element (Sb) (meas. (initial)) based on: reproduction LOEC (28 d): 72 mg/kg soil dw element (Sb) (meas. (initial)) based on: mortality LOEC (28 d): 1.79 mg Sb/l Sb dissolved in pore water (meas. (not specified)) based on: reproduction LOEC (28 d): 1.79 mg Sb/l Sb dissolved in pore water (meas. (not specified)) based on: mortality EC10 (28 d): 11 mg/kg soil dw element (Sb) (meas. (initial)) based on: reproduction EC10 (28 d): 0.2 mg/kg soil dwSb dissolved in pore water (meas. (not specified)) based on: reproduction EC50 (28 d): 65 mg/kg soil dw element (Sb) (meas. (initial)) based on: reproduction EC50 (28 d): 1.8 mg Sb/l	3 (not reliable) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material: diantimony trioxide**	Oorts K, Gasco G & Smolders E (2005b)

Method	Results	Remarks	Reference
	Sb dissolved in pore water (meas. (not specified)) based on: reproduction		
Folsomia candida (Collembola (soil-dwelling springtail)) long-term toxicity (laboratory study) ISO 11267 (Inhibition of Reproduction of Collembola by Soil Pollutants)	NOEC (28 d): 836 mg/kg soil dw element (Sb) (meas. (initial)) based on: mortality NOEC (28 d): <10 mg/kg soil dw element (Sb) (meas. (initial)) based on: reproduction NOEC (28 d): 14.35 mg Sb/l Sb dissolved in pore water (meas. (not specified)) based on: mortality NOEC (28 d): <0.62 mg Sb/l Sb dissolved in pore water (meas. (not specified)) based on: reproduction LOEC (28 d): 1741 mg/kg soil dwelement (Sb) (meas. (initial)) based on: mortality LOEC (28 d): 10 mg/kg soil dw element (Sb) (meas. (initial)) based on: reproduction LOEC (28 d): 15.85 mg Sb/l Sb dissolved in pore water (meas. (not specified)) based on: mortality LOEC (28 d): 0.62 mg Sb/l Sb dissolved in pore water (meas. (not specified)) based on: reproduction EC10 (28 d): 1452 mg/kg soil dw element (Sb) (meas. (initial)) based on: mortality EC10 (28 d): 389 mg/kg soil dw element (Sb) (meas. (initial)) based on: reproduction EC10 (28 d): 15.46 mg Sb/l Sb dissolved in pore water (meas. (not specified)) based on: mortality	3 (not reliable) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material: antimony trichloride**	Oorts K, Gasco G & Smolders E (2005b)

Method	Results	Remarks	Reference
	EC10 (28 d): 13.2 mg Sb/l Sb dissolved in pore water (meas. (not specified)) based on: reproduction EC50 (28 d): 1558 mg/kg soil dw element (Sb) (meas. (initial)) based on: mortality EC50 (28 d): 667 mg/kg soil dw element (Sb) (meas. (initial)) based on: reproduction EC50 (28 d): 15.51 mg Sb/l Sb dissolved in pore water (meas. (not specified)) based on: mortality EC50 (28 d): 14 mg Sb/l Sb dissolved in pore water (meas. (not specified)) based on: reproduction		
Folsomia candida (Collembola (soil-dwelling springtail)) long-term toxicity (laboratory study) ISO 11267 (Inhibition of Reproduction of Collembola by Soil Pollutants)	NOEC (28 d): 100 mg/kg soil dw element (Sb) (nominal) based on: mortality NOEC (28 d): 100 mg/kg soil dw element (Sb) (nominal) based on: reproduction LOEC (28 d): 126 mg/kg soil dw element (Sb) (nominal) based on: mortality LOEC (28 d): 126 mg/kg soil dw element (Sb) (nominal) based on: reproduction EC50 (28 d): 169 mg/kg soil dw element (Sb) (nominal) based on: reproduction	3 (not reliable) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material: antimony sulphate**	Phillips CT, Checkai RT, Kuperman RG, Simini M, Speicher JA & Barclift DJ (2002) Kuperman RG, Checkai RT, Simini M, Phillips CT, Speicher JA & Barclift DJ (2006)

There are no acute toxicity studies on soil invertebrates available. There are six studies available on antimony toxicity to invertebrates which included analytical confirmation of the exposure concentrations but, as stated above, only the study by Moser (2007), which results in a bounded NOEC of 999 mg Sb/kg dw, will be used when deriving a PNEC$_{soil}$.

Study 1

Moser (2007) studied the toxicity of Sb to the springtail *Folsomia candida* (reproduction and mortality) in approximately 32-week aged Sb_2O_3amended soil. This study was carried out according to ISO 11267 (1999). Ten (10-12 d old) synchronised springtails were put onto 30 g moist soil in a glass vessel during an exposure period of four weeks. Five replicates were used for each test concentration and the measured test concentrations used were 90, 322, 999, 2930, 10119 mg Sb/ kg soil dw. Additionally, the springtails were also tested in an uncontaminated field soil control and an untreated artificial soil as a further control, which was based on OECD 207. The positive control used on springtail reproduction was the herbicide Betosip (a. i. 159 g/L phenmedipham). Granulated dry yeast served as food for the springtails and was added onto the soil surface at the beginning of the test and after 14 days. At the end of the exposure period, the number of juveniles in each test vessel was counted after floating. The mortality of the springtails was also recorded. At day 28, the pH and the moisture of the artificial soil for each concentration in additional vessels without springtails were determined. It was shown that the pH and moisture content did not diverge from the guideline recommendations.

For both mortality and reproduction, the highest effect observed was below 50% in any of the treatments. Consequently, LC50 and EC50 values could not be calculated but were estimated as being >10119 mg Sb/kg soil dw for both endpoints. The NOEC for reproduction was determined as 999 mg Sb/kg dw. The LOEC for reproduction was derived as 2930 mg Sb/kg dw. All values refer to measured concentrations.

The results from this study are considered reliable. During the ageing period a substantial part of the Sb_2O_3 was transformed into soluble Sb. Further transformation of Sb_2O_3 after this ageing period would have been very slow and so a sufficiently constant toxic pressure is considered to have been obtained during these bioassays. Using Sb_2O_3 amended soils avoids the confounding effects of counter-ions or lowered pH, and therefore the observed toxic effects can be attributed to the increasing Sb dose alone.

However, since not all Sb_2O_3had dissolved during the aging period, the NOEC of 999 mg total Sb/kg dw underestimates the toxicity. Therefore, the NOEC is based on the pore water Sb concentration multiplied by the equilibrium solid: liquid distribution coefficient (Kd) for Sb in this soil. The Kd value for the soil used in the present study is 38 L/kg, which is the value observed for the Sb_2O_3 amended soil aged for five years and for the soluble $SbCl_3$ added to soil (Oorts et al., 2005). The resulting NOEC after this correction is 370 mg Sb/kg dw (9.7 mg Sb/l * 38 L/kg).

Study 2

Simini and co-workers (2002) exposed the earthworm *Eisenia fetida*, measuring adult survival and cocoon production according to ISO 11268-2 (International Organization for Standardization, 1998b), to various concentrations of $Sb_2(SO_4)_3$ in a natural sandy loam. The original ISO method was designed for use with artificial soil (USEPA Standard Artificial Soil). However, research by the authors showed that the test could also successfully be conducted using natural soils (Kuperman et al. 2004). The method was modified for use with natural soils having physical and chemical characteristics that support a relatively high level of metal bioavailability. After performing a range-finding test, a definitive test was performed with an exposure period of three weeks and seven concentration groups, besides the control. The nominal added concentrations used to assess effects on reproduction were 60, 86, 104, 124, 149, 179, and 215 mg Sb/kg. Four replicates were used per concentration, with five earthworms per replicate. Toxicity tests using the salt carrier control $CaSO_4.2H_2O$ were performed in order to evaluate the effect of sulphate. The positive control was 4-nitrophenol. All soil treatment concentrations and controls were subjected to simulated aging/weathering procedures, which included alternating wetting/air-drying cycles for three weeks prior to commencement of definite tests. Hydration and moisture equilibration followed the weathering and aging process before exposing organisms in definitive studies.

Sulphate control treatments showed no statistically significant effect on reproduction when compared with negative controls. Juvenile or cocoon production in positive controls (4-nitrophenol) were within the baseline established for the laboratory cultures of *E. fetida*. The decrease in pH in the highest Sb treatment was below 1.0 pH unit, compared with untreated soil (i. e. negative control). In the sulphate control, soil pH decreased by less than 1.0 pH unit in the 7000 and 35000 mg SO_4 treatments, when compared with negative controls.

Only about 58 % of nominal Sb concentrations were recovered. The nominal concentrations were used when determining the ecotoxicological parameters of Sb with the results of definitive tests of Sb toxicity resulting in NOEC/LOEC values for adult survival of 617/697 mg Sb/kg and 60/86 for juvenile production. The authors recommended that the nominal values should be adjusted to 58 % of the nominal values, as that was the average recovery. This may not necessarily be an exposure problem, but could instead be an analytical problem and therefore the nominal values are used. Since the Sb soil concentration was not measured during the course of the experiment it is not possible to know if a steady-state was reached after the three weeks of aging/weathering, but it is not considered likely. As a consequence, the toxicity pressure has probably not been constant during the exposure period.

The results from this study can only be used as supportive evidence. According to the ISO protocol on which the study was based, the earthworm reproduction test is considered valid only if the coefficient of variation for the mean number of cocoons from the control is ≤ 30 % at the end of the test. The coefficient of variation for the reproductive performance of the control in the study by Simini et al. (2002) could be calculated from the raw data in an annex and was 45 %.

To conclude, the results from this study are considered unreliable.

Study 3

Oorts et al. (2005) studied the toxicity of Sb to the springtail *Folsomia candida* (reproduction and mortality) in freshly spiked (Sb_2O_3or $SbCl_3$) and in five-year aged Sb_2O_3 amended soil. The study was carried out according to ISO 11267 (1999). Ten (10-12 d old) synchronised springtails were exposed to 30 g moist soil in a glass vessel during an exposure period of four weeks. Granulated dry yeast was added onto the soil surface every week and served as food for the springtails. At the end of the exposure period the number of juveniles in each test vessel was counted after floating. The mortality of the springtails was also recorded.

A large variation in the toxicity data in several of the exposed groups was noticeable and reduces the possibility of detecting deviations from the control. The authors, who used ANOVA and the post hoc Duncan test, reported an unbounded NOEC of 2000 mg Sb/kg dw nominal concentration (measured concentration of 1864 mg Sb/kg dw) for number of juveniles and adult mortality. The use of the step-down approach with the Jonckheere-Terpstra test results in a NOEC of 1000 mg Sb/kg dw nominal concentration (= measured concentration of 897 mg Sb/kg dw) and a LOEC of 2000 mg Sb/kg dw nominal concentration (measured concentration of 1864 mg Sb/kg dw).

An unbounded NOEC of 1804 mg Sb/kg dw (measured concentration) results from a freshly Sb_2O_3spiked soil. Using statistical methods considered more appropriate for dose-response studies (the step-down approach), rather than the method used by Oorts et al. (2005), which was ANOVA and Duncan´s method, results in a bounded NOEC of 897 mg Sb/kg dw. However, due to the increasing porewater concentration, which indicates that the toxicity could still increase during the exposure period, a derived NOEC (not unbounded) using freshly spiked Sb_2O_3 soils may be too high. Having the same soil solution concentration in an exposure regime with constant toxic pressure (i. e. aged soil) may have resulted in lower NOEC values.

The data from freshly $SbCl_3$spiked soils results in a NOEC < 20 mg Sb/kg dw (measured concentration of 10 mg Sb/kg dw). This "less than” value was considered unreliable by Oorts et al. (2005) since they considered that the weight of evidence showed no toxic effect at doses up to 500 mg Sb/kg dw nominal concentration (measured concentration of 384 mg Sb/kg dw). The difference in response between the control and the first five $SbCl_3$doses, up to 500 mg Sb/kg dw, nominal concentration was considered to be within the non-significant variation in response that was observed for Sb_2O_3 amended soils.

However, it is difficult to draw any firm conclusions about the absence of toxicity for the freshly spiked Sb_2O_3soils up to 500 mg Sb/kg dw nominal concentration, given the variation in response, within and between the different dose groups, especially for the number of juveniles. The NOEC < 20 mg Sb/kg nominal dose resulting from the freshly spiked $SbCl_3$, which was considered unreliable by Oorts et al. (2005), has a measured Sb soil solution concentration of 0.62 mg/L. This is almost identical to the Sb soil solution concentration of 0.63 mg Sb/L, which was measured in the freshly spiked Sb_2O_3 nominal concentration 200 mg Sb/kg dw group, a dose group with three out of four values lower than the lowest of the control values. In addition, the toxic pressure between the two concentrations most likely differed because Sb_2O_3 is expected to dissolve slowly over the time frame of the experiment. The Sb soil solution concentration measured in the freshly spiked $Sb_2O_3$500 mg nominal dose group, was 9 mg Sb/L, in which three out of four values were again lower than the lowest of the control values.

The effect observed in the aged Sb_2O_3 spiked soil study at the two highest doses may be explained by the presence of a herbicide, which was a mixture including substances with toxicity towards earthworms. The Sb soil solution concentration in the highest of the remaining doses, i. e. 24 mg Sb/kg dw., was 0.745 mg Sb/L. The four data points at that concentration indicate a response, but the difference is not significant.

Study 4

In Heijerick and Vangheluwe (2003) the microdrile oligochaete *Enchytraeus albidus* was exposed to various concentrations of trivalent antimony ($SbCl_3$) in an artificial soil and the endpoints mortality and reproduction were studied. The standard soil used is described and recommended by OECD (1984). This study was performed with five replicates per concentration, five concentrations (measured concentration range: 59.1 – 6980 mg Sb/kg dw) and a control (measured concentration 0.37 mg Sb/kg dw), with each replicate consisting of 10 enchytraeids with fully developed clitellum. Four replicates were used for the toxicity test and the remaining replicate was used for the chemical analyses. Adult enchytraeids were exposed for 21 days (which is the period in which cocoons are produced). After this period, the adult enchytraeids were removed from the soil and survival was examined. The cocoons were incubated for another 21 days (i. e. a total of 42 days) after which reproduction was measured (number of young enchytraeids). The resulting NOEC and LOEC were 760 mg Sb/mg kg dw and 2012 mg Sb/mg kg dw, respectively, for both endpoints. One of the three performance criteria specified in the OECD test guideline 220 (Enchytraeid reproduction test) that should be met in the control in order for the test to be valid was not fulfilled. This is that the coefficient of variation for number of juveniles should not be higher than 50 % at the end of the reproduction phase; in this study it was 81 %. The results from this study are therefore considered to be unreliable.

Study 5

Kuperman et al. (2002) exposed the enchytraeid *Enchytraeus crypticus*, measuring adult survival and juvenile production according to ISO 16387 (International Organization for Standardization, 2003) to various concentrations of $Sb_2(SO_4)_3$in a natural sandy loam. The original ISO methods were designed for use with artificial soil (USEPA Standard Artificial Soil). These methods were modified for use with natural soils having physical and chemical characteristics that support a relatively high level of metal bioavailability. The modifications included different soil hydration levels that have lower water holding capacity compared with the artificial soil, and a shorter duration test for*E. crypticus*(28 vs. 42 d) because of the shorter generation time of this species compared with *Enchytraeus albidus*, for which the ISO 16387 test conditions were optimized.

In the enchytraeid *Enchytraeus crypticus* reproduction test ten enchytraeid adults with eggs in the clitellum were placed on top of prepared soil in each container and exposed to $Sb_2(SO_4)_3$ for four weeks. The nominal concentrations of Sb used were 0, 100, 140, 196, 274, 384, 538, 753, and 1054 mg Sb/kg. Four replicates were used per concentration. After two weeks, soil in each test container was carefully searched and adult worms were removed and counted. The remaining test substrate, including any cocoons laid during the first two weeks of the test, was incubated for an additional two weeks. After four weeks from the start of the test, soil in the test containers was fixed with ethanol and Rose Bengal biological stain was added. Staining continued for a minimum of 24 hours. The content of each test container was wet-sieved and transferred to a counting tray and worms were counted. Measurement endpoints included number of surviving adults after 14 days and number of juveniles produced after 28 days.

The authors were not able to measure the Sb concentrations in the soils adequately. Despite a change of methods and improved efficiency of Sb extraction, on average only 58 % of the added antimony could be measured. For this reason, nominal concentrations were used to determine the ecotoxicological parameters for Sb. Using methods developed by the authors, the amended soils were weathered and aged for three weeks before definitive testing. Hydration and moisture equilibration followed the weathering and aging process before exposing organisms in definitive studies. The decrease in pH in the highest Sb treatment was 1.2 pH units when compared with untreated soil (i. e. negative control). In the sulphate control, soil pH decreased by less than 1.0 pH units in both the 7000 and 35000 mg SO_4-treatments when compared with the negative control. Sulphate control treatments showed no statistically significant ($p>0.05$) effect on adult survival or reproduction measurement endpoints when compared to the negative controls. Juvenile or cocoon production in positive controls (4-nitrophenol) were within the baseline established for the laboratory cultures of *E. crypticus*. Results of definitive tests of Sb toxicity resulted in NOEC/LOEC values for adult survival of 384/538 mg Sb/kg. For juvenile production the resulting NOEC/LOEC values were 100/140 mg Sb/kg. The authors recommended that the nominal values should be adjusted to 58 % of the nominal values, as that was the average recovery. This may not necessarily be an exposure problem, but could instead be an analytical problem. However, since it is not known which of the two alternatives is best it was decided to use the conversion factor of 0.58 which results in NOECs of 58 mg Sb/kg and 223 mg Sb/kg for juvenile production and adult survival respectively. Since the Sb soil concentration was not measured during the course of the experiment it is not possible to know if a steady-state was reached after the three weeks of aging/weathering, but this is not considered to be likely. As a consequence, the toxicity pressure was probably not constant during the exposure period.

The results indicate a NOEC for the reproduction of *Enchytraeus crypticus* of 58 mg Sb/kg dw. There are, however, some concerns about using this value since i) the result was obtained using $Sb_2(SO_4)_3$which means that counter ions (i. e. sulphate) and protons were also added to the soil, which may have influenced the results, ii) it is not known how the toxic pressure may have varied over the exposure period, and iii) the authors had difficulties in measuring the Sb concentration in soil.

Study 6

Phillips et al. (2002) exposed the collembolan *Folsomia candida*, measuring adult survival and juvenile production according to ISO 11267 (International Organization for Standardization, 1998a), to various concentrations of $Sb_2(SO_4)_3$ in a natural sandy loam.

In the *Folsomia candida* reproduction test, 10-12 day-old juveniles were exposed to $Sb_2(SO_4)_3$for four weeks. The nominal concentrations of Sb used were 0, 100, 140, 196, 274, 384, 538, 753, and 1054 mg Sb/kg. Five replicates were used per concentration. After the exposure period, purified water was added to each test chamber to bring the level up to half its volume. After gentle mixing with a spatula, the chamber was examined under a dissecting microscope for the presence of juveniles and adults. The juveniles that floated to the surface were counted and removed. This procedure was repeated until no other springtails floated to the surface. The chamber was given a final mixing and examined once more to ensure that all individuals were counted. Adult survival and juvenile production were used as endpoints.

The authors were not able to measure the Sb concentrations in the soils adequately. Despite a change of methods and improved efficiency of Sb extraction, on average only 58 % of the added antimony could be measured. For this reason, nominal concentrations were used to determine the ecotoxicological parameters for Sb. Using methods developed by the authors, the amended soils were weathered and aged for three weeks before definitive testing. Hydration and moisture equilibration followed the weathering and aging process before exposing organisms in definitive studies. The decrease in pH in the highest Sb treatment (nominal concentration = 1054 mg Sb/kg dw.) was 1.2 pH unit when compared with untreated soil (i. e. negative control). In the sulphate control, soil pH decreased by less than 1.0 pH unit in both the 7000 and 35000 mg SO_4-treatment when compared with the negative control. Sulphate control treatments showed no statistically significant ($p>0.05$) effect on adult survival or reproduction measurement endpoints when compared to the negative controls. Juvenile or cocoon production in positive controls (carbamate) were within the baseline established for the laboratory cultures of *F. candida*. Results of definitive tests of Sb toxicity resulted in NOEC/LOEC values of 100/126 mg Sb/kg for adult survival. Juvenile production was significantly ($p=0.045$) decreased in the lowest positive Sb treatment compared with the negative control, producing an unbound LOEC of 100 mg Sb/kg (based on Fisher's least-significant-difference pairwise comparison test). Bounded NOEC and LOEC values of 100 and 126 mg/kg were determined using the more conservative Bonferroni mean comparison test. The authors recommended that the nominal values should be adjusted to 58 % of the nominal values, as that was the average recovery. This may not necessarily be an exposure problem, but could instead be an analytical problem. However, since it is not known which of the two alternatives is best it was decided to use a conversion factor of 0.58 which results in a NOEC of 58 mg Sb/kg for both juvenile production and adult survival.

The results indicate that a NOEC for reproduction may be around 58 mg Sb/kg, and the authors suggested that it could be even lower. The post hoc test used by the authors (Fisher's LSD) does not correct for multiple comparisons, which means that it is easier to find statistical significance with the Fisher's LSD test (it has more power) than with other multiple comparison tests that correct for multiple comparisons, but that also means that false positive results occur in more than 5 % of analyses. In order to correct for this the authors used the Bonferroni correction on the p-values resulting from the *Folsomia candida* reproduction test, which resulted in a NOEC of 100 mg Sb/kg. The Bonferroni correction is generally overly conservative, especially for large k. However, the use of the step-down approach also results in a NOEC of 100 mg Sb/kg. There are some concerns about using this value since i) the result was obtained using $Sb_2(SO_4)_3$ which means that counter ions (i. e. sulphate) and protons were also added to soil, which may have influenced the results, ii) it is not known how the toxic pressure may have varied over the exposure period, and iii) the authors had difficulties when measuring the Sb concentration in soil.

The following information is taken into account for effects on soil arthropods for the derivation of PNEC:

The chronic NOEC for toxicity to soil invertebrates is 999 mg Sb/kg dw (Moser, 2007).

7.2.1.2. Toxicity to terrestrial plants

The results are summarised in the following table:

Table 78: Overview of effects on terrestrial plants

Method	Results	Remarks	Reference
Hordeum vulgare (Monocotyledonae (monocots)) short-term toxicity (laboratory study) seed germination/root elongation toxicity test Substrate: natural soil ISO 11269-1 (1993) Soil quality - Determination of the effects of pollutants on soil flora - Part 1: Method for the measurement of inhibition of root growth	*Hordeum vulgare*: NOEC (5 d): 999 mg/kg soil dw element (Sb) (meas. (initial)) based on: root elongation *Hordeum vulgare*: LOEC (5 d): 2930 mg/kg soil dw element (Sb) (meas. (initial)) based on: root elongation *Hordeum vulgare*: EC10 (5 d): 1931 mg/kg soil dw element (Sb) (meas. (initial)) based on: root elongation *Hordeum vulgare*: EC50 (5 d): 6937 mg/kg soil dw element (Sb) (meas. (initial)) based on: root elongation *Hordeum vulgare*: NOEC (5 d): 9.7 mg Sb/L Sb dissolved in pore water (meas. (not specified)) based on: root elongation *Hordeum vulgare*: LOEC (5 d): 18.7 mg Sb/L Sb dissolved in pore water (meas. (not specified)) based on: root elongation *Hordeum vulgare*: EC10 (5 d): 14 mg Sb/L Sb dissolved in pore water (meas. (not specified)) based on: root elongation *Hordeum vulgare*: EC50 (5 d): 40 mg Sb/L Sb dissolved in pore water (meas. (not specified)) based on: root elongation *Hordeum vulgare*: NOEC (5 d): 370 mg/kg soil dw element (total Sb in soil, corrected for complete dissolution of Sb2O3 in soil) (estimated) based on: root elongation *Hordeum vulgare*: LOEC (5	1 (reliable without restriction) key study read-across from supporting substance (structural analogue or surrogate) **Test material: diantimony trioxide**	Smolders E, Mertens J & Buekers, J (2007)

Method	Results	Remarks	Reference
	d): 710 mg/kg soil dw element (total Sb in soil, corrected for complete dissolution of Sb2O3 in soil) (estimated) based on: root elongation *Hordeum vulgare*: EC10 (5 d): 532 mg/kg soil dw element (total Sb in soil, corrected for complete dissolution of Sb2O3 in soil) (estimated) based on: root elongation *Hordeum vulgare*: EC50 (5 d): 1520 mg/kg soil dw element (total Sb in soil, corrected for complete dissolution of Sb2O3 in soil) (estimated) based on: root elongation		
Lactuca sativa (Dicotyledonae (dicots)) long-term toxicity (laboratory study) seedling emergence toxicity / vegetative vigour test Substrate: natural soil ISO 11269-2 (1995) Soil quality - Determination of the effects of pollutants on soil flora - Part 2: Effect of chemicals on the emergence and growth of higher plants	*Lactuca sativa*: NOEC (6 d): >= 10119 mg/kg soil dw element (Sb) (meas. (initial)) based on: seedling emergence *Lactuca sativa*: NOEC (17 d): 2930 mg/kg soil dw element (Sb) (meas. (initial)) based on: growth (shoot weight) *Lactuca sativa*: LOEC (17 d): 10119 mg/kg soil dw element (Sb) (meas. (initial)) based on: growth (shoot weight) *Lactuca sativa*: EC10 (17 d): 4517 mg/kg soil dw element (Sb) (meas. (initial)) based on: growth (shoot weight) *Lactuca sativa*: EC50 (17 d): 7514 mg/kg soil dw element (Sb) (meas. (initial)) based on: growth (shoot weight) *Lactuca sativa*: NOEC (17 d): 18.7 mg Sb/L Sb dissolved in pore water (meas. (not specified)) based on: growth (shoot weight)	2 (reliable with restrictions) key study read-across from supporting substance (structural analogue or surrogate) **Test material: diantimony trioxide**	Smolders E, Mertens J & Buekers, J (2007)

Method	Results	Remarks	Reference
	Lactuca sativa: LOEC (17 d): 54.4 mg Sb/L Sb dissolved in pore water (meas. (not specified)) based on: growth (shoot weight) *Lactuca sativa*: EC10 (17 d): 27 mg Sb/L Sb dissolved in pore water (meas. (not specified)) based on: growth (shoot weight) *Lactuca sativa*: EC50 (17 d): 42 mg Sb/L Sb dissolved in pore water (meas. (not specified)) based on: growth (shoot weight) *Lactuca sativa*: NOEC (17 d): 710 mg/kg soil dw element (total Sb in soil, corrected for complete dissolution of Sb2O3 in soil) (estimated) based on: growth (shoot weight) *Lactuca sativa*: LOEC (17 d): 2067 mg/kg soil dw element (total Sb in soil, corrected for complete dissolution of Sb2O3 in soil) (estimated) based on: growth (shoot weight) *Lactuca sativa*: EC10 (17 d): 1026 mg/kg soil dw element (total Sb in soil, corrected for complete dissolution of Sb2O3 in soil) (estimated) based on: growth (shoot weight) *Lactuca sativa*: EC50 (17 d): 1596 mg/kg soil dw element (total Sb in soil, corrected for complete dissolution of Sb2O3 in soil) (estimated) based on: growth (shoot weight)		
Lactuca sativa (Dicotyledonae (dicots)) long-term toxicity (laboratory study)	*Lactuca sativa*: NOEC (24 d): >= 1804 mg/kg soil dw element (Sb) (meas. (initial)) based on: growth (shoot yield)	3 (not reliable) supporting study read-across from	Oorts K, Gasco G & Smolders E (2005c)

Method	Results	Remarks	Reference
vegetative vigour test Substrate: natural soil ISO 11269-2 Soil quality - Determination of the effects of pollutants on soil flora - Part 2: Effects of chemicals on the emergence and growth of higher plants	*Lactuca sativa*: NOEC (24 d): >= 13.8 mg Sb/l Sb dissolved in pore water (meas. (not specified)) based on: growth (shoot yield)	supporting substance (structural analogue or surrogate) **Test material: diantimony trioxide**	
Lactuca sativa (Dicotyledonae (dicots)) long-term toxicity (laboratory study) vegetative vigour test Substrate: natural soil ISO 11269-2 Soil quality - Determination of the effects of pollutants on soil flora - Part 2: Effects of chemicals on the emergence and growth of higher plants	*Lactuca sativa*: NOEC (24 d): 28 mg/kg soil dw element (Sb) (meas. (initial)) based on: growth (shoot yield) *Lactuca sativa*: LOEC (24 d): 72 mg/kg soil dw element (Sb) (meas. (initial)) based on: growth (shoot yield) *Lactuca sativa*: NOEC (24 d): 0.75 mg Sb/l Sb dissolved in pore water (meas. (not specified)) based on: growth (shoot yield) *Lactuca sativa*: LOEC (24 d): 1.79 mg Sb/l Sb dissolved in pore water (meas. (not specified)) based on: growth (shoot yield) *Lactuca sativa*: NOEC (24 d): 5.8 mg/kg soil dw element (Sb) (meas. (initial)) based on: growth (shoot yield) *Lactuca sativa*: NOEC (24 d): 0.13 mg Sb/l Sb dissolved in pore water (meas. (not specified)) based on: growth (shoot yield)	3 (not reliable) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material: diantimony trioxide**	Oorts K, Gasco G & Smolders E (2005c)
Lactuca sativa (Dicotyledonae (dicots)) long-term toxicity (field study) vegetative vigour test Substrate: natural soil 2 months field study with Lactuca	*Lactuca sativa*: NOEC (65 d): >= 116 mg/kg soil dw element (Sb) (meas. (initial)) based on: growth (shoot yield) *Lactuca sativa*: NOEC (65 d): >= 116 mg/kg soil dw element (Sb) (meas. (initial)) based on: growth	3 (not reliable) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material:**	Oorts K, Gasco G & Smolders E (2005c)

Method	Results	Remarks	Reference
sativa	(root yield)	**diantimony trioxide**	
Lactuca sativa (Dicotyledonae (dicots)) long-term toxicity (laboratory study) vegetative vigour test Substrate: natural soil ISO 11269-2 Soil quality - Determination of the effects of pollutants on soil flora - Part 2: Effects of chemicals on the emergence and growth of higher plants	*Lactuca sativa*: NOEC (24 d): 43.2 mg/kg soil dw element (Sb) (meas. (initial)) based on: growth (shoot yield) *Lactuca sativa*: LOEC (24 d): 73.1 mg/kg soil dw element (Sb) (meas. (initial)) based on: growth (shoot yield) *Lactuca sativa*: EC10 (24 d): 222 mg/kg soil dw element (Sb) (meas. (initial)) based on: growth (shoot yield) *Lactuca sativa*: EC50 (24 d): 505 mg/kg soil dw element (Sb) (meas. (initial)) based on: growth (shoot yield) *Lactuca sativa*: NOEC (24 d): 1.4 mg Sb/l Sb dissolved in pore water (meas. (not specified)) based on: growth (shoot yield) *Lactuca sativa*: LOEC (24 d): 3.6 mg Sb/l Sb dissolved in pore water (meas. (not specified)) based on: growth (shoot yield) *Lactuca sativa*: EC10 (24 d): 12.6 mg Sb/l Sb dissolved in pore water (meas. (not specified)) based on: growth (shoot yield) *Lactuca sativa*: EC50 (24 d): 13.6 mg Sb/l Sb dissolved in pore water (meas. (not specified)) based on: growth (shoot yield)	3 (not reliable) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material: antimony trichloride**	Oorts K, Gasco G & Smolders E (2005c)
Pinus sylvestris Substrate: natural soil	*Pinus sylvestris*: NOEC (10 mo): > 0.3 mg/kg soil dw element (nominal) based on: root biomass, shoot biomass and fine root length	3 (not reliable) supporting study read-across from supporting substance	Hartley J, Cairney JWG, Freestone P, Woods C & Meharg AA (1999)

Method	Results	Remarks	Reference
		(structural analogue or surrogate) **Test material: antimony tartrate**	
Pinus sylvestris Substrate: natural soil	*Pinus sylvestris*: LOEC (10 mo): 1.1 mg/kg soil dw element (meas. (not specified)) based on: root biomass, shoot biomass and fine root length	3 (not reliable) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material: antimony**	Hartley J, Cairney JWG, Freestone P, Woods C & Meharg AA (1999)

Discussion

There are three studies available on Sb toxicity to plants that included analytical confirmation of the exposure concentrations. However, as stated above, only the study by Smolders et al. (2007), which resulted in a bounded NOEC of 999 mg Sb/kg dw, will be used when deriving PNEC$_{soil}$.

Study 1

(Smolders et al., 2007) studied the toxicity of Sb to plants (lettuce emergence and growth, and barley root elongation) in Sb_2O_3 amended soil, which had aged for 31 weeks in the field (starting 2006-12-19). The dose levels used were 3, 90, 322, 999, 2930 and 10119 mg Sb/kg dw (measured concentrations).

For the plant growth assay using lettuce (ISO 11269-2), the number of seedlings that emerged per pot and the shoot yield of the plants were determined. The soils were fertilized and pre-incubated for six days before twenty lettuce (*Lactuca sativa*) seeds were sown per pot. Four pots per concentration were used. The plants emerged after three days, and at day six the number of seedlings was counted and the plants were thinned out to five plants per pot. Fourteen days after 50 % of the control plants (day 3) had emerged, plants were harvested and the fresh biomass was weighed.

According to guideline ISO 11269-2 from 1995, emergence should be sufficient to provide five healthy seedlings per pot in the control. In the study, six healthy seedlings were recorded in one control replicate, and 7-16 seedlings were recorded in three replicates, resulting in an arithmetic mean number of 10 seedlings per control pot. However, according to guideline ISO 11269-2 from 2005, the emergence should be at least seven healthy seedlings out of 10 planted seeds, which means that the lettuce emergence is not valid according to these newer validity criteria.

The lettuce assay resulted in a bounded NOEC of 2930 mg Sb/kg dw, a LOEC of 10119 mg Sb/kg dw and an EC10 of 4517 mg Sb/kg dw for lettuce biomass (shoot) yield, and an unbounded NOEC of 10119 mg Sb/kg dw for lettuce seed emergence.

To conclude, this means that the lettuce results (emergence and growth) from this study are valid and reliable according to the guideline under which it was performed, but the results on emergence are not compliant with the criteria in the most recent ISO guideline (from 2005). However, even if emergence in the control group had been 70 % (and the study therefore would have been valid according to the most recent ISO guideline), an effect on emergence would still not have been detected. Based on this, the results are useful since they provide a very strong indication that growth is a more sensitive endpoint than emergence for lettuce.

In the barley root elongation assay (ISO 11269 -1), barley (*Hordeum vulgare*) was pre-germinated for three days and four seeds were planted in each pot. Three replicates per Sb concentration were used. After five days of growth, intact roots were washed out of the soil matrix and the length of the longest root on each plant was recorded. The mean length of the longest root of all replicate samples per soil was determined. There are no validity criteria given in the guideline. However, a mean root elongation in the controls at test end of 9.1 cm with a relative standard deviation of 5.1 % indicates that the results from the root elongation test are valid. The root elongation study resulted in a bounded NOEC of 999 mg Sb/kg dw, a LOEC of 2930 mg Sb/kg dw and an EC10 of 1931 mg Sb/kg dw.

The Sb pore water concentrations corresponding to the bounded NOECs of 999 and 2930 mg Sb/kg dw were 9.7 and 18.7 mg Sb/L respectively.

In order to answer the question of whether the soil amended with $Sb_2O_3$and aged for 31 weeks was fully reacted and equilibrated, the authors used modelling of the Sb_2O_3 solubilization process in soil based on all previously available data. It was found that 31 weeks of ageing in the field was sufficient to have fully reacted and equilibrated soils at high doses, but not at low doses. For example, the model predicts an Sb pore water concentration of 26 mg Sb/L at 999 mg Sb/kg dw whereas the observed concentration in this study was 9.7 mg Sb/L.

As long as equilibrium is not reached the pore water concentration will gradually increase during the course of time. How much the pore water concentration will have increased, from the initiation of the study until termination, is not possible to know since the pore water concentration was only measured at the end of the study. However, the difference in pore water concentration between the initiation and termination of the bioassay is not considered to be of importance because the test started after 31 weeks of ageing and the bioassay continued only for another 5 d. As a consequence, a sufficiently constant toxicity pressure is considered to have been maintained during the bioassays.

During the 31 weeks ageing period a substantial part of the Sb_2O_3 was transformed into soluble Sb. It is expected that further transformation of Sb_2O_3 after this ageing period would be very slow and so a sufficiently constant toxic pressure is considered to have been obtained during these bioassays. Using Sb_2O_3 amended soils avoids confounding effects of counter-ions or lowered pH, and therefore observed toxic effects can be attributed to the increasing Sb dose only. However, since not all Sb_2O_3 had dissolved during the aging period used, the NOEC of 999 mg Sb/kg dw would underestimate the toxicity at complete transformation of Sb_2O_3 into soluble forms. This is because the equilibrium pore water concentration was not reached at this test concentration during the study. Therefore, the NOEC is based on the porewater concentration (9.7 mg Sb/L), which is multiplied by the equilibrium solid: liquid distribution coefficient (Kd) for Sb in this soil. The Kd value for the soil used in the present study is 38 L/kg, which is the value observed for the Sb_2O_3 amended soil aged for five years and for the soluble $SbCl_3$added to soil (Oorts et al., 2005). The resulting NOEC after having performed this calculation is 370 mg Sb/kg dw (= 9.7 mg Sb/L x 38 L/kg).

Study 2

In the second study, Oorts et al. (2005) studied the toxicity of Sb to plants (lettuce shoot yield) in freshly spiked soil using Sb_2O_3 (measured concentrations 0.6, 12.4, 34.5, 67, 124, 422, 897, 1804 mg Sb/kg dw) or $SbCl_3$ (measured concentrations 0.6, 10, 43.2, 73.1, 159, 384, 836, 1741 mg Sb/kg dw), and in five year aged Sb_2O_3 spiked soil (measured concentrations 0.4, 5.8, 28.4, 71.7 and 116 mg Sb/kg dw.). In addition, a plant growth test was also performed in the field in the aged Sb_2O_3 spiked soil.

In order to study the potential effect of the counter ion (chloride) resulting from spiking with $SbCl_3$, soil was also spiked with $CaCl_2$ at equivalent chloride doses using identical preincubation and spiking procedures. Soil solution from all Sb amended soils was extracted four weeks after spiking by centrifugation and analysed using ICP within two days after extraction. Soil solution was also analysed with respect to pH and electrical conductivity.

The lettuce shoot yield test was based on ISO 11269-2. Twenty lettuce seeds (*Lactuca sativa* cv.) were sown in three replicate pots for each treatment. Following emergence, seedlings were thinned to five plants per pot. Plants were harvested 24 days after sowing. At harvest, shoots were cut just above the soil surface and dried at 70º C for at least 48 hours, and the dry matter yield was recorded.

In addition to the plant test performed in the laboratory, a field study using aged Sb_2O_3 spiked soil was also performed, using 18 day old pre-cultivated plants. Four plants were planted on each container with aged soil (control, and the originally added concentrations 10, 50 and 250 mg Sb/kg). After an exposure period of two months the plants were harvested (2005-09-15). Above ground biomass and root weight were measured for each plant. Edible parts were selected and oven dried at 50º C. Dry plant material was ground and used for Sb analysis. Total metal concentrations were determined by boiling nitric acid digestion and subsequent analysis with inductively coupled plasma - optical emission spectroscopy (ICP-OES).

The use of freshly spiked Sb_2O_3resulted in an unbound NOEC of 1804 mg Sb/kg dw (nominal added concentration of 2000 mg Sb/kg dw).

The use of freshly spiked $SbCl_3$ resulted in a NOEC of 43 mg Sb/kg dw (nominal concentration of 50 mg Sb/kg dw).

The use of five-year aged aged Sb_2O_3 spiked soil in a laboratory test resulted in dose-response effects of Sb, and a NOEC of 28 mg Sb/kg dw (nominal concentration, 50 mg Sb/kg dw). Oorts et al. (2005) did not consider that this result could be correct and found that the container with the highest concentration was located next to a hedgerow that had been treated with an herbicide (CANYON, a mixture of glyphosphate, diuron and diflufenican). The second highest concentration resulted from mixing soil from the highest dose with a lower dose, and this had therefore also been potentially contaminated with the herbicide. Thus, the effects observed in the two highest doses may be confounded due to the presence of an herbicide.

Another test using the aged Sb_2O_3 spiked soil in a field study with 18 day old precultivated plants resulted in unbounded NOECs of 116 mg Sb/kg dw for both lettuce shoot yield and root yield. However, the experimental set-up for the lettuce grown in the laboratory and in the field differed in several important aspects, which is why it is difficult to draw any conclusions based on the difference in toxicity (e. g. the field tests were initiated with 18 day old pre-cultivated plants while seeds were used in the laboratory tests).

Since the original test design for the aged Sb_2O_3 spiked soils tested in the laboratory included four doses and a control, removing the two highest doses results in two doses and a control. The highest remaining dose is 28 mg Sb/kg dw. The evaluation of the data using a step-down approach results in a NOEC of 5.8 mg Sb/kg dw (nominal added concentration of 10 mg Sb/kg dw). There are, however, several concerns about this value: (i) there are only two doses above the control (of which the lowest is the NOEC and the other is a LOEC), (ii) the NOEC value resulting from $SbCl_3$ is 43 mg Sb/kg (for which the observed effect is attributed to the effect of the chloride), (iii) the Sb pore water concentration, which is used as a simplified measure of toxic pressure, was far below the critical pore water concentration in the freshly spiked soils (the largest pore water concentration in the aged soils was 0.7 mg Sb/l, whereas the lowest LOEC in freshly $SbCl_3$ spiked soils was 3.6 mg Sb/l), and (iv) the maximum internal Sb concentration in the shoot for the five-year aged Sb_2O_3 spiked soils (1 mg Sb/kg dw) was far below the value at which toxicity was observed in soil freshly spiked with Sb_2O_3 or $SbCl_3$ (>10 mg Sb/kg dw).

Study 3

Hartley et al. (1999) investigated the effects of antimony exposure on Scots pine (*Pinus sylvestris*). In two experiments plants were either exposed to a natural soil that had been contaminated by a chemical accident or to control soil that was amended with antimony tartrate.

The natural soil was contaminated with multiple metals (Cd, Pb, Zn, Sb and Cu) and so the effects cannot be attributed solely to antimony. For this reason, this part of the study was considered unreliable.

In the second part of the experiment antimony tartrate was added directly to a pot containing the 6 month old seedlings, so there was no equilibration time. In addition, although the method states that soil concentrations were measured at 6, 7, 8 and 9 month harvests the results of these measurements are not reported in the paper. No effects on shoots or roots were observed at the single nominal concentration of 0.3 mg Sb/kg tested. For these reasons, this study is not considered reliable.

The following information is taken into account for toxicity on terrestrial plants for the derivation of PNEC:

The chronic NOEC for toxicity to plants is 999 mg Sb/kg dw (Smolders et al., 2007).

7.2.1.3. Toxicity to soil micro-organisms

The results are summarised in the following table:

Table 79: Overview of effects on soil micro-organisms

Method	Results	Remarks	Reference
Species/Inoculum: soil ISO 14238	NOEC (28 d): >= 10119 mg/kg soil dw element (Sb) (meas. (initial)) based on: nitrate formation rate (SIN)	1 (reliable without restriction) key study	Smolders E, Mertens J & Buekers J (2007)

Method	Results	Remarks	Reference
	NOEC (7 d): 2930 mg/kg soil dw element (Sb) (meas. (initial)) based on: nitrate formation rate (PNR) NOEC (7 d): 18.7 mg Sb/l Sb dissolved in pore water (meas. (not specified)) based on: nitrate formation rate (PNR) NOEC (7 d): 710 mg/kg soil dw element (total Sb in soil, corrected for complete dissolution of Sb2O3 in soil) (estimated) based on: nitrate formation rate (PNR) LOEC (7 d): 10119 mg/kg soil dw element (Sb) (meas. (initial)) based on: nitrate formation rate (PNR) LOEC (7 d): 54.4 mg Sb/l Sb dissolved in pore water (meas. (not specified)) based on: nitrate formation rate (PNR) LOEC (7 d): 2067 mg/kg soil dw element (total Sb in soil, corrected for complete dissolution of Sb2O3 in soil) (estimated) based on: nitrate formation rate (PNR)	read-across from supporting substance (structural analogue or surrogate) **Test material: diantimony trioxide**	
Species/Inoculum: soil OECD Guideline 216 (Soil Microorganisms: Nitrogen Transformation Test)	NOEC (28 d): >= 1804 mg/kg soil dw element (Sb) (meas. (initial)) based on: nitrate formation rate (SIN) NOEC (10 d): >= 1804 mg/kg soil dw element (Sb) (meas. (initial)) based on: nitrate formation rate (PNR) NOEC (28 d): >= 13.9 mg Sb/L Sb dissolved in pore water (meas. (not specified)) based on: nitrate formation rate (SIN) NOEC (10 d): >= 13.9 mg Sb/L Sb dissolved in pore water (meas. (not	3 (not reliable) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material: diantimony trioxide**	Oorts K, Gasco G & Smolders E (2005b)

Method	Results	Remarks	Reference
	specified)) based on: nitrate formation rate (PNR)		
Species/Inoculum: soil OECD Guideline 216 (Soil Microorganisms: Nitrogen Transformation Test)	NOEC (28 d): >= 116 mg/kg soil dw element (Sb) (meas. (initial)) based on: nitrate formation rate (SIN) NOEC (10 d): >= 116 mg/kg soil dw element (Sb) (meas. (initial)) based on: nitrate formation rate (PNR) NOEC (28 d): >= 4.2 mg Sb/L Sb dissolved in pore water (meas. (not specified)) based on: nitrate formation rate (SIN) NOEC (10 d): >= 4.2 mg Sb/L Sb dissolved in pore water (meas. (not specified)) based on: nitrate formation rate (PNR)	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material: diantimony trioxide**	Oorts K, Gasco G & Smolders E (2005b)
Species/Inoculum: soil OECD Guideline 216 (Soil Microorganisms: Nitrogen Transformation Test)	NOEC (28 d): 384 mg/kg soil dw element (Sb) (meas. (initial)) based on: nitrate formation rate (SIN) NOEC (7 d): 73.1 mg/kg soil dw element (Sb) (meas. (initial)) based on: nitrate formation rate (PNR) NOEC (28 d): 13.1 mg Sb/L Sb dissolved in pore water (meas. (not specified)) based on: nitrate formation rate (SIN) NOEC (7 d): 3.6 mg Sb/L Sb dissolved in pore water (meas. (not specified)) based on: nitrate formation rate (PNR) EC10 (28 d): 646 mg/kg soil dw element (Sb) (meas. (initial)) based on: nitrate formation rate (SIN) EC10 (7 d): 88 mg/kg soil dw element (Sb) (meas. (initial)) based on: nitrate formation rate (PNR) EC10 (28 d): 13.9 mg Sb/L Sb dissolved in pore water	3 (not reliable) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material: antimony trichloride**	Oorts K, Gasco G & Smolders E (2005b)

Method	Results	Remarks	Reference
	(meas. (not specified)) based on: nitrate formation rate (SIN) EC10 (7 d): 4.7 mg Sb/L Sb dissolved in pore water (meas. (not specified)) based on: nitrate formation rate (PNR) EC50 (28 d): 1126 mg/kg soil dw element (Sb) (meas. (initial)) based on: nitrate formation rate (SIN) EC50 (7 d): 335 mg/kg soil dw element (Sb) (meas. (initial)) based on: nitrate formation rate (PNR) EC50 (28 d): 14.9 mg Sb/L Sb dissolved in pore water (meas. (not specified)) based on: nitrate formation rate (SIN) EC50 (7 d): 9.7 mg Sb/L Sb dissolved in pore water (meas. (not specified)) based on: nitrate formation rate (PNR) LOEC (28 d): 836 mg/kg soil dw element (Sb) (meas. (initial)) based on: nitrate formation rate (SIN) LOEC (7 d): 159 mg/kg soil dw element (Sb) (meas. (initial)) based on: nitrate formation rate (PNR) LOEC (28 d): 14.4 mg Sb/L Sb dissolved in pore water (meas. (not specified)) based on: nitrate formation rate (SIN) LOEC (7 d): 6.2 mg Sb/L Sb dissolved in pore water (meas. (not specified)) based on: nitrate formation rate (PNR)		
Species/Inoculum: soil OECD Guideline 216 (Soil Microorganisms: Nitrogen Transformation Test)	NOEC (28 d): >= 823 mg/kg soil dw element (Sb) (meas. (initial)) based on: nitrate formation rate	3 (not reliable) supporting study read-across from	LISEC (2002)

Method	Results	Remarks	Reference
	LOEC (28 d): > 823 mg/kg soil dw element (Sb) (meas. (initial)) based on: nitrate formation rate	supporting substance (structural analogue or surrogate) **Test material: diantimony trioxide**	

Discussion

There are three studies available on antimony toxicity to microflora which included analytical confirmation of the exposure concentrations. However, as stated above, only the study by Smolders et al. (2007), which resulted in a bounded NOEC of 2930 mg Sb/kg dw, will be used when deriving PNEC$_{soil}$.

Study 1

Smolders et al. (2007) studied the toxicity of Sb to native microorganisms in 31 week aged Sb_2O_3amended soil (measured concentrations = 3, 90, 322, 999, 2930 and 10119 mg Sb/kg dw) using a nitrification assay based on ISO 14238-1 (1997). The test measures the Substrate Induced Nitrification rate (SIN), which is the nitrification rate induced after substrate (NH_4^+) supply measured during 28 days of incubation. Soils were preincubated for three days at a moisture content of 23 %, taking into account the volume of (NH_4) $_2SO_4$(80 mg N/ml) that was added later. Afterwards (NH_4) $_2SO_4$ was added tosoil to a final concentration of 100 mg NH_4-N/kg fresh soil by thoroughly mixing. Soils were incubated in an incubation room at 20° C. After 0, 7 (additional sampling compared to the ISO protocol) and 28 days, the $NO_3^-$and NH_4^+concentrations were measured colorimetrically in a shaken and centrifuged soil extract (soil in 12.5 ml KCl, 2 h end-over-end shaking, 15 min centrifugation at 3500g) and the SIN was calculated as the daily production of NO_3^-/kg soil, based on the measurements between day 0 and day 28. The nitrate production rate was also calculated in the initial period (0-7 days) during which there was unlimited substrate present; this endpoint is termed the Potential Nitrification Rate (PNR, also referred to as the nitrification potential in the literature). This means that two endpoints were defined: the SIN and the PNR. The ISO guideline only recommends the latter, but the PNR endpoint has been reported as being more sensitive than the SIN endpoint since the former is measured during the initial period after NH_4^+addition, i. e. when the substrate is still abundantly present (Smolders et al*.*, 2001). The test was performed in duplicate per soil. No validity criteria are given in the guideline ISO 14238-1 from 1997, but the nitrification rate in the control soil was considered to be within expected limits and the results are therefore considered reliable.

The SIN endpoint resulted in an unbounded NOEC of >10119 mg Sb/kg dw, while the PNR endpoint resulted in a bounded NOEC of 2930 mg Sb/kg dw and a LOEC of 10119 mg Sb/kg dw. The pore water concentrations corresponding to the NOEC and LOEC for the PNR were 18.7 and 54.4 mg Sb/L, respectively. It was not possible to derive an EC_{10}or EC_{50} for the PNR endpoint.

As already mentioned, when presenting the results for plants by the same authors (i. e. Smolders et al., 2007), the calculation of the PNEC$_{soil}$ needs to correct for the fact that the results were obtained from soils that were not fully equilibrated.

Study 2

Oorts et al. (2005) studied the toxicity of antimony to native microorganisms in freshly spiked soil (Sb_2O_3or $SbCl_3$; control (measured concentration of 0.6 mg Sb/kg dw, plus nominal added concentrations of 20, 50, 100, 200, 500, 1000 and 2000 mg Sb/kg dw.), and in five-year aged Sb_2O_3amended soil (measured concentrations 0.4, 5.8, 28.4, 71.7 and 116.3 mg Sb/kg dw). Seven days after metal spiking, triplicate subsamples of each Sb concentration of each soil were amended with 100 mg NH_4-N/kg fresh soil. The increase in soil NO_3-N in a period of 28 days after substrate addition was measured by analysing the soil nitrate colorimetrically in a centrifuged soil extract (KCl, subsample, L/S = 2.5, 2 h end-cover-end shaking, n=3). Two different endpoints were measured: the substrate induced nitrification (SIN) and the potential nitrification rate (PNR). SIN was calculated as the percentage of added NH_4-substrate transformed into NO_3-N during 28 days (OECD 216). PNR (mg NO_3-N/kg fresh soil/day) was calculated as the slope of the regression of soil nitrate concentration against time. The PNR endpoint has been reported as being more sensitive than the SIN endpoint since the former is measured during the initial period after NH_4^+addition, i. e. when the substrate is still abundantly present (Smolders et al*.*, 2001). For the $SbCl_3$amended samples, PNR was calculated for a seven day incubation period, and for a ten day period for all the other soils. The incubation time selected was identical for each sample within a dose-response study (i. e. for each Sb dose).

There was no toxicity observed in either of the Sb_2O_3 spiked soils, i. e. the freshly spiked soil and the five-year aged soils, for either of the two endpoints PNR and SIN. However, the reason for the lack of response in the aged Sb_2O_3 soil might be that the microflora had adapted to the different Sb concentrations during the five years of aging, and that therefore no response is to be expected. This is in contrast to the freshly spiked $SbCl_3$ soils where the $NOEC_{PNR}$ was 73 mg Sb/kg dw (nominal added concentration of 100 mg Sb/kg dw) and the $NOEC_{SIN}$ was 384 mg Sb/kg dw (nominal added concentration of 500 mg Sb/kg dw). The potential effect of the counter ion, i. e. Cl^-, was tested separately. Increased concentrations of chloride decreased the PNR but not the SIN (a slight stimulation was observed with increasing concentrations of chloride). The measured PNR and SIN in the separate chloride toxicity experiment were about 70-80 % of the PNR and SIN in the control of the freshly spiked $SbCl_3$ soils. In addition, the dose-response pattern with decreasing PNR with increasing concentrations of chloride (measured as electrical conductivity) differed. It is therefore not clear how much of the decrease in PNR resulted from increased concentrations of chloride. According to the authors (Oorts et al., 2005), about 50 % of the decrease was explained by increased concentrations of chloride. The rest of the decrease in PNR and all of the decrease of SIN was proposed by Oorts et al(2005) to be due to reduced pH, since the nitrification process has been reported to be sensitive to changes in pH.

The response observed for SIN is easier to interpret since there was no observed effect of the counter ion. The observed response may therefore be assumed to result either from increased concentrations of Sb or decreased pH. The NOEC for SIN in the freshly spiked $SbCl_3$ soil based on the measured Sb soil solution concentration was 13.1 mg Sb/L. This can be compared with the Sb soil solution concentration measured in the highest freshly Sb_2O_3 spiked soil, which was 13.9 mg Sb/L. Despite probable differences in toxic pressure in these two exposure regimes, the two results both appear to indicate that the toxicity to microorganisms measured via SIN is low. The reason for a large response in the freshly spiked $SbCl_3$ soils is unclear as there was a relatively small increase in the measured Sb soil solution concentration from 13.1 mg Sb/L (pH = 6.68) with 96 % substrate used, to 14.4 mg Sb/L (pH = 6.58) with 73 % substrate used, to 15.85 mg Sb/L (pH = 5.94) with 15 % substrate used. The decrease from 96 % substrate used at pH = 6.58 to 73 % substrate used at pH = 6.58 appears especially large if the reduction of pH is a major factor. This is since the decrease in pH from the control with 100 % of the substrate used at pH = 7.04 to pH = 6.68 only reduced the substrate used to 96 %.

There was no response of SIN in the aged Sb_2O_3 spiked soils up to soil solution concentrations of 4.2 mg Sb/L, which may be due to adapted microflora, but is also in agreement with the NOECs in the freshly spiked soils, since no toxicity was observed at that Sb concentration level.

Study 3

In this report by LISEC (2002), the effect of Sb_2O_3 on the nitrogen transformation activity of soil organisms was studied. The soil used was a sandy loam. The test substance was applied using quartz sand as a carrier. The test was performed with three replicates (with an additional fourth replicate for Sb measurement), and five concentrations (range: 2.6-823 mg Sb/mg dw) and a control (concentration below detection limit of 1.8 mg Sb/kg dw). The test was terminated after 28 days when the quantities of nitrate were determined. There were no significant difference in nitrogen transformation activity between the highest concentration used (823 mg Sb/kg dw) and the control, resulting in a LOEC > 823 mg Sb/kg dw. The value of this unbounded NOEC is unclear due to the uncertainty associated with a lack of response using freshly spiked Sb_2O_3 soils. It is not possible to know how the Sb soil solution concentration changed (most probably increased) during the exposure period. It can therefore not be excluded that the absence of observed effects, resulting in an unbounded NOEC, may be the consequence of too low an Sb soil solution concentration for too long during the exposure period. To conclude, the results from this study are not considered valid.

The following information is taken into account for toxicity on soil micro-organisms for the derivation of PNEC:

The NOEC for toxicity to soil microorganisms is 2930 mg Sb/kg dw (Smolders et al., 2007).

7.2.1.4. Toxicity to other terrestrial organisms

No studies were identified on other terrestrial organisms.

7.2.2. Calculation of Predicted No Effect Concentration (PNEC soil)

The derivation of the PNEC is described in the table below.

Table 80: PNEC soil

PNEC	Assessment factor	Remarks/Justification
PNEC soil: 37 mg/kg soil dw	10	Extrapolation method: assessment factor Valid chronic NOECs are available for plants (999 mg Sb/kg dw), invertebrates (999 mg Sb/kg dw), and microorganisms (2930 mg Sb/kg dw). The NOEC of 999 mg Sb/kg dw for plants is from the barley root elongation assay. There are no indications from the other available studies on antimony phytotoxicity that other endpoints are more sensitive when compared to root growth. According to the TGD, the resulting PNECsoil will be the lowest of these three NOECs divided by an assessment factor of 10. Since the lowest NOEC is 999 mg Sb/kg dw the resulting PNECsoil thus becomes 99.9 mg Sb/kg dw. These NOECs result from studies using soil spiked with Sb2O3 and aged for 31 weeks before testing. During the ageing period a substantial part of the Sb2O3 was transformed into soluble Sb. It is expected that further transformation of Sb2O3 after this ageing period would be very slow, and as a result a sufficiently constant toxic pressure is considered to have been obtained during these bioassays. Using Sb2O3 amended soils avoids confounding effects of counter ions or lowered pH, and therefore observed toxic effects can be attributed to the increasing Sb dose only. However, since not all Sb2O3 had dissolved during the aging period used, a standard TGD procedure of dividing the lowest NOEC (999 mg Sb/kg dw; Hordeum vulgare root elongation and Folsomia candida reproduction) with an assessment factor of 10, resulting in a PNECsoil of 99 mg Sb/kg dw, would underestimate the toxicity. This is because the equilibrium pore water concentration was not reached at this test concentration during the study. Instead the PNECsoil is based on the porewater concentration measured at the NOEC (9.7 mg Sb/L), divided by an assessment factor of 10 which is multiplied by the equilibrium solid:liquid distribution coefficient (Kd) for Sb in this soil. The Kd value for the soil used in the key studies (Moser, 2007 and Smolders et al, 2007) is 38 l/kg. This matches the PNEC derived in the EU RAR for diantimony trioxide of 37 mg Sb/kg soil dw.

7.3. Atmospheric compartment

In general, methods have not been developed to directly determine effects of substances that arise from exposure via the atmospheric compartment. One exception to this is the ability to perform inhalation studies with mammals. These studies have been performed for antimony, and they are evaluated in the relevant sections of the Human Health portion of the CSR. Also, the Man via the Environment evaluation considers exposure via the atmospheric compartment, and this is addressed in Sections 9 and 10. There is, however, no hazard assessment of risk characterization of effects of antimony in the air compartment for ecotoxicity endpoints. This is consistent with Section 10.7.1 of the REACH Guidance.

Antimony is not expected to contribute to ozone depletion, ozone formation, global warming or acidification. Therefore, the evaluation of atmospheric risk is not required

7.4. Microbiological activity in sewage treatment systems

7.4.1. Toxicity to aquatic micro-organisms

The results are summarised in the following table:

Table 81: Overview of effects on micro-organisms

Method	Results	Remarks	Reference
activated sludge freshwater static ISO DIS 9509 (Method for Assessing the Inhibition of Nitrification of Activated Sludge Microorganisms by Chemicals and Waste Waters)	NOEC (4 h): 2.55 mg/L dissolved (Sb) (meas. (not specified)) based on: nitrification rate (inhibition) EC50 (4 h): 27 mg/L dissolved (Sb) (meas. (not specified)) based on: nitrification rate (inhibition)	2 (reliable with restrictions) key study read-across from supporting substance (structural analogue or surrogate) **Test material: Antimony trichloride**	EPAS NV (2005)

Discussion

There is one study available providing reliable data for toxicity to aquatic microorganisms (EPAS, 2005). In this study (EPAS, 2005) the effect of $SbCl_3$on nitrification inhibition in activated sludge was assessed according to the ISO 9509 protocol (Water quality – Method for assessing the inhibition of nitrification of activated sludge micro-organisms by chemicals and waste waters). The protocol was slightly modified as the NH_4-N concentration in the prescribed medium had an inhibitory effect on nitrification. The test was performed by aerating a nitrifying sludge in the presence and absence of Sb. The nominal Sb concentrations used ranged from 1.1 mg Sb/L to 1200 mg Sb/L. The protocol was modified by washing the sludge with tap water instead of demineralised water and medium because the proposed buffer was not sufficient to ensure a stable pH. By modifying the protocol this way, an activity in the sludge of 4.5 mg N/(g. h) could be calculated, which lies within the proposed interval of 2 to 6.5 mg N/(g. h). Each test solution was set up in duplicate. The flasks were incubated for 4 hours at a constant temperature and aerated in the dark. No inhibitory effects could be observed at a measured concentration of 2.55 mg Sb/L. Based on measured Sb concentrations an EC50 of 27 mg Sb/L was derived (confidence interval of 14-52 mg/L).

The following information is taken into account for effects on aquatic micro-organisms for the derivation of PNEC:

The lowest valid value for toxicity to aquatic microorganisms is a NOEC of 2.55 mg Sb/L and an EC50 of 27 mg Sb/L for inhibition of nitrification (EPAS, 2005).

7.4.2. PNEC for sewage treatment plant

The derivation of the PNEC is described in the table below.

Table 82: PNEC sewage treatment plant

Value	Assessment factor	Remarks/Justification
PNEC STP: 2.55 mg/L	1	Extrapolation method: assessment factor There is one relevant and reliable study available on microorganisms that can be used to derive the PNEC STP. Based on measured Sb concentrations a NOEC of 2.55 mg Sb/L and an EC50 of 27 mg Sb/L was derived. The PNEC STP can be calculated from the EC50 from a test performed with nitrifying bacteria by dividing the EC50 by 10 or can be set equal to the NOEC from such a test (ECHA R10 guidance). This would result in a PNECmicroorganisms of 2.55 or 2.7 mg Sb/L. Selecting the lowest of these results in PNEC STP = 2.55 mg Sb/L.

7.5. Non compartment specific effects relevant for the food chain (secondary poisoning)

7.5.1. Toxicity to birds

Data waiving

Information requirement: Toxicity to birds

Reason: other justification

Justification: In accordance with column 2 of REACH Annex X, the study on birds does not need to be conducted as sufficient reliable data is available from the mammalian dataset.

7.5.2. Toxicity to mammals

The mammalian toxicity data are discussed in detail in section 5.

7.5.3. Calculation of PNECoral (secondary poisoning)

Antimony has an estimated BCF of 40 for aquatic organisms and a BSAF of 1 for earthworms and is therefore not considered bioaccumulative nor to have the potential to biomagnify (Section 4.3). An assessment of secondary poisoning is therefore not required.

7.6. Conclusion on the environmental hazard assessment and on classification and labelling

The effect assessment has found a 72 h LC50 of 1.77 – 1.95 mg Sb/L performed on the invertebrates Chlorohydra viridissma and Hydra oligactis (TAI, 1990) as the lowest valid value for acute toxicity. Although the hydra data is suitable for use in the risk assessment, the classification and labelling guidance is clear that we should prefer data from standard test species. In a case where both are available, as they are here, then we should use the more standard result. The principle of classification is to indicate the relative toxicities of different substances and the use of data from standard test species would give a more consistent comparison against other substances which have classifications based on standard tests.

For the purposes of classification, data for Daphnids (DSD) or crustacea (CLP regulations) is preferred to fulfil the invertebrate endpoint. Therefore, the data for Hydra will not be used for the purposes of classification. The LC50 of 6.9 mg Sb/L for fish (Takayanagi, 2001) is thus the acute reference value used in environmental classification. The lowest valid NOEC values are above 1 mg Sb/L.

The solubility of Sb2O3 has been measured in a 7-days and a 28-days full transfomation/dissolution test (CanMET, 2004, LISEC, WE-14-018 and WE-14-020) following the Transformation/Dissolution protocol (OECD, 2001) and is reported in the EU RAR for diantimony trioxide.

After 7 days the lowest loading rate does not result in a dissolved Sb concentration above the acute ecotoxicity reference value.

After 7 days the moderate loading rate does not result in a dissolved Sb concentration above the acute ecotoxicity reference value.

After 7 days the highest loading rate does not result in a dissolved Sb concentration above the acute ecotoxicity reference value.

This could lead to a classification of R53 under the DSD and Chronic Category 4 under the CLP regulations.

An escape clause (leading to the removal of the classification) may be used if the dissolved metal ion concentration at the low loading rate after a total period of 28 days is less than or equal to the long-term NOECs.

A 28-day test with loading of 1 mg/L resulted in a dissolved concentration of 0.118 mg Sb/L. This value is less than the lowest reliable NOEC and so the classification is removed. Therefore, diantimony trioxide would not be classified for the environment.

The results from CanMET (2010) show a concentration of 0.176 mg Sb/L at 1 mg/l loading after 28 days, a higher concentration than previously reported. These results do not alter the conclusion of the EU RAR that an environmental classification is not required for diantimony trioxide.

This assessment agrees with the no classification proposal (proposed and accepted in the EU RAR) for diantimony trioxide.

8. PBT AND VPVB ASSESSMENT

Overall conclusion:

Based on the assessment described in the subsections below, diantimony trioxide is not a PBT / vPvB substance.

Justification:

The REACH Regulation (EC) 1907/2006) states that a PBT and vPvB (very persistent very bioaccumulative) assessment shall be conducted as foreseen in Article 14 (3) (d) in conjunction with Annex I Section 4 according to the criteria as laid down in Annex XIII (as updated in Commission Regulation (EU) No 253/2011 of 15 March 2011). The PBT and vPvB criteria of Annex XIII however only apply to organic substances, including organometals.

The draft Guidance to Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of substances and mixtures for metals and metal compounds qualitatively distinguishes metals from organometals based on their dissociation behaviour upon dissolution in water: *"Organometals do not dissociate or dissolve in water as the metal ion, as metals and inorganic metal compounds do. ... Metal compounds that contain an organic component but that dissociate easily in water or dissolve as the metal ion should be treated in the same way as (inorganic) metal compounds".*

The following Sb compounds from the i2a substance list beyond doubt represent inorganic substances: Sb metal, Sb_2O_3, Sb_2S_3, $SbCl_3$, Sb_2O_5, $NaSbO_3$, $SbCl_5$and $NaSb(OH)_6$. Whereas antimony triacetate ($Sb(CH_3COO)_3$) and diantimony tris ethylene glycolate ($Sb_2(C_2H_4O_2)_3$) contain organic moieties, they also clearly constitute inorganic substances, since they lack a covalent bond between the metal and any carbon atom of the anionic organic moiety. Thus, they do not comply with the IUPAC definition of organometallic compounds, despite that results from the transformation/dissolution tests conducted for both compounds indicated that both ligands appeared to stabilise Sb(III) in solution compared to other Sb(III) substances, which showed a more pronounced oxidation of Sb(III) to Sb(V) upon dissolution (CanMET, 2010). This is, however, no direct proof for the occurrence of Sb-complexes in solution and up to 31% of the dissolved Sb is still oxidised to Sb(V) within 28 days at pH 8.5. As argued in sections 4 and 7, inorganic Sb substances will dissolve and generate antimony ions in the environment (Vangheluwe et al., 2001) and it is the fate and ecotoxicity of the antimony ion that is of most relevance in assessing potential persistence, bioaccumulation and toxicity

Therefore, strictly spoken, there is no legal obligation for a PBT and vPvB assessment for these inorganic Sb substances. However, the available data has nevertheless been compared to the criteria and is discussed below. All inorganic Sb substances are covered by the PBT assessment of the Sb-ion released upon dissolution.

8.1 Assessment of PBT/vPvB properties – comparison with the criteria of Annex XIII

The criteria set out under REACH Annex XIII for determining whether a substance is PBT/vPvB are as follows:

Table 83: The criteria set out under REACH Annex XIII for determining whether a substance is PBT/vPvB.

Criterion	PBT criteria	vPvB criteria
P	Half-life (T½) > 60 d in marine water or Half-life (T½) > 40 d in fresh or estuarine water or Half-life (T½) > 180 d in marine sediment or Half-life (T½) > 120 d in fresh or estuarine water; sediment or Half-life (T½) in soil > 120 d	Half-life (T½) > 60 d in marine fresh or estuarine water or Half-life (T½) > 180 d in marine, fresh or estuarine water; sediment Half-life (T½) > 180 d in soil

Criterion	PBT criteria	vPvB criteria
B	BCF > 2000 L/kg in fresh or marine aquatic species	BCF > 5000 L/kg
T	Chronic NOEC < 0.01 mg/l for marine or freshwater organisms, or Substance is classified as carcinogenic (category 1 or 2), mutagenic (category 1 or 2), or toxic for reproduction (category 1, 2 or 3) or There is other evidence of chronic toxicity, as identified by the classifications: T, R48, or Xn, R48 according to Directive 67/548/EEC.	Not applicable

Note: (a) BCF is bioconcentration factor, NOEC is no-observed effect concentration and CMR is a substance classified as carcinogenic, mutagenic or toxic for reproduction
(b) For marine environmental risk assessment, half-life data in freshwater sediment can be overruled by data obtained under marine conditions
(c) Substances are classified when they fulfil the criteria for all three inherent properties for P, B and T. However, there is certain flexibility, for instance in cases where one criterion is marginally not fulfilled but the others are exceeded considerably.

8.1.1 Persistence assessment

Whereas antimony formally meets the criterion for persistence based on the absence of any degradation, this criterion is considered not to be applicable to inorganic elements. In addition, under conditions of a standard EUSES lake and the median partition coefficient for suspended matter, Sb meets the criteria for rapid removal from the water column.

8.1.2 Bioaccumulation assessment

Antimony does not meet the criteria for bioaccumulation because the BCF values reported for aquatic organisms are all much lower than the threshold of 2,000 l/kg, and there is evidence to support that antimony does not biomagnify in the food chain.. Therefore, diantimony trioxide is not considered bioaccumulative (B) or very bioaccumulative (vB) based on the definitive criteria.

8.1.3 Toxicity assessment

Chronic NOEC values are available for fish (Section 7.1.1.1.2), invertebrates (Section 7.1.1.2.2) and algae (Section 7.1.1.3). The lowest NOEC is 1.13 mg Sb/l for fish (Kimball, 1978b). Antimony and antimony compounds do not meet any of the PBT criteria based on carcinogenicity, mutagenicity or reprotoxicity and there is no evidence of other chronic concerns. Therefore, diantimony trioxide is not considered toxic (T) based on the definitive criteria.

8.1.4 Summary and overall conclusions on PBT or vPvB

Based on the assessment described in the subsections above antimony, and therefore diantimony trioxide, is not a PBT / vPvB substance. Therefore the assessment stops at this point.

8.2 Emission characterisation

Diantimony trioxide is not PBT or vPvB therefore this assessment is not required.

9. EXPOSURE ASSESSMENT

The exposure scenarios have been developed and formatted according to REACH guidance (Guidance on information requirements and chemical safety assessment, Part D: Exposure Scenario Building). This guidance qualifies this format to be used in the chemical safety report as well as for the purpose of communication in the supply chain (i.e. to be used in the extended safety data sheets).

In order to achieve full compliance with the format of the chemical safety report as laid down in Annex I of regulation (EC) 1907/2006, the relevant parts of the individual exposure scenario are referenced under the respective headings below.

The exposure scenario includes a methodology section (Chapter 9.0) to which reference is given in the respective sections on exposure estimation.
The current document includes all relevant occupational exposure scenarios (ES) for the production and use of diantimony trioxide as required under the REACH Regulation (Regulation (EC) No 1907/2006). For the development of the ES the Regulation and the relevant REACH Guidance have been considered. For the description of the covered uses and processes, the “R.12 – Use descriptor system” guidance, for the description and implementation of risk management measures (RMM) the “R.13 – Risk management measures” guidance, for the actual occupational exposure assessment the “R.14 – Occupational Exposure Assessment” and for the environmental exposure assessment the “R.16 – Environmental Exposure Estimation” were used.

9.0.1 Methodology – occupational exposure

According to the REACH Guidance R.14 different methodologies may be used for occupational exposure assessment. Preference should be given to data measured under the same operational conditions (OC) and with the same risk management measures (RMM) in place. If such data are not available, analogous data can be used given that OCs and RMMs are similar to an extent which justifies such read-across. If no monitoring data are available at all, occupational exposure can be assessed by the aid of exposure assessment tools. For the assessment of exposure to diantimony trioxide in occupational settings, all of the above mentioned approaches have been used.
This chapter aims on a detailed description of the individual approaches. For the sake of brevity such descriptions were omitted in the actual exposure scenarios (ES) below. Instead, reference is given to the specific method used for each of the individual exposure estimates.
By definition an ES has to describe under which OC and RMMs the substances can be handled safely. This is demonstrated if the estimated exposure level is below the respective derived no-effect level (DNEL), which is expressed in the risk characterisation ratio (RCR).

9.0.1.1 Measured data

All measured data have been peer-reviewed in the risk assessment process for diantimony trioxide (ECB, 2008) under the existing substance regulation 793/93. In addition the scientific results of that risk assessment have been approved in October 2008 at the OECD level. Any information on OCs or RMMs have been reported in this risk assessment or in supportive documents prepared by industry during the risk assessment process (EBRC, 2005a, 2005b, 2006a, 2006b, 2006c, 2006d, 2006e, 2006f, 2006g, 2006h, 2008).
Regarding monitoring of antimony in air, all measured data used in the risk assessment and re-used in this document had to fulfil strict quality criteria as given below for inhalation exposure measurements.

9.0.1.1.1 Inhalation exposure data

A detailed description of the quality criteria applied to the measured inhalation exposure data is provided in the risk assessment report of diantimony trioxide. For the sake of clarity the most important qualifiers are listed below:

- In general, only personal measurements of inhalation exposure data have been used. For a few exceptions and for supportive information purposes only stationary measurements have been used (e.g. to demonstrate negligible exposure between task of actually handling the substance).
- Depending on the exposure duration, these values have to be either full-shift-representative (at minimum of 120 minutes measurement duration) or must have been obtained during the entire task duration. If the latter is the case and in addition it could be shown that exposure is negligible for the remaining shift, values have been

weighted accordingly to obtain time weighted averages (TWA). If applicable, the corresponding task durations can be found under Section 2.1, “Frequency and duration of use/exposure”.

- The measured fraction must be “inhalable” according to EN 481.
- All measurements have to be assigned to a specific workplace, process or task.
- The measurement date has to be reported.
- Additional information such as sampling equipment and method of analysis has to be provided for individual data sets.

9.0.1.1.2 Assessment of data quality and percentiles to be used

Whenever measured data are used in the ESs below they have been already checked for their quality by applying the quality criteria as outlined above in the risk assessment report on diantimony trioxide. The technical guidance on the old existing substance regulation 793/93 required the estimation of a typical and a reasonable worst case exposure level for workers. These levels had to be reflected by the median and the 90th percentile value, respectively. In contrast, according to R.14 (Version 2, May 2010) of the REACH guidance, the percentile to reflect the exposure level for workers has to be determined according to the specificity of the data to the ES of interest and the variability of the data (Table 14-2) as reflected by the geometric standard deviation (GSD). Additionally, the guidance requires a minimum number of measurements based on the GSD. Thus, the table below summarises this information for all data which can be found in the ESs below.

Table 84: Quality assessment of measured data

Exposure scenario	Exposure route	Counts	Specificity of data	GSD	Chosen percentile
9.1 – Conversion$^{A)}$	inhalation	47*	high (data originates from the workplace under scrutiny)	7.51	90th
9.1 – Refuming$^{A)}$		21		2.30	90th
9.1 – Packaging$^{A)}$		38		2.68	90th
9.2 – Raw material handling$^{A)}$	inhalation	60*	medium (data may partially include values from other workplaces due to job rotating)	7.61	90th
9.3 – Powder handling$^{A)}$	inhalation	35	medium (data originates from the workplace under scrutiny but combines large and medium scale operations)	4.64	90th
9.4 – Processing$^{B)}$	inhalation	42**	high (data originates from the workplace under scrutiny)	2.6	100th
9.9 – Use of back-coated textiles$^{B)}$	inhalation	42**	high (data originates from the workplace under scrutiny)	2.6	100th

*The high GSD can be explained by plenty of measurements at a very low level compared to those at the typical level. As these low measurements are not considered to influence the upper percentiles (i.e. 90th percentile) of a distribution of 47 values the 90th percentile is assumed to be appropriate for this scenario.

**As individual raw data were not available the maximum value has been selected for precautionary reasons. Measurements were summarised for each day. Thus the maximum daily is reported above.

Data sources: A) EBRC industry reports, all of these reports have been peer-reviewed in ECB, 2008 (European Union Risk Assessment Report, diantimony trioxide); B) Iavicoli et al. (2002): Biomonitoring data of a worker population exposed to low antimony levels

As can be seen in the table above, the 90th percentile was assumed to be appropriate for the first three workplaces. This is justified due to the high applicability (specificity) of the dataset to the scenario under scrutiny in combination with its high homogeneity (reflected by the GSD as given in R.14, Table 14-2). For the remaining scenarios, the maximum value has been used as a proxy for workers’ exposure because of significant short-comings of the underlying datasets in fulfilling the above requirements.

It has to be noted that all of analysed data above were measured outside any respiratory protective equipment. Such equipment is taken into account by dividing the calculated exposure level by the so-called assigned protection factor (APF) as reported in the exposure scenarios below. These APFs have been set according to BS EN 529:2005 and can also be looked up in the glossary of MEASE (http://www.ebrc.de/mease.html).

9.0.1.1.3 Analysis of air monitoring data

An analysis of the data is provided in the table below:

Table 85: Analysis of personal air monitoring measurements [mg Sb_2O_3/m^3]

Exposure scenario	Counts	GSD	Minimum	Median	75th percentile	90th percentile	Maximum
9.1 – Conversion[A)]	47*	7.51	<0.001	0.539	0.850	2.890	11.100
9.1 – Refuming[A)]	21	2.30	0.050	0.230	0.370	0.940	1.070
9.1 – Packaging[A)]	38	2.68	0.080	0.790	1.245	2.095	4.670
9.2 – Raw material handling[A)]	60*	7.61	<0.00001	0.002	0.008	0.026	0.063
9.3 – Powder handling[A)]	35	4.64	0.005	0.126	0.389	0.570	2.376
9.4 – Processing[B)]	42**	not reported	<0.00001	not reported	not reported	not reported	0.001
9.9 – Use of back-coated textiles[B)]	42**	not reported	<0.00001	not reported	not reported	not reported	0.001

Shaded cells indicate the selected percentile.
*The high GSD can be explained by plenty of measurements at a very low level compared to those at the typical level. As these low measurements are not considered to influence the upper percentiles (i.e. 90th percentile) of a distribution of 47 values the 90th percentile is assumed to be appropriate for this scenario.
**As individual raw data were not available the maximum value has been selected for precautionary reasons. Measurements were summarised for each day. Thus the maximum daily is reported above.
Data sources: A) EBRC industry reports, all of these reports have been peer-reviewed in ECB, 2008 (European Union Risk Assessment Report, diantimony trioxide); B) Iavicoli et al. (2002): Biomonitoring data of a worker population exposed to low antimony levels

9.0.1.2 Analogous data

For scenarios for which no measured data were available, analogous data have been used to estimate exposure. The table below summarises for which ES this was the case, from which sources the analogous data were taken, the specific justification for such a read-across and the used extrapolation methodology.

Table 86: Use of analogous data in occupational exposure scenarios for diantimony trioxide

Exposure scenario	Exposure route	Data source	Justification for read-across	Mode of extrapolation
9.4 – powder handling	inhalation	9.3	Inhalation exposure during powder handling at downstream user level is reflected in measured data from the plastics sector.	Powder handling in the plastics sector is conducted for 180 minutes whereas the same task is only conducted for 120 minutes. Since simple cross-reading was conducted, additional uncertainties are assumed to be sufficiently covered.
9.5 – raw material handling	inhalation	9.3	Inhalation exposure during powder handling at downstream user level is reflected in measured data from the plastics sector.	As handling durations are equal in both sectors simple cross-reading was conducted.
9.6 – loading & mixing, preparation	inhalation	9.3	Inhalation exposure during powder handling at downstream user level is reflected in measured data from the plastics sector.	Powder handling in the plastics sector is conducted for 180 minutes whereas the same task is only conducted for 60 minutes so that one third of the exposure level in the plastics sector has been extrapolated to the textile sector.
9.7 – powder handling	inhalation	9.3	Inhalation exposure during powder handling at downstream user level is reflected in measured data from the plastics sector.	As handling durations are equal in both sectors simple cross-reading was conducted.

9.0.1.3 Modelled exposure

When neither measured data nor analogous data were available, occupational exposure was assessed with the aid of modelling tools. At the first tier screening level, the MEASE tool (http://www.ebrc.de/mease.html) was used to assess inhalation exposure. All parameters needed to run the tool are provided in the ESs below. As can be seen in section 4 of each of the scenarios below, any downstream user who wants to slightly deviate from a specific scenario can use these parameters to run MEASE for demonstrating safe handling conditions. The required parameter “physical form” of the substance can be determined as defined in the glossary of MEASE under “Physical form”. A safe use is demonstrated if the exposure is below the respective derived no-effect level (DNEL), which is expressed in the RCR. In cases in which multiple PROCs have been assigned to a specific workplace, the corresponding exposure assessment for that specific workplace was made by using the PROC leading to the highest exposure estimate for precautionary reasons.

9.0.2 Methodology - environmental exposure

The approach used for environmental modelling followed that used in the EU RAR for diantimony trioxide. The modelling is based on the antimony, rather than the antimony compound. Tonnages have therefore been adjusted for this, and the physicochemical environmental fate and ecotoxicity data used in the modelling relates to the antimony. Antimony monitoring data from across Europe was used to determine the Reasonable Worst Case (RWC) ambient background concentrations for air, water, sediment and soil. These values have been used as the Regional Predicted Environmental Concentrations (PEC). The values selected as RWC ambient background concentrations are discussed in Section 4.2.5 and are the same as those used in the EU RAR for diantimony trioxide.

Monitoring data includes contributions from all possible sources of antimony, and does not discriminate between different possible sources such as different antimony containing substances or ambient background levels. The regional background concentrations calculated by modelling are actually added concentrations due to the manufacture and use of a specific antimony substance, so should be expected to be lower than the levels observed by environmental monitoring, which includes all possible sources of antimony in the environment, both natural and anthropogenic. The use of measured data for regional background concentrations also ensures that any emissions which may result from the use of antimony containing articles and products, and emissions from waste disposal are taken into account.

The environmental modelling of the local PEC has been carried out in EUSES. Exposure scenarios covering the point source emissions to the environment from production of diantimony trioxide and the use of diantimony trioxide in the formulation of various products and articles have been created. As RWC background monitoring data is used as the Regional PEC the local PEC are based on single sites with an assumed worst case tonnage.

A wide dispersive use exposure assessment is also included that covers both the professional and consumer use of diantimony trioxide containing products and articles. This follows the guidance given in R.16 (ECHA, 2010) and is based on the combined risk from all uses of diantimony trioxide containing products and articles in a region. The ERC for wide dispersive uses cover the whole service life of the article. The assessment is therefore based on an assumption of a relatively steady state tonnage of diantimony trioxide containing products and articles produced each year.

A recent report (Eurometaux, Arcadis, 2010) argues that with the expansion of the EU the default EU tonnage to regional tonnage ratio of 10:1 is no longer appropriate, as the tonnage now encompasses the EU 27 but the regional area remains as at EU15. This therefore allocates too high a proportion of EU tonnage to a region, and overestimates risk. As we are using RWC regional PEC based on monitoring data, rather than modelling the regional PEC, this criticism does not apply to the assessment of industrial sources. However, this argument would reduce the tonnage assumed to be released to a single sewage treatment works in the dispersive use assessment. The assessment presented here is based on current ECHA guidance and indicates that the risk is acceptable. An assessment based on a reduced tonnage would therefore also indicate only acceptable risk as it would be less conservative than the assessment presented here.

The input parameters are listed in Table 3 below. A log Kow value is required by EUSES, and an equivalent value has been estimated for antimony from environmental partitioning data, for the purpose of undertaking calculations in EUSES. The initial PEC calculations have employed default values from the technical guidance for a number of factors, such as local dilution factors for aquatic discharges.

Table 87: Input parameters for environmental modelling of diantimony trioxide

Substance	Diantimony trioxde
Substance volatility	1E-6 Pa at 25˚ C (minimum in EUSES)
Molecular weight of antimony	121.75 g/mole
Melting point	500˚ C (true melting point above this, but set to maximum in EUSES)
Boiling point	500˚ C (true boiling point above this, but set to maximum in EUSES)
Solubility	294 mg Sb/l at 25˚ C
Characterisation of biodegradability	Non-biodegradable
Log K_{OW}	6.98
Log Kp soil	2.07
Log Kp sediment	3.4
Log Kp suspended matter	3.65
Log Kp raw and settled sewage sludge	4.13
Log Kp activated and effluent sewage sludge	4.22
BioConcentration Factor aquatic	40
BioConcentration Factor soil	1

When available measured data from companies fitting in the ES were used to derive release factors. When no or not enough data was available the spERCs were used to estimate the release factors. SPERCs for metal and metal compounds have been generated (http://www.arche-consulting.be/Metal-CSA-toolbox/spercs-tool-for-metals) for some uses. If spERCs were not available (i.e. for wide dispersive uses) the default from the ERCs were used.

9.0.3 Methodology – consumer exposure

According to the REACH-guidance (REF R.15) different methodologies may be used for consumer exposure assessment.
In general measured data are preferred over modelled data provided they are reliable and representative for the situation that needs to be assessed. However, for most consumer exposure scenarios, measurements of the actual exposure of consumers will not be available. Therefore, exposure needs to be assessed with the aid of modelling tools. At the first tier screening level, the ECETOC TRA tool (http://www.ecetoc.org/tra) can be used to assess oral, dermal, and inhalation exposure. However, consumer exposure to Diantimony trioxide for some applications was already assessed during the risk assessment process for diantimony trioxide (ECB, 2008: European Union Risk Assessment Report, diantimony trioxide) under the existing substance regulation 793/93. The international antimony association (i2a) worked in close cooperation with the Swedish rapporteur on the development of these scenarios. In addition the scientific results of that risk assessment have been approved in October 2008 at OECD level. Therefore, all consumer exposure scenarios developed during the risk assessment process where taken over without further evaluation.

9.0.4 Methodology - indirect exposure via the environment

For the indirect exposure via the environment assessment the relevant guidance “R.16 – Environmental Exposure Estimation” has been considered.

Indirect exposure is principally assessed on a local and on a regional spatial scale. In this context, local and regional environments are not actual sites or regions, but standardised environments as defined in the before mentioned TGD section on Environmental Exposure Estimation. The local scale, in which all food products are derived from the vicinity of one point source, represents a worst-case situation. In contrast, the regional scale assessment depicts a highly averaged exposure situation.

Regarding the ingestion of food, the conventional partitioning-based TGD methodology for determining air-to-soil and soil-to-plant factors in the assessment of human uptake pathways may be considered as mostly inapplicable to metals. Therefore, the HERAG FACT Sheet on indirect exposure via the environment has been considered as guidance (http://www.ebrc.de/ebrc/ebrc-projects.php).

The concentrations in environmental compartments and intake media which are used to derive the daily intake are preferably based on monitored data, since the alternative route by modelling of environmental concentrations is associated with much higher uncertainties and also difficult to apply for metals, as parameters such as partitioning coefficients (p_{ow}) or vapour pressure are used, which are usually not applicable to metals.

In deviation from the TGD food basket approach for the exposure route “ingestion of food”, the following tools have been considered: duplicate meal studies, total diet studies and market basket studies.

9.0.4.1 General remark

The sources of human exposure to antimony handled under indirect exposure via the environment are food, breast milk, water and air. Antimony is released to the environment through air effluents and wastewater from manufacture, formulation, processing, use and disposal of antimony containing products. As a very conservative approach the content of antimony measured was converted by a factor of 1.2 to diantimony trioxide.

In the environment, diantimony trioxide, originating from production/use of diantimony trioxide, will dissolve to the trivalent and predominantly pentavalent ions. As a consequence, the actual exposure from drinking water, food and breast milk will be to the antimony ions.

Antimony is also a naturally occurring element. Therefore, its presence in the environment, and thereby also indirect in water and in food and beverages produced from agricultural goods, may also be attributed to natural sources. According to the EU risk assessment report for diantimony trioxide (ECB, 2008: European Union Risk Assessment Report, diantimony trioxide) global anthropogenic and natural emissions are of comparable size. A comparison, performed in Pacyna and Pacyna (2001), of global anthropogenic emission estimates of antimony from 1995 with the global natural emission estimates by Nriagu (1989) from 1983, provides values of 1.6×10^3 t/y and 2.4×10^3 t/y, respectively. The identified major sources of anthropogenic emissions were stationary fossil fuel combustion (47

%), nonferrous metal production (mostly Cu and Ni) (35 %), and refuse incineration (17 %), and the major identified sources of natural emissions were wind-borne soil particles (33 %), volcanoes (30 %), and sea salt spray (23 %). Other assessments have indicated that the importance of the natural sources was considerably minor, as compared to the anthropogenic. Both Lantzy and Mackenzie (1979) and Galloway (1982) estimated that the anthropogenic input was approximately 39 times higher than the natural. Recent results by Shotyk and colleagues (2005) indicate that the ratio of anthropogenic to natural Sb emissions may be about a factor of ten or more.

9.0.4.1. Source of literature and evaluation thereof

The EU risk assessment report for diantimony trioxide (ECB, 2008: European Union Risk Assessment Report, diantimony trioxide) under the existing substance regulation 793/93, was used as basis for the indirect exposure assessment.

Literature search on dietary intake:
To ensure that no recent, relevant data would be missed, (i) a very specific online search was conducted in the database CAPLUS (a documentation of the literature search is summarised in Appendix II). The search strategy was narrowed in a way that only literature published after 2006 was retrieved. Given the amount of data already available before the search, this narrow search strategy was chosen to reduce effort and costs, but on the other hand assuring that recent relevant literature would be considered. Furthermore, a search on (ii) the UK Food standard agency website was conducted as well as on the website of the French agency for food, environmental and occupational health and safety (ANSES)..

Evaluation:
Each evaluated piece of literature received a relevance / reliability score, which was derived under consideration of several aspects:

- primary literature or review
    - unless bibliographically unavailable, primary literature was always preferred over cited results
- geographical origin of the data/samples
    - preference on the EU, because evaluation took place in the context of REACH work
- date of the work
    - more recent data usually preferred, since best reflecting the current situation
    - the capabilities of analytical methods/equipment considerably increases over time
- quality of reporting, such as extent of detail given on study design, sampling, analytical methodology, quality assurance measures (e.g. use of reference materials for validation), reporting of raw data, ability to follow calculations ….
- for the assessment of dietary intake, preference was given to duplicate diet studies, over total diet and market basket studies, because the latter are less accurate in assessing the actual intake. However, a recent, large scale, e.g. country wide, total diet study may receive a higher score than a duplicate diet study in few individuals on a special diet, such as hospital diet because of its weak representative nature for the general population.

Having all these aspects in mind, a combined overall score between 1 and 4 was assigned to each evaluated reference. A score of “not relevant” (for this particular topic) was assigned to literature that completely lacked relevance to this topic.

Example for relevance/reliability scoring:

1: highly relevant, i.e. recent data from the EU, use of proper study methodology and analytical methods, good reporting, high number of samples
2: relevant, but with some limitations, i.e. low number of samples, study methodology of lower rank, but still more or less recent data from the EU. Also assigned to relevant review data
3: supplemental information, e.g. proper methodology and reporting, but data from outside the EU, or considered outdated
4: not reliable: applicable to this topic, e.g. deriving / reporting dietary intakes, but considered not reliable because of methodological / reporting deficiencies / language

9.0.4.2. Exposure from food

The most recent and also most extensive and reliable studies on daily antimony intake with food and beverages of the general EU population are the 1994 and 2006 UK total diet study (UK Ministry of Agriculture, 1998 and 2009), and the 1st and 2nd French total diet study (INRA, 2004 and ANSES, 2011). The exposure assessment via food and beverages is based on these studies, since they were conducted under governmental surveillance by well-established institutions and laboratories. Large numbers of food samples were processed, and consumption patterns were established in comprehensive surveys. Thus, the data from these studies may be considered adequately representative of the dietary intakes of the average EU population.

	µg/d		**µg/kg/d**	
Reference	**Mean**	**P97.5**	**Mean**	**P97.5**
UK TDS 1994	3	4	0.043***	0.057***
UK TDS 2006	1.8*	3.6*	0.03	0.06
1st French TDS	0.9	2	0.015*	0.033*
2nd French TDS	2.4*	4.02 (P95)*	0.0404	0.067 (P95)
2nd French TDS **	2.04*	3.4 (P95)*	0.034	0.057 (P95)

*These values have been calculate from the data presented, assuming a body weight of 60kg.
** The estimated daily intake has been reduced by the contributing antimony intake via water of 15%.
*** Provided in (UK Ministry of Agriculture, 2009), taking an average body weight of 70.1 kg into account.

A reduction of the daily antimony intake has been observed from the UK TDS 1994 to 2006, which can be explained by improvements in analytical methodology resulting in a LOD, being up to ten-fold lower in the 2006 TDS. Furthermore, it can be a result of changes in food consumption. However, it should be noted that dietary exposure estimates for the 2006 TDS are not directly comparable with those from other years as they are based on analyses of composite samples of each food from all the towns in the TDS rather than the upper bound mean concentrations of analyses of each food group from each town.

The results from the 2nd French TDS show that exposure to antimony was higher than in the 1st French TDS. This increase can be explained by i) a change in food consumption and ii) contamination during the preparation of food in the 2nd TDS.

The two most recent studies from the UK and France (2006 UK TDS and the 2nd French TDS) show almost identical values for the daily antimony intake per body weight, if the contributing water intake from the 2nd French TDS has been taken into account. As such the values from the 2006 UK TDS have been used further. The daily antimony intake (adults) via food and beverages taken forward to the risk characterisation are as follows:
- typical exposure: the mean value of the recent UK TDS: i.e. 0.03 µg Sb/kg bw/day ≅ 1.8 µg Sb/day
- worst-case: the 97.5th percentile from the 2006 UK total diet study as the more conservative value from these studies, i.e 0.06 µg Sb/kg bw/day ≅ 3.6 µg Sb/day

A detailed evaluation of the data available is provided in Appendix I in tabular format.

In order to enable comparison between exposure values and effect data at the risk characterisation the content of antimony was converted by a factor of 1.2 to diantimony trioxide given 2.16 µg/day as typical and 4.32 µg/day as worst case exposure.

9.0.4.3. Exposure via mother´s milk

According to the EU-RAR on Diantimony trioxide (2008), the typical values for exposure via mothers' milk are based on data from Wappelhorst et al. (2002) which is the most recent and representative data set for exposure to antimony via breast milk in Europe as of today and during the course of breast-feeding. Because of a higher milk consumption and lower body weight, children of 0-3 months of age have a higher exposure to antimony than older children. Thus, as an additional conservative measure, the exposure estimates for children of 0-3 months of age are taken forward to risk characterisation. The typical and reasonable worst-case exposure values taken forward to the risk characterisation are 0.140 and 0.522 µg Sb_2O_3/day (corresponding to 0.023 and 0.087 µg Sb_2O_3/kg/day). A detailed evaluation of the data is provided in ECB, 2008: European Union Risk Assessment Report, diantimony trioxide (http://esis.jrc.ec.europa.eu/doc/existing-chemicals/risk_assessment/REPORT/datreport415.pdf

When these data are taken forward to risk characterisation, it must be explicitly recognised that the origin of the Sb present in mother's milk is to a large extent due to indirect exposure via food, beverages and drinking water. It is not feasible to express this in terms of ATO, since uptake through the gastrointestinal tract is intrinsically coupled to transformation to Sb cations, thus rendering the origin independent of any particular Sb compound.

9.0.4.4. Exposure via drinking water

Antimony concentrations in water were taken from (i) ambient monitoring data (regional) and (ii) calculated industrial site emission data (local), which were taken from the environmental exposure assessment.

The PEC values are expressed as Sb. In order to enable comparison between exposure values and effect data at the risk characterisation the content of antimony was converted by a factor of 1.2 to diantimony trioxide. However, it should be borne in mind that the antimony present is not only derived from emissions from industrial production or the use but also from geogenic emissions and combustion of mineral fuels. Furthermore, not all the antimony presented (monitoring data, regional) can be traced back to diantimony trioxide.

9.0.4.5. Exposure via ambient air

Antimony concentrations in air were taken from (i) ambient monitoring data (regional) and (ii) calculated industrial site emission data (local), which were taken from the environmental risk assessment.

The PEC values are expressed as Sb. In order to enable comparison between exposure values and effect data at the risk characterisation the content of antimony was converted by a factor of 1.2 to diantimony trioxide. However, it should be borne in mind that the antimony present is not only derived from emissions from industrial production or the use but also from geogenic emissions and combustion of mineral fuels.

Table 88: Overview on exposure scenarios and coverage of substance life cycle

ES number	**Exposure scenario title**	**Volume** (tonne/year/site)	**Manufacture**	**Identified uses**				**Resulting life cycle stage**		**Linked to Identified Use**	**Sector of use category (SU)**	**Chemical product category (PC)**	**Process category (PROC)**	**Article category (AC, Taric code in brackets if applicable)**	**Environmental release category (ERC)**
				Formulation	**Use at industrial sites**	**Use by professional workers**	**Consumer use**	**Service life (for articles)**	**Waste stage**						
9.1	Use of antimony metal in the production of diantimony trioxide	9000	X								3, 8, 9	19	21, 22, 23, 26		1
9.2	Use of diantimony trioxide in PET (films/fibres, resin) production	250			X						3, 10, 12	32	1, 3, 4, 5, 6, 8a, 8b, 9, 14, 15, 21, 22, 24, 25	5, 6, 8 (4818), 13	5, 6b
9.3	Industrial use of diantimony trioxide in the plastics and rubber industry	2500			X						3, 5, 10, 11, 12, 16, 17, 18, 20, 23	19, 21, 24, 26, 32, 33	1, 2, 3, 4, 5, 6, 8a, 8b, 9, 10, 13, 14, 15, 21, 24, 26	1,2 (8544), 3, 5, 10, 13 (3925)	5
9.4	Industrial use of diantimony trioxide in the manufacture of flame retarded textiles	280			X						3, 5, 10	23, 32, 34	1, 5, 6, 7, 8a, 8b, 9, 10, 12, 13, 21, 22, 24, 26	6, 5 (59031090, 59032090)	5
9.5	Industrial use of diantimony trioxide in the production of glass, enamels, functional ceramics and semi-conductors	75			X						3, 8, 10, 13, 15, 16	0 (C23.1, UCN-G15000/15100), 9a, 19, 21, 33	1, 2, 3, 4, 5, 7, 8b, 9, 10, 13, 14, 15, 21, 22, 23, 24, 26	1, 2 (8525), 4 (6909), 7	5, 6a
9.6	Industrial use of diantimony trioxide in the production of pigments, paints, coatings, ceramics, brake pads and production and formulation of fine chemicals	500			X						3, 8, 9, 10, 13, 17, 19, 23	9a, 9b, 9c, 18, 19, 20, 32,	1, 2, 3, 4, 5, 6, 7, 8a, 8b, 9, 10, 13, 14, 15, 19, 21, 22, 23, 24, 26	1, 4, 7	5, 6a
9.7	Industrial use of diantimony trioxide in wood adhesives	15			X						3, 6a	1	5, 8b, 14, 21, 24, 26	11	5
9.8	Professional uses of diantimony trioxide preparations	6				X		X			22	1, 9a, 18, 20, 24, 26, 32, 34	10, 11, 19, 23,13, 8a		8c, 8f, 10a, 11a, 12a
9.9	Professional uses of diantimony trioxide contained in articles	6				X		X			22		21, 24	1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 13	8c, 8f, 10a, 11a, 12a
9.10	Service life/Use of articles with diantimony trioxide being embedded into the matrix	6					X	X			21			1, 2 (8544), 3, 5, 7, 10, 11, 13, (3925)	8c, 8f, 10a, 11a, 12a

ES number	**Exposure scenario title**	**Volume** (tonne/year/site)	**Manufacture**	**Identified uses**				**Resulting life cycle stage**		**Linked to Identified Use**	**Sector of use category (SU)**	**Chemical product category (PC)**	**Process category (PROC)**	**Article category (AC, Taric code in brackets if applicable)**	**Environmental release category (ERC)**
				Formulation	**Use at industrial sites**	**Use by professional workers**	**Consumer use**	**Service life (for articles)**	**Waste stage**						
9.11	Service life/Use of back-coated textiles	6					X	X			21			5 (59031090, 59032090)	8c, 8f, 10a, 11a, 12a
9.12	Service life/Use, wearing of articles made of PET/PES polymers	6					X	X			21			5, 6, 13, 8 (4818)	8c, 8f, 10a, 11a, 12a
9.13	Service life/ Wearing of clothes containing antimony trioxide for fire resistance	6					X	X			21			5	8c, 8f, 10a, 11a, 12a

9.1. Use of antimony metal in the production of diantimony trioxide

9.1.1. Exposure scenario

Exposure Scenario Format (1) addressing uses carried out by workers

1. Title

Free short title	Use of antimony metal in the production of diantimony trioxide
Systematic title based on use descriptor	SU3 (Industrial uses), SU8, 9 (Manufacture of fine/bulk chemicals) PC19 (appropriate PROCs and ERCs are given in section 2 below)
Processes, tasks and/or activities covered	Processes, tasks and/or activities covered are described in Section 2 below.
Assessment Method	The assessment of inhalation exposure is based on measured data from the production of diantimony trioxide. These data have been peer-reviewed in the risk assessment report on diantimony trioxide. The environmental assessment uses EUSES.

2. Operational conditions and risk management measures

Workplace	**Involved tasks**	**Involved PROCs**	**Involved ERC**
Conversion	Furnace loading, supervision, removal of impurities, occasional cleaning, exothermic furnace reaction	21, 22	1
Refuming	Furnace loading, volatilisation of diantimony trioxide, supervision, occasional tapping of impurities, occasional build-up removal	22, 23	
Packaging	Packaging, powder handling	26	

2.1 Control of workers exposure

Product characteristic

According to the MEASE approach, the substance-intrinsic emission potential is one of the main exposure determinants. This is reflected by an assignment of a so-called fugacity class in the MEASE tool. For operations conducted with solid substances at ambient temperature the fugacity is based on the dustiness of that substance. Whereas in hot metal operations, fugacity is temperature based, taking into account the process temperature and the melting point of the substance. As a third group, high abrasive tasks are based on the level of abrasion instead of the substance intrinsic emission potential.

Workplace	**Used in preparation?**	**Content in preparation**	**Physical form**	**Emission potential**
Conversion	not restricted		molten	high
Refuming	not restricted		molten	high
Packaging	not restricted		powder	high

Amounts used

The actual tonnage handled per shift is not considered to influence the exposure as such for this scenario. Instead, the combination of the scale of operation (industrial vs. professional) and level of containment/automation (as reflected in the PROC) is the main determinant of the process intrinsic emission potential.

Frequency and duration of use/exposure

Workplace	**Duration of exposure**
Conversion	480 minutes (not restricted)
Refuming	480 minutes (not restricted)
Packaging	480 minutes (not restricted)

Human factors not influenced by risk management

The shift breathing volume during all process steps reflected in the PROCs is assumed to be 10 m^3/shift (8 hours).

Other given operational conditions affecting workers exposure

Workplace	Room volume	Outdoors or indoors?	Process temperature	Process pressure
Conversion	>1,000 m³	indoors	1,000° C	Not considered relevant for occupational exposure assessment for the conducted processes.
Refuming			1,000° C	
Packaging			ambient temperature	

Technical conditions and measures at process level (source) to prevent release

Workplace	Level of containment	Level of segregation
Conversion	enclosed space (furnace)	not required
Refuming	enclosed space (furnace)	
Packaging	enclosed space	

Technical conditions and measures to control dispersion from source towards the worker

Workplace	Level of separation	Localised controls (LC)	Efficiency of LC (according to MEASE)	Further information
Conversion	not required	generic local exhaust ventilation	78 %	-
Refuming		generic local exhaust ventilation	78 %	-
Packaging		generic local exhaust ventilation	78 %	-

Organisational measures to prevent /limit releases, dispersion and exposure

Avoid inhalation or ingestion. General occupational hygiene measures are required to ensure a safe handling of the substance. These measures involve good personal and housekeeping practices (i.e. regular cleaning with suitable cleaning devices), no eating and smoking at the workplace, unless otherwise stated below the wearing of standard working clothes and shoes. Shower and change clothes at end of work shift. Do not wear contaminated clothing at home. Do not blow dust off with compressed air.

Historical observations of skin irritation have been made amongst workers caused by handling of diantimony trioxide powder under special conditions, namely substantial heat and sweat. The observed skin reactions, limited to workers at a diantimony trioxide (ATO) producing facility are likely to be evoked more by physically mediated processes associated with blocking of the sweat glands in the absence of any intrinsic substantial primary skin irritating potential of the substance and also in consideration of the poor solubility of ATO. Industry is committed to adequately control the risks of any adverse effects to workers who are exposed in hot, sweaty conditions to fumes or dust containing ATO by following the occupational hygiene practices as described in this exposure scenario. However, it is explicitly noted that the above described historical observations of skin effects have been scientifically evaluated by the Committee for Risk Assessment (RAC) of the European Chemicals Agency (ECHA) and did not lead to a classification of diantimony trioxide. As a precautionary measure, the wearing of chemical resistant gloves, long sleeved overalls and closed footwear, designed to minimize skin contact is suggested for all diantimony trioxide powder handling workplaces.

Conditions and measures related to personal protection, hygiene and health evaluation

Workplace	Specification of respiratory protective equipment (RPE)	RPE efficiency (assigned protection factor, APF)	Specification of gloves	Further personal protective equipment (PPE)
Conversion	FFP2 mask	APF=10	thermal-protective gloves	standard working clothes (overall with long sleeves) and safety shoes
Refuming	FFP1 mask	APF=4	thermal-protective gloves	
Packaging	FFP2 mask	APF=10	Use protective gloves when exposed to fumes or dust containing diantimony trioxide.	

Any RPE as defined above shall only be worn if the following principles are implemented in parallel: The duration of work (compare with “duration of exposure” above) should reflect the additional physiological stress for the worker due to the breathing resistance and mass of the RPE itself, due to the increased thermal stress by enclosing the head. In addition, it shall be considered that the worker’s capability of using tools and of communicating are reduced during the wearing of RPE.

For reasons as given above, the worker should therefore be (i) healthy (especially in view of medical problems that may affect the use of RPE), (ii) have suitable facial characteristics reducing leakages between face and mask (in view of scars and facial hair). The recommended devices above which rely on a tight face seal will not provide the required protection unless they fit the contours of the face properly and securely.

The employer and self-employed persons have legal responsibilities for the maintenance and issue of respiratory protective devices and the management of their correct use in the workplace. Therefore, they should define and document a suitable policy for a respiratory protective device programme including training of the workers.

An overview of the APFs of different RPE (according to BS EN 529:2005) can be found in the glossary of MEASE.

2.2a Control of environmental exposure for scenarios without waste water

Amounts used

9000 tonnes Sb/year/site

Frequency and duration of use

Continuous use/release, 365 days/year

Environment factors not influenced by risk management

Not relevant

Other given operational conditions affecting environmental exposure

None

Technical conditions and measures at process level (source) to prevent release

Water is not used/released during the production of diantimony trioxide

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

Release factor to air: 0.03%
Three emission factors could be calculated based on company specific data (range: 0.0006 - 0.001%). Due to the low number of datapoints it was preferred to use the Eurometaux spERC 1.2.v2.1 for manufacture of metal compounds. In order to obtain this release factor, direct air emissions should be reduced by implementing one or more of the following RMMs:

- Electrostatic precipitators using wide electrode spacing: 5 – 15 mg/Nm^3
- Wet electrostatic precipitators: < 5 mg/Nm^3
- Cyclones, but as primary collector: < 50 mg/Nm^3
- Fabric or bag filters: high efficiency in controlling fine particulate (melting): achieve emission values < 5mg/Nm^3. Membrane filtration techniques can achieve < 1 mg/Nm^3
- Ceramic and metal mesh filters. PM10 particles are removed: 0.1 mg/Nm^3
- Wet scrubbers: < 4 mg/Nm^3

One or more of these RMMs (of which fabric or bag filters and wet scrubbers are more common) were reported to be present in more than 90% of the sites. Overall range of reported RMM efficiencies ranged between 90% and 99.98% (spERC factsheet).

Release factor to water:
No emissions of waste water coming from the diantimony trioxide process to the environment.

Soil:
No direct emissions to soil.

Organizational measures to prevent/limit release from site

None

Conditions and measures related to municipal sewage treatment plant

There is no release to waste water therefore no STP is required

Conditions and measures related to external treatment of waste for disposal

Hazardous wastes from onsite risk management measures and solid or liquid wastes from production, use and cleaning processes should be disposed of separately to hazardous waste incineration plants or hazardous waste landfills as hazardous waste. Releases to the floor, water and soil are to be prevented. If the antimony content of the waste is elevated enough, internal or external recovery/recycling might be considered.

Fraction of daily/annual use expected in waste: 0.004 or 0.4%

Appropriate waste codes:
02 01 10*, 06 05 02*, 10 08 04, 10 08 08*, 10 08 15*, 15 01 10*, 16 06 01*, 19 02 05*, 19 12 03*

Suitable disposal: Keep separate and dispose of to either

- Hazardous waste incineration operated according to Council Directive 2008/98/EC on waste, Directive 2000/76/EC on the incineration of waste and the Reference Document on the Best Available Techniques for Waste Incineration of August 2006.
- Hazardous landfill operated under Directive 1999/31/EC.

A detailed assessment has been performed and is reported in the Waste report (ARCHE, 2012)

Conditions and measures related to external recovery of waste

Not applicable

2.2b Control of environmental exposure for scenarios with waste water

Amounts used

9000 tonnes Sb/year/site

Frequency and duration of use

Continuous use/release, 365 days/year

Environment factors not influenced by risk management

Default data for receiving water and for the municipal sewage treatment plant are18 000 m3/d and 2000 m3/d, respectively (resulting dilution factor 10). None of the sites discharge to a marine environment.

Other given operational conditions affecting environmental exposure

None

Technical conditions and measures at process level (source) to prevent release

None

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

Release factor to air: 0.03%
Three emission factors could be calculated based on company specific data (range: 0.0006 - 0.001%). Due to the low number of datapoints it was preferred to use the Eurometaux spERC 1.2.v2.1 for manufacture of metal compounds. In order to obtain this release factor, direct air emissions should be reduced by implementing one or more of the following RMMs:

- Electrostatic precipitators using wide electrode spacing: 5 – 15 mg/Nm^3
- Wet electrostatic precipitators: < 5 mg/Nm^3
- Cyclones, but as primary collector: < 50 mg/Nm^3
- Fabric or bag filters: high efficiency in controlling fine particulate (melting): achieve emission values < 5mg/Nm^3. Membrane filtration techniques can achieve < 1 mg/Nm^3
- Ceramic and metal mesh filters. PM10 particles are removed: 0.1 mg/Nm^3
- Wet scrubbers: < 4 mg/Nm^3

One or more of these RMMs (of which fabric or bag filters and wet scrubbers are more common) were reported to be present in more than 90% of the sites. Overall range of reported RMM efficiencies ranged between 90% and 99.98% (spERC factsheet).

Release factor to water: 0.0002%
Only two emission factor could be calculated based on measured data from companies producing diantimony trioxide (covering 100% of the sites). The highest of both emission factors was selected. The calculated release factor is achieved by using an on-site WWTP (chemical precipitation, sedimentation, filtration). Reported efficiency of the WWTP is 85%. Total yearly emissions from both sites is < 2 kg/year.

Soil:
No direct emissions to soil.

Organizational measures to prevent/limit release from site

None

Conditions and measures related to municipal sewage treatment plant

EUSES default STP with primary settler with effluent discharge rate 2000000l/d, serving 10000 inhabitants. Zero degradation assumed. 79.1% to sludge, 20.9% to water calculated in EUSES based on partition coefficients. Sludge assumed to be spread to agricultural land.

Conditions and measures related to external treatment of waste for disposal

Hazardous wastes from onsite risk management measures and solid or liquid wastes from production, use and cleaning processes should be disposed of separately to hazardous waste incineration plants or hazardous waste landfills as hazardous waste. Releases to the floor, water and soil are to be prevented. If the antimony content of the waste is elevated enough, internal or external recovery/recycling might be considered.

Fraction of daily/annual use expected in waste: 0.004 or 0.4%

Appropriate waste codes:
02 01 10*, 06 05 02*, 10 08 04, 10 08 08*, 10 08 15*, 15 01 10*, 16 06 01*, 19 02 05*, 19 12 03*

Suitable disposal: Keep separate and dispose of to either

- Hazardous waste incineration operated according to Council Directive 2008/98/EC on waste, Directive 2000/76/EC on the incineration of waste and the Reference Document on the Best Available Techniques for Waste Incineration of August 2006.
- Hazardous landfill operated under Directive 1999/31/EC.

A detailed assessment has been performed and is reported in the Waste report (ARCHE, 2012)

Conditions and measures related to external recovery of waste

Not applicable

3. Exposure estimation and reference to its source

Occupational exposure

The 90th percentile of the measured data for the individual workplaces in the production of diantimony trioxide is used for inhalation exposure assessment. The risk characterisation ratio (RCR) is the quotient of the refined exposure estimate and the respective DNEL (derived no-effect level) and has to be below 1 to demonstrate a safe use. For inhalation exposure, the RCR is based on the DNEL for diantimony trioxide of 0.5 mg/m^3.

Workplace	Method used for inhalation exposure assessment (refer to introduction)	Inhalation exposure estimate (RCR)	Method used for dermal exposure assessment (refer to introduction)	Dermal exposure estimate (RCR)
Conversion	measured data	0.289 mg/m^3 (0.578)	Due to the negligible dermal absorption of diantimony trioxide (0.26 % , ECB, 2008), the dermal route is not a relevant exposure path for diantimony trioxide. Thus, dermal exposure is not assessed in this exposure scenario. However, dermal exposure has to be minimised to an extent as technically feasible when working under certain conditions as described above.	
Refuming	measured data	0.235 mg/m^3 (0.47)		
Packaging	measured data	0.21 mg/m^3 (0.42)		

Environmental emissions

Environmental modelling was carried out in EUSES 2.1

Local PEC for exposure scenario a) without waste water releases

Air mg.m-3 (RCR)	Fresh water mg/l (RCR)	Marine water mg/l (RCR)	Sediment freshwater mg/kg wwt (RCR)	Sediment marine water mg/kg wwt (RCR)	Soil mg/kg wwt (RCR)	STP mg/l (RCR)
2.1E-03 (NA)	No discharge to water	No discharge to water	No discharge to water	No discharge to water	2.28 (0.07)	No discharge to water

Local PEC for exposure scenario a) with waste water releases

Air mg.m-3 (RCR)	Fresh water mg/l (RCR)	Marine water mg/l (RCR)	Sediment freshwater mg/kg wwt (RCR)	Sediment marine water mg/kg wwt (RCR)	Soil mg/kg wwt (RCR)	STP mg/l (RCR)
2.1E-03 (NA)	1.20E-03 (0.011)	No discharge to marine environment	1.12 (0.14)	No discharge to marine environment	3.07 (0.094)	0.005 (0.002)

4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES

Occupational exposure

The DU works inside the boundaries set by the ES if either the proposed risk management measures as described above are met or the downstream user can demonstrate on his own that his operational conditions and implemented risk management measures are adequate. This has to be done by showing that they limit the inhalation and dermal exposure to a level below the respective DNEL (given that the processes and activities in question are covered by the PROCs listed above) as given below. If measured data are not available, the DU may make use of an appropriate scaling tool such as MEASE (www.ebrc.de/mease.html) to estimate the associated exposure. The dustiness of the substance used can be determined according to the MEASE glossary.

$DNEL_{inhalation}$: 0.5 mg/m^3

Environmental emissions

The DU works inside the boundaries set by the ES if either the proposed risk management measures as described above are met or the downstream user can demonstrate on his own that his operational conditions and implemented risk management measures are adequate. This has to be done by showing that they limit the environmental exposure to a level below the respective PNEC as given below. The RCR will be equal to or lower than those stated above if they emit less than 23.4 kg Sb/day to air and less than 0.3kg Sb/day to on site or off site waste water treatment works (equivalent to 0.06 kg Sb/day to the receiving water) with a dilution rate of 1:10. The emission to water can be scaled if the dilution rates are higher (e.g. a ten times higher dilution rate would allow ten times greater emissions whilst still having an RCR<1). If measured data are not available, the DU may make use of an appropriate scaling tool such as MetalEUSES (free download: http://www.arche-consulting.be/Metal-CSA-toolbox/duscaling-tool) to estimate the associated exposure.

$PNEC_{freshwater}$: 0.113 mg Sb/l
$PNEC_{marine}$: 0.0113 mg Sb/l
$PNEC_{sediment\ freshwater}$: 7.8 mg Sb/kg wwt
$PNEC_{sediment\ marine}$: 1.56 mg Sb/kg wwt
$PNEC_{soil}$: 37 mg Sb/kg dw (32.6 mg Sb/kg wwt)
$PNEC_{STP}$: 2.55 mg Sb/l

9.1.2. Exposure estimation

9.1.2.1 Indirect exposure of humans via the environment (local)

Table 89: Concentration and risk characterization for local exposure of humans via the environment

Concentration for local exposure of humans via the environment					
	Estimated exposure concentrations		**Measured exposure concentrations**		**Explanation / source of measured data**
	value	**unit**	**value**	**unit**	
Air	2.1* 10-3	mgSb/m³	-	-	Local PEC has been calculated using EUSES 2.1 and converted from Sb to diantimony trioxide by a factor of 1.2.
	2.5* 10-3	mg Sb2O3/m³	-	-	
Drinking water	3.0* 10-2	mg Sb/L	-	-	Local PEC has been calculated using EUSES 2.1 and converted from Sb to diantimony trioxide by a factor of 1.2.
	3.5* 10-2	mg Sb2O3/L	-	-	

Total daily dose for oral exposure via the environment (mg/kg bw/d)		
µg Sb_2O_3/d	**mg Sb_2O_3/kg bw/d**	**Justification**
75.26	1.25* 10^{-3}	2L of drinking water from the local setting + the worst case exposure of 4.32 µg/d from food (section 9.0.4.3) and the default body weight of 60kg have been taken into account.

Quantitative risk characterisation for humans exposed via the environment			
Route	**exposure concentrations (EC)**	**DN(M)EL**	**Risk characterisation ratio**
Inhalation- local effects (long term)	2.5* 10^{-3}mg Sb_2O_3/m^3	0.1 mg/m³	2.5* 10^{-2}
Oral- systemic (long term)	1.25* 10^{-3} mg Sb_2O_3/kg bw/d	168.6 mg/kg/d	7.4* 10^{-6}
Combined routes			RCR Inhalation- systemic + RCR Oral- systemic

9.1.2.2 Environmental exposure

Table 90: Risk characterisation for the soil, sediment and water compartments for exposure scenario a) without releases to water

Compartment	**Local PEC**	**PNEC**	**PEC/PNEC (RCR)**
Terrestrial (mg Sb/kg wwt)	2.28	32.6	0.07

Table 91: Risk characterisation for the soil, sediment and water compartments for exposure scenario b) with releases to water

Compartment	**Local PEC**	**PNEC**	**PEC/PNEC (RCR)**
Freshwater aquatic (mg Sb/l)	1.20E-3	0.113	0.011
Freshwater sediment (mg Sb/kg wwt)	1.12	7.8	0.14
Terrestrial (mg Sb/kg wwt)	3.07	32.6	0.094
Sewage treatment plant (mg Sb/l)	0.005	2.55	0.002

9.2. Use of diantimony trioxide in PET (films/fibres, resin) production

9.2.1. Exposure scenario

Exposure Scenario Format (1) addressing uses carried out by workers

1. Title

Free short title	Use of diantimony trioxide in PET (films/fibres, resin) production
Systematic title based on use descriptor	SU3 (Industrial uses), SU10 (Formulation of preparations and/or re-packing), SU12 (Manufacture of plastic products, including compounding and conversion) PC32 (Polymer preparations and compounds) AC5, AC6, AC8 (TARIC 4818), AC13 (appropriate PROCs and ERCs are given in section 2 below)
Processes, tasks and/or activities covered	Processes, tasks and/or activities covered are described in Section 2 below.
Assessment Method	The assessment of inhalation exposure is based on measured data from diantimony trioxide powder handling in the production of PET. All of these data have been peer-reviewed in the risk assessment report on diantimony trioxide. The environmental assessment uses EUSES.

2. Operational conditions and risk management measures

Workplace	**Involved tasks**	**Involved PROCs**	**Involved ERC**
Raw material handling	Unloading, feeding of the mixing vessel, stirring, filtering	5, 8a, 8b, 9	5, 6b
Further processing	Esterification, polymerisation, distillation, melting, cutting, spinning, extrusion	1, 3, 4, 14, 15, 22, 24, 25	
Final processing	Thermal reforming, moulding, cutting	6, 21	

2.1 Control of workers exposure

Product characteristic

According to the MEASE approach, the substance-intrinsic emission potential is one of the main exposure determinants. This is reflected by an assignment of a so-called fugacity class in the MEASE tool. For operations conducted with solid substances at ambient temperature the fugacity is based on the dustiness of that substance. Whereas in hot metal operations, fugacity is temperature based, taking into account the process temperature and the melting point of the substance. As a third group, high abrasive tasks are based on the level of abrasion instead of the substance intrinsic emission potential.

Workplace	**Used in preparation?**	**Content in preparation**	**Physical form**	**Emission potential**
Raw material handling	not restricted		powder, wetted powder*	high - medium
Further processing	After polymerisation, diantimony trioxide is covalently bound in PET matrix, i.e. it is no longer bio-available as diantimony trioxide. Thus, an exposure assessment has been omitted for further processing steps.		liquid or chips	na
Final processing			final product	na

*Also other physical forms (i.e. wetted powders) than powder are used. As powder represents the worst case in terms of its emission potential the raw material handling of these physical forms is covered in the initial “powder handling” process step in this exposure scenario. If other physical forms render some of the proposed RMMs below unnecessary the downstream user is referred to section 4 of this exposure scenario to proof that.

Amounts used

The actual tonnage handled per shift is not considered to influence the exposure as such for this scenario. Instead, the combination of the scale of operation (industrial vs. professional) and level of containment/automation (as reflected in the PROC) is the main determinant of the process intrinsic emission potential.

Frequency and duration of use/exposure

Workplace	**Duration of exposure**
Raw material handling	≤ 90 minutes
Further processing	480 minutes (not restricted)
Final processing	480 minutes (not restricted)

Human factors not influenced by risk management

The shift breathing volume during all process steps reflected in the PROCs is assumed to be 10 m^3/shift (8 hours).

Other given operational conditions affecting workers exposure

Workplace	Room volume	Outdoors or indoors?	Process temperature	Process pressure
Raw material handling	>1,000 m^3	indoors	Not considered relevant for occupational exposure assessment of the conducted processes.	Not considered relevant for occupational exposure assessment of the conducted processes.
Further processing				
Final processing				

Technical conditions and measures at process level (source) to prevent release

Workplace	Level of containment	Level of segregation
Raw material handling	not required	not required
Further processing	closed system (reaction vessel)	
Final processing	not required	

Technical conditions and measures to control dispersion from source towards the worker

Workplace	Level of separation	Localised controls (LC)	Efficiency of LC (according to MEASE)	Further information
Raw material handling	Any potentially required separation of workers from the emission source is indicated above under "Frequency and duration of exposure". A reduction of exposure duration can be achieved, for example, by the installation of ventilated (positive pressure) control rooms or by removing the worker from workplaces involved with relevant exposure.	generic local exhaust ventilation	78 %	-
Further processing		no	na	-
Final processing		no	na	-

Organisational measures to prevent /limit releases, dispersion and exposure

Avoid inhalation or ingestion. General occupational hygiene measures are required to ensure a safe handling of the substance. These measures involve good personal and housekeeping practices (i.e. regular cleaning with suitable cleaning devices), no eating and smoking at the workplace, unless otherwise stated below the wearing of standard working clothes and shoes. Shower and change clothes at end of work shift. Do not wear contaminated clothing at home. Do not blow dust off with compressed air.

Historical observations of skin irritation have been made amongst workers caused by handling of diantimony trioxide powder under special conditions, namely substantial heat and sweat. The observed skin reactions, limited to workers at a diantimony trioxide (ATO) producing facility are likely to be evoked more by physically mediated processes associated with blocking of the sweat glands in the absence of any intrinsic substantial primary skin irritating potential of the substance and also in consideration of the poor solubility of ATO. Industry is committed to adequately control the risks of any adverse effects to workers who are exposed in hot, sweaty conditions to fumes or dust containing ATO by following the occupational hygiene practices as described in this exposure scenario. However, it is explicitly noted that the above described historical observations of skin effects have been scientifically evaluated by the Committee for Risk Assessment (RAC) of the European Chemicals Agency (ECHA) and did not lead to a classification of diantimony trioxide. As a precautionary measure, the wearing of chemical resistant gloves, long sleeved overalls and closed footwear, designed to minimize skin contact is suggested for all diantimony trioxide powder handling workplaces.

Conditions and measures related to personal protection, hygiene and health evaluation

Workplace	Specification of respiratory protective equipment (RPE)	RPE efficiency (assigned protection factor, APF)	Specification of gloves	Further personal protective equipment (PPE)
Raw material handling	not required	na	protective gloves	standard working clothes (overall with long sleeves) and safety shoes
Further processing	not required	na	not required	
Final processing	not required	na	not required	

2.2a Control of environmental exposure for scenarios discharging to an STP and freshwater river

Amounts used

250 tonnes Sb/year/site

Frequency and duration of use

Continuous use/release, 300 days/year

Environment factors not influenced by risk management

Default data for receiving water and for the municipal sewage treatment plant are18 000 m3/d and 2000 m3/d, respectively (resulting dilution factor 10).

Other given operational conditions affecting environmental exposure

None

Technical conditions and measures at process level (source) to prevent release

None

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

This exposure scenario can contains different steps that occur at the same site. First there might be a formulation step followed by an industrial use step. These two steps are covered by 2 different spERCs. The first step is covered by the Eurometaux spERC 2.2a.v2.1 formulation of metal (compounds) in plastics and rubber. The second step is covered by the Eurometaux spERC 2.5-6a.v2.1 industrial use of metal (compounds) in plastics and rubber. The first two selected spERCs do contain measured data from antimony (compounds) and antimony falls into the Kd range of these spERCs. In order to adequately cover this exposure scenario the worst case release factor from both spERCs is selected for each compartment i.e. 0.001% release to water (2.5-6a.v2.1) and 0.005% release to air (2.2a.v2.1). Note that these release factors are after on-site treatment.

Release factor to air: 0.005%
Eurometaux spERC 2.2a.v2.1. in combination with on-site treatment. In order to obtain this release factor, direct air emissions should be reduced by implementing one or more of the following RMMs:

- Electrostatic precipitators using wide electrode spacing: 5 – 15 mg/Nm^3
- Wet electrostatic precipitators: < 5 mg/Nm^3
- Cyclones, but as primary collector: < 50 mg/Nm^3
- Fabric or bag filters: high efficiency in controlling fine particulate (melting): achieve emission values < 5mg/Nm^3. Membrane filtration techniques can achieve < 1 mg/Nm^3
- Ceramic and metal mesh filters. PM10 particles are removed: 0.1 mg/Nm^3
- Wet scrubbers: < 4 mg/Nm^3

(spERC factsheet).

Release factor to water: 0.001%
Eurometaux spERC 2.5-6a.v2.1 in combination with on-site treatment. In order to obtain this release factor, direct water emissions should be reduced by implementing one or more of the following RMMs:

- Chemical precipitation: used primarily to remove the metal ions (e.g. Ca(OH)2, pH 11 precipitation: >99% removal efficiency; Fe(OH)3, pH 11: 96% removal efficiency)
- Sedimentation (e.g. Na2S, pH 11, >99% removal efficiency)
- Filtration: used as final clarification step (e.g. ultrafiltration, pH 5.1: 93% removal efficiency, nanofiltration: 97% removal efficiency, reverse osmosis, pH 4-11: 99% removal efficiency)
- Electrolysis: for low metal concentration (e.g. electrodialysis: 13% removal efficiency within 2 hours at 2g/L, membrane electrolysis, electrochemical precipitation, pH 4-10, >99% removal efficiency)
- Reverse osmosis: extensively used for the removal of dissolved metals
- Ion exchange: final cleaning step in the removal of heavy metal from process wastewater (e.g. 90% removal efficiency for clinoptinolite and 100% removal efficiency for synthetic zeolite)

More information can be found in EC (2001), Integrated Pollution Prevention and Control (IPCC): reference document on Best Available Techniques in the Non Ferrous Metals Industries (spERC factsheet).

Soil:
No direct emissions to soil.

Organizational measures to prevent/limit release from site

None

Conditions and measures related to municipal sewage treatment plant

EUSES default STP with primary settler with effluent discharge rate 2000000l/d, serving 10000 inhabitants. Zero degradation assumed. 79.1 % to sludge, 20.9 % to water calculated in EUSES based on partition coefficients. Sludge assumed to be spread to agricultural land.

Conditions and measures related to external treatment of waste for disposal

Hazardous wastes from onsite risk management measures and solid or liquid wastes from production, use and cleaning processes should be disposed of separately to hazardous waste incineration plants or hazardous waste landfills as hazardous waste. Releases to the floor, water and soil are to be prevented. If the antimony content of the waste is elevated enough, internal or external recovery/recycling might be considered.

Fraction of daily/annual use expected in waste: 0.004 or 0.4%

Appropriate waste codes:
02 01 10*, 06 05 02*, 10 08 04, 10 08 08*, 10 08 15*, 15 01 10*, 16 06 01*, 19 02 05*, 19 12 03*

Suitable disposal: Keep separate and dispose of to either

- Hazardous waste incineration operated according to Council Directive 2008/98/EC on waste, Directive 2000/76/EC on the incineration of waste and the Reference Document on the Best Available Techniques for Waste Incineration of August 2006.
- Hazardous landfill operated under Directive 1999/31/EC.

A detailed assessment has been performed and is reported in the Waste report (ARCHE, 2012)

Conditions and measures related to external recovery of waste

Not applicable

2.2b Control of environmental exposure for scenarios discharging directly to a freshwater river

Amounts used

250 tonnes Sb/year/site

Frequency and duration of use

Continuous use/release, 300 days/year

Environment factors not influenced by risk management

Default data for receiving water is18 000 m3/d (resulting dilution factor 10).

Other given operational conditions affecting environmental exposure

None

Technical conditions and measures at process level (source) to prevent release

None

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

This exposure scenario can contains different steps that occur at the same site. First there might be a formulation step followed by an industrial use step. These two steps are covered by 2 different spERCs. The first step is covered by the Eurometaux spERC 2.2a.v2.1 formulation of metal (compounds) in plastics and rubber. The second step is covered by the Eurometaux spERC 2.5-6a.v2.1 industrial use of metal (compounds) in plastics and rubber. The first two selected spERCs do contain measured data from antimony (compounds) and antimony falls into the Kd range of these spERCs. In order to adequately cover this exposure scenario the worst case release factor from both spERCs is selected for each compartment i.e. 0.001% release to water (2.5-6a.v2.1) and 0.005% release to air (2.2a.v2.1). Note that these release factors are after on-site treatment.

Release factor to air: 0.005%
Eurometaux spERC 2.2a.v2.1. in combination with on-site treatment. In order to obtain this release factor, direct air emissions should be reduced by implementing one or more of the following RMMs:

- Electrostatic precipitators using wide electrode spacing: 5 – 15 mg/Nm^3
- Wet electrostatic precipitators: < 5 mg/Nm^3
- Cyclones, but as primary collector: < 50 mg/Nm^3
- Fabric or bag filters: high efficiency in controlling fine particulate (melting): achieve emission values < 5mg/Nm^3. Membrane filtration techniques can achieve < 1 mg/Nm^3
- Ceramic and metal mesh filters. PM10 particles are removed: 0.1 mg/Nm^3
- Wet scrubbers: < 4 mg/Nm^3

(spERC factsheet).

Release factor to water: 0.001%
Eurometaux spERC 2.5-6a.v2.1 in combination with on-site treatment. In order to obtain this release factor, direct water emissions should be reduced by implementing one or more of the following RMMs:

- Chemical precipitation: used primarily to remove the metal ions (e.g. Ca(OH)2, pH 11 precipitation: >99% removal efficiency; Fe(OH)3, pH 11: 96% removal efficiency)
- Sedimentation (e.g. Na2S, pH 11, >99% removal efficiency)
- Filtration: used as final clarification step (e.g. ultrafiltration, pH 5.1: 93% removal efficiency, nanofiltration: 97% removal efficiency, reverse osmosis, pH 4-11: 99% removal efficiency)
- Electrolysis: for low metal concentration (e.g. electrodialysis: 13% removal efficiency within 2 hours at 2g/L, membrane electrolysis, electrochemical precipitation, pH 4-10, >99% removal efficiency)
- Reverse osmosis: extensively used for the removal of dissolved metals
- Ion exchange: final cleaning step in the removal of heavy metal from process wastewater (e.g. 90% removal efficiency for clinoptinolite and 100% removal efficiency for synthetic zeolite)

More information can be found in EC (2001), Integrated Pollution Prevention and Control (IPCC): reference document on Best Available Techniques in the Non Ferrous Metals Industries (spERC factsheet).

Soil:
No direct emissions to soil.

Organizational measures to prevent/limit release from site

None

Conditions and measures related to municipal sewage treatment plant

Waste water is not discharged to a municipal STP but treated on-site before discharge into a river.

Conditions and measures related to external treatment of waste for disposal

Hazardous wastes from onsite risk management measures and solid or liquid wastes from production, use and cleaning processes should be disposed of separately to hazardous waste incineration plants or hazardous waste landfills as hazardous waste. Releases to the floor, water and soil are to be prevented. If the antimony content of the waste is elevated enough, internal or external recovery/recycling might be considered.

Fraction of daily/annual use expected in waste: 0.004 or 0.4%

Appropriate waste codes:
02 01 10*, 06 05 02*, 10 08 04, 10 08 08*, 10 08 15*, 15 01 10*, 16 06 01*, 19 02 05*, 19 12 03*

Suitable disposal: Keep separate and dispose of to either
- Hazardous waste incineration operated according to Council Directive 2008/98/EC on waste, Directive 2000/76/EC on the incineration of waste and the Reference Document on the Best Available Techniques for Waste Incineration of August 2006.
- Hazardous landfill operated under Directive 1999/31/EC.

A detailed assessment has been performed and is reported in the Waste report (ARCHE, 2012)

Conditions and measures related to external recovery of waste

Not applicable

2.2c Control of environmental exposure for scenarios discharing into a marine environment

Amounts used

250 tonnes Sb/year/site

Frequency and duration of use

Continuous use/release, 300 days/year

Environment factors not influenced by risk management

For marine assessments a default dilution of 100 is assumed.

Other given operational conditions affecting environmental exposure

None

Technical conditions and measures at process level (source) to prevent release

None

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

This exposure scenario can contains different steps that occur at the same site. First there might be a formulation step followed by an industrial use step. These two steps are covered by 2 different spERCs. The first step is covered by the Eurometaux spERC 2.2a.v2.1 formulation of metal (compounds) in plastics and rubber. The second step is covered by the Eurometaux spERC 2.5-6a.v2.1 industrial use of metal (compounds) in plastics and rubber. The first two selected spERCs do contain measured data from antimony (compounds) and antimony falls into the Kd range of these spERCs. In order to adequately cover this exposure scenario the worst case release factor from both spERCs is selected for each compartment i.e. 0.001% release to water (2.5-6a.v2.1) and 0.005% release to air (2.2a.v2.1). Note that these release factors are after on-site treatment.

Release factor to air: 0.005%
Eurometaux spERC 2.2a.v2.1. in combination with on-site treatment. In order to obtain this release factor, direct air emissions should be reduced by implementing one or more of the following RMMs:

- Electrostatic precipitators using wide electrode spacing: 5 – 15 mg/Nm^3
- Wet electrostatic precipitators: < 5 mg/Nm^3
- Cyclones, but as primary collector: < 50 mg/Nm^3
- Fabric or bag filters: high efficiency in controlling fine particulate (melting): achieve emission values < 5mg/Nm^3. Membrane filtration techniques can achieve < 1 mg/Nm^3
- Ceramic and metal mesh filters. PM10 particles are removed: 0.1 mg/Nm^3
- Wet scrubbers: < 4 mg/Nm^3

(spERC factsheet).

Release factor to water: 0.001%
Eurometaux spERC 2.5-6a.v2.1 in combination with on-site treatment. In order to obtain this release factor, direct water emissions should be reduced by implementing one or more of the following RMMs:

- Chemical precipitation: used primarily to remove the metal ions (e.g. Ca(OH)2, pH 11 precipitation: >99% removal efficiency; Fe(OH)3, pH

11: 96% removal efficiency)
- Sedimentation (e.g. Na2S, pH 11, >99% removal efficiency)
- Filtration: used as final clarification step (e.g. ultrafiltration, pH 5.1: 93% removal efficiency, nanofiltration: 97% removal efficiency, reverse osmosis, pH 4-11: 99% removal efficiency)
- Electrolysis: for low metal concentration (e.g. electrodialysis: 13% removal efficiency within 2 hours at 2g/L, membrane electrolysis, electrochemical precipitation, pH 4-10, >99% removal efficiency)
- Reverse osmosis: extensively used for the removal of dissolved metals
- Ion exchange: final cleaning step in the removal of heavy metal from process wastewater (e.g. 90% removal efficiency for clinoptinolite and 100% removal efficiency for synthetic zeolite)

More information can be found in EC (2001), Integrated Pollution Prevention and Control (IPCC): reference document on Best Available Techniques in the Non Ferrous Metals Industries (spERC factsheet).

Soil:
No direct emissions to soil.

Organizational measures to prevent/limit release from site

None

Conditions and measures related to municipal sewage treatment plant

Waste water is not discharged to a municipal STP but treated on-site before discharge into a marine environment.

Conditions and measures related to external treatment of waste for disposal

Hazardous wastes from onsite risk management measures and solid or liquid wastes from production, use and cleaning processes should be disposed of separately to hazardous waste incineration plants or hazardous waste landfills as hazardous waste. Releases to the floor, water and soil are to be prevented. If the antimony content of the waste is elevated enough, internal or external recovery/recycling might be considered.

Fraction of daily/annual use expected in waste: 0.004 or 0.4%

Appropriate waste codes:
02 01 10*, 06 05 02*, 10 08 04, 10 08 08*, 10 08 15*, 15 01 10*, 16 06 01*, 19 02 05*, 19 12 03*

Suitable disposal: Keep separate and dispose of to either
- Hazardous waste incineration operated according to Council Directive 2008/98/EC on waste, Directive 2000/76/EC on the incineration of waste and the Reference Document on the Best Available Techniques for Waste Incineration of August 2006.
- Hazardous landfill operated under Directive 1999/31/EC.

A detailed assessment has been performed and is reported in the Waste report (ARCHE, 2012)

Conditions and measures related to external recovery of waste

Not applicable

3. Exposure estimation and reference to its source

Occupational exposure

For raw material handling, the 90th percentile of actual measured data is used for inhalation exposure. The risk characterisation ratio (RCR) is the quotient of the refined exposure estimate and the respective DNEL (derived no-effect level) and has to be below 1 to demonstrate a safe use. For inhalation exposure, the RCR is based on the DNEL for diantimony trioxide of 0.5 mg/m³.

Workplace	Method used for inhalation exposure assessment (refer to introduction)	Inhalation exposure estimate (RCR)	Method used for dermal exposure assessment (refer to introduction)	Dermal exposure estimate (RCR)
Raw material handling	measured data	0.026 mg/m³ (0.052)	Due to the negligible dermal absorption of diantimony trioxide (0.26 %, EURAR, 2008), the dermal route is not a relevant exposure path for diantimony trioxide. Thus, dermal exposure is not assessed in this exposure scenario. However, dermal exposure has to be minimised to an extent as technically feasible when working under certain conditions as described above.	
Further processing	qualitative assessment	negligible (<1)		
Final processing	qualitative assessment	negligible (<1)		

Environmental emissions

Environmental modelling was carried out in EUSES 2.1

Local PEC for scenario a) discharging to an STP and freshwater river

Air mg.m-3 (RCR)	Fresh water mg/l (RCR)	Marine water mg/l (RCR)	Sediment freshwater mg/kg wwt (RCR)	Sediment marine water mg/kg wwt (RCR)	Soil mg/kg wwt (RCR)	STP mg/l (RCR)
1.2E-05 (NA)	8.0E-04 (0.007)	No discharge to marine environment	0.73 (0.094)	No discharge to marine environment	1.64 (0.050)	0.001 (< 0.001)

Local PEC for scenario b) discharging directly to a freshwater river

Air mg.m-3 (RCR)	Fresh water mg/l (RCR)	Marine water mg/l (RCR)	Sediment freshwater mg/kg wwt (RCR)	Sediment marine water mg/kg wwt (RCR)	Soil mg/kg wwt (RCR)	STP mg/l (RCR)
1.2E-05 (NA)	1.11E-03 (0.010)	No discharge to marine environment	1.03 (0.132)	No discharge to marine environment	1.50 (0.046)	No discharge to STP

Local PEC for scenario c) discharing into a marine environment

Air mg.m-3 (RCR)	Fresh water mg/l (RCR)	Marine water mg/l (RCR)	Sediment freshwater mg/kg wwt (RCR)	Sediment marine water mg/kg wwt (RCR)	Soil mg/kg wwt (RCR)	STP mg/l (RCR)
1.2E-05 (NA)	No discharge to freshwater environment	2.4E-04 (0.021)	No discharge to freshwater environment	0.69 (0.441)	1.50 (0.046)	No discharge to STP

4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES

Occupational exposure

The DU works inside the boundaries set by the ES if either the proposed risk management measures as described above are met or the downstream user can demonstrate on his own that his operational conditions and implemented risk management measures are adequate. This has to be done by showing that they limit the inhalation and dermal exposure to a level below the respective DNEL (given that the processes and activities in question are covered by the PROCs listed above) as given below. If measured data are not available, the DU may make use of an appropriate scaling tool such as MEASE (www.ebrc.de/mease.html) to estimate the associated exposure. The dustiness of the substance used can be determined according to the MEASE glossary.

$DNEL_{inhalation}$: 0.5 mg/m^3

Environmental emissions

The DU works inside the boundaries set by the ES if either the proposed risk management measures as described above are met or the downstream user can demonstrate on his own that his operational conditions and implemented risk management measures are adequate. This has to be done by showing that they limit the environmental exposure to a level below the respective PNEC as given below. The RCR will be equal to or lower than those stated above if they emit less than 4.17 kg Sb/day to air and less than 0.3kg Sb/day to on site or off site waste water treatment works (equivalent to 0.06 kg Sb/day to the receiving water) with a dilution rate of 1:10. The emission to water can be scaled if the dilution rates are higher (e.g. a ten times higher dilution rate would allow ten times greater emissions whilst still having an RCR<1). If measured data are not available, the DU may make use of an appropriate scaling tool such as MetalEUSES (free download: http://www.arche-consulting.be/Metal-CSA-toolbox/duscaling-tool) to estimate the associated exposure.

$PNEC_{freshwater}$: 0.113 mg Sb/l
$PNEC_{marine}$: 0.0113 mg Sb/l
$PNEC_{sediment\ freshwater}$: 7.8 mg Sb/kg wwt
$PNEC_{sediment\ marine}$: 1.56 mg Sb/kg wwt
$PNEC_{soil}$: 37 mg Sb/kg dw (32.6 mg Sb/kg wwt)
$PNEC_{STP}$: 2.55 mg Sb/l

9.2.2. Exposure estimation

9.2.2.1 Indirect exposure of humans via the environment (local)

Table 92: Concentration and risk characterization for local exposure of humans via the environment

Concentration for local exposure of humans via the environment					
	Estimated exposure concentrations		**Measured exposure concentrations**		**Explanation / source of measured data**
	value	**unit**	**value**	**unit**	

Concentration for local exposure of humans via the environment

	Estimated exposure concentrations		**Measured exposure concentrations**		**Explanation / source of measured data**
	value	**unit**	**value**	**unit**	
Air	1.2* 10-5	mgSb/m^3	-	-	Local PEC has been calculated using EUSES 2.1 and converted from Sb to diantimony trioxide by a factor of 1.2.
	1.5* 10-5	mg Sb2O3/m^3	-	-	
Drinking water	1.6* 10-2	mg Sb/L	-	-	Local PEC has been calculated using EUSES 2.1 and converted from Sb to diantimony trioxide by a factor of 1.2.
	1.9* 10-2	mg Sb2O3/L	-	-	

Total daily dose for oral exposure via the environment (mg/kg bw/d)

µg Sb_2O_3/d	**mg Sb_2O_3/kg bw/d**	**Justification**
42.18	7.03* 10^{-4}	2L of drinking water from the local setting + the worst case exposure of 4.32 µg/d from food (section 9.0.4.3) and the default body weight of 60kg have been taken into account.

Quantitative risk characterisation for humans exposed via the environment

Route	**exposure concentrations (EC)**	**DN(M)EL**	**Risk characterisation ratio**
Inhalation- local effects (long term)	1.5* 10^{-5}mg Sb_2O_3/m^3	0.1 mg/m^3	1.5* 10^{-4}
Oral- systemic (long term)	7.03* 10^{-4} mg Sb_2O_3/kg bw/d	168.6 mg/kg/d	4.2* 10^{-6}
Combined routes			RCR Inhalation- systemic + RCR Oral- systemic

9.2.2.2 Environmental exposure

Table 93: Risk characterisation for the soil, sediment and water compartments for scenario a) discharging to an STP and freshwater river

Compartment	**Local PEC**	**PNEC**	**PEC/PNEC (RCR)**
Freshwater aquatic (mg Sb/l)	8.0E-04	0.113	0.007
Freshwater sediment (mg Sb/kg wwt)	0.73	7.8	0.094
Terrestrial (mg Sb/kg wwt)	1.64	32.6	0.050
Sewage treatment plant (mg Sb/l)	0.001	2.55	< 0.001

Table 94: Risk characterisation for the soil, sediment and water compartments for scenario b) discharging directly to a freshwater river

Compartment	**Local PEC**	**PNEC**	**PEC/PNEC (RCR)**
Freshwater aquatic (mg Sb/l)	1.1E-03	0.113	0.010
Freshwater sediment (mg Sb/kg wwt)	1.03	7.8	0.132
Terrestrial (mg Sb/kg wwt)	1.50	32.6	0.046

Table 95: Risk characterisation for the soil, sediment and water compartments for scenario c) discharing into a marine environment

Compartment	**Local PEC**	**PNEC**	**PEC/PNEC (RCR)**
Marine aquatic (mg Sb/l)	2.4E-03	0.0113	0.021
Marine sediment (mg Sb/kg wwt)	0.69	1.6	0.441
Terrestrial (mg Sb/kg wwt)	1.50	32.6	0.046

9.3. Industrial use of diantimony trioxide in the plastics and rubber industry

9.3.1. Exposure scenario

Exposure Scenario Format (1) addressing uses carried out by workers

1. Title

Free short title	Use of diantimony trioxide in flame retarded plastics, formulations, flame retarded rubber, polymer preparations and compounds, coating of textiles with flexible PVC, manufacture of fire proofing plastic films, manufacture of fire proofing cables, cable sheathing
Systematic title based on use descriptor	SU3 (Industrial use), SU5, SU10, SU11, SU12, SU16, SU17, SU18, SU20, SU23 PC19, PC21, PC24, PC26, PC32, PC33 AC1, AC2 (TARIC 8544), AC 3, AC5, AC10, AC13 (TARIC 3925) (appropriate PROCs and ERCs are given in section 2 below)
Processes, tasks and/or activities covered	Processes, tasks and/or activities covered are described in Section 2 below.
Assessment Method	For “powder handling”, the assessment of inhalation exposure is based on measured data. All of these data have been peer-reviewed in the risk assessment report on diantimony trioxide. For the remaining workplaces, MEASE was used for the assessment of inhalation exposure. The environmental assessment uses EUSES.

2. Operational conditions and risk management measures

Workplace	**Involved tasks**	**Involved PROCs**	**Involved ERC**
Powder handling	Powder handling, loading operations, mixing	5, 8a, 8b, 9, 26	5
Inclusion into matrix	Formulation of masterbatches, reaction	1, 2, 3, 4	
Further processing	Extrusion, calendaring, coating, gelling, thermal reforming, moulding, thermal joining, film blowing	6, 10, 13, 14, 15, 21, 24	

2.1 Control of workers exposure

Product characteristic

According to the MEASE approach, the substance-intrinsic emission potential is one of the main exposure determinants. This is reflected by an assignment of a so-called fugacity class in the MEASE tool. For operations conducted with solid substances at ambient temperature the fugacity is based on the dustiness of that substance. Whereas in hot metal operations, fugacity is temperature based, taking into account the process temperature and the melting point of the substance. As a third group, high abrasive tasks are based on the level of abrasion instead of the substance intrinsic emission potential.

Workplace	**Used in preparation?**	**Content in preparation**	**Physical form**	**Emission potential**
Powder handling	not restricted		powder*	high
Inclusion into matrix	not restricted		masterbatch / massive	very low
Further processing	yes (article)	<25 %	massive	very low

*Also other physical forms (i.e. aqueous paste, plasticisers, dispersions, granules and wetted powders) than powder are used. As powder represents the worst case in terms of its emission potential the raw material handling of these physical forms is covered in the initial “powder handling” process step in this exposure scenario. If other physical forms render some of the proposed RMMs below unnecessary the downstream user is referred to section 4 of this exposure scenario to proof that.

Amounts used

The actual tonnage handled per shift is not considered to influence the exposure as such for this scenario. Instead, the combination of the scale of operation (industrial vs. professional) and level of containment/automation (as reflected in the PROC) is the main determinant of the process intrinsic emission potential.

Frequency and duration of use/exposure

Workplace	**Duration of exposure**
Powder handling	≤ 180 minutes
Inclusion into matrix	480 minutes (not restricted)
Further processing	480 minutes (not restricted)

Human factors not influenced by risk management

The shift breathing volume during all process steps reflected in the PROCs is assumed to be 10 m^3/shift (8 hours).

Other given operational conditions affecting workers exposure

Workplace	Room volume	Outdoors or indoors?	Process temperature	Process pressure
Powder handling	>1,000 m^3	indoors	Not considered relevant for occupational exposure assessment of the conducted processes.	Not considered relevant for occupational exposure assessment of the conducted processes.
Inclusion into matrix				
Further processing				

Technical conditions and measures at process level (source) to prevent release

Workplace	Level of containment	Level of segregation
Powder handling	closed system	not required
Inclusion into matrix	not required	
Further processing		

Technical conditions and measures to control dispersion from source towards the worker

Workplace	Level of separation	Localised controls (LC)	Efficiency of LC (according to MEASE)	Further information
Powder handling	Any potentially required separation of workers from the emission source is indicated above under “Frequency and duration of exposure”. A reduction of exposure duration can be achieved, for example, by the installation of ventilated (positive pressure) control rooms or by removing the worker from workplaces involved with relevant exposure.	generic local exhaust ventilation	78 %	-
Inclusion into matrix		not required	na	-
Further processing		no	na	-

Organisational measures to prevent /limit releases, dispersion and exposure

Avoid inhalation or ingestion. General occupational hygiene measures are required to ensure a safe handling of the substance. These measures involve good personal and housekeeping practices (i.e. regular cleaning with suitable cleaning devices), no eating and smoking at the workplace, unless otherwise stated below the wearing of standard working clothes and shoes. Shower and change clothes at end of work shift. Do not wear contaminated clothing at home. Do not blow dust off with compressed air.

Historical observations of skin irritation have been made amongst workers caused by handling of diantimony trioxide powder under special conditions, namely substantial heat and sweat. The observed skin reactions, limited to workers at a diantimony trioxide (ATO) producing facility are likely to be evoked more by physically mediated processes associated with blocking of the sweat glands in the absence of any intrinsic substantial primary skin irritating potential of the substance and also in consideration of the poor solubility of ATO. Industry is committed to adequately control the risks of any adverse effects to workers who are exposed in hot, sweaty conditions to fumes or dust containing ATO by following the occupational hygiene practices as described in this exposure scenario. However, it is explicitly noted that the above described historical observations of skin effects have been scientifically evaluated by the Committee for Risk Assessment (RAC) of the European Chemicals Agency (ECHA) and did not lead to a classification of diantimony trioxide. As a precautionary measure, the wearing of chemical resistant gloves, long sleeved overalls and closed footwear, designed to minimize skin contact is suggested for all diantimony trioxide powder handling workplaces.

Conditions and measures related to personal protection, hygiene and health evaluation

Workplace	Specification of respiratory protective equipment (RPE)	RPE efficiency (assigned protection factor, APF)	Specification of gloves	Further personal protective equipment (PPE)
Powder handling	FFP1 mask	APF=4	protective gloves	standard working clothes (overall with long sleeves) and safety shoes
Inclusion into matrix	not required	not required	not required	
Further processing				

Any RPE as defined above shall only be worn if the following principles are implemented in parallel: The duration of work (compare with “duration of exposure” above) should reflect the additional physiological stress for the worker due to the breathing resistance and mass of the RPE itself, due to the increased thermal stress by enclosing the head. In addition, it shall be considered that the worker’s capability of using tools and of communicating are reduced during the wearing of RPE.

For reasons as given above, the worker should therefore be (i) healthy (especially in view of medical problems that may affect the use of RPE), (ii) have suitable facial characteristics reducing leakages between face and mask (in view of scars and facial hair). The recommended devices above which rely on a tight face seal will not provide the required protection unless they fit the contours of the face properly and securely.

The employer and self-employed persons have legal responsibilities for the maintenance and issue of respiratory protective devices and the management of their correct use in the workplace. Therefore, they should define and document a suitable policy for a respiratory protective device programme including training of the workers.

An overview of the APFs of different RPE (according to BS EN 529:2005) can be found in the glossary of MEASE.

2.2a Control of environmental exposure for scenarios discharging to an STP and freshwater river

Amounts used

2500 tonnes Sb/year/site

Frequency and duration of use

Continuous use/release, 300 days/year

Environment factors not influenced by risk management

Default data for receiving water and for the municipal sewage treatment plant are18 000 m3/d and 2000 m3/d, respectively (resulting dilution factor 10).

Other given operational conditions affecting environmental exposure

None

Technical conditions and measures at process level (source) to prevent release

None

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

This exposure scenario can contains different steps that occur at the same site. First there might be a formulation step followed by an industrial use step. These two steps are covered by 2 different spERCs. The first step is covered by the Eurometaux spERC 2.2a.v2.1 formulation of metal (compounds) in plastics and rubber. The second step is covered by the Eurometaux spERC 2.5-6a.v2.1 industrial use of metal (compounds) in plastics and rubber. The two selected spERCs do contain measured data from antimony (compounds) and antimony falls into the Kd range of these spERCs. In order to adequately cover this exposure scenario the worst case release factor from both spERCs is selected for each compartment i.e. 0.001% release to water (2.5-6a.v2.1) and 0.005% release to air (2.2a.v2.1). Note that these release factors are after on-site treatment.

Release factor to air: 0.005%
Eurometaux spERC 2.2a.v2.1. in combination with on-site treatment. In order to obtain this release factor, direct air emissions should be reduced by implementing one or more of the following RMMs:

- Electrostatic precipitators using wide electrode spacing: 5 – 15 mg/Nm^3
- Wet electrostatic precipitators: < 5 mg/Nm^3
- Cyclones, but as primary collector: < 50 mg/Nm^3
- Fabric or bag filters: high efficiency in controlling fine particulate (melting): achieve emission values < 5mg/Nm^3. Membrane filtration techniques can achieve < 1 mg/Nm^3
- Ceramic and metal mesh filters. PM10 particles are removed: 0.1 mg/Nm^3
- Wet scrubbers: < 4 mg/Nm^3

(spERC factsheet).

Release factor to water: 0.001%
Eurometaux spERC 2.5-6a.v2.1 in combination with on-site treatment. In order to obtain this release factor, direct water emissions should be reduced by implementing one or more of the following RMMs:

- Chemical precipitation: used primarily to remove the metal ions (e.g. Ca(OH)2, pH 11 precipitation: >99% removal efficiency; Fe(OH)3, pH 11: 96% removal efficiency)
- Sedimentation (e.g. Na2S, pH 11, >99% removal efficiency)
- Filtration: used as final clarification step (e.g. ultrafiltration, pH 5.1: 93% removal efficiency, nanofiltration: 97% removal efficiency, reverse osmosis, pH 4-11: 99% removal efficiency)
- Electrolysis: for low metal concentration (e.g. electrodialysis: 13% removal efficiency within 2 hours at 2g/L, membrane electrolysis, electrochemical precipitation, pH 4-10, >99% removal efficiency)
- Reverse osmosis: extensively used for the removal of dissolved metals
- Ion exchange: final cleaning step in the removal of heavy metal from process wastewater (e.g. 90% removal efficiency for clinoptinolite and 100% removal efficiency for synthetic zeolite)

More information can be found in EC (2001), Integrated Pollution Prevention and Control (IPCC): reference document on Best Available Techniques in the Non Ferrous Metals Industries (spERC factsheet).

Soil:
No direct emissions to soil.

Organizational measures to prevent/limit release from site

None

Conditions and measures related to municipal sewage treatment plant

EUSES default STP with primary settler with effluent discharge rate 2000000l/d, serving 10000 inhabitants. Zero degradation assumed. 79.1 % to sludge, 20.9 % to water calculated in EUSES based on partition coefficients. Sludge assumed to be spread to agricultural land.

Conditions and measures related to external treatment of waste for disposal

Hazardous wastes from onsite risk management measures and solid or liquid wastes from production, use and cleaning processes should be disposed of separately to hazardous waste incineration plants or hazardous waste landfills as hazardous waste. Releases to the floor, water and soil are to be prevented. If the antimony content of the waste is elevated enough, internal or external recovery/recycling might be considered.

Fraction of daily/annual use expected in waste: 0.004 or 0.4%

Appropriate waste codes:
02 01 10*, 06 05 02*, 10 08 04, 10 08 08*, 10 08 15*, 15 01 10*, 16 06 01*, 19 02 05*, 19 12 03*

Suitable disposal: Keep separate and dispose of to either
- Hazardous waste incineration operated according to Council Directive 2008/98/EC on waste, Directive 2000/76/EC on the incineration of waste and the Reference Document on the Best Available Techniques for Waste Incineration of August 2006.
- Hazardous landfill operated under Directive 1999/31/EC.

A detailed assessment has been performed and is reported in the Waste report (ARCHE, 2012)

Conditions and measures related to external recovery of waste

Not applicable

2.2b Control of environmental exposure for scenarios discharging directly to a freshwater river

Amounts used

2500 tonnes Sb/year/site

Frequency and duration of use

Continuous use/release, 300 days/year

Environment factors not influenced by risk management

Default data for receiving water is18 000 m3/d (resulting dilution factor 10).

Other given operational conditions affecting environmental exposure

None

Technical conditions and measures at process level (source) to prevent release

None

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

This exposure scenario can contains different steps that occur at the same site. First there might be a formulation step followed by an industrial use step. These two steps are covered by 2 different spERCs. The first step is covered by the Eurometaux spERC 2.2a.v2.1 formulation of metal (compounds) in plastics and rubber. The second step is covered by the Eurometaux spERC 2.5-6a.v2.1 industrial use of metal (compounds) in plastics and rubber. The two selected spERCs do contain measured data from antimony (compounds) and antimony falls into the Kd range of these spERCs. In order to adequately cover this exposure scenario the worst case release factor from both spERCs is selected for each compartment i.e. 0.001% release to water (2.5-6a.v2.1) and 0.005% release to air (2.2a.v2.1). Note that these release factors are after on-site treatment.

Release factor to air: 0.005%
Eurometaux spERC 2.2a.v2.1. in combination with on-site treatment. In order to obtain this release factor, direct air emissions should be reduced by implementing one or more of the following RMMs:
- Electrostatic precipitators using wide electrode spacing: 5 – 15 mg/Nm^3
- Wet electrostatic precipitators: < 5 mg/Nm^3
- Cyclones, but as primary collector: < 50 mg/Nm^3
- Fabric or bag filters: high efficiency in controlling fine particulate (melting): achieve emission values < 5mg/Nm^3. Membrane filtration techniques can achieve < 1 mg/Nm^3
- Ceramic and metal mesh filters. PM10 particles are removed: 0.1 mg/Nm^3
- Wet scrubbers: < 4 mg/Nm^3

(spERC factsheet).

Release factor to water: 0.001%
Eurometaux spERC 2.5-6a.v2.1 in combination with on-site treatment. In order to obtain this release factor, direct water emissions should be reduced by implementing one or more of the following RMMs:
- Chemical precipitation: used primarily to remove the metal ions (e.g. Ca(OH)2, pH 11 precipitation: >99% removal efficiency; Fe(OH)3, pH 11: 96% removal efficiency)
- Sedimentation (e.g. Na2S, pH 11, >99% removal efficiency)
- Filtration: used as final clarification step (e.g. ultrafiltration, pH 5.1: 93% removal efficiency, nanofiltration: 97% removal efficiency, reverse osmosis, pH 4-11: 99% removal efficiency)
- Electrolysis: for low metal concentration (e.g. electrodialysis: 13% removal efficiency within 2 hours at 2g/L, membrane electrolysis, electrochemical precipitation, pH 4-10, >99% removal efficiency)
- Reverse osmosis: extensively used for the removal of dissolved metals
- Ion exchange: final cleaning step in the removal of heavy metal from process wastewater (e.g. 90% removal efficiency for clinoptinolite and 100% removal efficiency for synthetic zeolite)

More information can be found in EC (2001), Integrated Pollution Prevention and Control (IPCC): reference document on Best Available Techniques in the Non Ferrous Metals Industries (spERC factsheet).

Soil:
No direct emissions to soil.

Organizational measures to prevent/limit release from site

None

Conditions and measures related to municipal sewage treatment plant

Waste water is not discharged to a municipal STP but treated on-site before discharge into a river.

Conditions and measures related to external treatment of waste for disposal

Hazardous wastes from onsite risk management measures and solid or liquid wastes from production, use and cleaning processes should be disposed of separately to hazardous waste incineration plants or hazardous waste landfills as hazardous waste. Releases to the floor, water and soil are to be prevented. If the antimony content of the waste is elevated enough, internal or external recovery/recycling might be considered.

Fraction of daily/annual use expected in waste: 0.004 or 0.4%

Appropriate waste codes:
02 01 10*, 06 05 02*, 10 08 04, 10 08 08*, 10 08 15*, 15 01 10*, 16 06 01*, 19 02 05*, 19 12 03*

Suitable disposal: Keep separate and dispose of to either

- Hazardous waste incineration operated according to Council Directive 2008/98/EC on waste, Directive 2000/76/EC on the incineration of waste and the Reference Document on the Best Available Techniques for Waste Incineration of August 2006.
- Hazardous landfill operated under Directive 1999/31/EC.

A detailed assessment has been performed and is reported in the Waste report (ARCHE, 2012)

Conditions and measures related to external recovery of waste

Not applicable

2.2c Control of environmental exposure for scenarios discharing into a marine environment

Amounts used

2500 tonnes Sb/year/site

Frequency and duration of use

Continuous use/release, 300 days/year

Environment factors not influenced by risk management

For marine assessments a default dilution of 100 is assumed.

Other given operational conditions affecting environmental exposure

None

Technical conditions and measures at process level (source) to prevent release

None

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

This exposure scenario can contains different steps that occur at the same site. First there might be a formulation step followed by an industrial use step. These two steps are covered by 2 different spERCs. The first step is covered by the Eurometaux spERC 2.2a.v2.1 formulation of metal (compounds) in plastics and rubber. The second step is covered by the Eurometaux spERC 2.5-6a.v2.1 industrial use of metal (compounds) in plastics and rubber. The two selected spERCs do contain measured data from antimony (compounds) and antimony falls into the Kd range of these spERCs. In order to adequately cover this exposure scenario the worst case release factor from both spERCs is selected for each compartment i.e. 0.001% release to water (2.5-6a.v2.1) and 0.005% release to air (2.2a.v2.1). Note that these release factors are after on-site treatment.

Release factor to air: 0.005%
Eurometaux spERC 2.2a.v2.1. in combination with on-site treatment. In order to obtain this release factor, direct air emissions should be reduced by implementing one or more of the following RMMs:

- Electrostatic precipitators using wide electrode spacing: 5 – 15 mg/Nm^3
- Wet electrostatic precipitators: < 5 mg/Nm^3
- Cyclones, but as primary collector: < 50 mg/Nm^3
- Fabric or bag filters: high efficiency in controlling fine particulate (melting): achieve emission values < 5mg/Nm^3. Membrane filtration techniques can achieve < 1 mg/Nm^3
- Ceramic and metal mesh filters. PM10 particles are removed: 0.1 mg/Nm^3
- Wet scrubbers: < 4 mg/Nm^3

(spERC factsheet).

Release factor to water: 0.001%
Eurometaux spERC 2.5-6a.v2.1 in combination with on-site treatment. In order to obtain this release factor, direct water emissions should be reduced by implementing one or more of the following RMMs:

- Chemical precipitation: used primarily to remove the metal ions (e.g. $Ca(OH)2$, pH 11 precipitation: >99% removal efficiency; $Fe(OH)3$, pH 11: 96% removal efficiency)
- Sedimentation (e.g. $Na2S$, pH 11, >99% removal efficiency)
- Filtration: used as final clarification step (e.g. ultrafiltration, pH 5.1: 93% removal efficiency, nanofiltration: 97% removal efficiency, reverse osmosis, pH 4-11: 99% removal efficiency)
- Electrolysis: for low metal concentration (e.g. electrodialysis: 13% removal efficiency within 2 hours at 2g/L, membrane electrolysis, electrochemical precipitation, pH 4-10, >99% removal efficiency)
- Reverse osmosis: extensively used for the removal of dissolved metals
- Ion exchange: final cleaning step in the removal of heavy metal from process wastewater (e.g. 90% removal efficiency for clinoptinolite and 100% removal efficiency for synthetic zeolite)

More information can be found in EC (2001), Integrated Pollution Prevention and Control (IPCC): reference document on Best Available Techniques in the Non Ferrous Metals Industries (spERC factsheet).

Soil:
No direct emissions to soil.

Organizational measures to prevent/limit release from site

None

Conditions and measures related to municipal sewage treatment plant

Waste water is not discharged to a municipal STP but treated on-site before discharge into a marine environment.

Conditions and measures related to external treatment of waste for disposal

Hazardous wastes from onsite risk management measures and solid or liquid wastes from production, use and cleaning processes should be disposed of separately to hazardous waste incineration plants or hazardous waste landfills as hazardous waste. Releases to the floor, water and soil are to be prevented. If the antimony content of the waste is elevated enough, internal or external recovery/recycling might be considered.

Fraction of daily/annual use expected in waste: 0.004 or 0.4%

Appropriate waste codes:
02 01 10*, 06 05 02*, 10 08 04, 10 08 08*, 10 08 15*, 15 01 10*, 16 06 01*, 19 02 05*, 19 12 03*

Suitable disposal: Keep separate and dispose of to either
- Hazardous waste incineration operated according to Council Directive 2008/98/EC on waste, Directive 2000/76/EC on the incineration of waste and the Reference Document on the Best Available Techniques for Waste Incineration of August 2006.
- Hazardous landfill operated under Directive 1999/31/EC.

A detailed assessment has been performed and is reported in the Waste report (ARCHE, 2012)

Conditions and measures related to external recovery of waste

Not applicable

3. Exposure estimation and reference to its source

Occupational exposure

For powder handling, the 90th percentile of measured data from the production of plastics is used to assess inhalation exposure. For the remaining workplaces, MEASE was used for the assessment of inhalation exposure. The risk characterisation ratio (RCR) is the quotient of the refined exposure estimate and the respective DNEL (derived no-effect level) and has to be below 1 to demonstrate a safe use. For inhalation exposure, the RCR is based on the DNEL for diantimony trioxide of 0.5 mg/m^3.

Workplace	Method used for inhalation exposure assessment (refer to introduction)	Inhalation exposure estimate (RCR)	Method used for dermal exposure assessment (refer to introduction)	Dermal exposure estimate (RCR)
Powder handling	measured data	0.143 mg/m^3 (0.29)	Due to the negligible dermal absorption of diantimony trioxide (0.26 %, ECB, 2008), the dermal route is not a relevant exposure path for diantimony trioxide. Thus, dermal exposure is not assessed in this exposure scenario. However, dermal exposure has to be minimised to an extent as technically feasible when working under certain conditions as described above.	
Inclusion into matrix	MEASE (PROC 4 as worst case assumption)	0.05 mg/m^3 (0.10)		
Further processing	MEASE (PROC 21 as worst case assumption)	0.03 mg/m^3 (0.06)		

Environmental emissions

Environmental modelling was carried out in EUSES 2.1

Local PEC for scenario a) discharging to an STP and freshwater river

Air mg.m-3 (RCR)	Fresh water mg/l (RCR)	Marine water mg/l (RCR)	Sediment freshwater mg/kg wwt (RCR)	Sediment marine water mg/kg wwt (RCR)	Soil mg/kg wwt (RCR)	STP mg/l (RCR)
9.8E-05 (NA)	1.54E-03 (0.014)	No discharge to marine environment	1.44 (0.185)	No discharge to marine environment	2.87 (0.088)	0.009 (0.003)

Local PEC for scenario b) discharging directly to a freshwater river

Air mg.m-3 (RCR)	Fresh water mg/l (RCR)	Marine water mg/l (RCR)	Sediment freshwater mg/kg wwt (RCR)	Sediment marine water mg/kg wwt (RCR)	Soil mg/kg wwt (RCR)	STP mg/l (RCR)
9.8E-05 (NA)	4.63E-03 (0.041)	No discharge to marine environment	4.45 (0.570)	No discharge to marine environment	1.54 (0.47)	No discharge to STP

Local PEC for scenario c) discharing into a marine environment

Air mg.m-3 (RCR)	Fresh water mg/l (RCR)	Marine water mg/l (RCR)	Sediment freshwater mg/kg wwt (RCR)	Sediment marine water mg/kg wwt (RCR)	Soil mg/kg wwt (RCR)	STP mg/l (RCR)
9.8E-05 (NA)	No discharge to freshwater environment	5.9E-04 (0.052)	No discharge to freshwater environment	1.03 (0.660)	1.54 (0.47)	No discharge to STP

4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES

Occupational exposure

The DU works inside the boundaries set by the ES if either the proposed risk management measures as described above are met or the downstream user can demonstrate on his own that his operational conditions and implemented risk management measures are adequate. This has to be done by showing that they limit the inhalation and dermal exposure to a level below the respective DNEL (given that the processes and activities in question are covered by the PROCs listed above) as given below. If measured data are not available, the DU may make use of an appropriate scaling tool such as MEASE (www.ebrc.de/mease.html) to estimate the associated exposure. The dustiness of the substance used can be determined according to the MEASE glossary.

DNEL$_{inhalation}$: 0.5 mg/m^3

Environmental emissions

The DU works inside the boundaries set by the ES if either the proposed risk management measures as described above are met or the downstream user can demonstrate on his own that his operational conditions and implemented risk management measures are adequate. The RCR will be equal to or lower than those stated above if they emit less than 41.7kg Sb/day to air and less than 0.3kg Sb/day to on site or off site waste water treatment works (equivalent to 0.06 kg Sb/day to the receiving water) with a dilution rate of 1:10. The emission to water can be scaled if the dilution rates are higher (e.g. a ten times higher dilution rate would allow ten times greater emissions whilst still having an RCR<1). This has to be done by showing that they limit the environmental exposure to a level below the respective PNEC as given below. If measured data are not available, the DU may make use of an appropriate scaling tool such as MetalEUSES (free download: http://www.arche-consulting.be/Metal-CSA-toolbox/duscaling-tool) to estimate the associated exposure.

PNEC$_{freshwater}$: 0.113 mg Sb/l
PNEC$_{marine}$: 0.0113 mg Sb/l
PNEC$_{sediment\ freshwater}$: 7.8 mg Sb/kg wwt
PNEC$_{sediment\ marine}$: 1.56 mg Sb/kg wwt
PNEC$_{soil}$: 37 mg Sb/kg dw (32.6 mg Sb/kg wwt)
PNEC$_{STP}$: 2.55 mg Sb/l

9.3.2. Exposure estimation

9.3.2.1 Indirect exposure of humans via the environment (local)

Table 96: Concentration and risk characterization for local exposure of humans via the environment

Concentration for local exposure of humans via the environment			
	Estimated exposure concentrations	Measured exposure concentrations	Explanation / source of measured data

	value	unit	value	unit	
Air	9.8* 10-5	9.8* 10-5	-	-	Local PEC has been calculated using EUSES 2.1 and converted from Sb to diantimony trioxide by a factor of 1.2.
	1.2* 10-4	1.2* 10-4	-	-	
Drinking water	2.8* 10-2	2.8* 10-2	-	-	Local PEC has been calculated using EUSES 2.1 and converted from Sb to diantimony trioxide by a factor of 1.2.
	3.3* 10-2	3.3* 10-2	-	-	
Total daily dose for oral exposure via the environment (mg/kg bw/d)					
µg Sb_2O_3/d	**mg Sb_2O_3/kg bw/d**		**Justification**		
70.71	1.18* 10^{-3}		2L of drinking water from the local setting + the worst case exposure of 4.32 µg/d from food (section 9.0.4.3) and the default body weight of 60kg have been taken into account.		
Quantitative risk characterisation for humans exposed via the environment					
Route	**exposure concentrations (EC)**		**DN(M)EL**		**Risk characterisation ratio**
Inhalation- local effects (long term)	1.2* 10^{-4}mg Sb_2O_3/m^3		0.1 mg/m³		1.2*10^{-3}
Oral- systemic (long term)	1.18* 10^{-3} mg Sb_2O_3/kg bw/d		168.6 mg/kg/d		7.0* 10^{-6}
Combined routes					RCR Inhalation- systemic + RCR Oral- systemic

9.3.2.2 Environmental exposure

Table 97: Risk characterisation for the soil, sediment and water compartments for scenario a) discharging to an STP and freshwater river

Compartment	**Local PEC**	**PNEC**	**PEC/PNEC (RCR)**
Freshwater aquatic (mg Sb/l)	1.54E-03	0.113	0.014
Freshwater sediment (mg Sb/kg wwt)	1.44	7.8	0.185
Terrestrial (mg Sb/kg wwt)	2.87	32.6	0.088
Sewage treatment plant (mg Sb/l)	0.009	2.55	0.003

Table 98: Risk characterisation for the soil, sediment and water compartments for scenario b) discharging directly to a freshwater river

Compartment	**Local PEC**	**PNEC**	**PEC/PNEC (RCR)**
Freshwater aquatic (mg Sb/l)	4.63E-03	0.113	0.041
Freshwater sediment (mg Sb/kg wwt)	4.45	7.8	0.570
Terrestrial (mg Sb/kg wwt)	1.54	32.6	0.047

Table 99: Risk characterisation for the soil, sediment and water compartments for scenario c) discharing into a marine environment

Compartment	**Local PEC**	**PNEC**	**PEC/PNEC (RCR)**
Marine aquatic (mg Sb/l)	5.9E-04	0.0113	0.052
Marine sediment (mg Sb/kg wwt)	1.03	1.6	0.660
Terrestrial (mg Sb/kg wwt)	1.54	32.6	0.047

9.4. Industrial use of diantimony trioxide in the manufacture of flame retarded textiles

9.4.1. Exposure scenario

Exposure Scenario Format (1) addressing uses carried out by workers

1. Title

Free short title	Use of diantimony trioxide in flame retarded textiles
Systematic title based on use descriptor	SU3 (Industrial uses), SU5 (Manufacture of textiles, leather, fur), SU10 (Formulation of preparations and/or re-packing) PC23, PC32, PC34 AC6, AC5 (TARIC 59031090, 59032090) (appropriate PROCs and ERCs are given in section 2 below)
Processes, tasks and/or activities covered	Processes, tasks and/or activities covered are described in Section 2 below.
Assessment Method	The assessment of inhalation exposure during “powder handling” is based on analogous data from the production of plastics. All of these data have been peer-reviewed in the risk assessment report on diantimony trioxide. For “processing”, inhalation exposure is based on published data from the upholstery manufacturing industry. For “further handling”, the inhalation exposure assessment is based on MEASE. The environmental assessment uses EUSES.

2. Operational conditions and risk management measures

Workplace	**Involved tasks**	**Involved PROCs**	**Involved ERC**
Powder handling	Powder handling, formulation	5, 8a, 8b, 9, 26	5
Processing	Mixing, rolling, foaming, back-coating, drying, unloading, cleaning	1, 6, 7, 10, 12, 13, 22	
Further handling	Joining of backings, rolling processes, cutting, sewing, upholstering, stuffing	21, 24	

2.1 Control of workers exposure

Product characteristic

According to the MEASE approach, the substance-intrinsic emission potential is one of the main exposure determinants. This is reflected by an assignment of a so-called fugacity class in the MEASE tool. For operations conducted with solid substances at ambient temperature the fugacity is based on the dustiness of that substance. Whereas in hot metal operations, fugacity is temperature based, taking into account the process temperature and the melting point of the substance. As a third group, high abrasive tasks are based on the level of abrasion instead of the substance intrinsic emission potential.

Workplace	**Used in preparation?**	**Content in preparation**	**Physical form**	**Emission potential**
Powder handling	not restricted		Powder*	high
Processing	yes	not restricted (concentration in solution)	aqueous dispersion	very low (except for PROC 7)
Further handling	yes	<25 % (concentration on textile)	solid bound to object	very low

*Also other physical forms (i.e. aqueous paste, plasticisers, dispersions and wetted powders) than powder are used. As powder represents the worst case in terms of its emission potential the raw material handling of these physical forms is covered in the initial “powder handling” process step in this exposure scenario. If other physical forms render some of the proposed RMMs below unnecessary the downstream user is referred to section 4 of this exposure scenario to proof that.

Amounts used

The actual tonnage handled per shift is not considered to influence the exposure as such for this scenario. Instead, the combination of the scale of operation (industrial vs. professional) and level of containment/automation (as reflected in the PROC) is the main determinant of the process intrinsic emission potential.

Frequency and duration of use/exposure

Workplace	**Duration of exposure**
Powder handling	≤ 120 minutes
Processing	≤ 30 minutes (for manual operations, e.g. cleaning during back-coating), automated operations are not restricted
Further handling	480 minutes (not restricted)

Human factors not influenced by risk management

The shift breathing volume during all process steps reflected in the PROCs is assumed to be 10 m^3/shift (8 hours).

Other given operational conditions affecting workers exposure

Workplace	Room volume	Outdoors or indoors?	Process temperature	Process pressure
Powder handling	>1,000 m³	indoors	Not considered relevant for occupational exposure assessment of the conducted processes.	Not considered relevant for occupational exposure assessment of the conducted processes.
Processing				
Further handling				

Technical conditions and measures at process level (source) to prevent release

Workplace	Level of containment	Level of segregation
Powder handling	closed system	not required
Processing	not required	
Further handling		

Technical conditions and measures to control dispersion from source towards the worker

Workplace	Level of separation	Localised controls (LC)	Efficiency of LC (according to MEASE)	Further information
Powder handling	Any potentially required separation of workers from the emission source is indicated above under “Frequency and duration of exposure”. A reduction of exposure duration can be achieved, for example, by the installation of ventilated (positive pressure) control rooms or by removing the worker from workplaces involved with relevant exposure.	generic local exhaust ventilation	78 %	-
Processing		no	na	-
Further handling		no	na	-

Organisational measures to prevent /limit releases, dispersion and exposure

Avoid inhalation or ingestion. General occupational hygiene measures are required to ensure a safe handling of the substance. These measures involve good personal and housekeeping practices (i.e. regular cleaning with suitable cleaning devices), no eating and smoking at the workplace, unless otherwise stated below the wearing of standard working clothes and shoes. Shower and change clothes at end of work shift. Do not wear contaminated clothing at home. Do not blow dust off with compressed air.

Historical observations of skin irritation have been made amongst workers caused by handling of diantimony trioxide powder under special conditions, namely substantial heat and sweat. The observed skin reactions, limited to workers at a diantimony trioxide (ATO) producing facility are likely to be evoked more by physically mediated processes associated with blocking of the sweat glands in the absence of any intrinsic substantial primary skin irritating potential of the substance and also in consideration of the poor solubility of ATO. Industry is committed to adequately control the risks of any adverse effects to workers who are exposed in hot, sweaty conditions to fumes or dust containing ATO by following the occupational hygiene practices as described in this exposure scenario. However, it is explicitly noted that the above described historical observations of skin effects have been scientifically evaluated by the Committee for Risk Assessment (RAC) of the European Chemicals Agency (ECHA) and did not lead to a classification of diantimony trioxide. As a precautionary measure, the wearing of chemical resistant gloves, long sleeved overalls and closed footwear, designed to minimize skin contact is suggested for all diantimony trioxide powder handling workplaces.

Conditions and measures related to personal protection, hygiene and health evaluation

Workplace	Specification of respiratory protective equipment (RPE)	RPE efficiency (assigned protection factor, APF)	Specification of gloves	Further personal protective equipment (PPE)
Powder handling	FFP1 mask	APF=4	protective gloves	standard working clothes (overall with long sleeves) and safety shoes
Processing	not required	not required	protective gloves water resistant	
Further handling			not required	

Any RPE as defined above shall only be worn if the following principles are implemented in parallel: The duration of work (compare with “duration of exposure” above) should reflect the additional physiological stress for the worker due to the breathing resistance and mass of the RPE itself, due to the increased thermal stress by enclosing the head. In addition, it shall be considered that the worker’s capability of using tools and of communicating are reduced during the wearing of RPE.

For reasons as given above, the worker should therefore be (i) healthy (especially in view of medical problems that may affect the use of RPE), (ii) have suitable facial characteristics reducing leakages between face and mask (in view of scars and facial hair). The recommended devices above which rely on a tight face seal will not provide the required protection unless they fit the contours of the face properly and securely.

The employer and self-employed persons have legal responsibilities for the maintenance and issue of respiratory protective devices and the management of their correct use in the workplace. Therefore, they should define and document a suitable policy for a respiratory protective device programme including training of the workers.

An overview of the APFs of different RPE (according to BS EN 529:2005) can be found in the glossary of MEASE.

2.2a Control of environmental exposure for scenarios discharging to an STP and freshwater river

Amounts used

280 tonnes Sb/year/site

Frequency and duration of use

Continuous use/release, 300 days/year

Environment factors not influenced by risk management

Default data for receiving water and for the municipal sewage treatment plant are18 000 m3/d and 2000 m3/d, respectively (resulting dilution factor 10).

Other given operational conditions affecting environmental exposure

None

Technical conditions and measures at process level (source) to prevent release

None

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

This exposure scenario covers the industrial use of Sb2O3 in the textile industry. This exposure scenario is covered by the Eurometaux spERC 2.5-6b.v2.1 industrial use of metal (compounds) in textile. The selected spERC does contain measured data from antimony (compounds) and antimony falls into the Kd range of this spERC. In order to cover this exposure scenario the release factor from the spERC is selected for each compartment i.e. 0.007% release to water (2.5-6b.v2.1) and 0.001% release to air (2.5-6b.v2.1). Note that these release factors are after on-site treatment.

Release factor to air: 0.001%
Eurometaux spERC 2.5-6b.v2.1. in combination with on-site treatment. In order to obtain this release factor, direct air emissions should be reduced by implementing one or more of the following RMMs:

- Electrostatic precipitators using wide electrode spacing: 5 – 15 mg/Nm^3
- Wet electrostatic precipitators: < 5 mg/Nm^3
- Cyclones, but as primary collector: < 50 mg/Nm^3
- Fabric or bag filters: high efficiency in controlling fine particulate (melting): achieve emission values < 5mg/Nm^3. Membrane filtration techniques can achieve < 1 mg/Nm^3
- Ceramic and metal mesh filters. PM10 particles are removed: 0.1 mg/Nm^3
- Wet scrubbers: < 4 mg/Nm^3

(spERC factsheet).

Release factor to water: 0.007%
Eurometaux spERC 2.5-6b.v2.1 in combination with on-site treatment. In order to obtain this release factor, direct water emissions should be reduced by implementing one or more of the following RMMs:

- Chemical precipitation: used primarily to remove the metal ions (e.g. Ca(OH)2, pH 11 precipitation: >99% removal efficiency; Fe(OH)3, pH 11: 96% removal efficiency)
- Sedimentation (e.g. Na2S, pH 11, >99% removal efficiency)
- Filtration: used as final clarification step (e.g. ultrafiltration, pH 5.1: 93% removal efficiency, nanofiltration: 97% removal efficiency, reverse osmosis, pH 4-11: 99% removal efficiency)
- Electrolysis: for low metal concentration (e.g. electrodialysis: 13% removal efficiency within 2 hours at 2g/L, membrane electrolysis, electrochemical precipitation, pH 4-10, >99% removal efficiency)
- Reverse osmosis: extensively used for the removal of dissolved metals
- Ion exchange: final cleaning step in the removal of heavy metal from process wastewater (e.g. 90% removal efficiency for clinoptinolite and 100% removal efficiency for synthetic zeolite)

More information can be found in EC (2001), Integrated Pollution Prevention and Control (IPCC): reference document on Best Available Techniques in the Non Ferrous Metals Industries (spERC factsheet).

Soil:
No direct emissions to soil.

Organizational measures to prevent/limit release from site

None

Conditions and measures related to municipal sewage treatment plant

EUSES default STP with primary settler with effluent discharge rate 2000000l/d, serving 10000 inhabitants. Zero degradation assumed. 79.1 % to sludge, 20.9 % to water calculated in EUSES based on partition coefficients. Sludge assumed to be spread to agricultural land.

Conditions and measures related to external treatment of waste for disposal

Hazardous wastes from onsite risk management measures and solid or liquid wastes from production, use and cleaning processes should be disposed of separately to hazardous waste incineration plants or hazardous waste landfills as hazardous waste. Releases to the floor, water and soil are to be prevented. If the antimony content of the waste is elevated enough, internal or external recovery/recycling might be considered.

Fraction of daily/annual use expected in waste: 0.004 or 0.4%

Appropriate waste codes:
02 01 10*, 06 05 02*, 10 08 04, 10 08 08*, 10 08 15*, 15 01 10*, 16 06 01*, 19 02 05*, 19 12 03*

Suitable disposal: Keep separate and dispose of to either
- Hazardous waste incineration operated according to Council Directive 2008/98/EC on waste, Directive 2000/76/EC on the incineration of waste and the Reference Document on the Best Available Techniques for Waste Incineration of August 2006.
- Hazardous landfill operated under Directive 1999/31/EC.

A detailed assessment has been performed and is reported in the Waste report (ARCHE, 2012)

Conditions and measures related to external recovery of waste

Not applicable

2.2b Control of environmental exposure for scenarios discharging directly to a freshwater river

Amounts used

280 tonnes Sb/year/site

Frequency and duration of use

Continuous use/release, 300 days/year

Environment factors not influenced by risk management

Default data for receiving water is18 000 m3/d (resulting dilution factor 10).

Other given operational conditions affecting environmental exposure

None

Technical conditions and measures at process level (source) to prevent release

None

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

This exposure scenario covers the industrial use of Sb_2O_3 in the textile industry. This exposure scenario is covered by the Eurometaux spERC 2.5-6b.v2.1 industrial use of metal (compounds) in textile. The selected spERC does contain measured data from antimony (compounds) and antimony falls into the Kd range of this spERC. In order to cover this exposure scenario the release factor from the spERC is selected for each compartment i.e. 0.007% release to water (2.5-6b.v2.1) and 0.001% release to air (2.5-6b.v2.1). Note that these release factors are after on-site treatment.

Release factor to air: 0.001%
Eurometaux spERC 2.5-6b.v2.1. in combination with on-site treatment. In order to obtain this release factor, direct air emissions should be reduced by implementing one or more of the following RMMs:
- Electrostatic precipitators using wide electrode spacing: 5 – 15 mg/Nm^3
- Wet electrostatic precipitators: < 5 mg/Nm^3
- Cyclones, but as primary collector: < 50 mg/Nm^3
- Fabric or bag filters: high efficiency in controlling fine particulate (melting): achieve emission values < 5mg/Nm^3. Membrane filtration techniques can achieve < 1 mg/Nm^3
- Ceramic and metal mesh filters. PM10 particles are removed: 0.1 mg/Nm^3
- Wet scrubbers: < 4 mg/Nm^3

(spERC factsheet).

Release factor to water: 0.007%
Eurometaux spERC 2.5-6b.v2.1 in combination with on-site treatment. In order to obtain this release factor, direct water emissions should be reduced by implementing one or more of the following RMMs:
- Chemical precipitation: used primarily to remove the metal ions (e.g. $Ca(OH)_2$, pH 11 precipitation: >99% removal efficiency; $Fe(OH)_3$, pH 11: 96% removal efficiency)
- Sedimentation (e.g. Na_2S, pH 11, >99% removal efficiency)
- Filtration: used as final clarification step (e.g. ultrafiltration, pH 5.1: 93% removal efficiency, nanofiltration: 97% removal efficiency, reverse osmosis, pH 4-11: 99% removal efficiency)
- Electrolysis: for low metal concentration (e.g. electrodialysis: 13% removal efficiency within 2 hours at 2g/L, membrane electrolysis, electrochemical precipitation, pH 4-10, >99% removal efficiency)
- Reverse osmosis: extensively used for the removal of dissolved metals
- Ion exchange: final cleaning step in the removal of heavy metal from process wastewater (e.g. 90% removal efficiency for clinoptinolite and 100% removal efficiency for synthetic zeolite)

More information can be found in EC (2001), Integrated Pollution Prevention and Control (IPCC): reference document on Best Available Techniques in the Non Ferrous Metals Industries (spERC factsheet).

Soil:
No direct emissions to soil.

Organizational measures to prevent/limit release from site

None

Conditions and measures related to municipal sewage treatment plant

Waste water is not discharged to a municipal STP but treated on-site before discharge into a river.

Conditions and measures related to external treatment of waste for disposal

Hazardous wastes from onsite risk management measures and solid or liquid wastes from production, use and cleaning processes should be disposed of separately to hazardous waste incineration plants or hazardous waste landfills as hazardous waste. Releases to the floor, water and soil are to be prevented. If the antimony content of the waste is elevated enough, internal or external recovery/recycling might be considered.

Fraction of daily/annual use expected in waste: 0.004 or 0.4%

Appropriate waste codes:
02 01 10*, 06 05 02*, 10 08 04, 10 08 08*, 10 08 15*, 15 01 10*, 16 06 01*, 19 02 05*, 19 12 03*

Suitable disposal: Keep separate and dispose of to either

- Hazardous waste incineration operated according to Council Directive 2008/98/EC on waste, Directive 2000/76/EC on the incineration of waste and the Reference Document on the Best Available Techniques for Waste Incineration of August 2006.
- Hazardous landfill operated under Directive 1999/31/EC.

A detailed assessment has been performed and is reported in the Waste report (ARCHE, 2012)

Conditions and measures related to external recovery of waste

Not applicable

2.2c Control of environmental exposure for scenarios discharing into a marine environment

Amounts used

280 tonnes Sb/year/site

Frequency and duration of use

Continuous use/release, 300 days/year

Environment factors not influenced by risk management

For marine assessments a default dilution of 100 is assumed.

Other given operational conditions affecting environmental exposure

None

Technical conditions and measures at process level (source) to prevent release

None

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

This exposure scenario covers the industrial use of Sb2O3 in the textile industry. This exposure scenario is covered by the Eurometaux spERC 2.5-6b.v2.1 industrial use of metal (compounds) in textile. The selected spERC does contain measured data from antimony (compounds) and antimony falls into the Kd range of this spERC. In order to cover this exposure scenario the release factor from the spERC is selected for each compartment i.e. 0.007% release to water (2.5-6b.v2.1) and 0.001% release to air (2.5-6b.v2.1). Note that these release factors are after on-site treatment.

Release factor to air: 0.001%
Eurometaux spERC 2.5-6b.v2.1. in combination with on-site treatment. In order to obtain this release factor, direct air emissions should be reduced by implementing one or more of the following RMMs:

- Electrostatic precipitators using wide electrode spacing: 5 – 15 mg/Nm^3
- Wet electrostatic precipitators: < 5 mg/Nm^3
- Cyclones, but as primary collector: < 50 mg/Nm^3
- Fabric or bag filters: high efficiency in controlling fine particulate (melting): achieve emission values < 5mg/Nm^3. Membrane filtration techniques can achieve < 1 mg/Nm^3
- Ceramic and metal mesh filters. PM10 particles are removed: 0.1 mg/Nm^3
- Wet scrubbers: < 4 mg/Nm^3

(spERC factsheet).

Release factor to water: 0.007%
Eurometaux spERC 2.5-6b.v2.1 in combination with on-site treatment. In order to obtain this release factor, direct water emissions should be reduced by implementing one or more of the following RMMs:

- Chemical precipitation: used primarily to remove the metal ions (e.g. Ca(OH)2, pH 11 precipitation: >99% removal efficiency; Fe(OH)3, pH 11: 96% removal efficiency)
- Sedimentation (e.g. Na2S, pH 11, >99% removal efficiency)

- Filtration: used as final clarification step (e.g. ultrafiltration, pH 5.1: 93% removal efficiency, nanofiltration: 97% removal efficiency, reverse osmosis, pH 4-11: 99% removal efficiency)
- Electrolysis: for low metal concentration (e.g. electrodialysis: 13% removal efficiency within 2 hours at 2g/L, membrane electrolysis, electrochemical precipitation, pH 4-10, >99% removal efficiency)
- Reverse osmosis: extensively used for the removal of dissolved metals
- Ion exchange: final cleaning step in the removal of heavy metal from process wastewater (e.g. 90% removal efficiency for clinoptinolite and 100% removal efficiency for synthetic zeolite)

More information can be found in EC (2001), Integrated Pollution Prevention and Control (IPCC): reference document on Best Available Techniques in the Non Ferrous Metals Industries (spERC factsheet).

Soil:
No direct emissions to soil.

Organizational measures to prevent/limit release from site

None

Conditions and measures related to municipal sewage treatment plant

Waste water is not discharged to a municipal STP but treated on-site before discharge into a marine environment.

Conditions and measures related to external treatment of waste for disposal

Hazardous wastes from onsite risk management measures and solid or liquid wastes from production, use and cleaning processes should be disposed of separately to hazardous waste incineration plants or hazardous waste landfills as hazardous waste. Releases to the floor, water and soil are to be prevented. If the antimony content of the waste is elevated enough, internal or external recovery/recycling might be considered.

Fraction of daily/annual use expected in waste: 0.004 or 0.4%

Appropriate waste codes:
02 01 10*, 06 05 02*, 10 08 04, 10 08 08*, 10 08 15*, 15 01 10*, 16 06 01*, 19 02 05*, 19 12 03*

Suitable disposal: Keep separate and dispose of to either
- Hazardous waste incineration operated according to Council Directive 2008/98/EC on waste, Directive 2000/76/EC on the incineration of waste and the Reference Document on the Best Available Techniques for Waste Incineration of August 2006.
- Hazardous landfill operated under Directive 1999/31/EC.

A detailed assessment has been performed and is reported in the Waste report (ARCHE, 2012)

Conditions and measures related to external recovery of waste

Not applicable

3. Exposure estimation and reference to its source

Occupational exposure

For “powder handling”, the 90th percentile of analogous data from raw material handling in the production of plastics are used for inhalation exposure assessment. For “processing”, the maximum value of published data from the upholstery was used for inhalation exposure assessment. For “further handling”, MEASE was used for the estimation of inhalation exposure. The risk characterisation ratio (RCR) is the quotient of the refined exposure estimate and the respective DNEL (derived no-effect level) and has to be below 1 to demonstrate a safe use. For inhalation exposure, the RCR is based on the DNEL for diantimony trioxide of 0.5 mg/m^3.

Workplace	Method used for inhalation exposure assessment (refer to introduction)	Inhalation exposure estimate (RCR)	Method used for dermal exposure assessment (refer to introduction)	Dermal exposure estimate (RCR)
Powder handling	analogous data from the handling of diantimony trioxide in plastics	0.143 mg/m^3 (0.29)	Due to the negligible dermal absorption of diantimony trioxide (0.26 %, EURAR, 2008), the dermal route is not a relevant exposure path for diantimony trioxide. Thus, dermal exposure is not assessed in this exposure scenario. However, dermal exposure has to be minimised to an extent as technically feasible when working under certain conditions as described above.	
Processing	published data (upholstery, Iavicoli, 2002)	0.001 mg/m^3 (0.002)		
Further handling	MEASE (PROC 21 as worst case assumption)	0.03 mg/m^3 (0.06)		

Environmental emissions

Environmental modelling was carried out in EUSES 2.1

Local PEC for scenario a) discharging to an STP and freshwater river

Air mg.m-3 (RCR)	Fresh water mg/l (RCR)	Marine water mg/l (RCR)	Sediment freshwater mg/kg wwt (RCR)	Sediment marine water mg/kg wwt (RCR)	Soil mg/kg wwt (RCR)	STP mg/l (RCR)
4.7E-06 (NA)	1.36E-03 (0.012)	No discharge to marine environment	1.27 (0.163)	No discharge to marine environment	2.55 (0.078)	0.007 (0.003)

Local PEC for scenario b) discharging directly to a freshwater river

Air mg.m-3 (RCR)	Fresh water mg/l (RCR)	Marine water mg/l (RCR)	Sediment freshwater mg/kg wwt (RCR)	Sediment marine water mg/kg wwt (RCR)	Soil mg/kg wwt (RCR)	STP mg/l (RCR)
4.7E-06 (NA)	3.78E-03 (0.033)	No discharge to marine environment	3.63 (0.465)	No discharge to marine environment	1.50 (0.046)	No discharge to STP

Local PEC for scenario c) discharing into a marine environment

Air mg.m-3 (RCR)	Fresh water mg/l (RCR)	Marine water mg/l (RCR)	Sediment freshwater mg/kg wwt (RCR)	Sediment marine water mg/kg wwt (RCR)	Soil mg/kg wwt (RCR)	STP mg/l (RCR)
4.7E-06 (NA)	No discharge to freshwater environment	5.1E-04 (0.045)	No discharge to freshwater environment	0.95 (0.607)	1.50 (0.046)	No discharge to STP

4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES

Occupational exposure

The DU works inside the boundaries set by the ES if either the proposed risk management measures as described above are met or the downstream user can demonstrate on his own that his operational conditions and implemented risk management measures are adequate. This has to be done by showing that they limit the inhalation and dermal exposure to a level below the respective DNEL (given that the processes and activities in question are covered by the PROCs listed above) as given below. If measured data are not available, the DU may make use of an appropriate scaling tool such as MEASE (www.ebrc.de/mease.html) to estimate the associated exposure. The dustiness of the substance used can be determined according to the MEASE glossary.

$DNEL_{inhalation}$: 0.5 mg/m³

Environmental emissions

The DU works inside the boundaries set by the ES if either the proposed risk management measures as described above are met or the downstream user can demonstrate on his own that his operational conditions and implemented risk management measures are adequate. The RCR will be equal to or lower than those stated above if they emit less than 4.67 kg Sb/day to air and less than 0.3 kg Sb/day to on site or off site waste water treatment works (equivalent to 0.06 kg Sb/day to the receiving water) with a dilution rate of 1:10. The emission to water can be scaled if the dilution rates are higher (e.g. a ten times higher dilution rate would allow ten times greater emissions whilst still having an RCR<1). This has to be done by showing that they limit the environmental exposure to a level below the respective PNEC as given below. If measured data are not available, the DU may make use of an appropriate scaling tool such as MetalEUSES (free download: http://www.arche-consulting.be/Metal-CSA-toolbox/duscaling-tool) to estimate the associated exposure.

$PNEC_{freshwater}$: 0.113 mg Sb/l
$PNEC_{marine}$: 0.0113 mg Sb/l
$PNEC_{sediment\ freshwater}$: 7.8 mg Sb/kg wwt
$PNEC_{sediment\ marine}$: 1.56 mg Sb/kg wwt
$PNEC_{soil}$: 37 mg Sb/kg dw (32.6 mg Sb/kg wwt)
$PNEC_{STP}$: 2.55 mg Sb/l

9.4.2. Exposure estimation

9.4.2.1 Indirect exposure of humans via the environment (local)

Table 100: Concentration and risk characterization for local exposure of humans via the environment

Concentration for local exposure of humans via the environment

	Estimated exposure concentrations		Measured exposure concentrations		Explanation / source of measured data
	value	unit	value	unit	

Concentration for local exposure of humans via the environment					
	Estimated exposure concentrations		**Measured exposure concentrations**		**Explanation / source of measured data**
	value	**unit**	**value**	**unit**	
Air	4.7* 10-6	mgSb/m^3	-	-	Local PEC has been calculated using EUSES 2.1 and converted from Sb to diantimony trioxide by a factor of 1.2.
	5.7* 10-6	mg Sb2O3/m^3	-	-	
Drinking water	2.5* 10-2	mg Sb/L	-	-	Local PEC has been calculated using EUSES 2.1 and converted from Sb to diantimony trioxide by a factor of 1.2.
	2.9* 10-2	mg Sb2O3/L	-	-	

Total daily dose for oral exposure via the environment (mg/kg bw/d)		
µg Sb_2O_3/d	**mg Sb_2O_3/kg bw/d**	**Justification**
63.23	1.05* 10^{-3}	2L of drinking water from the local setting + the worst case exposure of 4.32 µg/d from food (section 9.0.4.3) and the default body weight of 60kg have been taken into account.

Quantitative risk characterisation for humans exposed via the environment			
Route	**exposure concentrations (EC)**	**DN(M)EL**	**Risk characterisation ratio**
Inhalation- local effects (long term)	5.7* 10^{-6}mg Sb_2O_3/m^3	0.1 mg/m^3	5.7 * 10^{-5}
Oral- systemic (long term)	1.05* 10^{-3} mg Sb_2O_3/kg bw/d	168.6 mg/kg/d	6.3* 10^{-6}
Combined routes			RCR Inhalation- systemic + RCR Oral- systemic

9.4.2.2 Environmental exposure

Table 101: Risk characterisation for the soil, sediment and water compartments for scenario a) discharging to an STP and freshwater river

Compartment	**Local PEC**	**PNEC**	**PEC/PNEC (RCR)**
Freshwater aquatic (mg Sb/l)	1.36E-03	0.113	0.012
Freshwater sediment (mg Sb/kg wwt)	1.27	7.8	0.163
Terrestrial (mg Sb/kg wwt)	2.55	32.6	0.078
Sewage treatment plant (mg Sb/l)	0.007	2.55	0.003

Table 102: Risk characterisation for the soil, sediment and water compartments for scenario b) discharging directly to a freshwater river

Compartment	**Local PEC**	**PNEC**	**PEC/PNEC (RCR)**
Freshwater aquatic (mg Sb/l)	3.78E-03	0.113	0.033
Freshwater sediment (mg Sb/kg wwt)	3.63	7.8	0.465
Terrestrial (mg Sb/kg wwt)	1.50	32.6	0.046

Table 103: Risk characterisation for the soil, sediment and water compartments for scenario c) discharing into a marine environment

Compartment	**Local PEC**	**PNEC**	**PEC/PNEC (RCR)**
Marine aquatic (mg Sb/l)	5.1E-04	0.0113	0.045
Marine sediment (mg Sb/kg wwt)	0.95	1.6	0.607
Terrestrial (mg Sb/kg wwt)	1.50	32.6	0.046

9.5. Industrial use of diantimony trioxide in the production of glass, enamels, functional ceramics and semi-conductors

9.5.1. Exposure scenario

Exposure Scenario Format (1) addressing uses carried out by workers

1. Title

Free short title	Use of diantimony trioxide in glass manufacturing, production of enamel chip, additive for functional ceramics, semi-conductors
Systematic title based on use descriptor	SU3 (Industrial uses), SU8, SU10, SU13, SU 15, SU16 PC9a, PC19, PC21, PC33, PC0 (glazing materials, C23.1, UCN-G15000/15100) AC1, AC 2 (TARIC8525), AC4 (TARIC 6909), AC7 (appropriate PROCs and ERCs are given in section 2 below)
Processes, tasks and/or activities covered	Processes, tasks and/or activities covered are described in Section 2 below.
Assessment Method	The assessment of inhalation exposure is based on analogous data from diantimony trioxide powder handling in the production of plastics. The environmental assessment uses EUSES.

2. Operational conditions and risk management measures

Workplace	**Involved tasks**	**Involved PROCs**	**Involved ERC**
Raw material handling	Raw material handling, mixing, melting	5, 8b, 9, 15, 22, 26	5, 6a
Further processing	Forming, pressing, blowing, drawing, rolling, cutting	1, 2, 3, 4, 14, 21, 23, 24	
Application of enamel	Spraying, brushing, dipping	7, 10, 13	

2.1 Control of workers exposure

Product characteristic

According to the MEASE approach, the substance-intrinsic emission potential is one of the main exposure determinants. This is reflected by an assignment of a so-called fugacity class in the MEASE tool. For operations conducted with solid substances at ambient temperature the fugacity is based on the dustiness of that substance. Whereas in hot metal operations, fugacity is temperature based, taking into account the process temperature and the melting point of the substance. As a third group, high abrasive tasks are based on the level of abrasion instead of the substance intrinsic emission potential.

Workplace	**Used in preparation?**	**Content in preparation**	**Physical form**	**Emission potential**
Raw material handling	not restricted		powder*	high
Further processing	diantimony trioxide is no longer present after raw material handling (furnace feeding) (it has been transformed into another substance which is tightly bound into the matrix)		massive object	na
Application of enamel				

*Also other physical forms (i.e. wetted powders) than powder are used. As powder represents the worst case in terms of its emission potential the raw material handling of these physical forms is covered in the initial “Raw material handling” process step in this exposure scenario. If other physical forms render some of the proposed RMMs below unnecessary the downstream user is referred to section 4 of this exposure scenario to proof that.

Amounts used

The actual tonnage handled per shift is not considered to influence the exposure as such for this scenario. Instead, the combination of the scale of operation (industrial vs. professional) and level of containment/automation (as reflected in the PROC) is the main determinant of the process intrinsic emission potential.

Frequency and duration of use/exposure

Workplace	**Duration of exposure**
Raw material handling	≤ 180 minutes
Further processing	480 minutes (not restricted)
Application of enamel	480 minutes (not restricted)

Human factors not influenced by risk management

The shift breathing volume during all process steps reflected in the PROCs is assumed to be 10 m^3/shift (8 hours).

Other given operational conditions affecting workers exposure

Workplace	Room volume	Outdoors or indoors?	Process temperature	Process pressure
Raw material handling	>1,000 m³	indoors	Not considered relevant for occupational exposure assessment of the conducted processes.	Not considered relevant for occupational exposure assessment of the conducted processes.
Further processing				
Application of enamel				

Technical conditions and measures at process level (source) to prevent release

Workplace	Level of containment	Level of segregation
Raw material handling	closed system	not required
Further processing	not required	
Application of enamel	not required	

Technical conditions and measures to control dispersion from source towards the worker

Workplace	Level of separation	Localised controls (LC)	Efficiency of LC (according to MEASE)	Further information
Raw material handling	Any potentially required separation of workers from the emission source is indicated above under “Frequency and duration of exposure”. A reduction of exposure duration can be achieved, for example, by the installation of ventilated (positive pressure) control rooms or by removing the worker from workplaces involved with relevant exposure.	generic local exhaust ventilation	78 %	-
Further processing		not required	na	-
Application of enamel		not required	na	-

Organisational measures to prevent /limit releases, dispersion and exposure

Avoid inhalation or ingestion. General occupational hygiene measures are required to ensure a safe handling of the substance. These measures involve good personal and housekeeping practices (i.e. regular cleaning with suitable cleaning devices), no eating and smoking at the workplace, unless otherwise stated below the wearing of standard working clothes and shoes. Shower and change clothes at end of work shift. Do not wear contaminated clothing at home. Do not blow dust off with compressed air.

Historical observations of skin irritation have been made amongst workers caused by handling of diantimony trioxide powder under special conditions, namely substantial heat and sweat. The observed skin reactions, limited to workers at a diantimony trioxide (ATO) producing facility are likely to be evoked more by physically mediated processes associated with blocking of the sweat glands in the absence of any intrinsic substantial primary skin irritating potential of the substance and also in consideration of the poor solubility of ATO. Industry is committed to adequately control the risks of any adverse effects to workers who are exposed in hot, sweaty conditions to fumes or dust containing ATO by following the occupational hygiene practices as described in this exposure scenario. However, it is explicitly noted that the above described historical observations of skin effects have been scientifically evaluated by the Committee for Risk Assessment (RAC) of the European Chemicals Agency (ECHA) and did not lead to a classification of diantimony trioxide. As a precautionary measure, the wearing of chemical resistant gloves, long sleeved overalls and closed footwear, designed to minimize skin contact is suggested for all diantimony trioxide powder handling workplaces.

Conditions and measures related to personal protection, hygiene and health evaluation

Workplace	**Specification of respiratory protective equipment (RPE)**	**RPE efficiency (assigned protection factor, APF)**	**Specification of gloves**	**Further personal protective equipment (PPE)**
Raw material handling	FFP1 mask	APF=4	protective gloves	standard working clothes (overall with long sleeves) and safety shoes
Further processing	not required	na	not required	
Application of enamel	not required	na	not required	

Any RPE as defined above shall only be worn if the following principles are implemented in parallel: The duration of work (compare with "duration of exposure" above) should reflect the additional physiological stress for the worker due to the breathing resistance and mass of the RPE itself, due to the increased thermal stress by enclosing the head. In addition, it shall be considered that the worker's capability of using tools and of communicating are reduced during the wearing of RPE.
For reasons as given above, the worker should therefore be (i) healthy (especially in view of medical problems that may affect the use of RPE), (ii) have suitable facial characteristics reducing leakages between face and mask (in view of scars and facial hair). The recommended devices above which rely on a tight face seal will not provide the required protection unless they fit the contours of the face properly and securely.
The employer and self-employed persons have legal responsibilities for the maintenance and issue of respiratory protective devices and the management of their correct use in the workplace. Therefore, they should define and document a suitable policy for a respiratory protective device programme including training of the workers.
An overview of the APFs of different RPE (according to BS EN 529:2005) can be found in the glossary of MEASE.

2.2a Control of environmental exposure for scenarios discharging to an STP and freshwater river

Amounts used

75 tonnes Sb/year/site

Frequency and duration of use

Continuous use/release, 300 days/year

Environment factors not influenced by risk management

Default data for receiving water and for the municipal sewage treatment plant are18 000 m3/d and 2000 m3/d, respectively (resulting dilution factor 10).

Other given operational conditions affecting environmental exposure

None

Technical conditions and measures at process level (source) to prevent release

None

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

This exposure scenario covers the industrial use of Sb_2O_3 in the textile industry. This exposure scenario is covered by the Eurometaux spERC 2.5-6c.v2.1 industrial use of metal (compounds) in glass. The selected spERC does contain measured data from antimony (compounds) and antimony falls into the Kd range of this spERC. In order to cover this exposure scenario the release factor from the spERC is selected for each compartment i.e. 0.5% release to water (2.5-6c.v2.1) and 2% release to air (2.5-6c.v2.1). Note that these release factors are before on-site treatment. The same risk management measures as outlined in all the other spERCs should be installed and achieve a removal efficiency of at least 90%. This results in release factors of 0.2% to air and 0.05% to water.

Release factor to air: 0.2%
Eurometaux spERC 2.5-6c.v2.1. in combination with on-site treatment. In order to obtain this release factor, direct air emissions should be reduced by implementing one or more of the following RMMs:

- Electrostatic precipitators using wide electrode spacing: 5 – 15 mg/Nm^3
- Wet electrostatic precipitators: < 5 mg/Nm^3
- Cyclones, but as primary collector: < 50 mg/Nm^3
- Fabric or bag filters: high efficiency in controlling fine particulate (melting): achieve emission values < 5mg/Nm^3. Membrane filtration techniques can achieve < 1 mg/Nm^3
- Ceramic and metal mesh filters. PM10 particles are removed: 0.1 mg/Nm^3
- Wet scrubbers: < 4 mg/Nm^3

(spERC factsheet).

Release factor to water: 0.05%
Eurometaux spERC 2.5-6c.v2.1 in combination with on-site treatment. In order to obtain this release factor, direct water emissions should be reduced by implementing one or more of the following RMMs:

- Chemical precipitation: used primarily to remove the metal ions (e.g. $Ca(OH)_2$, pH 11 precipitation: >99% removal efficiency; $Fe(OH)_3$, pH 11: 96% removal efficiency)
- Sedimentation (e.g. Na_2S, pH 11, >99% removal efficiency)
- Filtration: used as final clarification step (e.g. ultrafiltration, pH 5.1: 93% removal efficiency, nanofiltration: 97% removal efficiency, reverse osmosis, pH 4-11: 99% removal efficiency)
- Electrolysis: for low metal concentration (e.g. electrodialysis: 13% removal efficiency within 2 hours at 2g/L, membrane electrolysis,

electrochemical precipitation, pH 4-10, >99% removal efficiency)
- Reverse osmosis: extensively used for the removal of dissolved metals
- Ion exchange: final cleaning step in the removal of heavy metal from process wastewater (e.g. 90% removal efficiency for clinoptinolite and 100% removal efficiency for synthetic zeolite)

More information can be found in EC (2001), Integrated Pollution Prevention and Control (IPCC): reference document on Best Available Techniques in the Non Ferrous Metals Industries (spERC factsheet).

Soil:
No direct emissions to soil.

Organizational measures to prevent/limit release from site

None

Conditions and measures related to municipal sewage treatment plant

EUSES default STP with primary settler with effluent discharge rate 2000000l/d, serving 10000 inhabitants. Zero degradation assumed. 79.1 % to sludge, 20.9 % to water calculated in EUSES based on partition coefficients. Sludge assumed to be spread to agricultural land.

Conditions and measures related to external treatment of waste for disposal

Hazardous wastes from onsite risk management measures and solid or liquid wastes from production, use and cleaning processes should be disposed of separately to hazardous waste incineration plants or hazardous waste landfills as hazardous waste. Releases to the floor, water and soil are to be prevented. If the antimony content of the waste is elevated enough, internal or external recovery/recycling might be considered.

Fraction of daily/annual use expected in waste: 0.004 or 0.4%

Appropriate waste codes:
02 01 10*, 06 05 02*, 10 08 04, 10 08 08*, 10 08 15*, 15 01 10*, 16 06 01*, 19 02 05*, 19 12 03*

Suitable disposal: Keep separate and dispose of to either
- Hazardous waste incineration operated according to Council Directive 2008/98/EC on waste, Directive 2000/76/EC on the incineration of waste and the Reference Document on the Best Available Techniques for Waste Incineration of August 2006.
- Hazardous landfill operated under Directive 1999/31/EC.

A detailed assessment has been performed and is reported in the Waste report (ARCHE, 2012)

Conditions and measures related to external recovery of waste

Not applicable

2.2b Control of environmental exposure for scenarios discharging directly to a freshwater river

Amounts used

75 tonnes Sb/year/site

Frequency and duration of use

Continuous use/release, 300 days/year

Environment factors not influenced by risk management

Default data for receiving water is18 000 m3/d (resulting dilution factor 10).

Other given operational conditions affecting environmental exposure

None

Technical conditions and measures at process level (source) to prevent release

None

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

This exposure scenario covers the industrial use of Sb2O3 in the textile industry. This exposure scenario is covered by the Eurometaux spERC 2.5-6c.v2.1 industrial use of metal (compounds) in glass. The selected spERC does contain measured data from antimony (compounds) and antimony falls into the Kd range of this spERC. In order to cover this exposure scenario the release factor from the spERC is selected for each compartment i.e. 0.5% release to water (2.5-6c.v2.1) and 2% release to air (2.5-6c.v2.1). Note that these release factors are before on-site treatment. The same risk management measures as outlined in all the other spERCs should be installed and achieve a removal efficiency of at least 90%. This results in release factors of 0.2% to air and 0.05% to water.

Release factor to air: 0.2%
Eurometaux spERC 2.5-6c.v2.1. in combination with on-site treatment. In order to obtain this release factor, direct air emissions should be reduced by implementing one or more of the following RMMs:
- Electrostatic precipitators using wide electrode spacing: 5 – 15 mg/Nm^3
- Wet electrostatic precipitators: < 5 mg/Nm^3

- Cyclones, but as primary collector: < 50 mg/Nm^3
- Fabric or bag filters: high efficiency in controlling fine particulate (melting): achieve emission values < 5mg/Nm^3. Membrane filtration techniques can achieve < 1 mg/Nm^3
- Ceramic and metal mesh filters. PM10 particles are removed: 0.1 mg/Nm^3
- Wet scrubbers: < 4 mg/Nm^3

(spERC factsheet).

Release factor to water: 0.05%
Eurometaux spERC 2.5-6c.v2.1 in combination with on-site treatment. In order to obtain this release factor, direct water emissions should be reduced by implementing one or more of the following RMMs:

- Chemical precipitation: used primarily to remove the metal ions (e.g. $Ca(OH)2$, pH 11 precipitation: >99% removal efficiency; $Fe(OH)3$, pH 11: 96% removal efficiency)
- Sedimentation (e.g. $Na2S$, pH 11, >99% removal efficiency)
- Filtration: used as final clarification step (e.g. ultrafiltration, pH 5.1: 93% removal efficiency, nanofiltration: 97% removal efficiency, reverse osmosis, pH 4-11: 99% removal efficiency)
- Electrolysis: for low metal concentration (e.g. electrodialysis: 13% removal efficiency within 2 hours at 2g/L, membrane electrolysis, electrochemical precipitation, pH 4-10, >99% removal efficiency)
- Reverse osmosis: extensively used for the removal of dissolved metals
- Ion exchange: final cleaning step in the removal of heavy metal from process wastewater (e.g. 90% removal efficiency for clinoptinolite and 100% removal efficiency for synthetic zeolite)

More information can be found in EC (2001), Integrated Pollution Prevention and Control (IPCC): reference document on Best Available Techniques in the Non Ferrous Metals Industries (spERC factsheet).

Soil:
No direct emissions to soil.

Organizational measures to prevent/limit release from site

None

Conditions and measures related to municipal sewage treatment plant

Waste water is not discharged to a municipal STP but treated on-site before discharge into a river.

Conditions and measures related to external treatment of waste for disposal

Hazardous wastes from onsite risk management measures and solid or liquid wastes from production, use and cleaning processes should be disposed of separately to hazardous waste incineration plants or hazardous waste landfills as hazardous waste. Releases to the floor, water and soil are to be prevented. If the antimony content of the waste is elevated enough, internal or external recovery/recycling might be considered.

Fraction of daily/annual use expected in waste: 0.004 or 0.4%

Appropriate waste codes:
02 01 10*, 06 05 02*, 10 08 04, 10 08 08*, 10 08 15*, 15 01 10*, 16 06 01*, 19 02 05*, 19 12 03*

Suitable disposal: Keep separate and dispose of to either

- Hazardous waste incineration operated according to Council Directive 2008/98/EC on waste, Directive 2000/76/EC on the incineration of waste and the Reference Document on the Best Available Techniques for Waste Incineration of August 2006.
- Hazardous landfill operated under Directive 1999/31/EC.

A detailed assessment has been performed and is reported in the Waste report (ARCHE, 2012)

Conditions and measures related to external recovery of waste

Not applicable

2.2c Control of environmental exposure for scenarios discharing into a marine environment

Amounts used

75 tonnes Sb/year/site

Frequency and duration of use

Continuous use/release, 300 days/year

Environment factors not influenced by risk management

For marine assessments a default dilution of 100 is assumed.

Other given operational conditions affecting environmental exposure

None

Technical conditions and measures at process level (source) to prevent release

None

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

This exposure scenario covers the industrial use of Sb2O3 in the textile industry. This exposure scenario is covered by the Eurometaux spERC 2.5-6c.v2.1 industrial use of metal (compounds) in glass. The selected spERC does contain measured data from antimony (compounds) and antimony falls into the Kd range of this spERC. In order to cover this exposure scenario the release factor from the spERC is selected for each compartment i.e. 0.5% release to water (2.5-6c.v2.1) and 2% release to air (2.5-6c.v2.1). Note that these release factors are before on-site treatment. The same risk management measures as outlined in all the other spERCs should be installed and achieve a removal efficiency of at least 90%. This results in release factors of 0.2% to air and 0.05% to water.

Release factor to air: 0.2%
Eurometaux spERC 2.5-6c.v2.1. in combination with on-site treatment. In order to obtain this release factor, direct air emissions should be reduced by implementing one or more of the following RMMs:

- Electrostatic precipitators using wide electrode spacing: 5 – 15 mg/Nm^3
- Wet electrostatic precipitators: < 5 mg/Nm^3
- Cyclones, but as primary collector: < 50 mg/Nm^3
- Fabric or bag filters: high efficiency in controlling fine particulate (melting): achieve emission values < 5mg/Nm^3. Membrane filtration techniques can achieve < 1 mg/Nm^3
- Ceramic and metal mesh filters. PM10 particles are removed: 0.1 mg/Nm^3
- Wet scrubbers: < 4 mg/Nm^3

(spERC factsheet).

Release factor to water: 0.05%
Eurometaux spERC 2.5-6c.v2.1 in combination with on-site treatment. In order to obtain this release factor, direct water emissions should be reduced by implementing one or more of the following RMMs:

- Chemical precipitation: used primarily to remove the metal ions (e.g. Ca(OH)2, pH 11 precipitation: >99% removal efficiency; Fe(OH)3, pH 11: 96% removal efficiency)
- Sedimentation (e.g. Na2S, pH 11, >99% removal efficiency)
- Filtration: used as final clarification step (e.g. ultrafiltration, pH 5.1: 93% removal efficiency, nanofiltration: 97% removal efficiency, reverse osmosis, pH 4-11: 99% removal efficiency)
- Electrolysis: for low metal concentration (e.g. electrodialysis: 13% removal efficiency within 2 hours at 2g/L, membrane electrolysis, electrochemical precipitation, pH 4-10, >99% removal efficiency)
- Reverse osmosis: extensively used for the removal of dissolved metals
- Ion exchange: final cleaning step in the removal of heavy metal from process wastewater (e.g. 90% removal efficiency for clinoptinolite and 100% removal efficiency for synthetic zeolite)

More information can be found in EC (2001), Integrated Pollution Prevention and Control (IPCC): reference document on Best Available Techniques in the Non Ferrous Metals Industries (spERC factsheet).

Soil:
No direct emissions to soil.

Organizational measures to prevent/limit release from site

None

Conditions and measures related to municipal sewage treatment plant

Waste water is not discharged to a municipal STP but treated on-site before discharge into a marine environment.

Conditions and measures related to external treatment of waste for disposal

Hazardous wastes from onsite risk management measures and solid or liquid wastes from production, use and cleaning processes should be disposed of separately to hazardous waste incineration plants or hazardous waste landfills as hazardous waste. Releases to the floor, water and soil are to be prevented. If the antimony content of the waste is elevated enough, internal or external recovery/recycling might be considered.

Fraction of daily/annual use expected in waste: 0.004 or 0.4%

Appropriate waste codes:
02 01 10*, 06 05 02*, 10 08 04, 10 08 08*, 10 08 15*, 15 01 10*, 16 06 01*, 19 02 05*, 19 12 03*

Suitable disposal: Keep separate and dispose of to either

- Hazardous waste incineration operated according to Council Directive 2008/98/EC on waste, Directive 2000/76/EC on the incineration of waste and the Reference Document on the Best Available Techniques for Waste Incineration of August 2006.
- Hazardous landfill operated under Directive 1999/31/EC.

A detailed assessment has been performed and is reported in the Waste report (ARCHE, 2012)

Conditions and measures related to external recovery of waste

Not applicable

3. Exposure estimation and reference to its source

Occupational exposure

For “raw material handling”, the 90th percentile of analogous data from the production of plastics was used for inhalation exposure assessment. The risk characterisation ratio (RCR) is the quotient of the refined exposure estimate and the respective DNEL (derived no-effect level) and has to be below 1 to demonstrate a safe use. For inhalation exposure, the RCR is based on the DNEL for diantimony trioxide of 0.5 mg/m^3.

Workplace	Method used for inhalation exposure assessment (refer to introduction)	Inhalation exposure estimate (RCR)	Method used for dermal exposure assessment (refer to introduction)	Dermal exposure estimate (RCR)
Raw material handling	analogous data from the handling of diantimony trioxide in plastics	0.143 mg/m³ (0.29)	Due to the negligible dermal absorption of diantimony trioxide (0.26 %, ECB, 2008), the dermal route is not a relevant exposure path for diantimony trioxide. Thus, dermal exposure is not assessed in this exposure scenario. However, dermal exposure has to be minimised to an extent as technically feasible when working under certain conditions as described above.	
Further processing	qualitative assessment	negligible (<1)		
Application of enamel	qualitative assessment	negligible (<1)		

Environmental emissions

Environmental modelling was carried out in EUSES 2.1

Local PEC for scenario a) discharging to an STP and freshwater river

Air mg.m-3 (RCR)	Fresh water mg/l (RCR)	Marine water mg/l (RCR)	Sediment freshwater mg/kg wwt (RCR)	Sediment marine water mg/kg wwt (RCR)	Soil mg/kg wwt (RCR)	STP mg/l (RCR)
1.2E-04 (NA)	1.94E-03 (0.017)	No discharge to marine environment	1.84 (0.236)	No discharge to marine environment	3.55 (0.109)	0.013 (0.005)

Local PEC for scenario b) discharging directly to a freshwater river

Air mg.m-3 (RCR)	Fresh water mg/l (RCR)	Marine water mg/l (RCR)	Sediment freshwater mg/kg wwt (RCR)	Sediment marine water mg/kg wwt (RCR)	Soil mg/kg wwt (RCR)	STP mg/l (RCR)
1.2E-04 (NA)	6.58E-03 (0.058)	No discharge to marine environment	6.34 (0.813)	No discharge to marine environment	1.54 (0.048)	No discharge to STP

Local PEC for scenario c) discharing into a marine environment

Air mg.m-3 (RCR)	Fresh water mg/l (RCR)	Marine water mg/l (RCR)	Sediment freshwater mg/kg wwt (RCR)	Sediment marine water mg/kg wwt (RCR)	Soil mg/kg wwt (RCR)	STP mg/l (RCR)
1.2E-04 (NA)	No discharge to freshwater environment	7.9E-04 (0.070)	No discharge to freshwater environment	1.22 (0.782)	1.54 (0.048)	No discharge to STP

4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES

Occupational exposure

The DU works inside the boundaries set by the ES if either the proposed risk management measures as described above are met or the downstream user can demonstrate on his own that his operational conditions and implemented risk management measures are adequate. This has to be done by showing that they limit the inhalation and dermal exposure to a level below the respective DNEL (given that the processes and activities in question are covered by the PROCs listed above) as given below. If measured data are not available, the DU may make use of an appropriate scaling tool such as MEASE (www.ebrc.de/mease.html) to estimate the associated exposure. The dustiness of the substance used can be determined according to the MEASE glossary.

$DNEL_{inhalation}$: 0.5 mg/m³

Environmental emissions

The DU works inside the boundaries set by the ES if either the proposed risk management measures as described above are met or the downstream user can demonstrate on his own that his operational conditions and implemented risk management measures are adequate. The RCR will be equal to or lower than those stated above if they emit less than 1.25kg Sb/day to air and less than 0.3kg Sb/day to on site or off site waste water treatment works (equivalent to 0.06 kg Sb/day to the receiving water) with a dilution rate of 1:10. The emission to water can be scaled if the dilution rates are higher (e.g. a ten times higher dilution rate would allow ten times greater emissions whilst still having an RCR<1). This has to be done by showing that they limit the environmental exposure to a level below the respective PNEC as given below. If measured data are not available, the DU may make use of an appropriate scaling tool such as MetalEUSES (free download: http://www.arche-consulting.be/Metal-CSA-toolbox/duscaling-tool) to estimate the associated exposure.

$PNEC_{freshwater}$: 0.113 mg Sb/l
$PNEC_{marine}$: 0.0113 mg Sb/l
$PNEC_{sediment\ freshwater}$: 7.8 mg Sb/kg wwt
$PNEC_{sediment\ marine}$: 1.56 mg Sb/kg wwt
$PNEC_{soil}$: 37 mg Sb/kg dw (32.6 mg Sb/kg wwt)
$PNEC_{STP}$: 2.55 mg Sb/l

9.5.2. Exposure estimation

9.5.2.1 Indirect exposure of humans via the environment (local)

Table 104: Concentration and risk characterization for local exposure of humans via the environment

Concentration for local exposure of humans via the environment					
	Estimated exposure concentrations		**Measured exposure concentrations**		**Explanation / source of measured data**
	value	**unit**	**value**	**unit**	
Air	1.2* 10-4	mgSb/m^3	-	-	Local PEC has been calculated using EUSES 2.1 and converted from Sb to diantimony trioxide by a factor of 1.2.
	1.4* 10-4	mg Sb2O3/m^3	-	-	
Drinking water	3.4* 10-2	mg Sb/L	-	-	Local PEC has been calculated using EUSES 2.1 and converted from Sb to diantimony trioxide by a factor of 1.2.
	4.1* 10-2	mg Sb2O3/L	-	-	

Total daily dose for oral exposure via the environment (mg/kg bw/d)		
µg Sb_2O_3/d	**mg Sb_2O_3/kg bw/d**	**Justification**
86.31	1.44* 10^{-3}	2L of drinking water from the local setting + the worst case exposure of 4.32 µg/d from food (section 9.0.4.3) and the default body weight of 60kg have been taken into account.

Quantitative risk characterisation for humans exposed via the environment			
Route	**exposure concentrations (EC)**	**DN(M)EL**	**Risk characterisation ratio**
Inhalation- local effects (long term)	1.4* 10^{-4}mg Sb_2O_3/m^3	0.1 mg/m^3	1.4* 10^{-3}
Oral- systemic (long term)	1.44* 10^{-3} mg Sb_2O_3/kg bw/d	168.6 mg/kg/d	8.5* 10^{-6}
Combined routes			RCR Inhalation- systemic + RCR Oral- systemic

9.5.2.2 Environmental exposure

Table 105: Risk characterisation for the soil, sediment and water compartments for scenario a) discharging to an STP and freshwater river

Compartment	**Local PEC**	**PNEC**	**PEC/PNEC (RCR)**
Freshwater aquatic (mg Sb/l)	1.94E-03	0.113	0.017
Freshwater sediment (mg Sb/kg wwt)	1.84	7.8	0.236
Terrestrial (mg Sb/kg wwt)	3.55	32.6	0.109
Sewage treatment plant (mg Sb/l)	0.013	2.55	0.005

Table 106: Risk characterisation for the soil, sediment and water compartments for scenario b) discharging directly to a freshwater river

Compartment	**Local PEC**	**PNEC**	**PEC/PNEC (RCR)**
Freshwater aquatic (mg Sb/l)	6.58E-03	0.113	0.058
Freshwater sediment (mg Sb/kg wwt)	6.34	7.8	0.813
Terrestrial (mg Sb/kg wwt)	1.54	32.6	0.047

Table 107: Risk characterisation for the soil, sediment and water compartments for scenario c) discharing into a marine environment

Compartment	**Local PEC**	**PNEC**	**PEC/PNEC**

			(RCR)
Marine aquatic (mg Sb/l)	7.9E-04	0.0113	0.070
Marine sediment (mg Sb/kg wwt)	1.22	1.6	0.782
Terrestrial (mg Sb/kg wwt)	1.54	32.6	0.047

9.6. Industrial use of diantimony trioxide in the production of pigments, paints, coatings, ceramics, brake pads and production and formulation of fine chemicals

9.6.1. Exposure scenario

Exposure Scenario Format (1) addressing uses carried out by workers

1. Title

Free short title	Use of diantimony trioxide in ceramics production, coatings, flame retarded paints, pigments, manufacture of coatings and inks, production of brake pads, formulation of suspensions, production of fine chemicals, industrial application of paints and coatings
Systematic title based on use descriptor	SU3 (Industrial uses), SU8, SU9, SU10, SU13, SU17, SU19, SU23 PC9a, PC9b, PC9c, PC18, PC19, PC20, PC32 AC1, AC4, AC7 (appropriate PROCs and ERCs are given in section 2 below)
Processes, tasks and/or activities covered	Processes, tasks and/or activities covered are described in Section 2 below.
Assessment Method	The assessment of inhalation exposure in the workplaces “loading & mixing” and “preparation” is based on measured data from diantimony trioxide powder handling in the production of plastics. Values are re-calculated for the actual task duration. All of these data have been peer-reviewed in the risk assessment report on diantimony trioxide. In addition, MEASE was used for the estimation of inhalation exposure. The environmental assessment uses EUSES.

2. Operational conditions and risk management measures

Workplace	**Involved tasks**	**Involved PROCs**	**Involved ERC**
Loading & mixing	Loading, mixing	5, 8a, 8b, 9, 26	5, 6a
Preparation	Powder compression, pelletisation	14	
Processing	Calcination, sintering, reaction, curing	1, 2, 3, 4, 22, 23	
Final handling	Milling, bagging, quality control	6, 15, 21, 24	
Application and mixing of paints	Mixing, brushing	10, 13, 19	
Spraying of paints and coatings	Spraying of paints and coatings	7	

2.1 Control of workers exposure

Product characteristic

According to the MEASE approach, the substance-intrinsic emission potential is one of the main exposure determinants. This is reflected by an assignment of a so-called fugacity class in the MEASE tool. For operations conducted with solid substances at ambient temperature the fugacity is based on the dustiness of that substance. Whereas in hot metal operations, fugacity is temperature based, taking into account the process temperature and the melting point of the substance. As a third group, high abrasive tasks are based on the level of abrasion instead of the substance intrinsic emission potential.

Workplace	**Used in preparation?**	**Content in preparation**	**Physical form**	**Emission potential**
Loading & Mixing	not restricted		powder*	high
Preparation	yes	1 - 15 %	powder*	high
Processing	yes	1 - 15 %	granular-type blend*	low
Final handling	After calcination, diantimony trioxide is incorporated in the pigment structures, i.e. it is no longer bio-available as diantimony trioxide. Thus, an exposure assessment has been omitted for further processing steps.		final pigment product	na
Application and mixing of paints	not restricted		aqueous solution	very low

Spraying of paints and coatings	yes	<25 %	aqueous solution	medium

*Also other physical forms (i.e. wetted powders) than powder are used. As powder represents the worst case in terms of its emission potential the raw material handling of these physical forms is covered in the initial "powder handling" process step in this exposure scenario. If other physical forms render some of the proposed RMMs below unnecessary the downstream user is referred to section 4 of this exposure scenario to proof that.

Amounts used

The actual tonnage handled per shift is not considered to influence the exposure as such for this scenario. Instead, the combination of the scale of operation (industrial vs. professional) and level of containment/automation (as reflected in the PROC) is the main determinant of the process intrinsic emission potential.

Frequency and duration of use/exposure

Workplace	**Duration of exposure**
Loading & Mixing	≤ 60 minutes
Preparation	≤ 60 minutes (for manual operations)
Processing	480 minutes (not restricted)
Final handling	480 minutes (not restricted)
Application and mixing of paints	480 minutes (not restricted)
Spraying of paints and coatings	≤ 240 minutes (for manual operations such as maintenance)

Human factors not influenced by risk management

The shift breathing volume during all process steps reflected in the PROCs is assumed to be 10 m^3/shift (8 hours).

Other given operational conditions affecting workers exposure

Workplace	**Room volume**	**Outdoors or indoors?**	**Process temperature**	**Process pressure**
Loading & Mixing	>1,000 m^3	indoors	Not considered relevant for occupational exposure assessment of the conducted processes.	Not considered relevant for occupational exposure assessment of the conducted processes.
Preparation				
Processing				
Final handling				
Application and mixing of paints				
Spraying of paints and coatings				

Technical conditions and measures at process level (source) to prevent release

Workplace	**Level of containment**	**Level of segregation**
Loading & Mixing	closed system	not required
Preparation	closed system	
Processing	not required	
Final handling		
Application and mixing of paints	not required	
Spraying of paints and coatings	closed system	application (spraying) chamber

Technical conditions and measures to control dispersion from source towards the worker

Workplace	**Level of separation**	**Localised controls (LC)**	**Efficiency of LC (according to MEASE)**	**Further information**
Loading & Mixing	Any potentially required separation of workers from the emission source is indicated above under "Frequency and duration of exposure". A reduction of exposure duration can be achieved, for example, by the installation of ventilated (positive pressure) control rooms or by removing the worker from workplaces involved with relevant exposure.	generic local exhaust ventilation	78 %	-
Preparation		generic local exhaust ventilation	78 %	-
Processing		not required	na	-
Final handling				-
Application and mixing of paints		not required	na	-
Spraying of paints and coatings		integrated local exhaust ventilation	84 %	The application (spraying) chamber/room must only be entered for a reduced duration (see above).

Organisational measures to prevent /limit releases, dispersion and exposure

Avoid inhalation or ingestion. General occupational hygiene measures are required to ensure a safe handling of the substance. These measures involve good personal and housekeeping practices (i.e. regular cleaning with suitable cleaning devices), no eating and smoking at the workplace, unless otherwise stated below the wearing of standard working clothes and shoes. Shower and change clothes at end of work shift. Do not wear contaminated clothing at home. Do not blow dust off with compressed air.
Historical observations of skin irritation have been made amongst workers caused by handling of diantimony trioxide powder under special conditions, namely substantial heat and sweat. The observed skin reactions, limited to workers at a diantimony trioxide (ATO) producing facility are likely to be evoked more by physically mediated processes associated with blocking of the sweat glands in the absence of any intrinsic substantial primary skin irritating potential of the substance and also in consideration of the poor solubility of ATO. Industry is committed to adequately control the risks of any adverse effects to workers who are exposed in hot, sweaty conditions to fumes or dust containing ATO by following the occupational hygiene practices as described in this exposure scenario. However, it is explicitly noted that the above described historical observations of skin effects have been scientifically evaluated by the Committee for Risk Assessment (RAC) of the European Chemicals Agency (ECHA) and did not lead to a classification of diantimony trioxide. As a precautionary measure, the wearing of chemical resistant gloves, long sleeved overalls and closed footwear, designed to minimize skin contact is suggested for all diantimony trioxide powder handling workplaces.

Conditions and measures related to personal protection, hygiene and health evaluation

Workplace	**Specification of respiratory protective equipment (RPE)**	**RPE efficiency (assigned protection factor, APF)**	**Specification of gloves**	**Further personal protective equipment (PPE)**
Loading & Mixing	not required	na	protective gloves	standard working clothes (overall with long sleeves) and safety shoes
Preparation	not required	na	protective gloves	
Processing	not required	na	not required	
Final handling	not required	na	not required	
Application and mixing of paints	not required	na	not required	
Spraying of paints and coatings	FFP2 mask	APF=10	water resistant gloves	

Any RPE as defined above shall only be worn if the following principles are implemented in parallel: The duration of work (compare with “duration of exposure” above) should reflect the additional physiological stress for the worker due to the breathing resistance and mass of the RPE itself, due to the increased thermal stress by enclosing the head. In addition, it shall be considered that the worker’s capability of using tools and of communicating are reduced during the wearing of RPE.
For reasons as given above, the worker should therefore be (i) healthy (especially in view of medical problems that may affect the use of RPE), (ii) have suitable facial characteristics reducing leakages between face and mask (in view of scars and facial hair). The recommended devices above which rely on a tight face seal will not provide the required protection unless they fit the contours of the face properly and securely.
The employer and self-employed persons have legal responsibilities for the maintenance and issue of respiratory protective devices and the management of their correct use in the workplace. Therefore, they should define and document a suitable policy for a respiratory protective device programme including training of the workers.
An overview of the APFs of different RPE (according to BS EN 529:2005) can be found in the glossary of MEASE.

2.2a Control of environmental exposure for scenarios discharging to an STP and freshwater river

Amounts used

500 tonnes Sb/year/site

Frequency and duration of use

Continuous use/release, 330 days/year

Environment factors not influenced by risk management

Default data for receiving water and for the municipal sewage treatment plant are 18 000 m3/d and 2000 m3/d, respectively (resulting dilution factor 10).

Other given operational conditions affecting environmental exposure

None

Technical conditions and measures at process level (source) to prevent release

None

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

This exposure scenario covers the industrial use of Sb_2O_3 in pigment, paints, coatings, ceramics, brake pads and fine chemicals. This exposure scenario is covered using measured data for emissions to water and is covered by the worst case Eurometaux spERC 2.5-6c.v2.1 industrial use of metal (compounds) in glass for emissions to air. The selected spERC does contain measured data from antimony (compounds) and antimony falls into the Kd range of this spERC. In order to cover this exposure scenario the release factor from the spERC is selected for the air i.e. 2% release to air (2.5-6c.v2.1). Note that this release factor is before on-site treatment. The same risk management measures as outlined in all the other spERCs should be installed and achieve a removal efficiency of at least 90%. This results in release factors of 0.2% to air.

Release factor to air: 0.2%
Eurometaux spERC 2.5-6c.v2.1. in combination with on-site treatment. In order to obtain this release factor, direct air emissions should be reduced by

implementing one or more of the following RMMs:

- Electrostatic precipitators using wide electrode spacing: 5 – 15 mg/Nm^3
- Wet electrostatic precipitators: < 5 mg/Nm^3
- Cyclones, but as primary collector: < 50 mg/Nm^3
- Fabric or bag filters: high efficiency in controlling fine particulate (melting): achieve emission values < 5mg/Nm^3. Membrane filtration techniques can achieve < 1 mg/Nm^3
- Ceramic and metal mesh filters. PM10 particles are removed: 0.1 mg/Nm^3
- Wet scrubbers: < 4 mg/Nm^3

(spERC factsheet).

Release factor to water: 0.012%
This release factor is based on the median value from 3 companies submitting data. One additional company reported no emissions of waste water to the environment. Waste water should be treated in order to obtain this kind of release factor.

Soil:
No direct emissions to soil.

Organizational measures to prevent/limit release from site

None

Conditions and measures related to municipal sewage treatment plant

EUSES default STP with primary settler with effluent discharge rate 2000000l/d, serving 10000 inhabitants. Zero degradation assumed. 79.1 % to sludge, 20.9 % to water calculated in EUSES based on partition coefficients. Sludge assumed to be spread to agricultural land.

Conditions and measures related to external treatment of waste for disposal

Hazardous wastes from onsite risk management measures and solid or liquid wastes from production, use and cleaning processes should be disposed of separately to hazardous waste incineration plants or hazardous waste landfills as hazardous waste. Releases to the floor, water and soil are to be prevented. If the antimony content of the waste is elevated enough, internal or external recovery/recycling might be considered.

Fraction of daily/annual use expected in waste: 0.004 or 0.4%

Appropriate waste codes:
02 01 10*, 06 05 02*, 10 08 04, 10 08 08*, 10 08 15*, 15 01 10*, 16 06 01*, 19 02 05*, 19 12 03*

Suitable disposal: Keep separate and dispose of to either

- Hazardous waste incineration operated according to Council Directive 2008/98/EC on waste, Directive 2000/76/EC on the incineration of waste and the Reference Document on the Best Available Techniques for Waste Incineration of August 2006.
- Hazardous landfill operated under Directive 1999/31/EC.

A detailed assessment has been performed and is reported in the Waste report (ARCHE, 2012)

Conditions and measures related to external recovery of waste

Not applicable

2.2b Control of environmental exposure for scenarios discharging directly to a freshwater river

Amounts used

500 tonnes Sb/year/site

Frequency and duration of use

Continuous use/release, 330 days/year

Environment factors not influenced by risk management

Data on dilution was available for 3 different companies, the median value of 16 has been used for this scenario.

Other given operational conditions affecting environmental exposure

None

Technical conditions and measures at process level (source) to prevent release

None

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

This exposure scenario covers the industrial use of Sb2O3 in pigment, paints, coatings, ceramics, brake pads and fine chemicals. This exposure scenario is covered using measured data for emissions to water and is covered by the worst case Eurometaux spERC 2.5-6c.v2.1 industrial use of metal (compounds) in glass for emissions to air. The selected spERC does contain measured data from antimony (compounds) and antimony falls into the Kd range of this spERC. In order to cover this exposure scenario the release factor from the spERC is selected for the air i.e. 2% release to air (2.5-6c.v2.1). Note that this release factor is before on-site treatment. The same risk management measures as outlined in all the other spERCs should be installed and achieve a removal efficiency of at least 90%. This results in release factors of 0.2% to air.

Release factor to air: 0.2%
Eurometaux spERC 2.5-6c.v2.1. in combination with on-site treatment. In order to obtain this release factor, direct air emissions should be reduced by implementing one or more of the following RMMs:

- Electrostatic precipitators using wide electrode spacing: 5 – 15 mg/Nm^3
- Wet electrostatic precipitators: < 5 mg/Nm^3
- Cyclones, but as primary collector: < 50 mg/Nm^3
- Fabric or bag filters: high efficiency in controlling fine particulate (melting): achieve emission values < 5mg/Nm^3. Membrane filtration techniques can achieve < 1 mg/Nm^3
- Ceramic and metal mesh filters. PM10 particles are removed: 0.1 mg/Nm^3
- Wet scrubbers: < 4 mg/Nm^3

(spERC factsheet).

Release factor to water: 0.012%
This release factor is based on the median value from 3 companies submitting data. One additional company reported no emissions of waste water to the environment. Waste water should be treated in order to obtain this kind of release factor.

Soil:
No direct emissions to soil.

Organizational measures to prevent/limit release from site

None

Conditions and measures related to municipal sewage treatment plant

Waste water is not discharged to a municipal STP but treated on-site before discharge into a river.

Conditions and measures related to external treatment of waste for disposal

Hazardous wastes from onsite risk management measures and solid or liquid wastes from production, use and cleaning processes should be disposed of separately to hazardous waste incineration plants or hazardous waste landfills as hazardous waste. Releases to the floor, water and soil are to be prevented. If the antimony content of the waste is elevated enough, internal or external recovery/recycling might be considered.

Fraction of daily/annual use expected in waste: 0.004 or 0.4%

Appropriate waste codes:
02 01 10*, 06 05 02*, 10 08 04, 10 08 08*, 10 08 15*, 15 01 10*, 16 06 01*, 19 02 05*, 19 12 03*

Suitable disposal: Keep separate and dispose of to either

- Hazardous waste incineration operated according to Council Directive 2008/98/EC on waste, Directive 2000/76/EC on the incineration of waste and the Reference Document on the Best Available Techniques for Waste Incineration of August 2006.
- Hazardous landfill operated under Directive 1999/31/EC.

A detailed assessment has been performed and is reported in the Waste report (ARCHE, 2012)

Conditions and measures related to external recovery of waste

Not applicable

2.2c Control of environmental exposure for scenarios discharing into a marine environment

Amounts used

500 tonnes Sb/year/site

Frequency and duration of use

Continuous use/release, 330 days/year

Environment factors not influenced by risk management

For marine assessments a default dilution of 100 is assumed.

Other given operational conditions affecting environmental exposure

None

Technical conditions and measures at process level (source) to prevent release

None

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

This exposure scenario covers the industrial use of $Sb2O3$ in pigment, paints, coatings, ceramics, brake pads and fine chemicals. This exposure scenario is covered using measured data for emissions to water and is covered by the worst case Eurometaux spERC 2.5-6c.v2.1 industrial use of metal (compounds) in glass for emissions to air. The selected spERC does contain measured data from antimony (compounds) and antimony falls into the Kd range of this spERC. In order to cover this exposure scenario the release factor from the spERC is selected for the air i.e. 2% release to air (2.5-6c.v2.1).

Note that this release factor is before on-site treatment. The same risk management measures as outlined in all the other spERCs should be installed and achieve a removal efficiency of at least 90%. This results in release factors of 0.2% to air.

Release factor to air: 0.2%
Eurometaux spERC 2.5-6c.v2.1. in combination with on-site treatment. In order to obtain this release factor, direct air emissions should be reduced by implementing one or more of the following RMMs:

- Electrostatic precipitators using wide electrode spacing: 5 – 15 mg/Nm^3
- Wet electrostatic precipitators: < 5 mg/Nm^3
- Cyclones, but as primary collector: < 50 mg/Nm^3
- Fabric or bag filters: high efficiency in controlling fine particulate (melting): achieve emission values < 5mg/Nm^3. Membrane filtration techniques can achieve < 1 mg/Nm^3
- Ceramic and metal mesh filters. PM10 particles are removed: 0.1 mg/Nm^3
- Wet scrubbers: < 4 mg/Nm^3

(spERC factsheet).

Release factor to water: 0.012%
This release factor is based on the median value from 3 companies submitting data. One additional company reported no emissions of waste water to the environment. Waste water should be treated in order to obtain this kind of release factor.

Soil:
No direct emissions to soil.

Organizational measures to prevent/limit release from site

None

Conditions and measures related to municipal sewage treatment plant

Waste water is not discharged to a municipal STP but treated on-site before discharge into a marine environment.

Conditions and measures related to external treatment of waste for disposal

Hazardous wastes from onsite risk management measures and solid or liquid wastes from production, use and cleaning processes should be disposed of separately to hazardous waste incineration plants or hazardous waste landfills as hazardous waste. Releases to the floor, water and soil are to be prevented. If the antimony content of the waste is elevated enough, internal or external recovery/recycling might be considered.

Fraction of daily/annual use expected in waste: 0.004 or 0.4%

Appropriate waste codes:
02 01 10*, 06 05 02*, 10 08 04, 10 08 08*, 10 08 15*, 15 01 10*, 16 06 01*, 19 02 05*, 19 12 03*

Suitable disposal: Keep separate and dispose of to either

- Hazardous waste incineration operated according to Council Directive 2008/98/EC on waste, Directive 2000/76/EC on the incineration of waste and the Reference Document on the Best Available Techniques for Waste Incineration of August 2006.
- Hazardous landfill operated under Directive 1999/31/EC.

A detailed assessment has been performed and is reported in the Waste report (ARCHE, 2012)

Conditions and measures related to external recovery of waste

Not applicable

3. Exposure estimation and reference to its source

Occupational exposure

In the workplaces “Loading & Mixing” and “Preparation”, the 90th percentile of analogous data from raw material handling in the production of plastics was used and extrapolated to 60 minutes exposure duration. In addition, MEASE was used for the estimation of inhalation exposure. The risk characterisation ratio (RCR) is the quotient of the refined exposure estimate and the respective DNEL (derived no-effect level) and has to be below 1 to demonstrate a safe use. For inhalation exposure, the RCR is based on the DNEL for diantimony trioxide of 0.5 mg/m^3.

Workplace	**Method used for inhalation exposure assessment (refer to introduction)**	**Inhalation exposure estimate (RCR)**	**Method used for dermal exposure assessment (refer to introduction)**	**Dermal exposure estimate (RCR)**
Loading & Mixing	analogous data from the handling of diantimony trioxide in the production of plastics	0.19 mg/m^3 (0.38)	Due to the negligible dermal absorption of diantimony trioxide (0.26 %, ECB, 2008), the dermal route is not a relevant exposure path for diantimony trioxide. Thus, dermal exposure is not assessed in this exposure scenario. However, dermal exposure has to be minimised to an extent as technically feasible when working under certain conditions as described above.	
Preparation	analogous data from the handling of diantimony trioxide in the production of plastics	0.19 mg/m^3 (0.38)		
Processing	qualitative assessment	negligible (<1)		
Final handling	qualitative assessment	negligible (<1)		
Application and mixing of paints	MEASE	0.05 mg/m^3 (0.1)		
Spraying of paints and coatings	MEASE	0.115 mg/m^3 (0.23)		

Environmental emissions

Environmental modelling was carried out in EUSES 2.1

Local PEC for scenario a) discharging to an STP and freshwater river

Air mg.m-3 (RCR)	**Fresh water mg/l (RCR)**	**Marine water mg/l (RCR)**	**Sediment freshwater mg/kg wwt (RCR)**	**Sediment marine water mg/kg wwt (RCR)**	**Soil mg/kg wwt (RCR)**	**STP mg/l (RCR)**
7.6E-04 (NA)	2.5E-03 (0.022)	No discharge to marine environment	2.38 (0.31)	No discharge to marine environment	4.70 (0.144)	0.019 (0.007)

Local PEC for scenario b) discharging directly to a freshwater river

Air mg.m-3 (RCR)	**Fresh water mg/l (RCR)**	**Marine water mg/l (RCR)**	**Sediment freshwater mg/kg wwt (RCR)**	**Sediment marine water mg/kg wwt (RCR)**	**Soil mg/kg wwt (RCR)**	**STP mg/l (RCR)**
7.6E-04 (NA)	6.5E-03 (0.053)	No discharge to marine environment	5.83 (0.747)	No discharge to marine environment	1.79 (0.055)	No discharge to STP

Local PEC for scenario c) discharging into a marine environment

Air mg.m-3 (RCR)	**Fresh water mg/l (RCR)**	**Marine water mg/l (RCR)**	**Sediment freshwater mg/kg wwt (RCR)**	**Sediment marine water mg/kg wwt (RCR)**	**Soil mg/kg wwt (RCR)**	**STP mg/l (RCR)**
7.6E-04 (NA)	No discharge to freshwater environment	1.1E-03 (0.093)	No discharge to freshwater environment	1.48 (0.947)	1.79 (0.055)	No discharge to STP

4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES

Occupational exposure

The DU works inside the boundaries set by the ES if either the proposed risk management measures as described above are met or the downstream user can demonstrate on his own that his operational conditions and implemented risk management measures are adequate. This has to be done by showing that they limit the inhalation and dermal exposure to a level below the respective DNEL (given that the processes and activities in question are covered by the PROCs listed above) as given below. If measured data are not available, the DU may make use of an appropriate scaling tool such as MEASE (www.ebrc.de/mease.html) to estimate the associated exposure. The dustiness of the substance used can be determined according to the MEASE glossary.

$DNEL_{inhalation}$: 0.5 mg/m^3

Environmental emissions
The DU works inside the boundaries set by the ES if either the proposed risk management measures as described above are met or the downstream user can demonstrate on his own that his operational conditions and implemented risk management measures are adequate. This has to be done by showing that they limit the environmental exposure to a level below the respective PNEC as given below. The RCR will be equal to or lower than those stated above if they emit less than 5kg Sb/day to air and less than 0.3kg Sb/day to on site or off site waste water treatment works (equivalent to 0.06 kg Sb/day to the receiving water) with a dilution rate of 1:10. The emission to water can be scaled if the dilution rates are higher (e.g. a ten times higher dilution rate would allow ten times greater emissions whilst still having an RCR<1). If measured data are not available, the DU may make use of an appropriate scaling tool such as MetalEUSES (free download: http://www.arche-consulting.be/Metal-CSA-toolbox/duscaling-tool) to estimate the associated exposure. PNEC$_{\text{freshwater}}$: 0.113 mg Sb/l PNEC$_{\text{marine}}$: 0.0113 mg Sb/l PNEC$_{\text{sediment freshwater}}$: 7.8 mg Sb/kg wwt PNEC$_{\text{sediment marine}}$: 1.56 mg Sb/kg wwt PNEC$_{\text{soil}}$: 37 mg Sb/kg dw (32.6 mg Sb/kg wwt) PNEC$_{\text{STP}}$: 2.55 mg Sb/l

9.6.2. Exposure estimation

9.6.2.1 Indirect exposure of humans via the environment (local)

Table 108: Concentration and risk characterization for local exposure of humans via the environment

Concentration for local exposure of humans via the environment					
	Estimated exposure concentrations		**Measured exposure concentrations**		**Explanation / source of measured data**
	value	**unit**	**value**	**unit**	
Air	7.6* 10-4	mgSb/m³	-	-	Local PEC has been calculated using EUSES 2.1 and converted from Sb to diantimony trioxide by a factor of 1.2.
	9.2* 10-4	mg Sb2O3/m³	-	-	
Drinking water	4.5* 10-2	mg Sb/L	-	-	Local PEC has been calculated using EUSES 2.1 and converted from Sb to diantimony trioxide by a factor of 1.2.
	5.4* 10-2	mg Sb2O3/L	-	-	
Total daily dose for oral exposure via the environment (mg/kg bw/d)					
µg Sb_2O_3/d	**mg Sb_2O_3/kg bw/d**		**Justification**		
113.02	1.88* 10^{-3}		2L of drinking water from the local setting + the worst case exposure of 4.32 µg/d from food (section 9.0.4.3) and the default body weight of 60kg have been taken into account.		
Quantitative risk characterisation for humans exposed via the environment					
Route	**exposure concentrations (EC)**		**DN(M)EL**		**Risk characterisation ratio**
Inhalation- local effects (long term)	9.2* 10^{-4}mg Sb_2O_3/m^3		0.1 mg/m³		9.2* 10^{-3}
Oral- systemic (long term)	1.88* 10^{-3} mg Sb_2O_3/kg bw/d		168.6 mg/kg/d		1.1* 10^{-5}
Combined routes					RCR Inhalation- systemic + RCR Oral- systemic

9.6.2.2 Environmental exposure

Table 109: Risk characterisation for the soil, sediment and water compartments for scenario a) discharging to an STP and freshwater river

Compartment	**Local PEC**	**PNEC**	**PEC/PNEC (RCR)**
Freshwater aquatic (mg Sb/l)	2.5E-03	0.113	0.022
Freshwater sediment (mg Sb/kg wwt)	2.38	7.8	0.31

Terrestrial (mg Sb/kg wwt)	4.70	32.6	0.144
Sewage treatment plant (mg Sb/l)	0.019	2.55	0.007

Table 110: Risk characterisation for the soil, sediment and water compartments for scenario b) discharging directly to a freshwater river

Compartment	Local PEC	PNEC	PEC/PNEC (RCR)
Freshwater aquatic (mg Sb/l)	6.5E-03	0.113	0.053
Freshwater sediment (mg Sb/kg wwt)	5.83	7.8	0.747
Terrestrial (mg Sb/kg wwt)	1.79	32.6	0.055

Table 111: Risk characterisation for the soil, sediment and water compartments for scenario c) discharing into a marine environment

Compartment	Local PEC	PNEC	PEC/PNEC (RCR)
Marine aquatic (mg Sb/l)	1.1E-03	0.0113	0.093
Marine sediment (mg Sb/kg wwt)	1.48	1.6	0.947
Terrestrial (mg Sb/kg wwt)	1.79	32.6	0.055

9.7. Industrial use of diantimony trioxide in wood adhesives

9.7.1. Exposure scenario

Exposure Scenario Format (1) addressing uses carried out by workers

1. Title

Free short title	Use of diantimony trioxide in the production and use of wood adhesives
Systematic title based on use descriptor	SU3 (Industrial uses), SU6a (Manufacture of wood and wood products) PC1 AC11 (appropriate PROCs and ERCs are given in section 2 below)
Processes, tasks and/or activities covered	Processes, tasks and/or activities covered are described in Section 2 below.
Assessment Method	For "Powder handling", the assessment of inhalation exposure is based on analogous data from diantimony trioxide powder handling in the production of plastics. For "Further processing", inhalation exposure assessment is based on MEASE. The environmental assessment uses EUSES.

2. Operational conditions and risk management measures

Workplace	**Involved tasks**	**Involved PROCs**	**Involved ERC**
Powder handling	Powder handling, mixing, formulation	5, 26	5
Further processing	Press-loading, pressing, rolling, sawing	8b, 14, 21, 24	

2.1 Control of workers exposure

Product characteristic

According to the MEASE approach, the substance-intrinsic emission potential is one of the main exposure determinants. This is reflected by an assignment of a so-called fugacity class in the MEASE tool. For operations conducted with solid substances at ambient temperature the fugacity is based on the dustiness of that substance. Whereas in hot metal operations, fugacity is temperature based, taking into account the process temperature and the melting point of the substance. As a third group, high abrasive tasks are based on the level of abrasion instead of the substance intrinsic emission potential.

Workplace	**Used in preparation?**	**Content in preparation**	**Physical form**	**Emission potential**
Powder handling	not restricted		powder*	high
Further processing	yes	<5 %	sticky mixture	high

*Also other physical forms (i.e. wetted powders) than powder are used. As powder represents the worst case in terms of its emission potential the raw material handling of these physical forms is covered in the initial "powder handling" process step in this exposure scenario. If other physical forms render some of the proposed RMMs below unnecessary the downstream user is referred to section 4 of this exposure scenario to proof that.

Amounts used

The actual tonnage handled per shift is not considered to influence the exposure as such for this scenario. Instead, the combination of the scale of operation (industrial vs. professional) and level of containment/automation (as reflected in the PROC) is the main determinant of the process intrinsic emission potential.

Frequency and duration of use/exposure

Workplace	Duration of exposure
Powder handling	≤ 180 minutes
Further processing	480 minutes (not restricted)

Human factors not influenced by risk management

The shift breathing volume during all process steps reflected in the PROCs is assumed to be 10 m^3/shift (8 hours).

Other given operational conditions affecting workers exposure

Workplace	Room volume	Outdoors or indoors?	Process temperature	Process pressure
Powder handling	>1,000 m^3	indoors	Not considered relevant for occupational exposure assessment of the conducted processes.	Not considered relevant for occupational exposure assessment of the conducted processes.
Further processing				

Technical conditions and measures at process level (source) to prevent release

Workplace	Level of containment	Level of segregation
Powder handling	closed system	not required
Further processing	not required	

Technical conditions and measures to control dispersion from source towards the worker

Workplace	Level of separation	Localised controls (LC)	Efficiency of LC (according to MEASE)	Further information
Powder handling	Any potentially required separation of workers from the emission source is indicated above under “Frequency and duration of exposure”. A reduction of exposure duration can be achieved, for example, by the installation of ventilated (positive pressure) control rooms or by removing the worker from workplaces involved with relevant exposure.	generic local exhaust ventilation	78 %	-
Further processing		not required	na	-

Organisational measures to prevent /limit releases, dispersion and exposure

Avoid inhalation or ingestion. General occupational hygiene measures are required to ensure a safe handling of the substance. These measures involve good personal and housekeeping practices (i.e. regular cleaning with suitable cleaning devices), no eating and smoking at the workplace, unless otherwise stated below the wearing of standard working clothes and shoes. Shower and change clothes at end of work shift. Do not wear contaminated clothing at home. Do not blow dust off with compressed air.

Historical observations of skin irritation have been made amongst workers caused by handling of diantimony trioxide powder under special conditions, namely substantial heat and sweat. The observed skin reactions, limited to workers at a diantimony trioxide (ATO) producing facility are likely to be evoked more by physically mediated processes associated with blocking of the sweat glands in the absence of any intrinsic substantial primary skin irritating potential of the substance and also in consideration of the poor solubility of ATO. Industry is committed to adequately control the risks of any adverse effects to workers who are exposed in hot, sweaty conditions to fumes or dust containing ATO by following the occupational hygiene practices as described in this exposure scenario. However, it is explicitly noted that the above described historical observations of skin effects have been scientifically evaluated by the Committee for Risk Assessment (RAC) of the European Chemicals Agency (ECHA) and did not lead to a classification of diantimony trioxide. As a precautionary measure, the wearing of chemical resistant gloves, long sleeved overalls and closed footwear, designed to minimize skin contact is suggested for all diantimony trioxide powder handling workplaces.

Conditions and measures related to personal protection, hygiene and health evaluation				
Workplace	**Specification of respiratory protective equipment (RPE)**	**RPE efficiency (assigned protection factor, APF)**	**Specification of gloves**	**Further personal protective equipment (PPE)**
Powder handling	FFP1 mask	APF=4	protective gloves	standard working clothes (overall with long sleeves) and safety shoes
Further processing	FFP1 mask	APF=4	protective gloves	

Any RPE as defined above shall only be worn if the following principles are implemented in parallel: The duration of work (compare with "duration of exposure" above) should reflect the additional physiological stress for the worker due to the breathing resistance and mass of the RPE itself, due to the increased thermal stress by enclosing the head. In addition, it shall be considered that the worker's capability of using tools and of communicating are reduced during the wearing of RPE.
For reasons as given above, the worker should therefore be (i) healthy (especially in view of medical problems that may affect the use of RPE), (ii) have suitable facial characteristics reducing leakages between face and mask (in view of scars and facial hair). The recommended devices above which rely on a tight face seal will not provide the required protection unless they fit the contours of the face properly and securely.
The employer and self-employed persons have legal responsibilities for the maintenance and issue of respiratory protective devices and the management of their correct use in the workplace. Therefore, they should define and document a suitable policy for a respiratory protective device programme including training of the workers.
An overview of the APFs of different RPE (according to BS EN 529:2005) can be found in the glossary of MEASE.

2.2 Control of environmental exposure for scenarios without waste water

Amounts used

15 tonnes Sb/year/site

Frequency and duration of use

Continuous use/release, 300 days/year

Environment factors not influenced by risk management

Not relevant

Other given operational conditions affecting environmental exposure

None

Technical conditions and measures at process level (source) to prevent release

Water is not used/released during the production of wood adhesives

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

This exposure scenario covers the industrial formulation and use of $Sb2O3$ in wood adhesives. This exposure scenario is covered by the FEICA spERCs 2.1a.v2, 2.2b.v2, 5.1a.v2, 5.1c.v2.
In order to calculate this exposure scenario the most worst case release factor from the spERCs is selected for the air compartment i.e. 1.7 % release to air (FEICA spERC 5.1a.v2 industrial use of substances other than solvents in water borne adhesives).
There are no releases of waste water so the release factor to water is considered 0%.

Release factor to air: 1.7%
FEICA spERC 5.1a.v2 industrial use of substances other than solvents in water borne adhesives: No onsite RMM considered as there is a very small release to air.

Release factor to water: 0%

Soil:
No direct emissions to soil.

Organizational measures to prevent/limit release from site

None

Conditions and measures related to municipal sewage treatment plant

There is no release to waste water therefore no STP is required

Conditions and measures related to external treatment of waste for disposal

Hazardous wastes from onsite risk management measures and solid or liquid wastes from production, use and cleaning processes should be disposed of separately to hazardous waste incineration plants or hazardous waste landfills as hazardous waste. Releases to the floor, water and soil are to be prevented. If the antimony content of the waste is elevated enough, internal or external recovery/recycling might be considered.

Fraction of daily/annual use expected in waste: 0.004 or 0.4%

Appropriate waste codes:
02 01 10*, 06 05 02*, 10 08 04, 10 08 08*, 10 08 15*, 15 01 10*, 16 06 01*, 19 02 05*, 19 12 03*

Suitable disposal: Keep separate and dispose of to either

- Hazardous waste incineration operated according to Council Directive 2008/98/EC on waste, Directive 2000/76/EC on the incineration of waste and the Reference Document on the Best Available Techniques for Waste Incineration of August 2006.
- Hazardous landfill operated under Directive 1999/31/EC.

A detailed assessment has been performed and is reported in the Waste report (ARCHE, 2012)

Conditions and measures related to external recovery of waste

Not applicable

3. Exposure estimation and reference to its source

Occupational exposure

For “Powder handling”, the 90th percentile of analogous data from the production of plastics was used for inhalation exposure assessment. For “Further processing”, the current version of MEASE was used for the estimation of inhalation exposure. The risk characterisation ratio (RCR) is the quotient of the refined exposure estimate and the respective DNEL (derived no-effect level) and has to be below 1 to demonstrate a safe use. For inhalation exposure, the RCR is based on the DNEL for diantimony trioxide of 0.5 mg/m^3.

Workplace	Method used for inhalation exposure assessment (refer to introduction)	Inhalation exposure estimate (RCR)	Method used for dermal exposure assessment (refer to introduction)	Dermal exposure estimate (RCR)
Powder handling	analogous data from the handling of diantimony trioxide in plastics	0.143 mg/m³ (0.29)	Due to the negligible dermal absorption of diantimony trioxide (0.26 %, EURAR, 2008), the dermal route is not a relevant exposure path for diantimony trioxide. Thus, dermal exposure is not assessed in this exposure scenario. However, dermal exposure has to be minimised to an extent as technically feasible when working under certain conditions as described above.	
Further processing	MEASE (PROC 24 as worst case assumption)	0.275 (0.55)		

Environmental emissions

Environmental modelling was carried out in EUSES 2.1

Local PEC

Air mg.m-3 (RCR)	Fresh water mg/l (RCR)	Marine water mg/l (RCR)	Sediment freshwater mg/kg wwt (RCR)	Sediment marine water mg/kg wwt (RCR)	Soil mg/kg wwt (RCR)	STP mg/l (RCR)
2.0E-04 (NA)	No discharge to waste water	No discharge to waste water	No discharge to waste water	No discharge to waste water	1.57 (0.05)	No discharge to waste water

4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES

Occupational exposure

The DU works inside the boundaries set by the ES if either the proposed risk management measures as described above are met or the downstream user can demonstrate on his own that his operational conditions and implemented risk management measures are adequate. This has to be done by showing that they limit the inhalation and dermal exposure to a level below the respective DNEL (given that the processes and activities in question are covered by the PROCs listed above) as given below. If measured data are not available, the DU may make use of an appropriate scaling tool such as MEASE (www.ebrc.de/mease.html) to estimate the associated exposure. The dustiness of the substance used can be determined according to the MEASE glossary.

DNEL$_{\text{inhalation}}$: 0.5 mg/m³

Environmental emissions

The DU works inside the boundaries set by the ES if either the proposed risk management measures as described above are met or the downstream user can demonstrate on his own that his operational conditions and implemented risk management measures are adequate. The RCR will be equal to or lower than those stated above if they emit less than 0.25 kg Sb/day to air and less than 0.3kg Sb/day to on site or off site waste water treatment works (equivalent to 0.06 kg Sb/day to the receiving water) with a dilution rate of 1:10. The emission to water can be scaled if the dilution rates are higher (e.g. a ten times higher dilution rate would allow ten times greater emissions whilst still having an RCR<1). This has to be done by showing that they limit the environmental exposure to a level below the respective PNEC as given below. If measured data are not available, the DU may make use of an appropriate scaling tool such as MetalEUSES (free download: http://www.arche-consulting.be/Metal-CSA-toolbox/duscaling-tool) to estimate the associated exposure.

PNEC$_{\text{freshwater}}$: 0.113 mg Sb/l
PNEC$_{\text{marine}}$: 0.0113 mg Sb/l
PNEC$_{\text{sediment freshwater}}$: 7.8 mg Sb/kg wwt
PNEC$_{\text{sediment marine}}$: 1.56 mg Sb/kg wwt
PNEC$_{\text{soil}}$: 37 mg Sb/kg dw (32.6 mg Sb/kg wwt)
PNEC$_{\text{STP}}$: 2.55 mg Sb/l

9.7.2. Exposure estimation

9.7.2.1 Indirect exposure of humans via the environment (local)

Table 112: Concentration and risk characterization for local exposure of humans via the environment

Concentration for local exposure of humans via the environment					
	Estimated exposure concentrations		**Measured exposure concentrations**		**Explanation / source of measured data**
	value	**unit**	**value**	**unit**	
Air	2.0* 10-4	mgSb/m^3	-	-	Local PEC has been calculated using EUSES 2.1 and converted from Sb to diantimony trioxide by a factor of 1.2.
	2.4* 10-4	mg Sb2O3/m^3	-	-	
Drinking water	1.5* 10-2	mg Sb/L	-	-	Local PEC has been calculated using EUSES 2.1 and converted from Sb to diantimony trioxide by a factor of 1.2.
	1.8* 10-2	mg Sb2O3/L	-	-	

Total daily dose for oral exposure via the environment (mg/kg bw/d)		
µg Sb_2O_3/d	**mg Sb_2O_3/kg bw/d**	**Justification**
40.71	6.78* 10^{-4}	2L of drinking water from the local setting + the worst case exposure of 4.32 µg/d from food (section 9.0.4.3) and the default body weight of 60 kg have been taken into account.

Quantitative risk characterisation for humans exposed via the environment			
Route	**exposure concentrations (EC)**	**DN(M)EL**	**Risk characterisation ratio**
Inhalation- local effects (long term)	2.4* 10^{-4}mg Sb_2O_3/m^3	0.1 mg/m^3	2.4* 10^{-3}
Oral- systemic (long term)	6.78* 10^{-4} mg Sb_2O_3/kg bw/d	168.6 mg/kg/d	4.0* 10^{-6}
Combined routes			RCR Inhalation- systemic + RCR Oral- systemic

9.7.2.2 Environmental exposure

Table 113: Risk characterisation for the soil, sediment and water compartments for exposure scenario without releases to water

Compartment	**Local PEC**	**PNEC**	**PEC/PNEC (RCR)**
Terrestrial (mg Sb/kg wwt)	1.57	32.6	0.05

9.8. Professional uses of diantimony trioxide preparations

9.8.1. Exposure scenario

Exposure Scenario Format (1) addressing uses carried out by workers

1. Title

Free short title	Use of diantimony trioxide in pigments, paints, coatings, flexible sealing materials
Systematic title based on use descriptor	SU22 (Professional uses) PC1, PC9a, PC18, PC20, PC24, PC26, PC32, PC34 (appropriate PROCs and ERCs are given in section 2 below)
Processes, tasks and/or activities covered	Processes, tasks and/or activities covered are described in Section 2 below.
Assessment Method	Inhalation exposure assessments are based on MEASE. All relevant parameters are provided in the exposure scenario below. The environmental assessment uses EUSES.

2. Operational conditions and risk management measures

Workplace	**Involved tasks**	**Involved PROCs**	**Involved ERC**
Mixing of paints	Mixing/handling of paints	8a, 19	8c, 8f, 10a, 11a, 12a
Application of paints	Painting, brushing and roller applications	10, 13	
Spraying of paints	Paint spraying	11	
Use of preparations at elevated temperatures	Application of flame retarded flexible sealing materials	23	

2.1 Control of workers exposure

Product characteristic

According to the MEASE approach, the substance-intrinsic emission potential is one of the main exposure determinants. This is reflected by an assignment of a so-called fugacity class in the MEASE tool. For operations conducted with solid substances at ambient temperature the fugacity is based on the dustiness of that substance. Whereas in hot metal operations, fugacity is temperature based, taking into account the process temperature and the melting point of the substance. As a third group, high abrasive tasks are based on the level of abrasion instead of the substance intrinsic emission potential.

Workplace	**Used in preparation?**	**Content in preparation**	**Physical form**	**Emission potential**
Mixing of paints	not restricted		aqueous solution	very low
Application of paints	not restricted		aqueous solution	very low
Spraying of paints	yes	<1 %	aqueous solution	medium
Use of preparations at elevated temperatures	yes	<25 %	bound in solid matrix	low (process temperature is far below melting point of diantimony trioxide)

Amounts used

The actual tonnage handled per shift is not considered to influence the exposure as such for this scenario. Instead, the combination of the scale of operation (industrial vs. professional) and level of containment/automation (as reflected in the PROC) is the main determinant of the process intrinsic emission potential.

Frequency and duration of use/exposure

Workplace	**Duration of exposure**
Mixing of paints	480 minutes (not restricted)
Application of paints	480 minutes (not restricted)
Spraying of paints	≤ 240 minutes
Use of preparations at elevated temperatures	480 minutes (not restricted)

Human factors not influenced by risk management

The shift breathing volume during all process steps reflected in the PROCs is assumed to be 10 m^3/shift (8 hours).

Other given operational conditions affecting workers exposure

Workplace	Room volume	Outdoors or indoors?	Process temperature	Process pressure
Mixing of paints	not restricted	not restricted	Not considered relevant for occupational exposure assessment of the conducted processes.	Not considered relevant for occupational exposure assessment of the conducted processes.
Application of paints				
Spraying of paints				
Use of preparations at elevated temperatures				

Technical conditions and measures at process level (source) to prevent release

Workplace	Level of containment	Level of segregation
Mixing of paints	not required	not required
Application of paints		
Spraying of paints		
Use of preparations at elevated temperatures		

Technical conditions and measures to control dispersion from source towards the worker

Workplace	Level of separation	Localised controls	Efficiency of ventilation (according to MEASE)	Further information
Mixing of paints	Any potentially required separation of workers from the emission source is indicated above under “Frequency and duration of exposure”. A reduction of exposure duration can be achieved, for example, by the installation of ventilated (positive pressure) control rooms or by removing the worker from workplaces involved with relevant exposure.	dilution ventilation	0 %	-
Application of paints		dilution ventilation	0 %	-
Spraying of paints		dilution ventilation	0 %	-
Use of preparations at elevated temperatures		dilution ventilation	0 %	-

Organisational measures to prevent /limit releases, dispersion and exposure

Avoid inhalation or ingestion. General occupational hygiene measures are required to ensure a safe handling of the substance. These measures involve good personal and housekeeping practices (i.e. regular cleaning with suitable cleaning devices), no eating and smoking at the workplace, unless otherwise stated below the wearing of standard working clothes and shoes. Shower and change clothes at end of work shift. Do not wear contaminated clothing at home. Do not blow dust off with compressed air.

Historical observations of skin irritation have been made amongst workers caused by handling of diantimony trioxide powder under special conditions, namely substantial heat and sweat. The observed skin reactions, limited to workers at a diantimony trioxide (ATO) producing facility are likely to be evoked more by physically mediated processes associated with blocking of the sweat glands in the absence of any intrinsic substantial primary skin irritating potential of the substance and also in consideration of the poor solubility of ATO. Industry is committed to adequately control the risks of any adverse effects to workers who are exposed in hot, sweaty conditions to fumes or dust containing ATO by following the occupational hygiene practices as described in this exposure scenario. However, it is explicitly noted that the above described historical observations of skin effects have been scientifically evaluated by the Committee for Risk Assessment (RAC) of the European Chemicals Agency (ECHA) and did not lead to a classification of diantimony trioxide. As a precautionary measure, the wearing of chemical resistant gloves, long sleeved overalls and closed footwear, designed to minimize skin contact is suggested for all diantimony trioxide powder handling workplaces.

Conditions and measures related to personal protection, hygiene and health evaluation

Workplace	Specification of respiratory protective equipment (RPE)	RPE efficiency (assigned protection factor, APF)	Specification of gloves	Further personal protective equipment (PPE)
Mixing of paints	not required	na	water-proof gloves	standard working clothes (overall with long sleeves) and safety shoes
Application of paints	not required	na	water-proof gloves	
Spraying of paints	FFP1 mask	APF=4	water-proof gloves	
Use of preparations at elevated temperatures	FFP2 mask	APF=10	heat resistant gloves	

Any RPE as defined above shall only be worn if the following principles are implemented in parallel: The duration of work (compare with “duration of exposure” above) should reflect the additional physiological stress for the worker due to the breathing resistance and mass of the RPE itself, due to the increased thermal stress by enclosing the head. In addition, it shall be considered that the worker’s capability of using tools and of communicating are reduced during the wearing of RPE.
For reasons as given above, the worker should therefore be (i) healthy (especially in view of medical problems that may affect the use of RPE), (ii) have suitable facial characteristics reducing leakages between face and mask (in view of scars and facial hair). The recommended devices above which rely on a tight face seal will not provide the required protection unless they fit the contours of the face properly and securely.
The employer and self-employed persons have legal responsibilities for the maintenance and issue of respiratory protective devices and the management of their correct use in the workplace. Therefore, they should define and document a suitable policy for a respiratory protective device programme including training of the workers.
An overview of the APFs of different RPE (according to BS EN 529:2005) can be found in the glossary of MEASE.

2.2 Control of environmental exposure

Amounts used

Based on a EU tonnage of 30000 tonnes Sb/year and equation given in R.16 (EU tonnage/10/2000*4) the modelled tonnage is 6 tonnes Sb/year/typical STP. This therefore covers the combined risk from all uses (professional and consumer) of diantimony trioxide containing products and articles.

Frequency and duration of use

Continuous use/release, 365 days/year

Environment factors not influenced by risk management

Default data for receiving water and for the municipal sewage treatment plant are18 000 m3/d and 2000 m3/d, respectively (resulting dilution factor 10). For marine assessments a default additional tenfold dilution is assumed.

Other given operational conditions affecting environmental exposure

None

Technical conditions and measures at process level (source) to prevent release

None

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

For local assessment of diffuse inputs of Sb all emissions are assumed to go to a local sewage treatment works.

Over 95% of Sb containing products and articles have a default release to water ≤ 3.2% based on the ERC. This has therefore been selected as the release fraction. The use of preparations containing antimony do not have intended or expected release to the environment. The ERC of 3.2% is a conservative value for this use.

Modelled release factors to water 3.2% before STP (ERC).

Release factors to air and soil are not relevant because only a local assessment of the municipal STP and subsecquent aquatic compartment is required. The release factors to air and soil are used to model the regional concentration but in the case of antimony measured data is used for the regional concentration, in this case release factors to air and soil are not relevant.

Organizational measures to prevent/limit release from site

None

Conditions and measures related to municipal sewage treatment plant

EUSES default STP with primary settler with effluent discharge rate 2000000l/d, serving 10000 inhabitants. Zero degradation assumed. 79.1 % to sludge, 20.9 % to water calculated in EUSES based on partition coefficients. Sludge assumed to be spread to agricultural land.

Conditions and measures related to external treatment of waste for disposal

Fraction of daily/annual use expected in waste: 91% of all articles, antimony in lead-acid batteries and PET bottles is partially recycled.

Appropriate waste codes:
20 01 34, 20 01 40, 20 03 01, 20 03 07

Suitable Disposal:
Waste from end-of-life articles can be disposed of as municipal waste, except when they are separately regulated, like electronic devices, batteries, vehicles, etc.
Disposal of wastes is possible via incineration (operated according to Directive 2000/76/EC on the incineration of waste) or landfilling (operated according to Reference Document on the Best available Techniques for Waste Industries of August 2006 and Council Directive 1999/31/EC and Council Decision 19 December 2002).

A detailed assessment has been performed and is reported in the Waste report (ARCHE, 2012)

Conditions and measures related to external recovery of waste

Not applicable

3. Exposure estimation and reference to its source

Occupational exposure

The current version of MEASE was used for the estimation of inhalation exposure. The risk characterisation ratio (RCR) is the quotient of the refined exposure estimate and the respective DNEL (derived no-effect level) and has to be below 1 to demonstrate a safe use. For inhalation exposure, the RCR is based on the DNEL for diantimony trioxide of 0.5 mg/m^3.

Workplace	Method used for inhalation exposure assessment (refer to introduction)	Inhalation exposure estimate (RCR)	Method used for dermal exposure assessment (refer to introduction)	Dermal exposure estimate (RCR)
Mixing of paints	MEASE	0.05 mg/m³ (0.1)	Due to the negligible dermal absorption of diantimony trioxide (0.26 %, ECB, 2008), the dermal route is not a relevant exposure path for diantimony trioxide. Thus, dermal exposure is not assessed in this exposure scenario. However, dermal exposure has to be minimised to an extent as technically feasible when working under certain conditions as described above.	
Application of paints	MEASE	0.05 mg/m³ (0.1)		
Spraying of paints	MEASE	0.3 mg/m³ (0.6)		
Using of preparations at elevated temperatures	MEASE	0.3 mg/m³ (0.6)		

Environmental emissions

Environmental modelling was carried out in EUSES 2.1

Local PEC for wide dispersive use with low or no intended releases

Air mg.m-3 (RCR)	Fresh water mg/l (RCR)	Marine water mg/l (RCR)	Sediment freshwater mg/kg wwt (RCR)	Sediment marine water mg/kg wwt (RCR)	Soil mg/kg wwt (RCR)	STP mg/l (RCR)
NR	5.87E-03 (0.052)	7.2E-04 (0.063)	5.6 (0.72)	1.15 (0.74)	9.93 (0.30)	5.5E-02 (0.022)

4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES

Occupational exposure

The DU works inside the boundaries set by the ES if either the proposed risk management measures as described above are met or the downstream user can demonstrate on his own that his operational conditions and implemented risk management measures are adequate. This has to be done by showing that they limit the inhalation and dermal exposure to a level below the respective DNEL (given that the processes and activities in question are covered by the PROCs listed above) as given below. If measured data are not available, the DU may make use of an appropriate scaling tool such as MEASE (www.ebrc.de/mease.html) to estimate the associated exposure. The dustiness of the substance used can be determined according to the MEASE glossary.

$DNEL_{inhalation}$: 0.5 mg/m³

Environmental emissions

An assessment based on the total EU tonnage of diantimony trioxide containing articles and products and REACH guidance default values has indicated RCR < 1. This assessment is considered to be extremely worst case and therefore indicates that the professional use of diantimony trioxide containing preparations does not pose a risk to the environment.

9.8.2. Exposure estimation

9.8.2.1 Indirect exposure of humans via the environment (local)

Table 114: Concentration and risk characterization for local exposure of humans via the environment

Concentration for local exposure of humans via the environment					
	Estimated exposure concentrations		**Measured exposure concentrations**		**Explanation / source of measured data**
	value	**unit**	**value**	**unit**	
Air	$2.6* 10^{-6}$	mgSb/m^3	-	-	Local PEC has been calculated using EUSES 2.1 and converted from Sb to diantimony trioxide by a factor of 1.2.
	$3.12* 10^{-6}$	mg Sb2O3/m^3	-	-	
Drinking water	$9.6* 10^{-2}$	mg Sb/L	-	-	Local PEC has been calculated using EUSES 2.1 and converted from Sb to diantimony trioxide by a factor of 1.2.
	$1.1* 10^{-1}$	mg Sb2O3/L	-	-	

Total daily dose for oral exposure via the environment (mg/kg bw/d)		
µg Sb_2O_3/d	**mg Sb_2O_3/kg bw/d**	**Justification**
233.9	$3.9* 10^{-3}$	2L of drinking water from the local setting + the worst case exposure of 4.32 µg/d from food (section 9.0.4.3) and the default body weight of 60 kg have been taken into account.

Quantitative risk characterisation for humans exposed via the environment			
Route	**exposure concentrations (EC)**	**DN(M)EL**	**Risk characterisation ratio**
Inhalation- local effects (long term)	$3.12* 10^{-6}$mg Sb_2O_3/m^3	0.1 mg/m^3	$3.12* 10^{-5}$
Oral- systemic (long term)	$3.9* 10^{-3}$ mg Sb_2O_3/kg bw/d	168.6 mg/kg/d	$2.3* 10^{-5}$
Combined routes			RCR Inhalation- systemic + RCR Oral- systemic

9.8.2.2 Environmental exposure

Table 115: Risk characterisation for the soil, sediment and water compartments

Compartment	Local PEC	PNEC	PEC/PNEC (RCR)
Freshwater aquatic (mg Sb/l)	5.87E-03	0.113	0.052
Marine aquatic (mg Sb/l)	7.2E-04	0.0113	0.063
Freshwater sediment (mg Sb/kg wwt)	5.6	7.8	0.72
Marine sediment (mg Sb/kg wwt)	1.15	1.6	0.74
Terrestrial (mg Sb/kg wwt)	9.93	32.6	0.30
Sewage treatment plant (mg Sb/l)	5.5E-02	2.55	0.022

9.9. Professional uses of diantimony trioxide contained in articles

9.9.1. Exposure scenario

Exposure Scenario Format (3) addressing service life resulting from downstream use (article handled by worker)

1. Title

Free short title	Professional uses of diantimony trioxide contained in articles
Systematic title based on use descriptor	SU22 (Professional uses) AC1, AC2, AC3, AC4, AC5, AC6, AC7, AC8, AC10, AC11, AC13 (appropriate PROCs and ERCs are given in section 2 below)
Processes, tasks and/or activities covered	Processes, tasks and/or activities covered are described in Section 2 below.
Assessment Method	Inhalation exposure assessments are based on published data and on MEASE. All relevant parameters are provided in the exposure scenario below. The environmental assessment uses EUSES.

2. Operational conditions and risk management measures

Workplace	**Involved tasks**	**Involved PROCs**	**Involved ERC**
Use of back-coated textiles	Cutting, pressing, smoothing, etc. of flame retarded textiles in upholstery industry	21	8c, 8f, 10a, 11a, 12a
Use of flame retarded rubber goods	Installation and use of flame retarded conveyor belts in underground mining and other niche applications	21	
Processing of flame retarded articles	Sawing and grinding of wood treated with flame retarded adhesives	24	
Handling of other flame-retarded articles	Use (installation and subsequent use) of flame retarded articles (such as plastic cases of electrical installations, flame retarded cable insulations, etc.)	21	

2.1 Control of workers exposure

Product (article) characteristic

According to the MEASE approach, the substance-intrinsic emission potential is one of the main exposure determinants. This is reflected by an assignment of a so-called fugacity class in the MEASE tool. For operations conducted with solid substances at ambient temperature the fugacity is based on the dustiness of that substance. Whereas in hot metal operations, fugacity is temperature based, taking into account the process temperature and the melting point of the substance. As a third group, high abrasive tasks are based on the level of abrasion instead of the substance intrinsic emission potential.

Workplace	**Content in article***	**Release potential**	**Emission potential**
Use of back-coated textiles	<25 %	applied to textile back-surface, not bound into matrix	medium dustiness during abrasive tasks, professional use of upholstery (very low dustiness) is assumed to be covered
Use of flame retarded rubber goods	<25 %	tightly bound into rubber matrix	very low dustiness
Processing of flame retarded articles	<25 %	tightly bound in wood adhesive	low dustiness during abrasive tasks (e.g. grinding)
Handling of other flame-retarded articles	<25 %	tightly bound in plastics matrix	very low dustiness

*Actual contents are known to be significantly lower, but have been chosen as worst case assumptions for exposure estimation.

Amounts (contained in articles) present at workplace

The actual tonnage handled per shift is not considered to influence the exposure as such for this scenario. Instead, the combination of the scale of operation (industrial vs. professional) and level of containment/automation (as reflected in the PROC) is the main determinant of the process intrinsic emission potential.

Frequency and duration of use/exposure

Workplace	Duration of exposure
Use of back-coated textiles	480 minutes (not restricted)
Use of flame retarded rubber goods	480 minutes (not restricted)
Processing of flame retarded articles	480 minutes (not restricted)
Handling of other flame-retarded articles	480 minutes (not restricted)

Human factors not influenced by risk management

The shift breathing volume during all process steps reflected in the PROCs is assumed to be 10 m^3/shift (8 hours).

Other given operational conditions affecting workers exposure

Workplace	Room volume	Outdoors or indoors?	Process temperature	Process pressure
Use of back-coated textiles	not restricted	not restricted	Not considered relevant for occupational exposure assessment of the conducted processes.	Not considered relevant for occupational exposure assessment of the conducted processes.
Use of flame retarded rubber goods				
Processing of flame retarded articles				
Handling of other flame-retarded articles				

Technical conditions and measures at process level (source) to prevent release

Workplace	Level of containment	Level of segregation
Use of back-coated textiles	not required	not required
Use of flame retarded rubber goods		
Processing of flame retarded articles		
Handling of other flame-retarded articles		

Technical conditions and measures to control dispersion from source towards the worker

Workplace	Level of separation	Localised controls	Efficiency of ventilation (according to MEASE)	Further information
Use of back-coated textiles	not required	dilution ventilation	0 %	-
Use of flame retarded rubber goods		dilution ventilation	0 %	-
Processing of flame retarded articles		integrated local exhaust ventilation	80 %	-
Handling of other flame-retarded articles		not required	0 %	-

Organisational measures to prevent /limit releases, dispersion and exposure

Avoid inhalation or ingestion. General occupational hygiene measures are required to ensure a safe handling of the substance. These measures involve good personal and housekeeping practices (i.e. regular cleaning with suitable cleaning devices), no eating and smoking at the workplace, unless otherwise stated below the wearing of standard working clothes and shoes. Shower and change clothes at end of work shift. Do not wear contaminated clothing at home. Do not blow dust off with compressed air.

Historical observations of skin irritation have been made amongst workers caused by handling of diantimony trioxide powder under special conditions, namely substantial heat and sweat. The observed skin reactions, limited to workers at a diantimony trioxide (ATO) producing facility are likely to be evoked more by physically mediated processes associated with blocking of the sweat glands in the absence of any intrinsic substantial primary skin irritating potential of the substance and also in consideration of the poor solubility of ATO. Industry is committed to adequately control the risks of any adverse effects to workers who are exposed in hot, sweaty conditions to fumes or dust containing ATO by following the occupational hygiene practices as described in this exposure scenario. However, it is explicitly noted that the above described historical observations of skin effects have been scientifically evaluated by the Committee for Risk Assessment (RAC) of the European Chemicals Agency (ECHA) and did not lead to a classification of diantimony trioxide. As a precautionary measure, the wearing of chemical resistant gloves, long sleeved overalls and closed footwear, designed to minimize skin contact is suggested for all diantimony trioxide powder handling workplaces.

Conditions and measures related to personal protection, hygiene and health evaluation

Workplace	Specification of respiratory protective equipment (RPE)	RPE efficiency (assigned protection factor, APF)	Specification of gloves	Further personal protective equipment (PPE)
Use of back-coated textiles	not required	na	not required	standard working clothes (overall with long sleeves) and safety shoes
Use of flame retarded rubber goods	not required	na	not required	
Processing of flame retarded articles	not required	na	protective gloves (mechanical protection)	
Handling of other flame-retarded articles	not required	na	not required	

2.2 Control of environmental exposure

Amounts used

Based on a EU tonnage of 30000 tonnes Sb/year and equation given in R.16 (EU tonnage/10/2000*4) the modelled tonnage is 6 tonnes Sb/year/typical STP. This therefore covers the combined risk from all uses (professional and consumer) of diantimony trioxide containing products and articles.

Frequency and duration of use

Continuous use/release, 365 days/year

Environment factors not influenced by risk management

Default data for receiving water and for the municipal sewage treatment plant are18 000 m3/d and 2000 m3/d, respectively (resulting dilution factor 10). For marine assessments a default additional tenfold dilution is assumed.

Other given operational conditions affecting environmental exposure

None

Technical conditions and measures at process level (source) to prevent release

None

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

For local assessment of diffuse inputs of Sb all emissions are assumed to go to a local sewage treatment works.

Over 95% of Sb containing products and articles have a default release to water ≤ 3.2% based on the ERC. This has therefore been selected as the release fraction. The use of articles containing antimony do not have intended or expected release to the environment. Antimony is incapsulated in a matrix with low to no potential to be released to the environment. The ERC of 3.2% is a very conservative value for this article.

Modelled release factors to water 3.2% before STP (ERC).

Release factors to air and soil are not relevant because only a local assessment of the municipal STP and subsecquent aquatic compartment is required. The release factors to air and soil are used to model the regional concentration but in the case of antimony measured data is used for the regional concentration, in this case release factors to air and soil are not relevant.

Organizational measures to prevent/limit release from site

None

Conditions and measures related to municipal sewage treatment plant

EUSES default STP with primary settler with effluent discharge rate 2000000l/d, serving 10000 inhabitants. Zero degradation assumed. 79.1 % to sludge, 20.9 % to water calculated in EUSES based on partition coefficients. Sludge assumed to be spread to agricultural land.

Conditions and measures related to external treatment of waste for disposal

Fraction of daily/annual use expected in waste: 91% of all articles, antimony in lead-acid batteries and PET bottles is partially recycled.

Appropriate waste codes:
20 01 34, 20 01 40, 20 03 01, 20 03 07

Suitable Disposal:
Waste from end-of-life articles can be disposed of as municipal waste, except when they are separately regulated, like electronic devices, batteries, vehicles, etc.
Disposal of wastes is possible via incineration (operated according to Directive 2000/76/EC on the incineration of waste) or landfilling (operated according to Reference Document on the Best available Techniques for Waste Industries of August 2006 and Council Directive 1999/31/EC and Council Decision 19 December 2002).

A detailed assessment has been performed and is reported in the Waste report (ARCHE, 2012)

Conditions and measures related to external recovery of waste

Not applicable

3. Exposure estimation and reference to its source

Occupational exposure

Published data and the current version of MEASE were used for the estimation of inhalation exposure. The risk characterisation ratio (RCR) is the quotient of the refined exposure estimate and the respective DNEL (derived no-effect level) and has to be below 1 to demonstrate a safe use. For inhalation exposure, the RCR is based on the DNEL for diantimony trioxide of 0.5 mg/m^3.

Workplace	Method used for inhalation exposure assessment (refer to introduction)	Inhalation exposure estimate (RCR)	Method used for dermal exposure assessment (refer to introduction)	Dermal exposure estimate (RCR)
Use of back-coated textiles	published data (upholstery, Iavicoli, 2002)	0.001 mg/m³ (0.002)	Due to the negligible dermal absorption of diantimony trioxide (0.26 %, ECB, 2008), the dermal route is not a relevant exposure path for diantimony trioxide. Thus, dermal exposure is not assessed in this exposure scenario. However, dermal exposure has to be minimised to an extent as technically feasible when working under certain conditions as described above.	
Use of flame retarded rubber goods	MEASE	0.03 mg/m³ (0.06)		
Processing of flame retarded articles	MEASE	0.24 mg/m³ (0.48)		
Handling of other flame-retarded articles	MEASE	0.03 mg/m³ (0.06)		

Environmental emissions

Environmental modelling was carried out in EUSES 2.1

Local PEC for wide dispersive uses with low release

Air mg.m-3 (RCR)	Fresh water mg/l (RCR)	Marine water mg/l (RCR)	Sediment freshwater mg/kg wwt (RCR)	Sediment marine water mg/kg wwt (RCR)	Soil mg/kg wwt (RCR)	STP mg/l (RCR)
NR	5.87E-03 (0.052)	7.2E-04 (0.063)	5.6 (0.72)	1.15 (0.74)	9.93 (0.30)	5.5E-02 (0.022)

4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES

Occupational exposure

The DU works inside the boundaries set by the ES if either the proposed risk management measures as described above are met or the downstream user can demonstrate on his own that his operational conditions and implemented risk management measures are adequate. This has to be done by showing that they limit the inhalation and dermal exposure to a level below the respective DNEL (given that the processes and activities in question are covered by the PROCs listed above) as given below. If measured data are not available, the DU may make use of an appropriate scaling tool such as MEASE (www.ebrc.de/mease.html) to estimate the associated exposure. The dustiness of the substance used can be determined according to the MEASE glossary.

$\mathrm{DNEL}_{\mathrm{inhalation}}$: 0.5 mg/m³

Environmental emissions

An assessment based on the total EU tonnage of diantimony trioxide containing articles and products and REACH guidance default values has indicated RCR < 1. This assessment is considered to be extremely worst case and therefore indicates that the professional use of diantimony trioxide containing articles does not pose a risk to the environment.

9.9.2. Exposure estimation

9.9.2.1 Indirect exposure of humans via the environment (local)

Table 116: Concentration and risk characterization for local exposure of humans via the environment

Concentration for local exposure of humans via the environment					
	Estimated exposure concentrations		**Measured exposure concentrations**		**Explanation / source of measured data**
	value	**unit**	**value**	**unit**	
Air	2.6* 10^{-6}	mgSb/m^3	-	-	Local PEC has been calculated using EUSES 2.1 and converted from Sb to diantimony trioxide by a factor of 1.2.
	3.12* 10^{-6}	mg Sb2O3/m^3	-	-	
Drinking water	9.6* 10^{-2}	mg Sb/L	-	-	Local PEC has been calculated using EUSES 2.1 and converted from Sb to diantimony trioxide by a factor of 1.2.
	1.1* 10^{-1}	mg Sb2O3/L	-	-	
Total daily dose for oral exposure via the environment (mg/kg bw/d)					
µg Sb_2O_3/d	**mg Sb_2O_3/kg bw/d**		**Justification**		
233.9	3.9* 10^{-3}		2L of drinking water from the local setting + the worst case exposure of 4. 32 µg/d from food (section 9.0.4.3) and the default body weight of 60kg have been taken into account.		
Quantitative risk characterisation for humans exposed via the environment					
Route	**exposure concentrations (EC)**		**DN(M)EL**		**Risk characterisation ratio**
Inhalation- local effects (long term)	3.12* 10^{-6}mg Sb_2O_3/m^3		0.1 mg/m^3		3.12* 10^{-5}
Oral- systemic (long term)	3.9* 10^{-3} mg Sb_2O_3/kg bw/d		168.6 mg/kg/d		2.3* 10^{-5}
Combined routes					RCR Inhalation- systemic + RCR Oral- systemic

9.9.2.2 Environmental exposure

Table 117: Risk characterisation for the soil, sediment and water compartments

Compartment	**Local PEC**	**PNEC**	**PEC/PNEC (RCR)**
Freshwater aquatic (mg Sb/l)	5.87E-03	0.113	0.052
Marine aquatic (mg Sb/l)	7.2E-04	0.0113	0.063
Freshwater sediment (mg Sb/kg wwt)	5.6	7.8	0.72
Marine sediment (mg Sb/kg wwt)	1.15	1.6	0.74
Terrestrial (mg Sb/kg wwt)	9.93	32.6	0.30
Sewage treatment plant (mg Sb/l)	5.5E-02	2.55	0.022

9.10 Service life/Use of articles with diantimony trioxide being embedded into the matrix

9.10.1 Exposure Scenario

Exposure Scenario Format (4) addressing service life resulting from downstream use (article handled by consumer)	
1. Title	
Free short title	Service life/Use of articles with diantimony trioxide being embedded in the matrix
Systematic title based on use descriptor for article service life	SU21 (Consumer use), AC1 (vehicles), SU21 (Consumer use), AC2 (Machinery, mechanical appliances, electrical/electronic articles, incl. TARIC 8544), SU21 (Consumer use), AC3 (Electrical batteries and accumulators), SU21 (Consumer use), AC5 (Fabrics, textiles and apparel), SU21 (Consumer use), AC7 (Metal articles), SU21 (Consumer use), AC10 (Rubber articles), SU21 (Consumer use), AC11 (Wood articles) SU21 (Consumer use), AC13 (Plastic articles, incl. TARIC 3925), ERC 8c, 8f, 10a, 11a, 12a
Systematic title based on use descriptor for downstream use leading to inclusion in article	SU5 (Manufacture of textiles, leather, fur) SU 6a (Manufacture of wood and wood products) SU10 (Formulation of preparations and/or re-packing) SU11 (Manufacture of rubber products) SU12 (Manufacture of plastic products) SU16 (Manufacture of computer, electronic and optical products, electrical equipment) SU17 (General manufacturing, e.g. machinery, equipment, vehicles, other transport equipment) SU18 (Manufacture of furniture)
Processes, tasks activities covered	Activities covered are described in Section 2 below.
Assessment Method*	Data from ATO EU RAR (2008) and wider literature.Qualitative assessment for oral, dermal and inhalation exposure. The environmental assessment uses EUSES.

2. Operational conditions and risk management measures	
AC/ERC	**Description of activity referring to article categories (AC) and environmental release categories (ERC)**
AC 1	Handling of flame retarded plastic in automotive parts under ambient temperature. No consumer risk management measures are in place.
AC 2	Handling of flame retarded plastic in electrical and electronic equipment under ambient temperature. No consumer risk management measures are in place.
AC 3	Handling of batteries covered with flame retarded plastic under ambient temperature. No consumer risk management measures are in place.
AC 5	Handling of flame retarded textiles (e.g. curtains, carpeting/flooring, car seats) under ambient temperature. No consumer risk management measures are in place.
AC 7	Handling of metal objects with a flame retarded PVC coating under ambient temperature. No consumer risk management measures are in place.
AC 10	Handling of flame retarded rubber products under ambient temperature. No consumer risk management measures are in place.
AC 11	Handling of flame retarded wood articles (plywood) under ambient temperature. No consumer risk management measures are in place.
AC 13	Handling of flame retarded plastic products under ambient temperature. No consumer risk management measures are in place.
ERC 8c	Wide dispersive indoor use, inclusion into or onto a matrix
ERC 8f	Wide dispersive outdoor use, inclusion in matrix
ERC 10a	Wide dispersive outdoor use of long life articles, low release

Exposure Scenario Format (4) addressing service life resulting from downstream use (article handled by consumer)

ERC 11a	Wide dispersive indoor use of long life articles, low release
ERC 12a	Industrial processing of articles with abrasive techniques (low release)

2.1 Control of consumers exposure

Product (article) characteristic

AC	Article characteristics	Release potential
AC 1, 2, 3, 13	Articles made out of flame retarded plastic where antimony trioxide is tightly bound into the plastic matrix.	not expected, due to the characteristics of the material
AC 1, 5, 10	Articles made out of flame retarded rubber where antimony trioxide is tightly bound into the rubber matrix.	not expected, due to the characteristics of the material
AC 7	Metal articles with a coating of flame retarded PVC-paint, in which antimony trioxide is tightly bound into the matrix.	not expected, due to the characteristics of the material
AC 11	Plywood made with flame retarded adhesives, in which antimony trioxide is tightly bound into the matrix (adhesive).	not expected, due to the characteristics of the material

Amounts used

AC	Amount of substance in article
AC 1, 2, 3, 13	Flame retarded plastic 1.6 – 11.6 %
AC 1, 5, 10	Flame retarded rubber 2-10 %, typical 3 %
AC 7	Dried PVC paint on metal objects: 2-4 %
AC 11	Plywood with up to 2.3 % in the adhesive

Frequency and duration of use/exposure from service life

Description of article	Contact time per event (day)	Frequency of events/day
AC 1, 2, 3, 5, 7, 10, 11, 13	Short contact time (min), but will also be highly variable	Occasional contact, but also highly variable over time and from one person to another

Human factors not influenced by risk management

Description of article	Population exposed	Weight	Ingestion rate	Exposed body part	Contact skin area [cm²]
AC 1, 2, 3, 5, 7, 10, 11, 13	Adult	60 kg (default)	-	hands	-

Other given operational conditions affecting consumers exposure from article service life

Not applicable

Conditions and measures at level of article production to prevent release during service life

Not applicable

Conditions and measures related to information and behavioural advice to consumers

Not applicable

Conditions and measures related to personal protective equipment and hygiene

Not applicable

2.2 Control of environmental exposure

Amounts used

Based on a EU tonnage of 30000 tonnes Sb/year and equation given in R.16 (EU tonnage/10/2000*4) the modelled tonnage is 6 tonnes Sb/year/typical STP. This therefore covers the combined risk from all uses (professional and consumer) of diantimony trioxide containing products and articles.

Frequency and duration of use

Continuous use/release, 365 days/year

Environment factors not influenced by risk management

Default data for receiving water and for the municipal sewage treatment plant are18 000 m3/d and 2000 m3/d, respectively (resulting dilution factor 10). For marine assessments a default additional tenfold dilution is assumed.

Exposure Scenario Format (4) addressing service life resulting from downstream use (article handled by consumer)

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

For local assessment of diffuse inputs of Sb all emissions are assumed to go to a local sewage treatment works.

Over 95% of Sb containing products and articles have a default release to water ≤ 3.2% based on the ERC. This has therefore been selected as the release fraction. The use of massive objects containing antimony do not have intended or expected release to the environment. Antimony is incapsulated in a matrix with low to no potential to be released to the environment. The ERC of 3.2% is a very conservative value for this article.

Modelled release factors to water 3.2% before STP (ERC).

Release factors to air and soil are not relevant because only a local assessment of the municipal STP and subsecquent aquatic compartment is required. The release factors to air and soil are used to model the regional concentration but in the case of antimony measured data is used for the regional concentration, in this case release factors to air and soil are not relevant.

Conditions and measures related to disposal of articles at end of service life

Fraction of daily/annual use expected in waste: 91% of all articles, antimony in lead-acid batteries and PET bottles is partially recycled.

Appropriate waste codes:
20 01 34, 20 01 40, 20 03 01, 20 03 07

Suitable Disposal:
Waste from end-of-life articles can be disposed of as municipal waste, except when they are separately regulated, like electronic devices, batteries, vehicles, etc.
Disposal of wastes is possible via incineration (operated according to Directive 2000/76/EC on the incineration of waste) or landfilling (operated according to Reference Document on the Best available Techniques for Waste Industries of August 2006 and Council Directive 1999/31/EC and Council Decision 19 December 2002).

A detailed assessment has been performed and is reported in the Waste report (ARCHE, 2012)

Conditions and measures related to recovery of articles at the end of service life

No specific measures in place; most articles used will end up at a landfill or will be recycled.

3. Exposure estimation and reference to its source

Human exposure

Route of exposure	**Exposure estimate**	**Method used, comments**
Oral	negligible	Qualitative assessment Oral exposure does not occur as part of the intended product use.
Dermal	negligible	Qualitative assessment As antimony trioxide is included in the plastic, rubber, enamel or adhesive matrix a physical barriers preclude consumer contact with antimony trioxide used in these applications. Furthermore, the contact time will be short and infrequent and clothing will be a further barrier. This prevents dermal exposure.
Inhalation	negligible	Qualitative assessment Inhalation exposure is insignificant due to the extremely low vapour pressure of diantimony trioxide. Inhalation exposure due to abrasion is covered under the indoor air ES (ES2c).

Environmental exposure

Environmental modelling was carried out in EUSES 2.1

Local PEC for wide dispersive uses with low release

Air mg.m-3 (RCR)	**Fresh water mg/l (RCR)**	**Marine water mg/l (RCR)**	**Sediment freshwater mg/kg wwt (RCR)**	**Sediment marine water mg/kg wwt (RCR)**	**Soil mg/kg wwt (RCR)**	**STP mg/l (RCR)**
NR	5.87E-03 (0.052)	7.2E-04 (0.063)	5.6 (0.72)	1.15 (0.74)	9.93 (0.30)	5.5E-02 (0.022)

4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES

An assessment based on the total EU tonnage of diantimony trioxide containing articles and REACH guidance default values has indicated RCR < 1. This assessment is considered to be extremely worst case and therefore indicates that the consumer use of diantimony trioxide containing articles does not pose a risk to the environment.

9.10.2 Exposure estimation

9.10.2.1 Indirect exposure of humans via the environment (local)

Table 118: Concentration and risk characterization for local exposure of humans via the environment

<table>
<tr><th colspan="6">Concentration for local exposure of humans via the environment</th></tr>
<tr><th rowspan="2"></th><th colspan="2">Estimated exposure concentrations</th><th colspan="2">Measured exposure concentrations</th><th rowspan="2">Explanation / source of measured data</th></tr>
<tr><th>value</th><th>unit</th><th>value</th><th>unit</th></tr>
<tr><td rowspan="2">Air</td><td>$2.6* 10^{-6}$</td><td>$mgSb/m^3$</td><td>-</td><td>-</td><td rowspan="2">Local PEC has been calculated using EUSES 2.1 and converted from Sb to diantimony trioxide by a factor of 1.2.</td></tr>
<tr><td>$3.12* 10^{-6}$</td><td>$mg\ Sb2O3/m^3$</td><td>-</td><td>-</td></tr>
<tr><td rowspan="2">Drinking water</td><td>$9.6* 10^{-2}$</td><td>mg Sb/L</td><td>-</td><td>-</td><td rowspan="2">Local PEC has been calculated using EUSES 2.1 and converted from Sb to diantimony trioxide by a factor of 1.2.</td></tr>
<tr><td>$1.1* 10^{-1}$</td><td>mg Sb2O3/L</td><td>-</td><td>-</td></tr>
<tr><th colspan="6">Total daily dose for oral exposure via the environment (mg/kg bw/d)</th></tr>
<tr><th>µg Sb_2O_3/d</th><th colspan="2">mg Sb_2O_3/kg bw/d</th><th colspan="3">Justification</th></tr>
<tr><td>18.4</td><td colspan="2">$3.9* 10^{-3}$</td><td colspan="3">2L of drinking water from the local setting + the worst case exposure of 4.32 µg/d from food (section 9.0.4.3) and the default body weight of 60kg have been taken into account.</td></tr>
<tr><th colspan="6">Quantitative risk characterisation for humans exposed via the environment</th></tr>
<tr><th>Route</th><th colspan="2">exposure concentrations (EC)</th><th colspan="2">DN(M)EL</th><th>Risk characterisation ratio</th></tr>
<tr><td>Inhalation- local effects
(long term)</td><td colspan="2">$3.12* 10^{-6}mg\ Sb_2O_3/m^3$</td><td colspan="2">$0.1\ mg/m^3$</td><td>$3.12* 10^{-5}$</td></tr>
<tr><td>Oral- systemic
(long term)</td><td colspan="2">$3.9* 10^{-3}$ mg Sb_2O_3/kg bw/d</td><td colspan="2">168.6 mg/kg/d</td><td>$2.3* 10^{-5}$</td></tr>
<tr><td>Combined routes</td><td colspan="2"></td><td colspan="2"></td><td>RCR Inhalation- systemic + RCR Oral- systemic</td></tr>
</table>

9.10.2.2 Environmental exposure

Table 119: Risk characterisation for the soil, sediment and water compartments

Compartment	**Local PEC**	**PNEC**	**PEC/PNEC (RCR)**
Freshwater aquatic (mg Sb/l)	5.87E-03	0.113	0.052
Marine aquatic (mg Sb/l)	7.2E-04	0.0113	0.063
Freshwater sediment (mg Sb/kg wwt)	5.6	7.8	0.72
Marine sediment (mg Sb/kg wwt)	1.15	1.6	0.74
Terrestrial (mg Sb/kg wwt)	9.93	32.6	0.30
Sewage treatment plant (mg Sb/l)	5.5E-02	2.55	0.022

9.11 Service life/Use of back-coated textiles

9.11.1 Exposure scenario

Exposure Scenario Format (4) addressing service life resulting from downstream use (article handled by consumer)	
1. Title	
Free short title	Service life/Use of back-coated textiles
Systematic title based on use descriptor for article service life	SU21 (Consumer use), AC5 (Fabrics, textiles and apparel; TARIC: 59031090 and 59032090), ERC 8c, 8f, 10a, 11a, 12a
Systematic title based on use descriptor for downstream use leading to inclusion in article	SU5 (Manufacture of textiles, leather, fur) SU10 (Formulation of preparations and/or re-packing)
Processes, tasks activities covered	Activities covered are described in Section 2 below.
Assessment Method*	The quantitative assessment of dermal and inhalation exposure and oral exposure to children is based on exposure scenarios provided in the EU-RAR on diantimony trioxide. The environmental assessment uses EUSES.

2. Operational conditions and risk management measures	
AC/ERC	**Description of activity referring to article categories (AC) and environmental release categories (ERC)**
AC 5 (back-coated) TARIC: 59031090, 59032090	Sitting on flame retarded textiles. Inhalation or ingestion of wear debris as a release potential for diantimony trioxide from back-coated textiles (house-dust). No consumer risk management measured are in place.
ERC 8c	Wide dispersive indoor use, inclusion into or onto a matrix
ERC 8f	Wide dispersive outdoor use, inclusion in matrix
ERC 10a	Wide dispersive outdoor use of long life articles, low release
ERC 11a	Wide dispersive indoor use of long life articles, low release
ERC 12a	Industrial processing of articles with abrasive techniques (low release)

2.1 Control of consumers exposure			
Product (article) characteristic			
AC	**Article characteristics**	**Fraction released to skin**	**Fraction released to air**

Exposure Scenario Format (4) addressing service life resulting from downstream use (article handled by consumer)

AC 5 (back-coated) TARIC: 59031090, 59032090	Flame-retarded textiles (back-coated) are used in e.g. vehicles, curtains, upholstered furniture, tents, canvas, straps etc. A special approach is the use of diantimony trioxide in back-coating, where a fire-resistant layer is attached to one side of the finished textile. This textile is then typically used in textile-covered articles (e g furniture).	0.0088 % (EU-RAR)	-
House-dust	House-dust was used as surrogate for particles released from back-coated textiles due to wear.	-	Particular matter (dust) in indoor air: 52.3 µg/m^3 (EU-RAR)

Amounts used

AC	Amount of the substance in the article
AC5 (back coated)	Max. 2.5 mg/cm^2 (EU-RAR)
House-dust	typical: 15.6 µg/g (EU-RAR) 90th percentile: 60 µg/g (EU-RAR)

Frequency and duration of use/exposure from service life

Description of article	Duration of exposure per event (day)	Frequency of events/day
AC5 (back coated)	1/4d dermal exposure (EU-RAR)	1
House-dust	15.3 h (default, indoor residence time)	1

Human factors not influenced by risk management

Description of article	Population exposed	Weight	Ingestion rate	Exposed body part	Contact skin area [cm^2]
AC5 (back coated)	adult	60 kg (default)	-	¼ of upper part of the body (EU-RAR)	1934 (EU-RAR)
House-dust	adult	60 kg (default)	-	-	-
House-dust	child	10 kg (default)	100 mg house-dust /d	-	-

Other given operational conditions affecting consumers exposure from article service life

Not applicable

Conditions and measures at level of article production to prevent release during service life

Not applicable

Conditions and measures related to information and behavioural advice to consumers

Not applicable

Conditions and measures related to personal protective equipment and hygiene

Not applicable

2.2 Control of environmental exposure

Amounts used

Based on a EU tonnage of 30000 tonnes Sb/year and equation given in R.16 (EU tonnage/10/2000*4) the modelled tonnage is 6 tonnes Sb/year/typical STP. This therefore covers the combined risk from all uses (professional and consumer) of diantimony trioxide containing products and articles.

Frequency and duration of use

Continuous use/release, 365 days/year

Environment factors not influenced by risk management

Default data for receiving water and for the municipal sewage treatment plant are 18 000 m3/d and 2000 m3/d, respectively (resulting dilution factor 10). For marine assessments a default additional tenfold dilution is assumed.

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

For local assessment of diffuse inputs of Sb all emissions are assumed to go to a local sewage treatment works.

Over 95% of Sb containing products and articles have a default release to water $\leq$ 3.2% based on the ERC. This has therefore been selected as the release fraction. The use of massive objects containing antimony do not have intended or expected release to the environment. Antimony is incapsulated in a matrix with low to no potential to be released to the environment. The ERC of 3.2% is a very

Exposure Scenario Format (4) addressing service life resulting from downstream use (article handled by consumer)

conservative value for this article.

Modelled release factors to water 3.2% before STP (ERC).

Release factors to air and soil are not relevant because only a local assessment of the municipal STP and subsecquent aquatic compartment is required. The release factors to air and soil are used to model the regional concentration but in the case of antimony measured data is used for the regional concentration, in this case release factors to air and soil are not relevant.

Conditions and measures related to disposal of articles at end of service life

Fraction of daily/annual use expected in waste: 91% of all articles, antimony in lead-acid batteries and PET bottles is partially recycled.

Appropriate waste codes:
20 01 34, 20 01 40, 20 03 01, 20 03 07

Suitable Disposal:
Waste from end-of-life articles can be disposed of as municipal waste, except when they are separately regulated, like electronic devices, batteries, vehicles, etc.
Disposal of wastes is possible via incineration (operated according to Directive 2000/76/EC on the incineration of waste) or landfilling (operated according to Reference Document on the Best available Techniques for Waste Industries of August 2006 and Council Directive 1999/31/EC and Council Decision 19 December 2002).

A detailed assessment has been performed and is reported in the Waste report (ARCHE, 2012).

Conditions and measures related to recovery of articles at the end of service life

No specific measures in place; most articles used will end up at a landfill or will be recycled.

3. Exposure estimation and reference to its source

Human exposure

The risk characterisation ratio (RCR) is based on the DNEL for diantimony trioxide of 0.1 mg/m^3 for inhalation exposure, 16.86 mg/kg bw/d (child) for oral exposure and 168.6 mg/kg bw/d for dermal exposure.

Route of exposure	Exposure estimate (RCR)	Method used, comments
Oral (child)	Worst case: 0.6 µg/kg bw/d ($3.6 * 10^{-5}$)	Exposure: (amount house-dust ingested * amount of Sb_2O_3 in house-dust)/ weight The specific hand-to-mouth behaviour of small children may play a particular role for their exposure. Therefore oral exposure to diantimony trioxide for children via ingestion of house dust has been estimated.
Dermal	0.11 mg/d 1.8 µg/kg bw/d ($1.1 * 10^{-4}$)	Exposure= $S_a * A_b * \mu_w * t$ S_a = application rate A_b = skin area in contact with textile μ_w = fraction release t = time in days This exposure assessment assumes that clothing presents no barrier to movement of diantimony trioxide. Furthermore the release fraction from the contact-blotting test represents dermal contact with only liquid between the skin and the layer containing diantimony trioxide, i.e. where a person is in contact with wet (from perspiration or spill) furniture. This is unlikely to occur six hours per day, therefore the derived exposure should be seen as a worst case, with potential for refining. It should however be noticed that when diantimony trioxide is dissolved and leaches from the textile matrix, it will not be present in the form of diantimony trioxide.
Inhalation	Worst case: 3.15 ng /m³ ($3.2 * 10^{-5}$)	Assuming that all antimony present in house dust will be in the form of diantimony trioxide and that all the diantimony trioxide comes from wear of back-coated textiles.

Environmental exposure

Environmental modelling was carried out in EUSES 2.1

Local PEC for wide dispersive uses with low release

Exposure Scenario Format (4) addressing service life resulting from downstream use (article handled by consumer)

Air mg.m-3 (RCR)	**Fresh water mg/l (RCR)**	**Marine water mg/l (RCR)**	**Sediment freshwater mg/kg wwt (RCR)**	**Sediment marine water mg/kg wwt (RCR)**	**Soil mg/kg wwt (RCR)**	**STP mg/l (RCR)**
NR	5.87E-03 (0.052)	7.2E-04 (0.063)	5.6 (0.72)	1.15 (0.74)	9.93 (0.30)	5.5E-02 (0.022)

4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES

The DU works inside the boundaries set by the ES if the concentrations in the products are not exceeded.

Optional an assessment can be performed using the algorithm as used in the EU-RAR Diantimony trioxide, 2008 (http://esis.jrc.ec.europa.eu/doc/existing-chemicals/risk_assessment/REPORT/datreport415.pdf).

An assessment based on the total EU tonnage of diantimony trioxide containing articles and REACH guidance default values has indicated RCR < 1. This assessment is considered to be extremely worst case and therefore indicates that the consumer use of diantimony trioxide containing articles does not pose a risk to the environment.

9.11.2 Exposure estimation

9.11.2.1 Indirect exposure of humans via the environment (local)

Table 120: Concentration and risk characterization for local exposure of humans via the environment

Concentration for local exposure of humans via the environment

	Estimated exposure concentrations		Measured exposure concentrations		Explanation / source of measured data
	value	**unit**	**value**	**unit**	
Air	$2.6* 10^{-6}$	mgSb/m^3	-	-	Local PEC has been calculated using EUSES 2.1 and converted from Sb to diantimony trioxide by a factor of 1.2.
	$3.12* 10^{-6}$	mg Sb2O3/m^3	-	-	
Drinking water	$9.6* 10^{-2}$	mg Sb/L	-	-	Local PEC has been calculated using EUSES 2.1 and converted from Sb to diantimony trioxide by a factor of 1.2.
	$1.1* 10^{-1}$	mg Sb2O3/L	-	-	

Total daily dose for oral exposure via the environment (mg/kg bw/d)

µg Sb_2O_3/d	mg Sb_2O_3/kg bw/d	Justification
233.9	$3.9* 10^{-3}$	2L of drinking water from the local setting + the worst case exposure of 4.32 µg/d from food (section 9.0.4.3) and the default body weight of 60 kg have been taken into account.

Quantitative risk characterisation for humans exposed via the environment

Route	exposure concentrations (EC)	DN(M)EL	Risk characterisation ratio
Inhalation- local effects (long term)	$3.12* 10^{-6}$mg Sb_2O_3/m^3	0.1 mg/m^3	$3.12* 10^{-5}$
Oral- systemic (long term)	$3.9* 10^{-3}$ mg Sb_2O_3/kg bw/d	168.6 mg/kg/d	$2.3* 10^{-5}$
Combined routes			RCR Inhalation- systemic + RCR Oral- systemic

9.11.2.2 Environmental exposure

Table 121: Risk characterisation for the soil, sediment and water compartments

Compartment	Local PEC	PNEC	PEC/PNEC (RCR)
Freshwater aquatic (mg Sb/l)	5.87E-03	0.113	0.052
Marine aquatic (mg Sb/l)	7.2E-04	0.0113	0.063
Freshwater sediment (mg Sb/kg wwt)	5.6	7.8	0.72
Marine sediment (mg Sb/kg wwt)	1.15	1.6	0.74
Terrestrial (mg Sb/kg wwt)	9.93	32.6	0.30
Sewage treatment plant (mg Sb/l)	5.5E-02	2.55	0.022

9.12 Service life/Use, wearing of articles made of PET/PES polymers

9.12.1 Exposure scenario

Exposure Scenario Format (4) addressing service life resulting from downstream use (article handled by consumer)

1. Title

Free short title	Service life/Use, wearing of articles made out of PET/PES polymers
Systematic title based on use descriptor for article service life	SU21 (Consumer use), AC5/6 (Fabrics, textile, apparel and artificial leather), SU21 (Consumer use), AC13 (Plastic articles), SU21 (Consumer use), AC8 (Paper articles, TARIC4818 Sanitary products), ERC 8c, 8f, 10a, 11a, 12a
Systematic title based on use descriptor for downstream use leading to inclusion in article	SU5 (Manufacture of textile, leather fur) SU10 (Formulation of preparations and/or re-packing) SU12 (Manufacture of plastic products, including compounding and conversion) SU 20 Health services SU 6b Manufacture of pulp, paper and paper products
Processes, tasks activities covered	Activities covered are described in Section 2 below.
Assessment Method*	The assessment of oral exposure to children is based on the exposure scenario provided in the EU-RAR on diantimony trioxide. Quantitative assessment (1. Tier) for the dermal route was performed. A qualitative assessment has been performed for oral (general population) and inhalation exposure. The environmental assessment uses EUSES.

2. Operational conditions and risk management measures

RMMs	Product integrated risk management measures are in place, as the producer of PET/PES guarantees to comply with regulation 2002/72/EC.
AC/ERC	**Description of activity referring to article categories (AC) and environmental release categories (ERC)**
AC 5	Wearing of textiles (incl. artificial leather) made out of PET/PES fibres or filament yarn. Ingestion of toy particles made out of PET.
AC 6	Wearing of "artificial leather", refer to AC5
AC 8 (TARIC 4818)	Use of personal sanitary products, hygienic paper made out of PET/PES.
AC 13	Handling of plastic products made out of PET under ambient temperature. Ingestion of toy particles made out of PET.
ERC 8c	Wide dispersive indoor use, inclusion into or onto a matrix
ERC 8f	Wide dispersive outdoor use, inclusion in matrix
ERC 10a	Wide dispersive outdoor use of long life articles, low release
ERC 11a	Wide dispersive indoor use of long life articles, low release
ERC 12a	Industrial processing of articles with abrasive techniques (low release)

2.1 Control of consumers exposure

Product (article) characteristic

AC	**Article characteristics**	**Release potential**
AC 5 (6), 13	Textiles, personal sanitary products, hygienic paper and plastic products made out of PET/PES, where antimony trioxide is covalently bound in the PET matrix, i.e. it is no longer bio-available as antimony trioxide. However, some unbound residues will remain in the product.	Up to 0.02 ppm Sb acc. to regulation 2002/72/EC (≅ 0.024 ppm Sb_2O_3) – to ensure a conservative approach, this value is used rather than the 0.04 ppm Sb specific migration limit according to the new regulation (EU) No 10/2011
AC 8 (TARIC 4818)	Personal sanitary products and hygienic paper products made with PET/PES, where antimony trioxide is covalently bound in the polymer matrix, i.e. it is no longer bio-available as antimony trioxide.	Up to 0.02 ppm Sb acc. to regulation 2002/72/EC (≅ 0.024 ppm Sb_2O_3) – to ensure a conservative approach, this value is used rather than the 0.04 ppm Sb specific migration limit according to the new

Exposure Scenario Format (4) addressing service life resulting from downstream use (article handled by consumer)

	However, some unbound residues will remain in the product.	regulation (EU) No 10/2011
Cuddly toys (AC5, 13)	Cuddly toys made out of PET, where antimony trioxide is covalently bound in the PET matrix.	100 % assumed due to ingestion

Amounts used

AC	Amount of the substance in the article	Amount of article used
AC 5 (6), 13	Up to 0.055 % for antimony trioxide residues from PET/PES catalysis	500 g (default from ECETOC TRA)
AC 8 (TARIC 4818)	Up to 0.036 % for antimony trioxide (300ppm Sb) residues from PET/PES catalysis. These polymeric fibre or filament yarns are further used in personal sanitary and hygienic products.	~ 40 g (worst case, as not 100 % of the diaper consists of PET/PES)

Frequency and duration of use/exposure from service life

Description of article	Duration of exposure per event (day)	Frequency of events/day
Cuddly toys (AC5, 13)	-	1
AC 5 (6) ,13	24 h for clothes (worst case)	1
AC 8 (TARIC 4818)	24 h for diapers	5 (assumption)

Human factors not influenced by risk management

Description of article	Population exposed	Weight	Ingestion rate	Exposed body part	Contact skin area [cm²]
Cuddly toys (AC5, 13)	child	10 kg (default)	8 mg/day	-	-
AC 5 (6) ,13	adult	60 kg (default)	-	Whole body except feet, hands and head	14315 (ECETOC TRA)
AC 8 (TARIC 4818)	child	10 kg (default)	-	Diaper region (~1/2 lower part of the body from ECETOC TRA)	1200 (1/2 lower part of the body, ECETOC TRA)

Other given operational conditions affecting consumers exposure from article service life

Not applicable

Conditions and measures at level of article production to prevent release during service life

Not applicable

Conditions and measures related to information and behavioural advice to consumers

Not applicable

Conditions and measures related to personal protective equipment and hygiene

Not applicable

2.2 Control of environmental exposure

Amounts used

Based on a EU tonnage of 30000 tonnes Sb/year and equation given in R.16 (EU tonnage/10/2000*4) the modelled tonnage is 6 tonnes Sb/year/typical STP. This therefore covers the combined risk from all uses (professional and consumer) of diantimony trioxide containing products and articles.

Frequency and duration of use

Continuous use/release, 365 days/year

Environment factors not influenced by risk management

Default data for receiving water and for the municipal sewage treatment plant are18 000 m3/d and 2000 m3/d, respectively (resulting dilution factor 10). For marine assessments a default additional tenfold dilution is assumed.

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

For local assessment of diffuse inputs of Sb all emissions are assumed to go to a local sewage treatment works.

Over 95% of Sb containing products and articles have a default release to water ≤ 3.2% based on the ERC. This has therefore been selected as the release fraction. The use of massive objects containing antimony do not have intended or expected release to the environment. Antimony is incapsulated in a matrix with low to no potential to be released to the environment. The ERC of 3.2% is a very conservative value for this article.

Modelled release factors to water 3.2% before STP (ERC).

Release factors to air and soil are not relevant because only a local assessment of the municipal STP and subsecquent aquatic compartment is required. The release factors to air and soil are used to model the regional concentration but in the case of antimony measured data is used for the regional concentration, in this case release factors to air and soil are not relevant.

Exposure Scenario Format (4) addressing service life resulting from downstream use (article handled by consumer)

Conditions and measures related to disposal of articles at end of service life

Fraction of daily/annual use expected in waste: 91% of all articles, antimony in lead-acid batteries and PET bottles is partially recycled.

Appropriate waste codes:
20 01 34, 20 01 40, 20 03 01, 20 03 07

Suitable Disposal:
Waste from end-of-life articles can be disposed of as municipal waste, except when they are separately regulated, like electronic devices, batteries, vehicles, etc.
Disposal of wastes is possible via incineration (operated according to Directive 2000/76/EC on the incineration of waste) or landfilling (operated according to Reference Document on the Best available Techniques for Waste Industries of August 2006 and Council Directive 1999/31/EC and Council Decision 19 December 2002).

A detailed assessment has been performed and is reported in the Waste report (ARCHE, 2012).

Conditions and measures related to recovery of articles at the end of service life

No specific measures in place; most articles used will end up at a landfill or will be recycled.

3. Exposure estimation and reference to its source

Human exposure

The risk characterisation ratio (RCR) is based on the DNEL for diantimony trioxide of 16.86 mg/kg bw/d for oral exposure (child) and 168.6 mg/kg bw/d and 16.86 mg/kg bw/d for dermal exposure to adults and children, respectively.

AC5 (6), 13

Route of exposure	**Exposure estimate (RCR)**	**Method used, comments**
Oral (child)	0.44µg/kg/d (2.6 * 10^{-5})	Quantitative assessment acc to EU-RAR Diantimony trioxide, 2008: Exposure: (ingested amount * highest amount in PET)/weight
Oral (general population)	-	Qualitative assessment Oral exposure does not occur as part of the intended product use.
Dermal	Local: 8.3 * 10^{-4} µg/ cm²/d Systemic: 0.2 µg/kg bw/d (1.2 * 10^{-6})	Quantitative assessment (1.Tier) Exposure (local): (weight of clothes * release rate)/ skin area/day Exposure (systemic): (weight of clothes * release rate)/ body weight/day
Inhalation	negligible	Qualitative assessment Inhalation exposure is insignificant due to the extremely low vapour pressure of antimony trioxide.

AC8 (TARIC 4818)

Route of exposure	**Exposure estimate (RCR)**	**Method used, comments**
Oral (general population)	-	Qualitative assessment Oral exposure does not occur as part of the intended product use.
Dermal (child)	Local: 4 * 10^{-3} µg/ cm²/d Systemic: 0.48 µg/kg bw/d (2.8 * 10^{-5})	Quantitative assessment (1.Tier): Exposure (local): (weight of diaper * release rate * events per day)/ skin area/day Exposure (systemic): (weight of diaper * release rate * events per day)/ body weight/day Exposure to diantimony trioxide from sanitary products can occur for each category of the general population (children and adults). Using the diaper scenario as a worst case, protecting children under the age of 36 months should also protect the rest of the general population.
Inhalation	negligible	Qualitative assessment Inhalation exposure is insignificant due to the extremely low vapour pressure of antimony trioxide.

Environmental exposure

Exposure Scenario Format (4) addressing service life resulting from downstream use (article handled by consumer)						
Environmental modelling was carried out in EUSES 2.1						
Local PEC for wide dispersive uses with low release						
Air mg.m-3 (RCR)	**Fresh water mg/l (RCR)**	**Marine water mg/l (RCR)**	**Sediment freshwater mg/kg wwt (RCR)**	**Sediment marine water mg/kg wwt (RCR)**	**Soil mg/kg wwt (RCR)**	**STP mg/l (RCR)**
NR	5.87E-03 (0.052)	7.2E-04 (0.063)	5.6 (0.72)	1.15 (0.74)	9.93 (0.30)	5.5E-02 (0.022)
4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES						
The DU works inside the boundaries set by the ES if the concentrations in the products are not exceeded (cuddly toys scenario) or for the dermal exposure if the polymeric matrix used complies with the SML set in the food contact regulation (2002/72/EC). Optional a 1.Tier assessment can be performed using the ECETOC TRA algorithm for consumer exposure (http://www.ecetoc.org/tra) or the algorithm as used in the EU-RAR Diantimony trioxide, 2008 (http://esis.jrc.ec.europa.eu/doc/existing-chemicals/risk_assessment/REPORT/datreport415.pdf).						
An assessment based on the total EU tonnage of diantimony trioxide containing articles and REACH guidance default values has indicated RCR < 1. This assessment is considered to be extremely worst case and therefore indicates that the consumer use of diantimony trioxide containing articles does not pose a risk to the environment.						

9.12.2 Exposure estimation

9.12.2.1 Indirect exposure of humans via the environment (local)

Table 122: Concentration and risk characterization for local exposure of humans via the environment

Concentration for local exposure of humans via the environment					
	Estimated exposure concentrations		**Measured exposure concentrations**		**Explanation / source of measured data**
	value	**unit**	**value**	**unit**	
Air	$2.6 * 10^{-6}$	mgSb/m^3	-	-	Local PEC has been calculated using EUSES 2.1 and converted from Sb to diantimony trioxide by a factor of 1.2.
	$3.12 * 10^{-6}$	mg Sb2O3/m^3	-	-	
Drinking water	$9.6 * 10^{-2}$	mg Sb/L	-	-	Local PEC has been calculated using EUSES 2.1 and converted from Sb to diantimony trioxide by a factor of 1.2.
	$1.1 * 10^{-1}$	mg Sb2O3/L	-	-	
Total daily dose for oral exposure via the environment (mg/kg bw/d)					
µg Sb_2O_3/d	**mg Sb_2O_3/kg bw/d**		**Justification**		
18.4	$3.9 * 10^{-3}$		2L of drinking water from the local setting + the worst case exposure of 4.32 µg/d from food (section 9.0.4.3) and the default body weight of 60 kg have been taken into account.		
Quantitative risk characterisation for humans exposed via the environment					
Route	**exposure concentrations (EC)**		**DN(M)EL**		**Risk characterisation ratio**
Inhalation- local effects (long term)	$3.12 * 10^{-6}$ mg Sb_2O_3/m^3		0.1 mg/m^3		$3.12 * 10^{-5}$
Oral- systemic (long term)	$3.9 * 10^{-3}$ mg Sb_2O_3/kg bw/d		168.6 mg/kg/d		$2.3 * 10^{-5}$
Combined routes					RCR Inhalation- systemic + RCR Oral- systemic

9.12.2.2 Environmental exposure

Table 123: Risk characterisation for the soil, sediment and water compartments

Compartment	Local PEC	PNEC	PEC/PNEC (RCR)

Freshwater aquatic (mg Sb/l)	5.87E-03	0.113	0.052
Marine aquatic (mg Sb/l)	7.2E-04	0.0113	0.063
Freshwater sediment (mg Sb/kg wwt)	5.6	7.8	0.72
Marine sediment (mg Sb/kg wwt)	1.15	1.6	0.74
Terrestrial (mg Sb/kg wwt)	9.93	32.6	0.30
Sewage treatment plant (mg Sb/l)	5.5E-02	2.55	0.022

9.13 Service life/ Wearing of clothes containing antimony trioxide for fire resistance

9.13.1 Exposure scenario

Exposure Scenario Format (4) addressing service life resulting from downstream use (article handled by consumer)

1. Title

Free short title	Service life/ Wearing of clothes containing antimony trioxide for fire resistance
Systematic title based on use descriptor for article service life	SU21 (Consumer use), AC 5 (Textile articles), ERC 8c, 8f, 10a, 11a, 12a
Systematic title based on use descriptor for downstream use leading to inclusion in article	SU5 (Manufacture of textiles, leather, fur)
Processes, tasks activities covered	Activities covered are described in Section 2 below.
Assessment Method*	Quantitative assessment for the dermal and oral route. No assessment for the inhalation route. The environmental assessment uses EUSES.

2. Operational conditions and risk management measures

RMMs	The producer needs to assure that the migration rate complies with Ökotex 100.
AC/ERC	**Description of activity referring to article categories (AC) and environmental release categories (ERC)**
AC 5 (clothes)	Wearing of textiles/clothes containing diantimony trioxide. Sucking on textiles/clothes containing diantimony trioxide by children.
ERC 8c	Wide dispersive indoor use, inclusion into or onto a matrix
ERC 8f	Wide dispersive outdoor use, inclusion in matrix
ERC 10a	Wide dispersive outdoor use of long life articles, low release
ERC 11a	Wide dispersive indoor use of long life articles, low release
ERC 12a	Industrial processing of articles with abrasive techniques (low release)

2.1 Control of consumers exposure

Product (article) characteristic

AC	**Article characteristics**	**Fraction released to skin (oral)**
AC 5 (clothes)	Textiles like children sleepwear containing diantimony trioxide as additive for fire resistance.	30 ppm Sb (Ökotex 100) ≅ 36 ppm Sb_2O_3

Amounts used

AC	**Amount of the substance in the article**	**Amount of article used**
AC5 (clothes)	7 % (found in 60/40 or 55/45 cotton/modacrylic knitted blends in childrens sleepwear)	100g (children sleepwear)

Frequency and duration of use/exposure from service life

Description of article	**Duration of exposure per event (day)**	**Frequency of events/day**
AC5 (clothes)	1 day dermal exposure (worst case)	1

Human factors not influenced by risk management

Description of article	**Population exposed**	**Weight**	**Volume product mouthed**	**Exposed body part**	**Contact skin area $[cm^2]$**
AC5 (clothes)	child	10 kg (default)	10% of textile (conservative estimate)	Whole body except feet, hands and head	3393.6

Other given operational conditions affecting consumers exposure from article service life

Not applicable

Conditions and measures at level of article production to prevent release during service life

Not applicable

Exposure Scenario Format (4) addressing service life resulting from downstream use (article handled by consumer)

Conditions and measures related to information and behavioural advice to consumers

Not applicable

Conditions and measures related to personal protective equipment and hygiene

Not applicable

2.2 Control of environmental exposure

Amounts used

Based on a EU tonnage of 30000 tonnes Sb/year and equation given in R.16 (EU tonnage/10/2000*4) the modelled tonnage is 6 tonnes Sb/year/typical STP. This therefore covers the combined risk from all uses (professional and consumer) of diantimony trioxide containing products and articles.

Frequency and duration of use

Continuous use/release, 365 days/year

Environment factors not influenced by risk management

Default data for receiving water and for the municipal sewage treatment plant are18 000 m3/d and 2000 m3/d, respectively (resulting dilution factor 10). For marine assessments a default additional tenfold dilution is assumed.

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

For local assessment of diffuse inputs of Sb all emissions are assumed to go to a local sewage treatment works.

Over 95% of Sb containing products and articles have a default release to water ≤ 3.2% based on the ERC. This has therefore been selected as the release fraction. The use of massive objects containing antimony do not have intended or expected release to the environment. Antimony is incapsulated in a matrix with low to no potential to be released to the environment. The ERC of 3.2% is a very conservative value for this article.

Modelled release factors to water 3.2% before STP (ERC).

Release factors to air and soil are not relevant because only a local assessment of the municipal STP and subsecquent aquatic compartment is required. The release factors to air and soil are used to model the regional concentration but in the case of antimony measured data is used for the regional concentration, in this case release factors to air and soil are not relevant.

Conditions and measures related to disposal of articles at end of service life

Fraction of daily/annual use expected in waste: 91% of all articles, antimony in lead-acid batteries and PET bottles is partially recycled.

Appropriate waste codes:
20 01 34, 20 01 40, 20 03 01, 20 03 07

Suitable Disposal:
Waste from end-of-life articles can be disposed of as municipal waste, except when they are separately regulated, like electronic devices, batteries, vehicles, etc.
Disposal of wastes is possible via incineration (operated according to Directive 2000/76/EC on the incineration of waste) or landfilling (operated according to Reference Document on the Best available Techniques for Waste Industries of August 2006 and Council Directive 1999/31/EC and Council Decision 19 December 2002).

A detailed assessment has been performed and is reported in the Waste report (ARCHE, 2012)

Conditions and measures related to recovery of articles at the end of service life

No specific measures in place; most articles used will end up at a landfill or will be recycled.

3. Exposure estimation and reference to its source

Human exposure

The risk characterisation ratio (RCR) is based on the DNEL for diantimony trioxide of 16.86 mg/kg bw/d for oral and dermal exposure (child).

AC5 (clothes)

Route of exposure	Exposure estimate (RCR)	Method used, comments
Oral (child)	36 µg/kg bw/d (2.1 * 10^{-3})	Exposure: (weight of textile mouthed * release rate)/ body weight/day
Dermal (child)	Local: 1.1 µg/ cm^2/d Systemic: 360 µg/kg bw/d (2.1 * 10^{-2})	Exposure (local): (weight of clothes * release rate)/ skin area/day Exposure (systemic): (weight of clothes * release rate)/ body weight/day
Inhalation	-	Inhalation exposure is insignificant due to the extremely low vapour pressure of diantimony trioxide. However, exposure due to wear debris will be covered by the indoor air scenario in ES2c.

Exposure Scenario Format (4) addressing service life resulting from downstream use (article handled by consumer)						
Environmental exposure						
Environmental modelling was carried out in EUSES 2.1						
Local PEC for wide dispersive uses with low release						
Air mg.m-3 (RCR)	**Fresh water mg/l (RCR)**	**Marine water mg/l (RCR)**	**Sediment freshwater mg/kg wwt (RCR)**	**Sediment marine water mg/kg wwt (RCR)**	**Soil mg/kg wwt (RCR)**	**STP mg/l (RCR)**
NR	5.87E-03 (0.052)	7.2E-04 (0.063)	5.6 (0.72)	1.15 (0.74)	9.93 (0.30)	5.5E-02 (0.022)
4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES						
The DU works inside the boundaries set by the ES if the textile complies to the conditions set by Ökotex Standard 100 (http://www.oeko-tex.com/OekoTex100_PUBLIC/content1.asp?area=hauptmenue&site=grenzwerte&cls=01).						
An assessment based on the total EU tonnage of diantimony trioxide containing articles and REACH guidance default values has indicated RCR < 1. This assessment is considered to be extremely worst case and therefore indicates that the consumer use of diantimony trioxide containing articles does not pose a risk to the environment.						

9.13.2 Exposure estimation

9.13.2.1 Indirect exposure of humans via the environment (local)

Table 124: Concentration and risk characterization for local exposure of humans via the environment

Concentration for local exposure of humans via the environment					
	Estimated exposure concentrations		**Measured exposure concentrations**		**Explanation / source of measured data**
	value	**unit**	**value**	**unit**	
Air	$2.6* 10^{-6}$	mg Sb/m³	-	-	Local PEC has been calculated using EUSES 2.1 and converted from Sb to diantimony trioxide by a factor of 1.2.
	$3.12* 10^{-6}$	mg Sb2O3/m³	-	-	
Drinking water	$9.6* 10^{-2}$	mg Sb/L	-	-	Local PEC has been calculated using EUSES 2.1 and converted from Sb to diantimony trioxide by a factor of 1.2.
	$1.1* 10^{-1}$	mg Sb2O3/L	-	-	

Total daily dose for oral exposure via the environment (mg/kg bw/d)		
µg Sb_2O_3/d	**mg Sb_2O_3/kg bw/d**	**Justification**
233.9	$3.9* 10^{-3}$	2L of drinking water from the local setting + the worst case exposure of 4.32 µg/d from food (section 9.0.4.3) and the default body weight of 60 kg have been taken into account.

Quantitative risk characterisation for humans exposed via the environment			
Route	**exposure concentrations (EC)**	**DN(M)EL**	**Risk characterisation ratio**
Inhalation- local effects (long term)	$3.12* 10^{-6}$mg Sb_2O_3/m^3	0.1 mg/m³	$3.12* 10^{-5}$
Oral- systemic (long term)	$3.9* 10^{-3}$ mg Sb_2O_3/kg bw/d	168.6 mg/kg/d	$2.3* 10^{-5}$
Combined routes			RCR Inhalation- systemic + RCR Oral- systemic

9.13.2.2 Environmental exposure

Table 125: Risk characterisation for the soil, sediment and water compartments

Compartment	**Local PEC**	**PNEC**	**PEC/PNEC (RCR)**
Freshwater aquatic (mg Sb/l)	5.87E-03	0.113	0.052

Marine aquatic (mg Sb/l)	7.2E-04	0.0113	0.063
Freshwater sediment (mg Sb/kg wwt)	5.6	7.8	0.72
Marine sediment (mg Sb/kg wwt)	1.15	1.6	0.74
Terrestrial (mg Sb/kg wwt)	9.93	32.6	0.30
Sewage treatment plant (mg Sb/l)	5.5E-02	2.55	0.022

9.14 Regional exposure concentrations

Table 126: Regional exposure concentrations

Compartments					
Air mg/m3 (RCR)	**Fresh water mg/l (RCR)**	**Marine water mg/l (RCR)**	**Fresh water Sediment mg/kg wwt (RCR)**	**Marine water Sediment mg/kg wwt (RCR)**	**Soil mg/kg wwt (RCR)**
2.6E-6 (NA)	**7.2E-4 (6.37E-03)**	**2E-4 (0.018)**	**0.65 (0.083)**	**0.65 (0.42)**	**1.5 (0.046)**

9.14.1 Indirect exposure of humans via the environment (regional)

Table 127: Regional concentrations in food and drinking water and risk characterization for exposure of humans via the environment

Measured concentration for regional exposure of humans via the environment					
	typical		**Worst case**		**Explanation / source of measured data**
	value	**unit**	**value**	**unit**	
Air	-	-	2.6 * 10-6	mgSb/m^3	Has been taken from the regional exposure assessment and converted from Sb to Sb2O3 by a factor of 1.2.
	-	-	3.12 * 10-6	mg Sb2O3/m^3	
Drinking water	-	-	7.2 * 10-4	mg Sb/L	Has been taken from the regional exposure assessment and converted from Sb to Sb2O3 by a factor of 1.2.
	-	-	8.64 * 10-4	mg Sb2O3/L	
Food	2.16	µg/d	4.32	µg/d	typical exposure: the mean value from the 2006 UK total diet study worst-case: the 97.5th percentile from the 2006 UK total diet study please refer to section 9.0.4.3
Mother´s milk	0.14	µg/d	0.522	µg/d	Wappelhorst et al 2008, using an ingested amount of 0.8 L/day for a child of 0-3 month. please refer to section 9.0.4.4
Total daily dose for oral exposure via the environment (mg/kg bw/d)					
	µg Sb2O3/d		mg Sb2O3/kg bw/d		Justification
Adult	3.89		6.48 * 10-5		2L of drinking water from the regional assessment + the typical exposure of 1.08 µg/d from food and the default body weight of 60kg have been taken into account.
child	0.522		5.22 * 10-5		An ingested amount of 0.8 L/day mother´s milk for a child of 0-3 month and the default body weight of 10kg (child) have been taken into account.

Quantitative risk characterisation for humans exposed via the environment			
Route	**exposure concentrations (EC)**	**DN(M)EL**	**Risk characterisation ratio**
Inhalation- local effects (long term)	$3.12 * 10^{-6}$mg Sb_2O_3/m^3	0.1 mg/m³	$3.12 * 10^{-5}$
Oral- systemic (long term)	$6.48 * 10^{-5}$ mg Sb_2O_3/kg bw/d	168.6 mg/kg/d	$3.84 * 10^{-7}$
Combined routes			RCR Inhalation- systemic + RCR Oral- systemic
CHILD via mother´s milk			
Route	**exposure concentrations (EC)**	**DN(M)EL**	**Risk characterisation ratio**
Oral- systemic (long term)	$5.22 * 10^{-5}$mg Sb_2O_3/kg bw/d	16.86 mg/kg/d	$3.1 * 10^{-6}$

9.14.2 Regional environmental exposure

Table 128: Risk characterisation for the soil, sediment and water compartments

Compartment	**Regional PEC**	**PNEC**	**PEC/PNEC (RCR)**
Freshwater aquatic (mg Sb/l)	7.2E-04	0.113	6.37E-03
Marine aquatic (mg Sb/l)	2E-04	0.0113	0.018
Freshwater sediment (mg Sb/kg wwt)	0.65	7.8	0.083
Marine sediment (mg Sb/kg wwt)	0.65	1.6	0.42
Terrestrial (mg Sb/kg wwt)	1.5	32.6	0.046

10. RISK CHARACTERISATION

10.1. Use of antimony metal in the production of diantimony trioxide

10.1.1. Human Health

10.1.1.1. Workers

Due to the negligible dermal absorption of diantimony trioxide (0.26 %, ECB, 2008), the dermal route is not a relevant exposure path for diantimony trioxide. Thus, dermal exposure is not assessed in this exposure scenario. However, dermal exposure has to be minimised to an extent as technically feasible when working under certain conditions as described above.
For inhalation exposure, the RCR is based on the DNEL for antimony metal of 0.5 mg/m^3. This is a long-term inhalation DNEL for local effects of antimony trioxide for workers, which was derived because the route of exposure was relevant and local effects were observed in inhalation toxicity and carcinogenicity studies.

The risk characterisation is given in Chapter 9.1, Section 3 of the exposure scenario.

10.1.1.2. Consumers

Not relevant.

10.1.1.3. Indirect exposure to humans via the environment

The risk characterisation is given in Chapter 9.1.2.1 of the exposure scenario.

10.1.2. Environment

10.1.2.1. Aquatic compartment (including sediment)

The risk characterisation is given in Chapter 9.1, Section 3 of the exposure scenario.

10.1.2.2. Terrestrial compartment

The risk characterisation is given in Chapter 9.1, Section 3 of the exposure scenario.

10.1.2.3. Atmospheric compartment

The risk characterisation is given in Chapter 9.1, Section 3 of the exposure scenario.

10.1.2.4. Microbiological activity in sewage treatment systems

The risk characterisation is given in Chapter 9.1, Section 3 of the exposure scenario.

10.2. Use of diantimony trioxide in PET (films/fibres, resin) production

10.2.1. Human Health

10.2.1.1. Workers

Due to the negligible dermal absorption of diantimony trioxide (0.26 %, EURAR, 2008), the dermal route is not a relevant exposure path for diantimony trioxide. Thus, dermal exposure is not assessed in this exposure scenario. However, dermal exposure has to be minimised to an extent as technically feasible when working under certain conditions as described above.

For inhalation exposure, the RCR is based on the DNEL for antimony metal of 0.5 mg/m^3. This is a long-term inhalation DNEL for local effects of antimony trioxide for workers, which was derived because the route of exposure was relevant and local effects were observed in inhalation toxicity and carcinogenicity studies.

The risk characterisation is given in Chapter 9.2, Section 3 of the exposure scenario.

10.2.1.2. Consumers

Not relevant.

10.2.1.3. Indirect exposure to humans via the environment

The risk characterisation is given in Chapter 9.2.2.1 of the exposure scenario.

10.2.2. Environment

10.1.2.1. Aquatic compartment (including sediment)

The risk characterisation is given in Chapter 9.2, Section 3 of the exposure scenario.

10.2.2.2. Terrestrial compartment

The risk characterisation is given in Chapter 9.2, Section 3 of the exposure scenario.

10.2.2.3. Atmospheric compartment

The risk characterisation is given in Chapter 9.2, Section 3 of the exposure scenario.

10.2.2.4. Microbiological activity in sewage treatment systems

The risk characterisation is given in Chapter 9.2, Section 3 of the exposure scenario.

10.3. Industrial use of diantimony trioxide in the plastics and rubber industry

10.3.1. Human Health

10.3.1.1. Workers

Due to the negligible dermal absorption of diantimony trioxide (0.26 %, ECB, 2008), the dermal route is not a relevant exposure path for diantimony trioxide. Thus, dermal exposure is not assessed in this exposure scenario. However, dermal exposure has to be minimised to an extent as technically feasible when working under certain conditions as described above.
For inhalation exposure, the RCR is based on the DNEL for antimony metal of 0.5 mg/m^3. This is a long-term inhalation DNEL for local effects of antimony trioxide for workers, which was derived because the route of exposure was relevant and local effects were observed in inhalation toxicity and carcinogenicity studies.

The risk characterisation is given in Chapter 9.3, Section 3 of the exposure scenario.

10.3.1.2. Consumers

Not relevant.

10.3.1.3. Indirect exposure to humans via the environment

The risk characterisation is given in Chapter 9.3.2.1 of the exposure scenario.

10.3.2. Environment

10.3.2.1. Aquatic compartment (including sediment)

The risk characterisation is given in Chapter 9.3, Section 3 of the exposure scenario.

10.3.2.2. Terrestrial compartment

The risk characterisation is given in Chapter 9.3, Section 3 of the exposure scenario.

10.3.2.3. Atmospheric compartment

The risk characterisation is given in Chapter 9.3, Section 3 of the exposure scenario.

10.3.2.4. Microbiological activity in sewage treatment systems

The risk characterisation is given in Chapter 9.3, Section 3 of the exposure scenario.

10.4. Industrial use of diantimony trioxide in the manufacture of flame retarded textiles

10.4.1. Human Health

10.4.1.1. Workers

Due to the negligible dermal absorption of diantimony trioxide (0.26 %, EURAR, 2008), the dermal route is not a relevant exposure path for diantimony trioxide. Thus, dermal exposure is not assessed in this exposure scenario. However, dermal exposure has to be minimised to an extent as technically feasible when working under certain conditions as described above.
For inhalation exposure, the RCR is based on the DNEL for antimony metal of 0.5 mg/m^3. This is a long-term inhalation DNEL for local effects of antimony trioxide for workers, which was derived because the route of exposure was relevant and local effects were observed in inhalation toxicity and carcinogenicity studies.

The risk characterisation is given in Chapter 9.4, Section 3 of the exposure scenario.

10.4.1.2. Consumers

Not relevant.

10.4.1.3. Indirect exposure to humans via the environment

The risk characterisation is given in Chapter 9.4.2.1 of the exposure scenario.

10.4.2. Environment

10.4.2.1. Aquatic compartment (including sediment)

The risk characterisation is given in Chapter 9.4, Section 3 of the exposure scenario.

10.4.2.2. Terrestrial compartment

The risk characterisation is given in Chapter 9.4, Section 3 of the exposure scenario.

10.4.2.3. Atmospheric compartment

The risk characterisation is given in Chapter 9.4, Section 3 of the exposure scenario.

10.4.2.4. Microbiological activity in sewage treatment systems

The risk characterisation is given in Chapter 9.4, Section 3 of the exposure scenario.

10.5. Industrial use of diantimony trioxide in the production of glass, enamels, functional ceramics and semi-conductors

10.5.1. Human Health

10.5.1.1. Workers

Due to the negligible dermal absorption of diantimony trioxide (0.26 %, ECB, 2008), the dermal route is not a relevant exposure path for diantimony trioxide. Thus, dermal exposure is not assessed in this exposure scenario. However, dermal exposure has to be minimised to an extent as technically feasible when working under certain

conditions as described above.
For inhalation exposure, the RCR is based on the DNEL for antimony metal of 0.5 mg/m^3. This is a long-term inhalation DNEL for local effects of antimony trioxide for workers, which was derived because the route of exposure was relevant and local effects were observed in inhalation toxicity and carcinogenicity studies.

The risk characterisation is given in Chapter 9.5, Section 3 of the exposure scenario.

10.5.1.2. Consumers

Not relevant.

10.5.1.3. Indirect exposure to humans via the environment

The risk characterisation is given in Chapter 9.5.2.1 of the exposure scenario.

10.5.2. Environment

10.5.2.1. Aquatic compartment (including sediment)

The risk characterisation is given in Chapter 9.5, Section 3 of the exposure scenario.

10.5.2.2. Terrestrial compartment

The risk characterisation is given in Chapter 9.5, Section 3 of the exposure scenario.

10.5.2.3. Atmospheric compartment

The risk characterisation is given in Chapter 9.5, Section 3 of the exposure scenario.

10.5.2.4. Microbiological activity in sewage treatment systems

The risk characterisation is given in Chapter 9.5, Section 3 of the exposure scenario.

10.6. Industrial use of diantimony trioxide in the production of pigments, paints, coatings, ceramics, brake pads and production and formulation of fine chemicals

10.6.1. Human Health

10.6.1.1. Workers

Due to the negligible dermal absorption of diantimony trioxide (0.26 %, ECB, 2008), the dermal route is not a relevant exposure path for diantimony trioxide. Thus, dermal exposure is not assessed in this exposure scenario. However, dermal exposure has to be minimised to an extent as technically feasible when working under certain conditions as described above.
For inhalation exposure, the RCR is based on the DNEL for antimony metal of 0.5 mg/m^3. This is a long-term inhalation DNEL for local effects of antimony trioxide for workers, which was derived because the route of exposure was relevant and local effects were observed in inhalation toxicity and carcinogenicity studies.

The risk characterisation is given in Chapter 9.6, Section 3 of the exposure scenario.

10.6.1.2. Consumers

Not relevant.

10.6.1.3. Indirect exposure to humans via the environment

The risk characterisation is given in Chapter 9.6.2.1 of the exposure scenario.

10.6.2. Environment

10.6.2.1. Aquatic compartment (including sediment)

The risk characterisation is given in Chapter 9.6, Section 3 of the exposure scenario.

10.6.2.2. Terrestrial compartment

The risk characterisation is given in Chapter 9.6, Section 3 of the exposure scenario.

10.6.2.3. Atmospheric compartment

The risk characterisation is given in Chapter 9.6, Section 3 of the exposure scenario.

10.6.2.4. Microbiological activity in sewage treatment systems

The risk characterisation is given in Chapter 9.6, Section 3 of the exposure scenario.

10.7. Industrial use of diantimony trioxide in wood adhesives

10.7.1. Human Health

10.7.1.1. Workers

Due to the negligible dermal absorption of diantimony trioxide (0.26 %, EURAR, 2008), the dermal route is not a relevant exposure path for diantimony trioxide. Thus, dermal exposure is not assessed in this exposure scenario. However, dermal exposure has to be minimised to an extent as technically feasible when working under certain conditions as described above.
For inhalation exposure, the RCR is based on the DNEL for antimony metal of 0.5 mg/m^3. This is a long-term inhalation DNEL for local effects of antimony trioxide for workers, which was derived because the route of exposure was relevant and local effects were observed in inhalation toxicity and carcinogenicity studies.

The risk characterisation is given in Chapter 9.7, Section 3 of the exposure scenario.

10.7.1.2. Consumers

Not relevant.

10.7.1.3. Indirect exposure to humans via the environment

The risk characterisation is given in Chapter 9.7.2.1 of the exposure scenario .

10.7.2. Environment

10.7.2.1. Aquatic compartment (including sediment)

The risk characterisation is given in Chapter 9.7, Section 3 of the exposure scenario .

10.7.2.2. Terrestrial compartment

The risk characterisation is given in Chapter 9.7, Section 3 of the exposure scenario .

10.7.2.3. Atmospheric compartment

The risk characterisation is given in Chapter 9.7, Section 3 of the exposure scenario .

10.7.2.4. Microbiological activity in sewage treatment systems

The risk characterisation is given in Chapter 9.7, Section 3 of the exposure scenario .

10.8. Professional uses of diantimony trioxide preparations

10.8.1. Human Health

10.8.1.1. Workers

Due to the negligible dermal absorption of diantimony trioxide (0.26 %, ECB, 2008), the dermal route is not a relevant exposure path for diantimony trioxide. Thus, dermal exposure is not assessed in this exposure scenario. However, dermal exposure has to be minimised to an extent as technically feasible when working under certain conditions as described above.
For inhalation exposure, the RCR is based on the DNEL for antimony metal of 0.5 mg/m^3. This is a long-term inhalation DNEL for local effects of antimony trioxide for workers, which was derived because the route of exposure was relevant and local effects were observed in inhalation toxicity and carcinogenicity studies.
The risk characterisation is given in Chapter 9.8, Section 3 of the exposure scenario .

10.8.1.2. Consumers

Not relevant.

10.8.1.3. Indirect exposure to humans via the environment

The risk characterisation is given in Chapter 9.8.2.1 of the exposure scenario .

10.8.2. Environment

10.8.2.1. Aquatic compartment (including sediment)

The risk characterisation is given in Chapter 9.8, Section 3 of the exposure scenario .

10.8.2.2. Terrestrial compartment

The risk characterisation is given in Chapter 9.8, Section 3 of the exposure scenario .

10.8.2.3. Atmospheric compartment

The risk characterisation is given in Chapter 9.8, Section 3 of the exposure scenario .

10.8.2.4. Microbiological activity in sewage treatment systems

The risk characterisation is given in Chapter 9.8, Section 3 of the exposure scenario .

10.9. Professional uses of diantimony trioxide containing articles

10.9.1. Human Health

10.9.1.1. Workers

Due to the negligible dermal absorption of diantimony trioxide (0.26 %, ECB, 2008), the dermal route is not a relevant exposure path for diantimony trioxide. Thus, dermal exposure is not assessed in this exposure scenario. However, dermal exposure has to be minimised to an extent as technically feasible when working under certain conditions as described above.
For inhalation exposure, the RCR is based on the DNEL for antimony metal of 0.5 mg/m^3. This is a long-term inhalation DNEL for local effects of antimony trioxide for workers, which was derived because the route of exposure was relevant and local effects were observed in inhalation toxicity and carcinogenicity studies.

The risk characterisation is given in Chapter 9.9, Section 3 of the exposure scenario .

10.9.1.2. Consumers

Not relevant.

10.9.1.3. Indirect exposure to humans via the environment

The risk characterisation is given in Chapter 9.9.2.1 of the exposure scenario .

10.9.2. Environment

10.9.2.1. Aquatic compartment (including sediment)

The risk characterisation is given in Chapter 9.9, Section 3 of the exposure scenario .

10.9.2.2. Terrestrial compartment

The risk characterisation is given in Chapter 9.9, Section 3 of the exposure scenario .

10.9.2.3. Atmospheric compartment

The risk characterisation is given in Chapter 9.9, Section 3 of the exposure scenario .

10.9.2.4. Microbiological activity in sewage treatment systems

The risk characterisation is given in Chapter 9.9, Section 3 of the exposure scenario .

10.10. Service life/Use of articles with diantimony trioxide being embedded into the matrix

10.10.1. Human Health

10.10.1.1. Workers

Not relevant.

10.10.1.2. Consumers

The risk characterisation is given in Chapter 9.10, Section 3 of the exposure scenario.

10.10.1.3. Indirect exposure to humans via the environment

The risk characterisation is given in Chapter 9.10.2.1 of the exposure scenario.

10.10.2. Environment

10.10.2.1. Aquatic compartment (including sediment)

The risk characterisation is given in Chapter 9.10, Section 3 of the exposure scenario.

10.10.2.2. Terrestrial compartment

The risk characterisation is given in Chapter 9.10, Section 3 of the exposure scenario.

10.10.2.3. Atmospheric compartment

The risk characterisation is given in Chapter 9.10, Section 3 of the exposure scenario.

10.10.2.4. Microbiological activity in sewage treatment systems

The risk characterisation is given in Chapter 9.10, Section 3 of the exposure scenario.

10.11. Service life/Use of back-coated textiles

10.11.1. Human Health

10.11.1.1. Workers

Not relevant.

10.11.1.2. Consumers

The risk characterisation is given in Chapter 9.11, Section 3 of the exposure scenario..

10.11.1.3. Indirect exposure to humans via the environment

The risk characterisation is given in Chapter 9.11.2.1 of the exposure scenario.

10.11.2. Environment

10.11.2.1. Aquatic compartment (including sediment)

The risk characterisation is given in Chapter 9.11, Section 3 of the exposure scenario.

10.11.2.2. Terrestrial compartment

The risk characterisation is given in Chapter 9.11, Section 3 of the exposure scenario.

10.11.2.3. Atmospheric compartment

The risk characterisation is given in Chapter 9.11, Section 3 of the exposure scenario.

10.11.2.4. Microbiological activity in sewage treatment systems

The risk characterisation is given in Chapter 9.11, Section 3 of the exposure scenario.

10.12. Service life/Use, wearing of articles made of PET/PES polymers

10.12.1. Human Health

10.12.1.1. Workers

Not relevant.

10.12.1.2. Consumers

The risk characterisation is given in Chapter 9.12, Section 3 of the exposure scenario.

10.12.1.3. Indirect exposure to humans via the environment

The risk characterisation is given in Chapter 9.12.2.1 of the exposure scenario.

10.12.2. Environment

10.12.2.1. Aquatic compartment (including sediment)

The risk characterisation is given in Chapter 9.12, Section 3 of the exposure scenario.

10.12.2.2. Terrestrial compartment

The risk characterisation is given in Chapter 9.12, Section 3 of the exposure scenario.

10.12.2.3. Atmospheric compartment

The risk characterisation is given in Chapter 9.12, Section 3 of the exposure scenario.

10.12.2.4. Microbiological activity in sewage treatment systems

The risk characterisation is given in Chapter 9.12, Section 3 of the exposure scenario.

10.13. Service life/ Wearing of clothes containing antimony trioxide for fire resistance

10.13.1. Human Health

10.13.1.1. Workers

Not relevant.

10.13.1.2. Consumers

The risk characterisation is given in Chapter 9.13, Section 3 of the exposure scenario.

10.13.1.3. Indirect exposure to humans via the environment

The risk characterisation is given in Chapter 9.13.2.1 of the exposure scenario.

10.13.2. Environment

10.13.2.1. Aquatic compartment (including sediment)

The risk characterisation is given in Chapter 9.13, Section 3 of the exposure scenario.

10.13.2.2. Terrestrial compartment

The risk characterisation is given in Chapter 9.13, Section 3 of the exposure scenario.

10.13.2.3. Atmospheric compartment

The risk characterisation is given in Chapter 9.13, Section 3 of the exposure scenario.

10.13.2.4. Microbiological activity in sewage treatment systems

The risk characterisation is given in Chapter 9.13, Section 3 of the exposure scenario.

10.14. Overall exposure (combined for all relevant emission/release sources)

Due to the identified uses of diantimony trioxide as well as diffuse emissions from products, the general population may be exposed from different sources. However, the largest source of exposure of the general population is via geogenic background concentration of pentavalent antimony including ambient air and surface water levels resulting from combustion of fossil fuels. Therefore, the total exposure (body burden) is the summary of all the specific exposures. The most important sources of human exposure are identified.

Since the indirect exposure assessment is based on monitoring data (air, drinking water, food as exposure sources), all geogenic, industrial and diffuse emissions may be considered to be inherently reflected.

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ABBREVIATIONS

(Q)SAR	**Quantitative structure activity relationship, mathematical method to predict e.g. biological activity based on chemical structure**
AC	**Article category**
AF	**Assessment factor**
ANOVA	**Analysis of Variance**
AS	**Allometric scaling**
ASTM	**American Society for Testing and Materials**
ATO	**Diantimony trioxide**
ATSDR	**Agency for Toxic Substances and Disease Registry**
AUC	**Area under the curve; area under the blood/plasma concentration curve vs. time curve, representing the total amount of substance reaching the blood/plasma**
B	**Bioaccumulation**
BAF	**Bioaccumulation Factor**
BCF	**Bioconcentration Factor**
BMD	**Benchmark dose; The BMD concept involves fitting a mathematical model to dose-response data. The BMD is defined as the dose causing a predetermined change in response.**
BMD10	**The benchmark-dose associated with a 10% response (for tumours upon lifetime exposure after correction for spontaneous incidence, for other effects in a specified study)**
BMDL10	**The lower 95% confidence interval of a benchmark-dose representing a 10% response (e.g., tumour response upon lifetime exposure), i.e. the lower 95% confidence interval of a BMD10**
BMF	**Bio magnification factor**
BOD	**Biological Oxygen Demand**
BREF	**Best available technique reference document**
BSAF	**Biological soil accumulation factor**
Bw	**Body weight**
CAD	**Chemical Agent Directive**
CAS	**Chemical Abstract Services**
CBI	**Confidential business information**
CGS	**Control guidance sheets**
CLP	**Classification Labelling and Packaging**
Cmax	**Peak plasma concentration**
CMR	**Carcinogenic, Mutagenic and toxic to Reproduction**
CNS	**Central nervous system**

COD	**Chemical Oxygen Demand**
CSA	**Chemical safety assessment**
CSR	**Chemical Safety Report**
DMEL	**Derived minimum effect level**
DNEL	**Derived no effect level**
DOC	**Dissolved Organic Carbon**
DSD	**Dangerous Substances Directive**
DT50	**Degradation half-life or period required for 50 percent dissipation / degradation**
DU	**Downstream user**
DU-CSA	**Downstream user chemical safety assessment**
DU-TGD	**Downstream user technical guidance document**
dw	**dry weight / dwt**
EASE	**Estimation and assessment of substance exposure**
EbC50	**Effect Concentration measured as 50 % reduction in biomass growth in algae tests**
EC	**European Communities**
EC10	**Effect Concentration measured as 10 % effect**
EC50	**median Effect Concentration**
ECB	**European Chemicals Bureau**
ECHA	**European Chemicals Agency**
ED10	**Effective dose 10 %; a dose representing an increased incidence of 10 % due to a specific exposure (e.g., to a chemical).**
EDTA	**ethylenediaminetetraacetic acid**
EFSA	**European Food Safety Authority**
EINECS	**European Inventory of Existing Commercial Chemical Substances**
ELR	**Excess lifetime risk; additional lifetime risk over the background normal risk (or incidence of disease)**
EPA	**Environmental Protection Agency (USA)**
EPIWIN	**Estimation Program Interface for Windows**
EPL	**Exposure predictor band liquid**
EPS	**Exposure predictor band solid**
ERC	**Environmental release class**
ErC50	**Effect Concentration measured as 50 % reduction in growth rate in algae tests**
ES	**Exposure scenario**
ESD	**Emission Scenario Document**
eSDS	**extended safety data sheet**

EU	**European Union**
EUSES	**European Union System for the Evaluation of Substances [software tool in support of the Technical Guidance Document on risk assessment]**
EWL	**European waste list**
FELS	**Fish Early Life Stage**
FOREGS	**Forum of European Geological Surveys**
GDMF	**General decision making framework**
GEMAS	**Geochemical mapping of agricultural and grazing land soil**
GHS	**Globally Harmonised System**
GLP	**Good Laboratory Practice**
HBMD10	**Human BMD10**
HEvE	**Human exposure via environment**
HH	**Human health**
HPLC	**High Pressure Liquid Chromatography**
HSE	**Health safety environment**
HT25	**Human T25**
HtLF	**High to low dose risk extrapolation factor**
IC	**Industry category**
IC50	**median Immobilisation Concentration or median Inhibitory Concentration**
IPCS	**International Programme on Chemical Safety**
IPPC	**Integrated pollution prevention and control**
ISO	**International Organization for Standardization**
ITS	**Integrated testing strategy**
IUCLID	**International Uniform Chemical Information Database**
Koc	**organic carbon normalised distribution coefficient**
Kow	**octanol/water partition coefficient**
Kp	**solids-water partition coefficient**
L(E)C50	**median Lethal (Effect) Concentration**
LC1	**Lethal Concentration measured as 1 % effect**
LC10	**Lethal Concentration measured as 10 % effect**
LC50	**Median lethal concentration. The concentration causing 50 % lethality**
LCS	**Life cycle stage**
LD50	**Median lethal dose. The dose causing 50 % lethality**
LED10	**Lowest confidence limit of the ED10**
LEV	**Local exhaust ventilation**
LMS	**Linear multistage model**

LOAEL	**Lowest Observed Adverse Effect Level**
LOEC	**Lowest Observed Effect Concentration**
LOEL	**Lowest Observed Effect Level**
LOQ	**Limit of quantitation**
LSD	**Least Significant Difference**
M/I	**Manufacturer / importer**
MAC	**Maximum Allowable Concentration**
MATC	**Maximum Acceptable Toxic Concentration**
MITI	**Ministry of International Trade and Industry, Japan**
MoE	**Margin of exposure**
MTD	**Maximum tolerated dose**
NACE	**Nomenclature générale des activités économiques dans les Communautés Européennes**
NAEC	**No adverse effect concentration**
NAEL	**No adverse effect level**
NOAEL	**No observed adverse effect level**
NOEC	**No Observed Effect Concentration**
NOEL	**No observed effect level**
NOEL	**No Observed Effect Level**
NOM	**Natural organic matter**
OC	**Operational condition**
OECD	**Organisation for Economic Cooperation and Development**
OR	**Odds ratio; the ratio of the odds of an event occurring in one group to the odds of it occurring in another group**
ORL	**Lowest confidence limit of the OR**
OSPAR	**Oslo and Paris Convention for the protection of the marine environment of the Northeast Atlantic**
OU	**Operational unit**
P	**Persistent**
PBPK	**Physiologically-based pharmacokinetic modelling**
PBT	**Persistent, Bioaccumulative and Toxic**
PC	**Chemical product category**
PEC	**Predicted Environmental Concentration**
pH	**logarithm (to the base 10) (of the hydrogen ion concentration {H+}**
PNEC	**Predicted No Effect Concentration**
PNR	**Potential Nitrification Rate**
POP	**Persistent Organic Pollutant**
PPE	**Personal protection equipment**

PROC	**Process category**
QSAR	**(Quantitative) Structure-Activity Relationship**
RAR	**Risk Assessment Report**
RC	**Risk Characterisation**
RCR	**Risk Characterisation Rates**
REACH	**Registration, Evaluation, Authorisation and Restriction of Chemicals**
RMM	**Risk management measure**
RR	**Relative risk**
RRL	**Lower bound exposure value associated with the RR-value of 1.1**
RWC	**Reasonable Worst Case**
SAR	**Structure-Activity Relationships**
Sb	**Antimony**
SDS	**Safety data sheet**
SETAC	**Society of Environmental Toxicology And Chemistry**
SHHA	**Sodium hexahydroxyantimonate**
SIEF	**Substance information exchange forum**
SIN	**Substrate Induced Nitrification**
SME	**Small and medium enterprise**
SMR	**Standardised mortality ratio**
SMRL	**Lower bound exposure value associated with the SMR-value of 1.1**
SPM	**Suspended particulate matter**
sRV	**Standard respiratory volume**
SSD	**Species Sensitivity Distribution**
STP	**Sewage Treatment Plant**
SU	**Sectors of use**
SVHC	**Substances of very high concern**
T25	**The chronic dose rate that will give 25% of the animals' tumours at a specific tissue site after correction for spontaneous incidence, within the stan-dard life time of that species**
TARIC	**Tarif intégré des Communautés Européennes**
TCNES	**Technical Committee for New and Existing Substances**
TG	**Test Guideline**
TGD	**Technical Guidance Document**
TNO	**The Netherlands Organisation for Applied Scientific Research**
TNsG	**Technical Notes for Guidance (for Biocides)**
TTC	**Threshold of toxicological concern**
TWA	**Time-weighted average exposure**
UC	**Use category**

UCN	**Use code Nordic**
UDS	**Use descriptor system**
UEC	**Use and exposure categories**
UN	**United Nations**
UNEP	**United Nations Environment Programme**
US EPA	**Environmental Protection Agency, USA**
UV	**Ultraviolet Region of Spectrum**
UVCB	**Substances of unknown or variable composition, complex reaction products or biological materials as defined in the Guidance on substance identification**
v/v	**volume per volume ratio**
vB	**very Bioaccumulative**
vP	**very Persistent**
vPvB	**very Persistent and very Bioaccumulative**
w/w	**weight per weight ratio**
WHO	**World Health Organization**
wRV	**Worker respiratory volume**
wwt	**Wet weight**
WWTP	**Waste Water Treatment Plant**

APPENDIX I: MEASURED DATA ON DIETARY INTAKE OF ANTIMONY

Table 129: Literature on dietary intake of antimony

Reference	Study type / description	Origin of samples, time and location of sampling	Analytical method: Description, Detection Limit, Blanks / Contamination	Results	Overall comment / rating
ANSES, 2011: Etude de l'alimentation totale française 2 /EAT 2) Tome 1, Contaminants inorganiques, persistants, mycotoxines, phyto-estrogènes, Juin 2011	A Total Diet Study was performed taking samples of foods which are regularly consumed by the population, from different outlets, and which are representative 'shopping baskets' of food consumption. The collected food samples, were prepared 'as consumed' (washed, peeled, cooked, etc.), and then analysed for 445 substances of interest. This method is used to provide a realistic 'background level'. The analysis results were collected, and cross-referenced with the food consumption data from the Agency's INCA2 study, in order to estimate consumers' overall dietary exposure to various substances. INCA 2 (AFSSA, 2009) was conducted between end of 2005 and April of 2007. This survey contains food consumption data gathered over 7 days for over 4,000 participants (2,624 adults and 1,455 children) mainly from	Approximately 20,000 samples were purchased all across mainland France (eight regions and around thirty cities). 212 different food categories were analysed, of which 116 were considered as having no or little inter-regional variability. They were sampled in only one region. The 96 others were specifically sampled at regional level in order to take into account potential variations in composition or contamination among the regions which might reflect, for example, different production and/or animal feeding methods or environmental pressure. Each sample was acquired at two different periods of the year to take possible seasonal variations into consideration.	ICP-MS was used for the determination of 21 elements and minerals after closed-vessel microwave digestion in the food samples. Quality control measures are documented in the report. LOQ: 0.001 mg/kg f.w. Where individual sample analyses were less than the limit of detection, the result is expressed as zero (lower bound), or as equal to the limit of detection (upper bound) and were less than the limit of quantification, the result is expressed as LOD (lower bound), or as equal to the LOQ (upper bound). The exposure was calculated accordingly in the report.	Highest concentrations of antimony were observed in sugars and confectionery (8.9 µg/kg fw), chocolate (4.2 µg/kg fw), cake and small pastry (3.8 µg/kg fw), cream dessert (3.1 µg/kg fw) shellfish and molluscs and dried vegetables (2.2 µg/kg fw each), whereas water (15%), alcoholic beverages (9%), and coffee (9%) are the main contributors to the adults daily antimony intake. The daily antimony intake was calculated in accordance with WHO´s international recommendations by combining the INCA2 study´s consumption data with the analytical results. For adults (>18y) this distribution is characterised by mean 0.0404 µg/kg bw/day, and P95 = 0.0671 µg/kg bw/day. For children (3-17y) this distribution is characterised by mean 0.055 µg/kg bw/day, and P95 = 0.1 µg/kg bw/day.	RL = 1 This study gives the recent and reliable data on antimony intake with food and beverages. It uses modern analytical techniques including a quality assurance programme and it is well documented. Estimates of daily intakes are based on mean concentrations in a large variety of food samples and the population's consumption pattern has frequently (2006/07) been updated. By using the upper bound estimates the results for mean and high intake, are of conservative nature, as it is assumed that each element is present in food at concentrations equal to or greater than the LODs. Furthermore, the daily intake does not contribute to food only but also takes beverages into account.

Reference	Study type / description	Origin of samples, time and location of sampling	Analytical method: Description, Detection Limit, Blanks / Contamination	Results	Overall comment / rating
	France.				
UK Food Standard Agency, 2009: Measurement of the concentrations of metals and other elements from the 2006 UK Total diet study. UK Ministry of Agriculture, Fishery and Food. Food Survey Information Sheet 01/09	Total Diet Study (TDS) The results of the routinely conducted survey from 2006 are reported: food samples were grouped into 20 groups, e.g. bread, cereals, meat, fish, eggs, etc…) . (1) Population daily intake is estimated by multiplying the average element concentration in each food group with the amounts of food consumed (Family Food - Expenditure & Food Survey, 2003/04). (2) Consumption data from the relevant NDNS were used to estimate dietary exposures for individuals in the general population who eat average amounts of each food group (i.e. mean consumers) and those who eat significantly more than average amounts (i.e. 97.5th percentile consumers).	Samples were collected in 24 cities throughout the UK in 2006.	ICP-MS was used as the analytical method. Quality control measures are documented in the report. The limit of detection for antimony is given as 0.1 – 0.5 µg/kg fresh weight. Where individual sample analyses were less than the limit of detection, the result is expressed as zero (lower bound), or as equal to the limit of detection (upper bound) and the exposure calculated accordingly in the report.	The Meat Products group which has the highest concentration of antimony contributes the highest percentage (24%) to the total population dietary exposure. (1) For Antimony, the population dietary exposure is estimated as 2.5 µg/day. Giving that the population dietary exposure has slightly decreased from 1994 (3 µg/d) to 2006 (2.5 µg/d). (2) Furthermore, consumer exposure estimates (NDNS) were given for adults (upper bound) to be: mean: 0.03 µg Sb/kg bw*d high: 0.06 µg Sb/kg bw*d Further values are given for toddlers, young people, elderly and vegetarians.	RL = 1 This UK Total Diet Study is the most recent study giving scientifically sound results. It uses modern analytical techniques including a quality assurance programme and it is well documented. Estimates of daily intakes are based on mean concentrations in a large variety of food samples and the population's consumption pattern is frequently updated. The results for mean and high intake appear reasonable. In fact, these intakes are already of conservative nature, as it is assumed that each element is present in food at concentrations equal to or greater than the LODs. For antimony this was the case for three food groups, namely Oil & Fats, Eggs and Milk.
INRA, 2004: Etude de l'alimentation totale française Mycotoxines, minéraux et éléments traces 2004;	This large market basket study was conducted under supervision of the French "Direction générale de l'alimentation". The selection of food samples was based on a recent (1998/1999) survey on the food consumption pattern of the French population.	Approximately 1000 food and beverage samples were collected throughout France in 2000/2001.	ICP-MS was used for the determination of trace elements and minerals in the food samples. A limit of quantification (LOQ) is given for antimony as 1 µg/kg fresh weight. The LOQ is the double of the limit of detection (0.5 µg/kg fresh weight).	Highest concentrations of Sb were observed in cured meats and fruit (2.4 µg/kg), sea food, vegetables and dried fruits (1.8 µg/kg), and meat (1.7 µg/kg), while most other values were below the limit of quantification (tabulated as 0.3 µg/kg). Based on the concentrations measured in food samples and on the average consumption pattern, a distribution of daily antimony intake is calculated for adults (>15y), which is represented by P2.5=0.5 µg/day, P50=0.9µg/day and P97.5=2 µg/day.	RL = 1 This study gives the recent and reliable data on antimony intake with food (including beverages).

Reference	Study type / description	Origin of samples, time and location of sampling	Analytical method: Description, Detection Limit, Blanks / Contamination	Results	Overall comment / rating
				For children (3-14y) this distribution is characterised by P2.5=0.3 µg/day, P50=0.7µg/day and P97.5=1.6 µg/day.	
UK Ministry of Agriculture, 1998: UK Ministry of Agriculture, Fishery and Food. Food surveillance information sheet number 149; 1994 Total diet study (Part 2) - Dietary intakes of metals and other elements. Published in 1998.	The Total Diet Study (TDS) is used to determine dietary intakes by the general population of chemicals (such as metals) in food. Samples from the 1994 TDS were analysed in 1996/97 for 30 metals and other elements. The results of these analyses were reported in Food Surveillance Information Sheet No. 131, including daily intake estimates for 18 of the 30 elements. The daily intake estimates for the further 12 elements was published in this document.	The quantities of foods that make up the Total Diet Study samples and the relative proportion of each food are largely based on data from the National Food Survey and are updated annually. Applying these quantities to the mean concentration of each element gives an estimate of population average intake (covering both adults and children). Mean and upper range (97.5 percentile) intakes have also been estimated for adult consumers using the mean concentrations of each element and data on consumption of each food group from the Dietary and Nutritional Survey of British Adults.	ICP-MS was used as the analytical method. Quality control measures are documented in the report. The limit of detection for antimony is given as 0.001 mg/kg fresh weight.	For dietary intakes estimated from results less than the LODs, it has been assumed that the concentrations of these elements are at the appropriate LODs and are thus upper bound estimates. These intakes can be regarded as 'worst cases' as it is assumed that each element is present in food at concentrations equal to or greater than the LODs. For Antimony, the median total daily intake is estimated as 3 µg/day and the 97.5th percentile is 4 µg/day.	RL = 1 Overall, the UK Total Diet Study gives scientifically sound results. It uses modern analytical techniques including a quality assurance programme and it is well documented. Estimates of daily intakes are based on mean concentrations in a large variety of food samples and the population's consumption pattern is frequently updated. The results for mean and 97.5% intake appear reasonable. In fact, these intakes are already of conservative nature, as it is assumed that each element is present in food at concentrations equal to or greater than the LODs. For antimony this was the case for three food groups, namely Green vegetables, Beverages and Milk.
UK MAFF, 1998: UK Ministry of Agriculture, Fishery and Food. Food surveillance information sheet number 150; Metals and other elements in cow´s milk and vegetables produced near industrial sites. Published in 1998. (http://archive.food.gov.uk/maff/archive/food/infsheet/index.htm)	This survey was conducted to determine if there are any differences between concentrations of antimony in cows' milk and vegetables produced in areas around industrial sites compared with those in foods on general retail sale, but it is recognized that it is not representative of all such sites in the UK. Furthermore, the samples were not cooked before analysis. Dietary intakes have been estimated using the	UK 1994 and 1996 The survey was conducted in two separate parts: (i) cows' milk samples taken in 1994 from individual farms' bulk tanks as part of a survey of dioxins in cows' milk from farms close to industrial sites (29), and (ii) vegetables collected in 1996 from allotments, and 'Pick-Your-Own' and farm shops from around identified potential point sources of heavy metal pollution in Redcar, Bristol, Newcastle, Rotherham and the Wear Valley.	ICP-MS was used as the analytical method. Quality control measures are documented in the report. LOD (vegetables): 1 µg/kg fw LOD (cow´s milk): 0.3 µg/kg fw	The study showed that mean concentrations of antimony in cow´s milk (mean value < 0.3 µg Sb/kg fw (< LOD)) were comparable to the mean concentrations found in samples taken in 1994 as part of the Total Diet Study (TDS). In general, mean concentrations of antimony in green vegetables (cabbage, runner beans and kale) were higher than those found in previous surveys. However, the mean values found in this survey are not significantly different to	RL = 2 Supplemental information – Proper methodology and reporting however, the aim of the study was the comparison of metal concentrations in vegetables and cow's milk in different regions and not the assessment of dietary intake.

Reference	Study type / description	Origin of samples, time and location of sampling	Analytical method: Description, Detection Limit, Blanks / Contamination	Results	Overall comment / rating
	concentrations of metals detected in this survey and consumption data from The Dietary and Nutritional Survey of British Adults. It has been assumed that consumers are unlikely to eat both the cows' milk and the vegetables analysed in this survey, since the milk and vegetable samples came from different locations. Thus, for the purposes of estimating dietary intakes, cows' milk and vegetable samples have been treated as separate cases. Worst-case intakes from local crops were estimated at each location as the sum of the two highest upper-range (97.5th percentile) intakes for any individual local crops plus the mean intakes for any remaining local crops. This is a worst case as it assumes that the local site provides 100 per cent of the consumption of the types of vegetables that are grown there. For cows' milk, the worst-case intake was simply taken as that of an upper range (97.5th percentile) consumer of local milk. Intakes from the rest of the diet were added, as the average intake from the 1994 TDS.			those found in other surveys of vegetables widely on retail sale. Furthermore, a statistical analysis was carried out by the authors on the results of the determination of antimony concentrations in vegetables. No significant differences were observed in concentrations between vegetables grown in locations potentially more likely to be affected by emissions from the industrial site and those in vegetables from locations less likely to be so affected. For antimony, the worst-case intakes (4 and 6 µg/day for cow´s milk and vegetables respectively) exceed the upper-range intakes from the 1994 TDS (97.5th percentile, 4 µg/person/day).	
Bettinelli, M.; et al. 2007: Trace elements in the total diet typical of northern Italy. Determination of Chemical Elements in Food, 333-351.	Total diet study: The intake of trace elements from the total diet of the population in northern Italy was determined. Samples of the most representative food groups (cereals and cereal products, vegetables, fruit, milk and dairy products, meat and meat products, fish, sweet products and beverages) were collected in	Samples were collected in Northern Italy in two areas of Piemonte, Lombardia and Veneto each. Sampling year was not stated (<2007).	ICP-MS was used as the analytical method. Quality control measures are documented in the report. The limit of detection for antimony is given as 1 µg/kg fresh weight.	Daily intake (incl. beverages): Mean: 8.5 µg/d Range: 4.1 – 19.6 µg/d Cereals and tubers (30 % of the Sb intake) contributed mostly to the total daily antimony intake followed by vegetables and meat (22 % and 19 %, respectively). Beverages (14 %).	RL=2 Proper methodology and reporting of a recent total diet study. However, several details on the data evaluation are not reported in this paper: raw data on concentrations in food samples, number of samples and sampling

Reference	Study type / description	Origin of samples, time and location of sampling	Analytical method: Description, Detection Limit, Blanks / Contamination	Results	Overall comment / rating
	different shops and prepared acc. to local cooking traditions. Data on northern Italian population dietary consumption was used from a TDS 1994-1996 (A. Turrini : 2001).			No individual values are given.	year.
Wappelhorst, 2002: Transfer of Selected Elements from Food Into Human Milk. Nutrition, Volume 18, Number 4, 316-322, 2002	To measure the transfer factors of several elements from food to mother's milk, food and breast milk samples were analyses. Food (and beverages) duplicate samples (part of the original food) were collected and the actual amounts of each food consumed were recorded.	For 19 mothers from Germany, Poland and the Czech Republic, food and milk samples were collected daily for 2-8 weeks. The year or month of sampling are not given, but is may be assumed that sampling was done within 2-3 years before publication. The sampling methodology is described in detail in this paper.	The analysis of the elements was performed by ICP-MS. The sample preparation is described in the paper in detail as well as the used standard materials. The detection limit is not given in the publication.	From the analysis of the food and beverage samples, a mean antimony intake of 10.9±28.1 µg/day is derived. Given this large variation, it is more reasonable to use the median value, which is 4.1 µg/day.	RL = 2 In general, duplicate diet studies are preferred and ICP-MS is a well-established sensitive method for the determination of trace elements in food samples. However, several details on the data evaluation are not reported in this paper: detection limit, raw data on concentrations in food samples, ingested amounts and composition of food. Further, it is not clear whether these nursing mothers are representative for the whole population with respect to their consumption pattern. Though this is very recent data from the EU, the median intake of 4.1 µg/d can only be seen as additional information.
Aras & Kumpulainen, 1995: Trace elements in Turkish wheat and human diets. Proceedings of the technical Workshop on trace elements, natural antioxidants and contaminants (Finland: Helsinki-Espoo 25-26 August). 1995; www.mtt.fi/etl/etk/fao/fao.htm.	Study on dietary intake in Turkey (duplicate diet samples) and on Sb concentrations in wheat (not further addressed here).	Two series of duplicated diet samples were taken in the Ankara University Hospital in January-March 1992 ("winter", n=8) and June-July 1992 ("summer", n=10). The diets were mainly composed of the regular hospital diet, plus a few home-made or store-bought products. The food of three days was collected as one sample.	Instrumental Neutron Activation Analysis was used as the analytical method. The method is described in this paper and in earlier publications.	Concentrations of antimony in the total diet samples are given in µg/kg dry weight as (39±43) for the summer samples and as (11.1±5) for the winter samples. From this data and the daily consumed amount, the daily intake is calculated as (14±3) µg/day in summer and (4.1±0.4) µg/day in winter.	RL = 3 This study is very well documented and the study methodology "duplicate diet" is preferable. However, the geographical origin of the samples lies outside the EU and more recent data would be preferred. It is also questionable, whether hospital diet is a suitable representative for the alimentation of the general public.
Iyengar et al., 1987: Preparation of a mixed human diet material for the determination	This methodological paper demonstrates the feasibility of the mixed diet concept as a viable	A mixed diet sample was prepared from 201 individual food samples collected within the	For Sb, Instrumental Neutron Activation Analysis (INAA) was used, which is described in the	The concentration of Sb in the mixed diet is reported as (9.3±1.4) ng/g dry weight. From	RL = 3 Though of general methodological interest, this

Reference	Study type / description	Origin of samples, time and location of sampling	Analytical method: Description, Detection Limit, Blanks / Contamination	Results	Overall comment / rating
of nutrient elements, selected toxic elements and organic nutrients: A preliminary report. Sci Total Environ 1987; 61: 235-252.	approach for a reliable assessment of daily intakes, especially for elements that occur at low concentrations in individual food items. For several elements, the daily intake estimated from the analysis of a mixed diet sample was compared to the daily intake derived from the analysis of individual food items. Good agreement was observed. However, antimony was only analysed in the mixed diet sample.	US Food and Drug Administration's (FDA) Total Diet Study of 1985, representing the intake of 25-30 year old males in the US.	paper. Sb was analyses in the mixed diet sample also in some standard reference materials.	this figure, the daily intake is calculated as 4.6 µg/day, based on a daily diet of 498 g dry weight (3075 g wet weight).	article is of limited use with respect to the antimony data. With one US mixed diet sample from 1985, this data is likely not to represent the current situation in the EU.
Maihara et al., 1998: Estimate of toxic element intake in diets of pre-school children and elderly collected by duplicate portion sampling. Food Addit Contam 1998; 15: 782-788.	Duplicate diet study. Determination of As, Cd, Sb, W, Th and U.	Two population groups were studied in Sao Paulo, Brazil in 1992, that are considered to be the most sensitive to contaminants in food: 19 pre-school children and 23 elderly people. Duplicate diet samples were collected over three full days. The sampling methodology and sample storage is described in detail.	A Radiochemical Neutron Activation Analysis (RNAA) method was applied, which is well described in the publication. As a quality assurance measure, standard reference materials were studied. Though the analysis of blank samples is not reported, it is anticipated that contamination from used equipment is low because of the thorough cleaning and short contact times. The detection limit and the determination limit for mass antimony per sample mass are given as 0.28 ng/g and 1.7 ng/g, respectively.	For concentrations of Sb in the total diet, and for the calculated daily intakes, averages with standards deviation, ranges and media are given for both population groups. The range of daily intake cited in the current Draft RAR (1.1 - 2.3 µg/day), is the range between the mean for the children and the mean for the elderly.	RL = 3 This study is very well documented. However, dated 1992 and measured in Brazil, this data is likely not to represent the current situation in the EU.
Schelenz, 1977: Dietary Intake of 25 elements by man estimated by neutron activation analysis. Radioanal Chem 1977; 37: 539-548.	Duplicate diet study.	Duplicate diet samples including beverages were collected from 4 adult male men in Germany (location not further specified) for one week. Though the sampling date is not explicitly given, it may be assumed that the sampling was conducted in 1976, since the article was received for publication in November of that year.	Daily samples from each subject were collected in polyethylene boxes, weighed and homogenized, and aliquots were taken for the analysis. The analysis was performed by Radiochemical Neutron Activation Analysis, as described in detail in the publication. The method had previously been validated by the analysis of SRMs and participation in	The average daily antimony intake per person is given as 23 µg/day (extreme values 5-74). The following discussion mainly deals with the intake of toxic elements, and antimony is not further addressed.	RL = 3 Though duplicate diet studies are principally a good way of estimating daily intakes, and neutron activation is a suitable method for element determination in food matrices this study should not be considered further for the exposure assessment because (i) the data is rather old, (ii) the exact geographical origin is not reported and (iii) not information

Reference	**Study type / description**	**Origin of samples, time and location of sampling**	**Analytical method: Description, Detection Limit, Blanks / Contamination**	**Results**	**Overall comment / rating**
			interlaboratory comparisons.		is given on the composition of the sample, so that a possible contamination from food storage material cannot be excluded.
Wester, 1974: Trace element balances in relation to variations in calcium intake. Atherosclerosis 1974; 20: 207-215.	This study tries to evaluate the influence of calcium intake on the balance (intake vs. excretion) of other trace elements. Four test subjects received a constant controlled diet over 5 days, either poor or high in calcium content. Intake and excretion for several elements were monitored by analysing duplicate diet samples, urine and faeces.	A constant diet prepared in the metabolic ward was provided.	Radiochemical Neutron Activation Analysis (RNAA). Details are described elsewhere.	The daily intake of antimony, obtained by duplicate diet study on 4 test persons over 2 study periods of 5 days each, ranged from 2.2 µg/day to 15.6 µg/day (n=8), with the mean being approximately 9.8 µg/day.	RL = 3 In general, duplicate diet studies are preferred and RNAA is a well-established sensitive method for the determination of trace elements in food samples. However, the controlled diet provided in this experimental setup to 4 persons is unlikely to be representative for a whole population. In addition, dating back more than 30 year, the results are unlikely to represent the current situation.
Moll & Moll, 2000: Lexique Précis des risques alimentaires. In Lexique Précis des risques alimentaires. Edited by Tec & Doc 2000; 2, pp 193-383, Paris.	Book about all kinds of contaminants and toxins in food and drinks.	-	-	Antimony is addressed at two occasions in this book. Firstly a daily intake for a 70 kg person is tabulated as 0.25 to 1.5 mg. No source of this information is given. Secondly, in the glossary of this book, some concentrations of antimony in some food items are given. Again, no source of the cited information is given, and for the concentrations in solid foodstuff it is not stated, whether these are based on dry or wet weight.	RL = 4 The relevance of the figures in this book cannot be assessed, because the source of the data is unknown (no references).
Murthy et al., 1971: Levels of Antimony, Cadmium, Chromium, Cobalt, Manganese and Zinc in institutional total diets. Environ Sci Technol 1971; 5: 436-442.	Duplicate diet study.	Duplicate diet samples from institutionalised children, aged 9-12, were collected in 28 US cities in 1967 (approx. monthly samples, each representing the food of one week). The institutions ranged from financially well-to-do boarding schools to orphanages with severe	In brief the, analytical methods comprised of ashing of the previously freezed samples, followed by acidic digestion of the ash and determination of the elements by atomic absorption spectroscopy. As measures of quality assurance, the recovery was determined by adding known	Average (over one year) antimony content in the diets of children from different U.S. cities varied between 0.279-0.693 mg/kg fresh weight. Intake values are reported in the summary as 0.247 to 1.275 mg/day, but the way these values were derived is not reported in	RL = 4 Though duplicate diet studies are principally a good way of estimating daily intakes, this study should not be considered further for the exposure assessment because (i) the diet was for children, (ii) the samples

Reference	**Study type / description**	**Origin of samples, time and location of sampling**	**Analytical method: Description, Detection Limit, Blanks / Contamination**	**Results**	**Overall comment / rating**
		economic limitations.	amounts of standards to the ashed samples. Also, the repeatability of the method was testes by analysing 8 aliquots of one sample. Because other investigators had reported the loss of Sb during sample preparation of some sample matrices, here the effect of using three different ashing temperatures was studied, but no difference in Sb content was observed.	detail. Further, significant seasonal and geographical variations were observed. It is also mentioned in the study that enamel vessels and tin cans used for food storage may contain appreciable amounts of antimony (which may lead to a contamination of the samples).	date back to 1967 (iii) the samples were taken in the US, (iv) large seasonal and geographical variation were observed that were not further investigated.

APPENDIX II: LITERATURE SEARCH

Documentation of literature search on “indirect exposure to antimony via food”

Date of search: 17.12.2009

Background:

The basis for this search was that the issue of “indirect exposure” to antimony via food has to be addressed in the context of REACH. A very specific online search was conducted in the database CAPLUS, to ensure that no recent, relevant data would be missed. The search strategy was narrowed in a way that only literature published after 2006 was retrieved. Given the amount of data already available before the search, this narrow search strategy was chosen to reduce effort and costs, but on the other hand assuring that recent relevant literature would be considered.

Note: this literature search is a part of the project collecting data on antimony in food given above. The overall database used for deriving the final exposure figures was complemented by conducting searches on the internet and by following up on further relevant literature cited in any reference evaluated during the progress of this work.

Selection of database(s):

The literature search was conducted using the database host STN international, which provides access to a multitude of bibliographic and factual databases, covering all scientific fields.
Based on database description and previous experience with similar searches, the databases cluster “FOOD” and the database ANABSTR were selected for this search:

Database name	**Content (abbreviated from STN description)**
ANABSTR	…bibliographic database that covers worldwide literature on analytical chemistry…
AGRICOLA	...bibliographic database containing selected worldwide literature of agriculture and related fields...
BIOSIS	....largest and most comprehensive life science database in the world, ... covering biological and biomedical areas....
BIOTECHNO	.. a comprehensive international database covering all areas of science, technology, and professional biotechnology ... including modern biotechnology and traditional biotechnology ....subject coverage: .... agriculture, food industry, environmental science...
CABA	...a database covering all areas of agriculture and related sciences including biotechnology, forestry, and veterinary medicine.....
CAPLUS	… the most current and comprehensive chemistry bibliographic database available … covering all areas of chemistry and engineering…
DISSABS	.... covering every dissertation granted at accredited North American universities since 1861 and selected masters theses from 1962 and dissertations from other institutions worldwide ....
FOMAD	...a database providing detailed analyses of international food and drink markets, ...assessing consumer attitudes and retail trends... covering Europe, North America, Australia, and the Pacific Rim, as well as emerging markets in South America, Eastern Europe, and the Far East. .....
FOREGE	.... a unique and authoritative source of additive, composition, and labelling legislation, covering legal regulations concerning the food industry worldwide....
FROSTI	... contains citations to the worldwide literature on food science and technology. Covering food and beverages, analytical methods, quality control, ... health and nutrition....
FSTA	...a database covering scientific and technological aspects of the processing and manufacture of human food products. Including basic food sciences, biotechnology, hygiene and toxicology, engineering, packaging, and all individual foods and food products.....
NTIS	… a multidisciplinary database covering all areas of science, engineering technology, and environmental protection….

NUTRACEUT	... contains information on the global nutraceuticals, functional foods, dietary supplement and natural products industries....
PASCAL	… a multidisciplinary bibliographic database covering the major international literature in science, technology and medicine … subject coverage: food industry … chemistry and related fields… environment…
PROMT	....provides information on companies, products, applied technologies, and markets for all manufacturing and service industries worldwide.
SCISEARCH	… contains all records published in the Science Citation Index Expanded … covering every subject area within the broad fields of science … such as environmental science, chemistry, medicine, ecology …
TOXCENTER	...covers the pharmacological, biochemical, physiological, and toxicological effects of drugs and other chemicals.

Search strategy for only search and further evaluation

Several search terms were used in this search and combined by using the Boolean operators ON and AND, as follows. The search strategy was narrowed to literature published after 2006, and published in English, French or German. Furthermore, patent literature was excluded.

1. (antimony) and py>2006 and (DE or EN or FR)/LA not patent/DT

2. dietary intake or diet study or food basket or market basket or duplicate diet or duplicate meal or total diet or daily intake or daily allowance

These searches were then combined, and the overall search was conducted in all databases listed above. All searches in the different databases were combined and duplicates were automatically removed, leading to an answer set of 16 answers. For these 16 references the abstracts were obtained.

The selection of potentially relevant references based on the titles was done by application of the following criteria:

- The aim of the search was to obtain literature reporting measured concentrations of Antimony in total diets. Where this clearly appeared to be the case as assessed by the abstract, this reference was marked for further assessment.

- Titles or abstracts indicating that antimony concentrations were measured in specific individual food items only were excluded.

- Literatures reporting measured concentrations of antimony in countries outside of the EU were excluded.

By applying these criteria and excluding any obviously irrelevant references, 1 reference was manually selected to be obtained in full, and added to the overall antimony database.