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**COMMITTEE OF EXPERTS ON THE TRANSPORT OF  
DANGEROUS GOODS AND ON THE GLOBALLY  
HARMONIZED SYSTEM OF CLASSIFICATION  
AND LABELLING OF CHEMICALS**

Sub-Committee of Experts on the Globally  
Harmonized System of Classification  
and Labelling of Chemicals

Sixteenth session,  
Geneva, 10 -12 (a.m) December 2008  
Item 2 (b) of the provisional agenda

**UPDATING OF THE SECOND REVISED EDITION OF THE GLOBALLY HARMONIZED  
SYSTEM OF CLASSIFICATION AND LABELLING OF CHEMICALS (GHS)**

Health hazards

Revision of Chapter 3.4 with respect to strong versus weak sensitizers

Addendum

Note by the secretariat

1. At the request of the Sub-Committee (ST/SG/AC.10/C.4/30, para. 33) the secretariat reproduced in document ST/SG/AC.10/C.4/2008/18 a proposal for amendment of Chapter 3.4 of the GHS provisionally adopted at the 15<sup>th</sup> session. The secretariat has noted some inconsistencies in these proposed amendments and therefore proposes corrections and additional amendments in annexes I, II and III to this document, as follows:

- Annex I: Corrections to the list of amendments in document ST/SG/AC.10/C.4/2008/18;
- Annex II: Proposed additional amendments to the text of Chapter 3.4 and consequential amendments to Annex 3; and
- Annex III: Draft corrections to the text of current Chapter 3.4 and Annexes 1, 2 and 3 to the GHS (to be included in a corrigendum to the second revised edition of the GHS)

2. The Sub-Committee may wish to consider the proposed corrections and consequential amendments listed hereafter.

GE.08-

## Annex I

### **Corrections to the list of amendments in ST/SG/AC.10/C.4/2008/18**

3.4.2.2.1.4 (c) and 3.4.2.2.1.5 (c) Replace “epidemiology evidence” with “epidemiological evidence”

3.4.2.2.2.2 Add the following amendment:

In the fourth sentence, replace “contact sensitization” with “skin sensitization”.

3.4.2.2.2.3 The amendment should read:

In the first sentence, insert a comma after “met” and replace “contact sensitizer” with “skin sensitizer”. In the second sentence, replace “contact sensitization” with “skin sensitization”.

3.4.3.3 In the table, replace “Note 1” with “see note” and in the note, replace “NOTE 1” with “NOTE”.

*Note by the secretariat: In the table, the rows and columns related to respiratory sensitization should appear before those related to skin sensitization, to be consistent with the order followed through the whole chapter, where the criteria and decision logics for respiratory sensitization are always listed before that related to skin sensitization.*

3.4.5.1 The first amendment should read:

“Add a reference to a new footnote 6 in the first box from the top for “Category 1”, as follows: “Category 1<sup>6</sup>”

Add a new footnote “6” to read as follows: “<sup>6</sup> See 3.4.2.1.1 for details on use of Category 1 sub-categories”

*(Justification: The reference to the exclamation mark symbol for respiratory sensitizers is wrong)*

3.4.5.2 The amendment should read:

“Add a reference to a new footnote 7 in the first box from the top for “Category 1”, as follows: “Category 1<sup>7</sup>”

Add a new footnote “7” to read as follows: “<sup>7</sup> See 3.4.2.2.1 for details on use of Category 1 sub-categories”

*(Justification: It cannot be footnote 6 as initially proposed since the text of the footnote is not the same).*

Annex 2

A2.20 The amendment starting with “Replace the text” should read:

For Category 1:

- In paragraph 1 (a), replace “human evidence that the individual substance leads” with “evidence in humans that the substance can lead”;
- In paragraph 1 (b), replace “Where” with “If”;
- In paragraphs 3 (a) (i) and (ii) and 3 (b) (i) and (ii), delete figures “3” ,“4”, “5” and “6” after “note” in the text between brackets.

*(Justification: notes 3, 4, 5 and 6 have been deleted)*

A2.21 The amendment starting with “Replace the text” should read:

For Category 1:

- In paragraph 1 (b), replace “Where” with “If”
- In paragraphs 3 (a) and (b) delete figures “1” and “2” after “note” in the text between brackets.

*(Justification: notes 1 and 2 have been deleted)*

Note by the secretariat: For comments regarding the hazard statements see Annex III to this document.

## Annex II

### **Proposed additional amendments to the text of Chapter 3.4 and consequential amendments to Annex 3**

3.4.2.1.1.2 Insert “according to 3.4.2.1.1.3” after “a refined evaluation”

*(Justification: Consistency with the equivalent paragraph for skin sensitizers, where a reference to the paragraph where the evaluation criteria can be found has been included)*

Figures 3.4.1 and 3.4.2

Rename as “Table 3.4.1” and “Table 3.4.2” and renumber subsequent tables accordingly.

### Annex 3

Section 1: In table A3.1.2, for codes H317 and H334, replace “1” with “1, 1A, 1B” in column (4).

Section 2: In table A3.2.2, replace “1” with “1, 1A, 1B” in column (4) against each reference to chapter 3.4 in column (3). (Apply to codes P261, P272, P280 and P285)

In table A3.2.3, replace “1” with “1, 1A, 1B” in column (4) against each reference to chapter 3.4 in column (3). (Apply to codes P302, P304, P311, P313, P321, P333, P341, P342, P352, P363, P302+P352, P304+P341, P333+P313 and P342+P311).

In table A3.2.5, replace “1” with “1, 1A, 1B” in column (4) against each reference to chapter 3.4 in column (3).

Section 3: In the matrix for respiratory and skin sensitization (pages 379 and 380 of the English version of the GHS), under “hazard category” replace “1” with “1, 1A, 1B”.

### ***Structure of new section 3.4.2.2 for skin sensitizers***

The secretariat would like to bring the attention of the Sub-Committee to the fact that the structure of sections 3.4.2.1 and 3.4.2.2, as amended in accordance with document ST/SG/AC.10/C.4/2008/18, is not consistent (see list hereafter):

#### Section 3.4.2.1 for respiratory sensitizers

- 3.4.2.1 Respiratory sensitizers
  - 3.4.2.1.1 Hazard categories
  - 3.4.2.1.2 Human evidence
  - 3.4.2.1.3 Animal studies

Section 3.4.2.2 for skin sensitizers (as amended by ST/SG/AC.10/C.4/2008/18)

- 3.4.2.2 Skin sensitizers
  - 3.4.2.2.1 Hazard categories
    - 3.4.2.2.1.4 Human evidence for 1A (includes also animal evidence under the same heading)
    - 3.4.2.2.1.5 Human evidence for 1B (includes also animal evidence under the same heading)
  - 3.4.2.2.2 Specific considerations
  - 3.4.2.2.3 Immunological contact urticaria
  - 3.4.2.2.4 Animal studies (applicable only to animal evidence for Category 1 skin sensitizers)

In order to rationalize the structure of section 3.4.2.2, the secretariat suggests reorganizing the paragraphs regarding the classification criteria for skin sensitizers, as follows:

- 3.4.2.2 Skin sensitizers
  - 3.4.2.2.1 Hazard categories (includes paragraphs 3.4.2.2.1.1 to 3.4.2.2.1.3)
  - 3.4.2.2.2 Human evidence (new) (new heading)
    - 3.4.2.2.2.1 (new) Human evidence for sub-category 1A (former 3.4.2.2.1.4) (including subparagraphs (a) to (c) but excluding the last sentence applicable to animal evidence and table 3.4.1)
    - 3.4.2.2.2.2 (new) Human evidence for sub-category 1B (former 3.4.2.2.1.5) (including subparagraphs (a) to (c) but excluding the last sentence applicable to animal evidence and table 3.4.2)
  - 3.4.2.2.3 Animal studies (new) (*heading from paragraph 3.4.2.2.4 of the GHS, renumbered*)
    - 3.4.2.2.3.1 Evidence from animal studies for Category 1 (new) (*Text from paragraph 3.4.2.2.4.1 of the GHS, renumbered*)
    - 3.4.2.2.3.2 Evidence from animal studies for 1A (new) (includes last sentence from former 3.4.2.2.1.4 and table 3.4.1)
    - 3.4.2.2.3.3 Evidence from animal studies for 1B (new) (includes last sentence from former 3.4.2.2.1.5 and table 3.4.2)
  - 3.4.2.2.4 Specific considerations (new) (*includes heading and text from sub-sections 3.4.2.2.2 and 3.4.2.2.3 (Immunological urticaria) of the GHS, renumbered*)

The text of section 3.4.2.2, as amended in accordance with document ST/SG/AC.10/C4/2008/18, and reorganized as explained above, may be found in information document UN/SCEGHS/16/INF.3.

**Annex III****Draft corrections to the current text of Chapter 3.4 and Annexes 1, 2 and 3 (to be included in a corrigendum to the second revised edition of the GHS)**

- 3.4.1.4 Replace “at section 3.4.4” with “in 3.4.4.2”.
- 3.4.5.2 In decision logic 3.4.2 for skin sensitization, in the sentence “Does the mixture as a whole have respiratory sensitization data? (see 3.4.3.1)” replace “respiratory” with “skin”.

**Annex 2**

A2.20 and A2.21 The secretariat notes that there are currently two different wordings for the same hazard statements relating to respiratory and skin sensitization.

It is also noted that the proposal in document ST/SG/AC.10/C.4/2008/18 introduces a third wording for respiratory sensitization (see table below).

	Respiratory sensitization	Skin sensitization
Chapter 3.4, Annex 1 and Annex 3 (codes H334 and H317)	May cause allergy or asthma symptoms or breathing difficulties if inhaled	May cause an allergic skin reaction
Annex 2 (A2.20 and A2.21)	May cause allergic or asthmatic symptoms or breathing difficulties if inhaled	May cause allergic skin reaction
As proposed in – C4/2008/18	May cause allergic or asthma symptoms or breathing difficulties if inhaled	May cause allergic skin reaction

The Sub-Committee is invited to specify the appropriate wording to be used for respiratory and skin sensitization hazard statements.

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