



Pipeline and Hazardous Material Administration (PHMSA)

Department of Transportation 3Rs Assessment of Animal Toxicity Data

Presented at the Public Forum, Zoom Meeting

May 26, 2022

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Needs for Toxicity Data at PHMSA

- **Incorporated in Regulation**
- **Emergency Response Guidebook**
- **Input to** - UN Transportation Subcommittee
 - ICAO TI
 - IMDG
 - GHS



Hazards in Transportation

There are 9 classifications: Toxic or Infectious Info needed in **Red**.

Class	1	2	3	4	5	6	7	8	9
Division		2.1		4.1	5.1	6.1			
		2.2		4.2	5.2	6.2			
		2.3		4.3					



Need for Toxicity Information for Hazard Identification

2.3 (LC₅₀) Gas inhalation for acute toxicity

4.3 (LC₅₀) Gas inhalation toxicity for acute toxicity when reacted with water

6.1 (LC₅₀) Gas or vapor inhalation

(LD₅₀) Oral ingestion

(LD₅₀) Dermal contact

6.2 Infectious substance – Bacterial hazards, Virus hazards

8 Skin corrosivity

9 Miscellaneous hazards – Toxic gas by-products (batteries)



Toxicity Data Not Needed

- **Chronic Data**
- **Subchronic Data**
- **Reference dose data for effects other than lethal or skin corrosion data**
- **Skin irritation data**
- **Eye damage data**
- **No tracking of animal data**



Transportation Packagings as they relate to toxicity in terms of routes and severity

- **Lithium Batteries**
- **Cylinders**
- **Cargo Tanks**
- **Rail Cars**
- **Aircraft**
- **Vessels**



Animal Ranking (in order of preference)

(Taken from an open, non-DOT publication)

Rat

Mouse

Rabbit

Guinea Pig

Cat

Dog

Monkey



TEST GUIDELINES FOR ACUTE TOXICITY

- Inhalation

OECD TG 403 (Dusts and Aerosol) – Acute Inhalation Toxicity - In-vivo
OECD TG 436 (Acute Toxic Gas Method) – In-vivo

- Oral - In-vivo

OECD TG 423 – Acute Oral Toxicity – Acute Toxic Class Method
OECD TG 420 - Fixed Dose Procedure
OECD TG 425 – Acute Oral Toxicity : Up-and-Down Procedure



TEST GUIDELINES FOR CORROSIVITY

DOT E-10904 – An In Vitro alternative to the In Vivo method (1993 granted, revised 2002).

OECD TG 404 – In Vivo method

OECD TG 435 – “In Vitro Membrane Barrier Test Method for Skin Corrosion” 2006

OECD TG 430 – “In Vitro Skin Corrosion: Transcutaneous Electrical Resistance Test (TER)” 2004.

OECD TG 431 – “In Vitro Skin Corrosion: Human Skin Model Test” 2004.



3R Assessments

2.3 (LC₅₀) Gas inhalation for acute toxicity **1 2 3 4 5 6 7 8 9 10**

4.3 (LC₅₀) Gas inhalation toxicity for acute toxicity when reacted with water
1 2 3 4 5 6 7 8 9 10

6.1 (LC₅₀) Gas or vapor inhalation **1 2 3 4 5 6 7 8 9 10**
(LD₅₀) Oral ingestion **1 2 3 4 5 6 7 8 9 10**
(LD₅₀) Dermal contact **1 2 3 4 5 6 7 8 9 10**

6.2 Infectious substances – Bacterial hazards, Virus hazards
1 2 3 4 5 6 7 8 9 10

8 Skin corrosivity **1 2 3 4 5 6 7 8 9 10**

9 Miscellaneous hazards – Toxic gas by-products (batteries)



Challenges

- **BBA proposals for research**
- **No ICCVAM related research at present**
- **No in-house testing**
- **No reporting requirements on use of animals**

