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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

Thirty-first session
Geneva, 5-8 July 2016
Item 3 (c) of the provisional agenda
Classification criteria and related hazard communication: Practical classification issues

Proposals to address issues from the programme of work for the practical classification issues correspondence group

Transmitted by the expert from the United States of America on behalf of the informal correspondence group on practical classification issues[1]

Purpose

1. By way of this document, the informal correspondence working group on practical classification issues (PCI) is providing recommendations to clarify classification criteria in the GHS.

Background

2. During the thirtieth session, the PCI Group submitted informal document INF.16 to the Sub-Committee, providing an update on the work undertaken by the group. The PCI group met surrounding the Sub-Committee meeting to further discuss the proposals presented in INF.16, in addition to two other proposals. As a result of discussions on these issues, the PCI has developed the proposed editorial changes to the GHS as provided in this working document.

[1] In accordance with the programme of work of the Sub-Committee for 2015–2016 approved by the Committee at its seventh session (see ST/SG/AC.10/C.4/56, annex III and ST/SG/AC.10/42, para. 15).

Proposal

3. The correspondence group invites the Sub-Committee to consider the recommended editorial amendments to the GHS text as set forth in the Annex of this document.

4. With respect to the proposed editorial changes to the health hazard definitions (item (a)), the PCI group will submit an informal paper documenting the conforming changes to GHS Chapter 1.2.

Annex

Proposed editorial amendments to the GHS

Note by the secretariat*: Items (a), (d), (g), (h) and (i) below refer to items in the programme of work for the informal correspondence group agreed by the Sub-Committee at its 28th session (refer to information document INF.32 (28th session)).*

Item (a): Review the definitions in each of the health hazard chapters for consistency in the way the definitions are provided. For example, some definitions are taken directly from OECD test guidelines while others are more general (i.e., they don't refer to specific tests)

Chapter 3.1

3.1.1 Amend the definition for "acute toxicity" to read as follows:

"Acute toxicity refers to serious adverse health effects (i.e., lethality) occurring after a single or short-term oral, dermal or inhalation exposure to a substance or mixture."

3.1.2.1 Amend as follows *(new text is underlined)*:

"3.1.2.1 Substances can be allocated to one of five hazard categories based on acute toxicity by the oral, dermal or inhalation route according to the numeric cut-off criteria as shown in the table below. Acute toxicity values are expressed as (approximate) LD_{50} (oral, dermal) or LC_{50} (inhalation) values or as acute toxicity estimates (ATE). <u>While some *in vivo* methods determine LD_{50}/LC_{50} values directly, other newer *in vivo* methods (e.g., using fewer animals) consider other indicators of acute toxicity, such as significant clinical signs of toxicity, which are used by reference to assign the hazard category.</u> Explanatory notes are shown following Table 3.1.1.".

Chapter 3.2

3.2.1.1 Amend to read as follows:

"Skin corrosion refers to the production of irreversible damage to the skin; namely, visible necrosis through the epidermis and into the dermis occurring after exposure to a substance or mixture.

Skin irritation refers to the production of reversible damage to the skin occurring after exposure to a substance or mixture.".

Chapter 3.3

3.3.1.1 Amend to read as follows:

"Serious eye damage refers to the production of tissue damage in the eye, or serious physical decay of vision, which is not fully reversible, occurring after exposure of the eye, to a substance or mixture.

Eye irritation refers to the production of changes in the eye, which are fully reversible, occurring after exposure of the eye, to a substance or mixture.".

Chapter 3.4

3.4.1.1 Amend to read as follows:

"Respiratory sensitization refers to hypersensitivity of the airways after inhalation of a substance or a mixture.

Skin sensitization refers to an allergic response after skin contact with a substance or a mixture.".

Chapter 3.5

3.5.1.1 Insert a new paragraph to read as follows:

"3.5.1.1 *Germ cell mutagenicity* refers to heritable gene mutations, including heritable structural and numerical chromosome aberrations in germ cells occurring after exposure to a substance or mixture.".

Current paragraphs 3.5.1.1 to 3.5.1.4 become new paragraphs 3.5.1.2 to 3.5.1.5.

Chapter 3.6

3.6.1 Amend the first sentence to read as follows:

"Carcinogenicity refers to the induction of cancer or an increase in the incidence of cancer after exposure to a substance or mixture.".

Chapter 3.7

3.7.1.1 Amend the first sentence as follows *(new text is underlined, deleted text is struck through)*:

"Reproductive toxicity ~~includes~~ refers to adverse effects on sexual function and fertility in adult males and females, as well as developmental toxicity in the offspring, occurring after exposure to a substance or mixture."

In the last paragraph, replace "Nonetheless, chemicals with these effects" with "Nonetheless, substances and mixtures with these effects".

Chapter 3.8

3.8.1.1 Amend to read as follows:

"Specific target organ toxicity – single exposure refers to specific, non-lethal toxic effects on target organs that arise from a single exposure to a substance or mixture. All significant health effects that can impair function, both reversible and irreversible, immediate and/or delayed and not specifically addressed in chapters 3.1 to 3.7 and 3.10 are included (see also para. 3.8.1.6).".

Chapter 3.9

3.9.1.1 Amend to read as follows:

"Specific target organ toxicity – repeated exposure refers to specific toxic effects on target organs that arise from repeated exposure to a substance or mixture. All significant health effects that can impair function, both reversible and irreversible, immediate and/or delayed are included.".

Chapter 3.10

3.10.1 Amend the title to read: "**Definitions and general considerations**"

3.10.1.1 Delete.

3.10.1.2 Renumber as 3.10.1.1.

3.10.1.3 Renumber as 3.10.1.2 and amend to read:

"*Aspiration hazard* refers to severe acute effects such as chemical pneumonia, pulmonary injury or death after aspiration of a substance or mixture."

3.10.1.4 and 3.10.1.5 Renumber as 3.10.1.3 and 3.10.1.4.

Item (d): Propose an editorial revision to the last sentence in GHS paragraph 3.1.2.3, which provides guidance on the use of data when evaluating acute toxicity "in several animal species". Currently, reference to effect in humans is only contained in a footnote (g) to Table 3.1.1 and with many competent authorities not selecting Category 5 the human reference has been lost in implementing regulations. The goal of the proposed editorial revision is to make clear that both data from animal tests and human epidemiological studies should be considered

Chapter 3.1

3.1.2.3 Add the following new sentence at the end of the paragraph:

"In cases where data from human experience (i.e., occupational data, data from accident databases, epidemiology studies) is also available, it should be considered in a weight of evidence approach consistent with the principles described in section 1.3.2.4.9. ".

Item (g): Propose updating Table 3.1.1 to express acute toxicity values as a range. For example, acute toxicity values for acute oral toxicity Category 3 would be expressed as > 50 and ≤ 300 or 50 < ATE ≤ 300

Chapter 3.1

3.1.2 Amend Table 3.1.1 to read:

Table 3.1.1: Acute toxicity estimate (ATE) values and criteria for acute toxicity hazard categories

Exposure route	Category 1	Category 2	Category 3	Category 4	Category 5
Oral (mg/kg bodyweight) *See notes (a) and (b)*	ATE ≤ 5	5 < ATE ≤ 50	50 <ATE ≤ 300	300< ATE ≤ 2000	5000 *See detailed criteria in Note (g)*
Dermal (mg/kg bodyweight) *See notes (a) and (b)*	ATE ≤ 50	50 < ATE ≤ 200	200< ATE ≤ 1000	1000< ATE ≤ 2000	
Gases (ppmV) *See notes (a), (b) and (c)*	ATE ≤ 100	100< ATE ≤ 500	500< ATE ≤ 2500	2500< ATE ≤ 20000	*See detailed criteria in Note (g)*
Vapours (mg/l) *See notes (a), (b), (c), (d) and (e)*	ATE ≤ 0.5	0.5 <ATE ≤ 2.0	2.0< ATE ≤ 10.0	10.0< ATE ≤ 20.0	
Dusts and Mists (mg/l) *See notes (a), (b), (c) and (f)*	ATE ≤ 0.05	0.05< ATE ≤ 0.5	0.5< ATE ≤ 1.0	1.0< ATE ≤ 5.0	

***Note**: Gases concentration are expressed in parts per million per volume (ppmV).*

Item (h): Review the information in Table 1.5.1 for aspiration hazard Category 1 and Category 2 and determine if an update is necessary

Chapter 1.5

In table 1.5.1 amend the rows applicable to aspiration hazard categories 1 and 2 as follows *(new text is underlined, deleted text is struck through)*:

Hazard class	Cut-off value/concentration limit
Aspiration hazard (Category 1)	≥ 1.0% ~~≥ 10% of Category 1 ingredient(s) and kinematic viscosity ≤ 20.5 mm²/s at 40°C~~
Aspiration hazard (Category 2)	≥ 1.0% ~~≥ 10% of Category 2 ingredient(s) and kinematic viscosity ≤ 14 mm²/s at 40°C~~

Item (i): Propose updating the reference to the European Union Safety Data Sheet Directive 91/155/EEC in paragraph 1.5.3.3.3 since the EU Directive 91/155/EEC has been repealed and replaced by Annex II of Regulation (EC) No 1907/2006 (REACH)

Chapter 1.5

1.5.3.3.1 Add the following sentence at the end of the paragraph:

"Guidance on the preparation of SDS's under the requirements of the GHS can be found in Annex 4.".

1.5.3.3.3 Delete.

1.5.3.3.4 Renumber as 1.5.3.3.3.