UN/SCEGHS/26/INF.18

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

26 November 2013

Twenty-sixth session
Geneva, 4 – 6 December 2013
Item 2 (b) of the provisional agenda
Classification criteria and hazard communication:
Practical classification issues

Update on the work of the informal correspondence group on practical classification issues

Transmitted by the United States of America on behalf of the informal correspondence group

Purpose

1. The purpose of this document is to provide an update on the work undertaken by the informal correspondence group on practical classification issues (PCI).

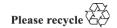
Background

- 2. At its 24th session, the Sub-Committee approved¹ the program of work to be undertaken by the practical classification issues informal correspondence group for the current biennium (INF.34).
- 3. The PCI met during the 25th session for discussion of several proposals to modify the GHS text outlined in the agreed program of work. Based on discussions during this meeting, the PCI has reached agreement for the proposed editorial amendments to the GHS text as presented in the Annex to this document.

Next steps

4. Pending feedback from this document, the PCI group plans to submit a working paper to the 27th session for consideration by the Sub-Committee.

¹ Refer to the report of the Sub-Committee on its 24th session, document ST/SG/AC.10/C.4/48, paragraph 71.



Annex Proposed editorial amendments to the GHS text

1. PCI correspondence group item:

Review Chapter 3.8, Specific Target Organ Toxicity-Single Exposure and determine if the concept of "relevant ingredient" is needed in this chapter. The additivity principle was introduced in Section 3.8.3.4.5, but a "relevant ingredient" for this procedure has not been established.

Proposed recommendation:

Insert a new paragraph 3.8.3.4.6 as follows:

"3.8.3.4.6 In cases where the additivity approach is used for Category 3 ingredients, the "relevant ingredients" of a mixture are those which are present in concentrations ≥1% (w/w for solids, liquids, dusts, mists, and vapours and v/v for gases), unless there is a reason to suspect that an ingredient present at a concentration <1% is still relevant when classifying the mixture for respiratory tract irritation or narcotic effects."

2. PCI correspondence group item:

Make correction to the heading in the left column in Table 3.7.1 from "Ingredients classified as" to "Ingredient classified as". The current text is confusing and may suggest that the additivity principle applies.

Proposed recommendation:

Amend Table 3.7.1 as follows (the text of note ^a and Notes 1 to 4 to the table remain unchanged):

Table 3.7.1: Cut-off values/concentration limits of ingredients of a mixture classified as reproductive toxicants or for effects on or via lactation that would trigger classification of the mixtures^a

	Cut-off/concentration limits triggering classification of a mixture as:				
Ingredients classified as:	Category 1 reproductive toxicant		Category 2 reproductive	Additional category	
	Category 1A	Category 1B	toxicant	for effects on or via lactation	
Category 1A	≥ 0.1% (note 1)				
reproductive toxicant	≥ 0.3% (note 2)				
Category 1B		≥ 0.1% (note 1)			
reproductive toxicant		≥ 0.3% (note 2)			
Category 2			≥ 0.1% (note 3)		
reproductive toxicant			≥ 3.0% (note 4)		
Additional category for				≥ 0.1% (note 1)	
effects on or via lactation				≥ 0.3% (note 2)	

3. PCI correspondence group item:

Provide clarification regarding the untested mixture criteria for aspiration hazards. Specifically, clarify that the approach is additive, and also update the criteria to include the concept of "Relevant Ingredients" since this is an additivity approach.

Proposed recommendation:

Amend section 3.10.3.3 as follows:

"3.10.3.3 Classification of mixtures when data are available for all ingredients or only for some ingredients of the mixture

3.10.3.3.1 The "relevant ingredients" of a mixture are those which are present in concentrations $\geq 1\%$.

3.10.3.3.42 Category 1

<u>3.10.3.3.42.1</u> A mixture which contains $\geq 10\%$ of an ingredient or <u>the sum of</u> ingredients classified in Category 1, and has a kinematic viscosity $\leq 20.5 \text{ mm}^2/\text{s}$, measured at 40 °C, will be classified in Category 1.

3.10.3.3.42.2 In the case of a mixture which separates into two or more distinct layers, one of which contains ≥ 10% of an ingredient or ingredients classified in Category 1 and has a kinematic viscosity ≤ 20.5 mm²/s, measured at 40 °C, then the entire mixture is classified in Category 1.

3.10.3.3.23 *Category* 2

<u>3.10.3.3.23.1</u> A mixture which contains \geq 10% of an ingredient or <u>the sum of</u> ingredients classified in Category 2, and has a kinematic viscosity \leq 14 mm²/s, measured at 40 °C, will be classified in Category 2.

<u>3.10.3.3.23.2</u> In classifying mixtures in this category, the use of expert judgment that considers surface tension, water solubility, boiling point, volatility is critical and especially when Category 2 substances are mixed with water.

3.10.3.3.23.3 In the case of classifying a mixture which separates into two or more distinct layers, one of which contains ≥ 10% of an ingredient or ingredients classified in Category 2 and has a kinematic viscosity ≤ 14 mm²/s, measured at 40 °C, then the entire mixture is classified in Category 2."

4. PCI correspondence group item:

Propose updated text in sections 4.1.3.5.5.3 and 4.1.3.5.5.4 to reflect that the M-Factor must be taken into consideration when applying the Summation Method. Tables 4.1.3 and 4.1.4 appropriately illustrate this concept; however, the test describing the Summation Method criteria in Sections 4.1.3.5.5.3 and 4.1.3.5.5.4 do not currently include application of the M-Factor.

Proposed recommendation:

Amend sections 4.1.3.5.5.3 and 4.1.3.5.5.4 as follows:

4.1.3.5.5.3 Classification for categories Acute 1, 2 and 3

- 4.1.3.5.5.3.1 First, all ingredients classified as Acute 1 are considered. If the sum of the concentrations (in %) of these ingredients <u>multiplied by their corresponding M factors</u> is $\geq 25\%$ the whole mixture is classified as Acute 1. If the result of the calculation is a classification of the mixture as Acute 1, the classification process is completed.
- 4.1.3.5.5.3.2 In cases where the mixture is not classified as Acute 1, classification of the mixture as Acute 2 is considered. A mixture is classified as Acute 2 if 10 times the sum of the concentrations (in %) of all ingredients classified as Acute 1 multiplied by their corresponding M factors plus the sum of the concentrations (in %) of all ingredients classified as Acute 2 is \geq 25%. If the result of the calculation is classification of the mixture as Acute 2, the classification process is completed.
- 4.1.3.5.5.3.3 In cases where the mixture is not classified either as Acute 1 or Acute 2, classification of the mixture as Acute 3 is considered. A mixture is classified as Acute 3 if 100 times the sum of the concentrations (in %) of all ingredients classified as Acute 1 multiplied by their corresponding M factors plus 10 times the sum of the concentrations (in %) of all ingredients classified as Acute 2 plus the sum of the concentrations (in %) of all ingredients classified as Acute 3 is $\geq 25\%$.
- 4.1.3.5.5.3.4 The classification of mixtures for acute hazards based on this summation of the concentrations of classified ingredients is summarized in Table 4.1.3.

Table 4.1.3: Classification of a mixture for acute hazards based on summation of the concentrations of classified ingredients

Sum of the concentrations (in %) of ingredients class	Mixture is classified as:	
Acute $1 \times M^a$	≥ 25%	Acute 1
$(M \times 10 \times Acute \ 1) + Acute \ 2$	≥ 25%	Acute 2
$(M \times 100 \times Acute 1) + (10 \times Acute 2) + Acute 3$	≥ 25%	Acute 3

^a For explanation of the M factor, see 4.1.3.5.5.5.

- 4.1.3.5.5.4 Classification for categories Chronic 1, 2, 3 and 4
- 4.1.3.5.5.4.1 First, all ingredients classified as Chronic 1 are considered. If the sum of the concentrations (in %) of these ingredients <u>multiplied by their corresponding M factors</u> is $\geq 25\%$ the mixture is classified as Chronic 1. If the result of the calculation is a classification of the mixture as Chronic 1 the classification procedure is completed.
- 4.1.3.5.5.4.2 In cases where the mixture is not classified as Chronic 1, classification of the mixture as Chronic 2 is considered. A mixture is classified as Chronic 2 if 10 times the sum of the concentrations (in %) of all ingredients classified as Chronic 1 multiplied by their corresponding M factors plus the sum of the concentrations (in %) of all ingredients classified as Chronic 2 is \geq 25%. If the result of the calculation is classification of the mixture as Chronic 2, the classification process is completed.
- 4.1.3.5.5.4.3 In cases where the mixture is not classified either as Chronic 1 or Chronic 2, classification of the mixture as Chronic 3 is considered. A mixture is classified as Chronic 3 if 100 times the sum of the concentrations (in %) of all ingredients classified as Chronic 1 multiplied by their corresponding M factors plus 10 times the sum of the concentrations (in %) of all ingredients classified as Chronic 2 plus the sum of the concentrations (in %) of all ingredients classified as Chronic 3 is \geq 25%.

- 4.1.3.5.5.4.4 If the mixture is still not classified in either category Chronic 1, 2 or 3, classification of the mixture as Chronic 4 should be considered. A mixture is classified as Chronic 4 if the sum of the concentrations (in %) of ingredients classified as Chronic 1, 2, 3 and 4 is \geq 25%.
- 4.1.3.5.5.4.5 The classification of mixtures for long-term hazards based on this summation of the concentrations of classified ingredients is summarized in Table 4.1.4."

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