

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**

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Item 4 (a) of the provisional agenda

Implementation of the GHS –Implementation issues

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

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

I. 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).

II. Background

2. During its 21st session, the Sub-Committee approved the program of work to be undertaken by the PCI informal correspondence group for the current biennium (UN/SCEGHS/21/INF.13). This program of work was drawn from a variety of sources, including discussions in working group meetings, through email correspondence, and from the paper submitted by the implementation issues correspondence group at the seventeenth session (ST/SG/AC.10/C.4/2008/22).

3. The PCI group met in the plenary during the 21st session and subsequently reached agreement on the proposals presented below:

- (a) Annex 1 sets forth the recommended editorial amendments to the GHS.
- (b) Annex 2 provides a worked example to be included in the UNITAR training documents.

III. Next steps

4. Pending feedback from this document, the PCI group plans to submit a working paper for the 23rd session.

Annex 1

Proposed editorial amendments to the GHS text

1. PCI correspondence group item:

Review the GHS text for inconsistencies in the use of the terminology “toxicity category” and “hazard category”.

Proposed recommendation: To replace “toxicity category” with “hazard category”, where appropriate.

The amendment does not apply to paragraphs 3.1.4.2 and footnote 1 to 3.1.2.5 (Chapter 3.1); A4.3.2.1.2 (Annex 4); and the table in A8.1 (Annex 8), since the term “toxicity” is referring to “acute oral toxicity”

Proposed amendments to the GHS

- (a) In the paragraphs listed below, for “toxicity category” and “toxicity categories” read “hazard category” and “hazard categories”, respectively.

Chapter 3.1: 3.1.2.1; 3.1.2.4; 3.1.2.6.4; 3.1.3.5.5 (3 times); Chapter 3.2: 3.2.3.2.5 (twice)

Chapter 3.3: 3.3.3.2.5 (twice)

Chapter 3.8: 3.8.3.3.5 (3 times)

Chapter 3.9: 3.9.3.3.5 (3 times)

Chapter 3.10: 3.10.3.2.5 (3 times)

Chapter 4.1: 4.1.3.4.5 (3 times); 4.1.5.1.1 (decision logic 4.1.1): sub-paragraph (a) in the text box preceding classification as Acute Category 1 in page 234 of the English version of the GHS)

- (b) To provide clarification to paragraphs 3.1.3.6.1 (a) and 3.1.4.1, replace “acute toxicity categories” with “acute toxicity hazard categories”.

Annex 2

Bridging principles example

PCI correspondence group item: Provide clarity for the conditions necessary for the use of bridging principles through the provision of agreed examples

Proposed recommendation: The following example of the application of Bridging principle Interpolation within one hazard category, below will be suggested for inclusion in UNITAR's advanced training document, which is under development.

1. Interpolation within one hazard category bridging principle example

The following example uses skin corrosion/irritation *in vitro* data from a Human Skin Model (HSM) test (OECD TG 431) to demonstrate the application of the interpolation within one hazard category bridging principle.

Interpolation within one hazard category

For three mixtures (A, B and C) with identical ingredients, where mixtures A and B have been tested and are in the same irritation/corrosion hazard category, and where untested mixture C has the same toxicologically active ingredients as mixtures A and B but has concentrations of toxicologically active ingredients intermediate to the concentrations in mixtures A and B, then mixture C is assumed to be in the same irritation/corrosion hazard category as A and B.

Tested mixture information:

| Skin corrosion/Irritation classification and test data | | | |
|--|--------------------|---------------------|------------------------|
| Test substance | % Viability 3 mins | % Viability 60 mins | Classification |
| Mixture A | 100 | 30 | Not Skin Cat. 1 |
| positive control | 23 | 12 | |
| Mixture B | 88 | 77 | Not Skin Cat. 1 |
| positive control | 20 | 12 | |

The test substance is considered to be non-corrosive to skin:

(i) if the viability after three minutes exposure is $\geq 50\%$ and the viability after 1 hour exposure is $\geq 15\%$.

Information on ingredients in the tested mixture:

| Ingredient | Ingredient classification | Weight % | |
|---------------|---------------------------|-----------|-----------|
| | | Mixture A | Mixture B |
| Ingredient 1* | Eye Irritant Category 2 | 25 | 10 |
| Ingredient 2 | Not Classified | 0.5 | 7 |
| Ingredient 3 | Not Classified | 2 | 6 |
| Ingredient 4 | Not Classified | 0.2 | 0.2 |
| Ingredient 5 | Not Classified | 2 | 2 |
| Water | Not Classified | 70.3 | 74.8 |

* Ingredient 1 is not classified for skin corrosion/irritation based on the results of an OECD TG 404 study

Mixture A – pH (neat liquid): 1.3; Acid reserve: 6.8; Consideration of pH and acid reserve indicates the mixture may not be corrosive

Mixture B – pH (neat liquid): 1.8; Acid reserve: 2.5; Consideration of pH and acid reserve indicates the mixture may not be corrosive

Untested mixture information:

| Ingredient | Weight % | | |
|--------------|-----------|-----------|-----------|
| | Mixture A | Mixture C | Mixture B |
| Ingredient 1 | 25 | 15 | 10 |
| Ingredient 2 | 0.5 | 5.6 | 7 |
| Ingredient 3 | 2 | 6 | 6 |
| Ingredient 4 | 0.2 | 0.2 | 0.2 |
| Ingredient 5 | 2 | 2 | 2 |
| Water | 70.3 | 71.2 | 74.8 |

Mixture C – pH (neat liquid): 1.8; Acid reserve: 3.8; Consideration of pH and acid reserve indicates the mixture may not be corrosive

Answer:

Applying the Interpolation within one hazard category bridging principle the Untested Mixture C is not classified as Skin Corrosive Category 1.

Further evaluation will be required to determine the final classification of Mixture C regarding Skin Irritation.

Rationale:

- (a) Classification via application of substance criteria is not possible since skin corrosion/irritation test data was not provided for the untested mixture;
- (b) Classification via the application of bridging principles can be considered since there are sufficient data on both the individual ingredients and a similar tested mixture;
- (c) Classification of the mixture based on ingredient information should be considered if the classifier chooses not to apply the bridging principle or sufficient data had not been available to apply the bridging principle;
- (d) The interpolation within one hazard category bridging principle can be applied because:
 - (i) Mixtures A and B have both been tested and are in the same irritation/corrosion hazard category (i.e. Not classified as skin corrosive Cat. 1); AND
 - (ii) Untested mixture C has the same toxicologically active ingredient (i.e. Ingredient 1) as tested Mixtures A and B; AND
 - (iii) The concentration of ingredient 1 in mixture C is intermediate to the concentration of ingredient 1 in mixtures A and B.