

## 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**

## Report 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

The Informal Correspondence Group on Practical Classification Issues (PCI) held a meeting on 12 December 2012 to discuss additional comments received on working document ST/SG/AC.10/C.4/2012/25. The PCI Correspondence Group recommends adoption of the working paper with the amendments provided below:

### Amendments to ST/SG/AC.10/C.4/2012/25

#### Annex 1

##### 1. Annex 4

A4.3.12.4 Insert a new paragraph A4.3.12.4 to read as follows:

“A4.3.12.4 Provide also a short summary of the data given under A4.3.12.5 ~~and to~~ A4.3.12.9 in relation to the hazard classification criteria. Where data are not available for classification, this should be clearly stated on the SDS for each basic property concerned. Additionally, if data are available showing that the substance or mixture does not meet the criteria for classification, it should be stated on the SDS that the substance or mixture has been evaluated and, based on available data, does not meet the classification criteria. Additionally, if a substance or mixture is found to be not classified for other reasons, for example, due to technical impossibility to obtain the data, or inconclusive data, this should be clearly stated on the SDS.”

Renumber current paragraphs A4.3.12.3 to A4.3.12.7 as new paragraphs A4.3.12.5 to A4.3.12.9.

##### 2. Chapter 1.2

The proposed recommendations for Chapter 1.2 are withdrawn

### 3. Chapter 1.5

~~1.5.1.3~~ 1.5.3.3.4 Add a new paragraph ~~1.5.1.3~~ 1.5.3.3.4 to read as follows:

~~1.5.1.3~~ 1.5.3.3.4 Additional safety and environmental information is required to ~~To~~ address the needs of seafarers and other transport workers in the bulk transport of dangerous goods in sea-going or inland navigation bulk carriers or tank-vessels subject to IMO or national regulations, ~~additional safety and environmental information is required.~~ Paragraph A4.3.14.7 of Annex 4 recommends the inclusion of basic classification information when such cargoes are transported as liquids in bulk according to Annex II of MARPOL and the IBC Code. In addition, ships carrying oil or oil fuel, as defined in Annex I of MARPOL, in bulk or bunkering ~~of~~ oil fuel are required before loading to be provided with a 'material safety data sheet.' in accordance with the IMO's Maritime Safety Committee (MSC) resolution "Recommendations for Material Safety Data Sheets (MSDS) for MARPOL Annex I Oil Cargo and Oil Fuel" (MSC.286(86)). Therefore, in order to have one harmonized SDS for maritime and non-maritime use, the additional provisions of Resolution MSC.286(86) may be included in the GHS SDS, where appropriate, for marine transport of MARPOL Annex I cargoes and marine fuel oils ~~to allow for the generation of one harmonized safety data sheet."~~ .

## Annex 2

### Example illustrating a use of the bridging principle interpolation within one hazard category

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 program, which is under development.

This example uses skin corrosion 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.

OECD TG 431 indicates that the HSM test:

- (i) allows the identification of corrosive substances and mixtures; and
- (ii) enables the identification of non-corrosive substance and mixtures when supported by a weight of evidence determination using other existing information (e.g. pH).

#### 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 corrosion/irritation 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 corrosion/irritation hazard category as A and B (GHS 3.2.3.2.5).

#### Tested mixture information:

Mixture A – pH (neat liquid): 1.3; Acid reserve: 6.8; Consideration of pH and acid reserve according to Young *et al.* method<sup>1,2</sup> indicates the mixture may not be corrosive

Mixture B – pH (neat liquid): 1.8; Acid reserve: 2.5; Consideration of pH and acid reserve according to Young *et al.* method<sup>1,2</sup> indicates the mixture may not be corrosive

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

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

<sup>1</sup> Young J.R., How M.J., Walker A.P., Worth W.M.H. (1988): Classification as corrosive or irritant to skin of preparations containing acidic or alkaline substances, without test on animals. *Toxicology in Vitro* 2, 19-26.

<sup>2</sup> Young J.R., How M.J. (1994), Product classification as corrosive or irritant by measuring pH and acid/alkali reserve. In *Alternative Methods in Toxicology* vol. 10 - *In Vitro* Skin Toxicology: Irritation, Phototoxicity, Sensitization, eds. A.Rougier, A.M. Goldberg and H.I Maibach, Mary Ann Liebert, Inc. 23-27.

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

Mixtures A and B are not classified as Skin Corrosion Category 1 based on test data and consideration of pH/acid reserve. ~~The classification of Mixtures A and B, based on the generic concentration limits of the ingredients, is Eye Irritation Category 2.~~

Information on ingredients in the tested mixtures:

Ingredient	Ingredient Skin/Eye 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

\*\* Not classified for skin corrosion/irritation or serious eye damage/eye irritation based on test data

Untested mixture information:

Mixture C – pH (neat liquid): 1.8; Acid reserve: 3.8; Consideration of pH and acid reserve according to Young *et al.*<sup>1,2</sup> method indicates the mixture may not be corrosive

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

**NOTE:** In Chapter 1.3 Classification of Hazardous Substances and Mixtures, the principle that the GHS itself does not include requirements for testing substances or mixtures is clearly stated. However, the GHS also recognizes that some parts of regulatory systems (e.g., pesticides) may require data to be generated. In reviewing this example there were different interpretations on whether negative in vitro data in combination with  $\text{pH} \leq 2$  could be used to justify not being classified as a Skin corrosion Category 1. Where a competent authority requires additional test data, testing and classification should be undertaken in accordance with the competent authority's requirements.

Answer:

Applying the Interpolation within one hazard category bridging principle, the untested Mixture C is not classified as Skin Corrosion Category 1 based on test data of Mixtures A and B and consideration of pH/acid reserve.

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

The classification of Mixture C is ~~Eye Irritation Category 2~~ Serious Eye Damage Category 1.

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 similar tested mixtures;
- (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 corrosion/irritation hazard category (i.e. Not classified as Skin Corrosion Category 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.
- (e) Classification of the mixture based on ingredient information should be considered for Serious eye damage/eye irritation (GHS paragraph ~~3.3.3.2~~ 3.3.3.1.2 and ~~Table 3.3.3~~).

(End of example)

### Annex 3

#### Classification of a mixture for skin corrosion/irritation and serious eye damage/irritation following the tiered evaluation approach

This example uses Serious Eye Damage/Eye Irritation *in vitro* data from a Bovine Corneal Opacity and Permeability (BCOP) test (OECD TG 437) to illustrate classification of a mixture following the proposed tiered evaluation approach in GHS Chapter 3.3.

##### Information on Mixture A

pH of mixture (neat liquid): 7 – 8

~~Mixture is not classified for skin corrosion/irritation based on test data.~~ There are no test data available on the mixture to evaluate skin corrosion/irritation.

Composition:

Ingredient	Weight %	Skin/Eye classification
Ingredient 1	22.06	Eye Cat. 1; Skin Cat. 2
Ingredient 2	4.00	Eye Cat. 1; Skin Cat. 2
Ingredient 3	5.50	Eye Cat. 2A
Ingredient 4	8.00	Not classified *
Ingredient 5	0.05	Not classified *
Ingredient 6	0.2	Not classified *
Water	60.19	Not classified

\* Not classified for skin corrosion/irritation or serious eye damage/eye irritation based on test data

Test data:

BCOP test data			
	Mean opacity value	Mean permeability OD <sub>490</sub> value	IVIS
Mixture	15	5	90
Concurrent positive and negative controls acceptable			

IVIS: *In Vitro* Irritancy Score

IVIS = mean opacity value + (15 x mean permeability OD<sub>490</sub> value)

A test sample that induces an IVIS  $\geq 55.1$  is defined as a corrosive or severe irritant to eyes.

##### Classification of Mixture A

Answer:

Applying the proposed tiered evaluation approach in GHS Chapter 3.3, Mixture A is classified as Serious Eye Damage Category 1 based on test data.

Based on the information of the ingredients of the mixture and generic concentration limits Mixture A is classified as Skin Irritation Category 2.

Rationale:

- (a) Classification based on existing human eye data is not possible since such data are not available;
- (b) Classification via application of substance criteria in GHS Table 3.3.1 and Table 3.3.2 is not possible since existing animal data are not available;
- (c) Classification via the bridging principles is not possible since data on a similar mixture are not available (3.2.3.2);
- ~~(d)~~ Test results derived using the BCOP test method indicate Mixture A is a corrosive or severe eye irritant.
- ~~(d)~~(e) Classification of the mixture based on ingredient information should be considered for skin irritation (GHS paragraph 3.2.3.3.2 and Table 3.2.3).

(End of example)