Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals

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Sub-Committee of Experts on the Transport of Dangerous Goods

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Twenty-second session Geneva, 7 – 9 December 2011 Item 4 (c) of the provisional agenda Implementation of the GHS: Cooperation with other bodies or international organizations

Harmonization of classification criteria for transport with the classification criteria of the GHS for substances and mixtures corrosive to skin

Transmitted by the International Council of Chemical Associations (ICCA)

Background

Contribution to Work stream (b) of document UN/SCEGHS/21/INF.6 - UN/SCETDG/39/INF.14:

"Identify and analyse the discrepancies between assignment to subcategories 1A, 1B and 1C, based on in vitro and in vivo testing and alternative approaches (bridging principles, mixtures calculations, pH...)."

Summary

Recognizing that skin corrosion classification based on test data is already harmonized, chemical industry proposes for the classification of mixtures the adoption of current GHS additivity approach to transport regulations and the implementation of a modified non-additivity approach, taking into account that the current general worst-case classifications currently required in the GHS are not reasonable.

Introduction

1. The harmonization of the classification criteria for transport and for supply and use needs to be pushed forward to avoid confusion during the transport, based on contradicting classifications and label information. The chemical industry appreciates the work of the informal joint correspondence group on corrosivity criteria and would like to contribute some information and proposals regarding the



terms of reference for the work (b). In order to find a common basis transport should accept the GHS conditions for corrosive mixtures for which the additivity approach can be applied. But for the non additivity approach general worst-case classifications are not reasonable.

2. This paper tries to explain the concerns and makes proposals for the harmonization of the classification criteria for substances and mixtures corrosive to skin.

I. **Classification based on test data**

(reference to: [1] ANNEX II para 16 and 18)

3. As already mentioned in Annex II to the report of the corresponding working group, assignment of GHS subcategories 1A, 1B and 1C and TDG packing groups I, II and III is harmonized for in vivo testing according OECD Test Guideline 404 (same exposure and observation period requirements) and for in vitro testing according OECD Test Guideline 435 (criteria are completely referenced in the Test Guideline). These classification criteria are also applicable for mixtures and solutions, if relevant data are available.

4. Application of the test based criteria results in equivalent classification for use and transportation without any discrepancies. Therefore no substantial amendments are necessary.

II. Classification based on human experience or expert judgment (reference to: [1] ANNEX II para 19)

Classification based on human experience or expert judgment has to be 5. considered equivalently as recommended in GHS and REACh. A similar approach needs to be implemented into the transport regulation to avoid discrepancies.

III. Classification of mixtures based on the classification of the ingredient (additivity approach),

(no reference, new issue)

6. If there are no test data for the mixture available, the classification will be based on the classification of the ingredients, following the additivity approach of the GHS. This approach helps to determine the classification of mixtures and therefore should be implemented in the transport regulations.

7. From the European point of view the implementation of the GHS classification threshold values (see table 1) result in a more stringent classification, compared with criteria of the EU-directive 1999/45/EC, which is still valid until 1.6.2015. The GHS implementation in the European Union has led to a stricter classification for supply and use and these criteria should be used for transportation as well. Not following this approach would cause differences and confusion in both areas transport and supply and use.

Table 1			
Concentration of corrosive ingredients [%]	Classification of the mixture		
	EU-directive 1999/45 EG	GHS and CLP regulation 1272/2008	
10 - 100	corrosive, C, R34	Skin corrosive, Category 1	
5 - 10	irritant, Xi, R38		

8. If there are subcategories assigned to all relevant ingredients, the subcategory can be calculated and with that the assignment of a packing group would be possible. The formula for the calculation of the subcategory can be found in the note following table 3.2.3. In case not all relevant ingredients are linked to a subcategory, the same approach as proposed for the non additivity approach should be used to guarantee consistency (see section V of this document).

Proposal

9. Adopt parts of GHS Table 3.2.3 regarding category 1 and the note to table 3.2.3 to transport regulations.

IV. Classification of mixtures based on the classification of the ingredient (non additivity approach)

(no reference, new issue)

10. According to the GHS criteria, the additivity approach cannot always be applied. Particular care must be taken when classifying chemicals such as acids and bases, inorganic salts, aldehydes, phenols, and surfactants. For these cases the additivity approach cannot always be applied. It has to be considered that the application or non-application of additivity approach is still in discussion in the relevant GHS correspondence group. The result has to be implemented in the transport regulations as well.

11. The limits according the non additivity approach (see GHS table 3.2.4) are as follows:

Table 2				
Ingredient:	Concentration:	Mixture classified skin corrosive:		
Acid with $pH \le 2$	≥ 1%	Category 1		
Base with $pH \ge 11.5$	$\geq 1\%$	Category 1		
Other corrosive (Category 1) ingredients for which additivity does not apply	$\geq 1\%$	Category 1		

12. An assessment based on the pH value shall only be done if the additivity approach cannot be applied. The result by applying this approach is category 1, without a possibility to determine the subcategory. For the implementation in the transport regulations the determination of the packaging group is mandatory, as without the packing group the transport would not be allowed.

Proposal

13. Implement the following text in the TDG classification criteria for mixtures:

"In case the non additivity approach is applied, packing group III is assigned. Only if data are available for a more stringent classification, a stricter packing group shall be applied."

14. A similar approach was also used for certain hazard classes by the European Union for the classifications of listed substances in Annex I of the EU directive 67/548/EC when they were "translated" into the CLP classifications (Annex VI of 1272/2008/EC):

"1.2.1. Minimum classification

For certain hazard classes, including acute toxicity and STOT repeated exposure; the classification according to the criteria in Directive 67/548/EEC does not correspond directly to the classification in a hazard class and category under this Regulation. In these cases the classification in criteria of this Annex shall be considered as a minimum classification.

This classification shall be applied if none of the following conditions are fulfilled:

- The manufacturer or importer has access to data or other information as specified in Part 1 of Annex I that lead to classification in a more severe category compared to the minimum classification. Classification in the more severe category must then be applied;

- The minimum classification can be further refined based on the translation table in Annex VII when the physical state of the substance used in the acute inhalation toxicity test is known to the manufacturer or importer. The classification as obtained from Annex VII shall then substitute the minimum classification indicated in this Annex if it differs from it.".

V. Tiered Approach

(no reference, new issue)

15. The GHS contains a tiered approach to provide the sequence and the application of the classification criteria. The TDG Sub-Committee needs to decide whether this approach should be implemented in addition into the transport regulations. This would provide a good overview on the classification criteria.

Proposal

16. Adopt tiered approach provisions regarding skin corrosion to transport regulations.

Proposal

17. The tiered approach should be amended according to the transport regulations (see UN MR 2.8.2.4) which means: If a validated in vitro test is available and this shows a negative response, it shall lead to the classification: non corrosive classification to skin.

Reference:

[1] UN/SCEGHS/21/INF.6 - UN/SCETDG/39/INF.14