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 **22 November 2016**

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Hazard communication issues: miscellaneous

Proposal to amend Annex 4 (sub-section A4.3.3.2.3) of the GHS on guidance on the preparation of safety data sheets

Transmitted by the European Chemical Industry Council (CEFIC)

Background

1. According to sub-section A4.3.3.2.2 of Annex 4 of the GHS, the concentrations of the ingredients of a mixture should be described in section 3 of the safety data sheet either as exact percentages or as ranges of percentages. Percentage ranges are commonly used by industry since these help to protect confidential business information (exact composition details), as well as allowing for inherent natural/manufacturing variability and/or uncertainty due to a lack of exact concentration data for raw materials which are themselves mixtures.

2. Sub-section A4.3.3.2.3 of Annex 4 then states:

> "When using a proportion range, the health and environmental hazard effects should describe the effects of the highest concentration of each ingredient, provided that the effects of the mixture as a whole are not available.
>
> ***NOTE:*** *The "proportion range" refers to the concentration or percentage range of the ingredient in the mixture.*"

3. The concentration ranges to be used in section 3 are typically pre-defined in the company's IT system and reflect the classification boundaries for the relevant hazard classes. The true exact concentration of each substance will lie somewhere within the quoted range, not necessarily at the maximum of the range.

4. For some hazard classes, e.g. skin corrosion/irritation or chronic aquatic toxicity, additivity applies and summation of the relevant ingredients is required to classify the mixture correctly if other methods like weight of evidence or expert judgment are not applicable. The overall calculated classification of the mixture (given in section 2 of the safety data sheet) will normally be based on the actual total concentration of the ingredients, and therefore may not reflect the total of all standard ranges quoted per substance in section 3 – i.e. the classification is lower than that which would be obtained by calculation using the maxima of all ranges.

5. It is the view of CEFIC that the above discrepancy is inevitable. However the implementation of A4.3.3.2.3 as a mandatory requirement in legislation has created serious practical problems for industry, including challenges from customers as well as

enforcement action from national competent authorities. This is particularly notable in the European Union, where the provision has been transposed into Annex II of REACH (Regulation (EC) No 1907/2006) as follows:

> "When using a range of percentages, the health and environmental hazards shall describe the effects of the highest concentration of each ingredient.
>
> If the effects of the mixture as a whole are available, this information shall be included under Section 2."

6. Some real-life examples of the difference between actual classifications and those derived from the maxima of percentage ranges are shown in the annex to this document.

Discussion

7. The primary purpose of a safety data sheet is to communicate information to the recipient on the safe use of the mixture. Due to the classification principles of GHS it will not always be possible to verify the classification of a mixture using the information provided in section 3 of the safety data sheet. If authorities need to understand mixture classifications, or downstream formulators require more specific information for classification, industry is willing to provide relevant information for this purpose under the appropriate conditions of confidentiality.

8. Adjusting the information in section 3 to allow confirmation of the mixture classification would also render the use of ranges redundant, since the maximum of each range would have to be set at, or very close to, the actual exact concentration. This would effectively disclose confidential business information. In addition, it is technically difficult and impractical to adjust concentration ranges on a case-by-case basis to accommodate the summation of constituent substances. This would require manual intervention on all documents where additivity applies, which is not feasible in a production environment often involving thousands of formulations.

9. In the case of a tested mixture, or one classified using bridging principles from similar tested mixtures, the overall mixture classification will not necessarily reflect the sum of the ranges in any case (or even the sum of exact substance concentrations). This is acknowledged and accommodated in Annex 4 of GHS, but not necessarily in legislation based on GHS, as noted in paragraph 5 above.

Proposal

10. The provision in A4.3.3.2.3 of Annex 4 is impractical and inappropriate in the context of additive effects. It is therefore proposed that A4.3.3.2.3 be deleted, or else replaced by more appropriate alternative text such as the following:

> "When using a range of percentages, the range for each substance should reflect relevant classification thresholds. The health and environmental hazards of the mixture should however describe the effects of the mixture as a whole or the effects based on the actual concentration of each ingredient, as appropriate."

11. CEFIC invites the views of the Sub-Committee on this issue, with a view to developing a formal proposal for the next biennium.

Annex

Examples of differences in classification and labelling using actual concentrations and the highest concentrations of ranges

Example 1:
Eye Category 2 *vs* Eye Category 1

Ingredient and classification	**Actual concentration in mixture**	**Range specified in Section 3**
Surfactant A Eye Cat. 1, no SCL	1.24%	1 – 2.5%
Surfactant B Eye Cat. 1, no SCL	1.13%	1 – 2.5%
Total	*Total concentration:* **2.37%**	*Total of highest concentrations:* **5%**
Classification and labelling based on calculation method[1]:	Eye Cat. 2 Warning H319 Causes serious eye irritation 	Eye Cat. 1 Danger H318 Causes serious eye damage 

[1] *Generic concentration limit for classification of mixture as Eye Cat.1 based on substances classified as Eye Cat.1 is 3%.*
Generic concentration limit for classification of mixture as Eye Cat.2 based on substances classified as Eye Cat.1 is 1%.

Example 2:
Aquatic toxicity Chronic 3 *vs* Aquatic toxicity Chronic 2

Ingredients (all classified Aquatic Chronic 2)	**Actual concentration in mixture**	**Range specified in Section 3**
Substance D	13.343%	10 - <15%
Substance E	6.915%	5 - <7%
Substance F	0.964%	0.25 - <2.5%
Substance G	0.396%	0.25 - <1%
Substance H	0.241%	<0.25%
Total	*Total concentration:* **21.859%**	*Total of highest concentrations:* **25.75%**
Classification and labelling based on calculation method[2]:	Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects	Aquatic Chronic 2 H411 Toxic to aquatic life with long lasting effects 

[2] *Generic concentration limit for classification of mixture as Aquatic Chronic 2 based on substances classified as Aquatic Chronic 2 only is 25%.*
Formula for classification of mixture as Aquatic Chronic 3 based on substances classified as Aquatic Chronic 2 only is (10 x Chronic 2) ≥ 25%.

Example 3:
Aquatic toxicity [Acute/]Chronic 2 *vs* Aquatic toxicity Acute/Chronic 1

Ingredient and classification	**Actual concentration in mixture**	**Range specified in Section 3**
Substance J Aq. Acute 1 and Chronic 1, M factor 100	0.1203%	<0.25%
Substance K Aq. Acute 1 and Chronic 1, M factor 10	0.0579%	<0.1%
Total	*Total concentration (taking M factors into account):* **For Acute/Chronic 1: 12.609%** **For Acute/Chronic 2: 126.09%**	*Total of highest concentrations (taking M factors into account):* **For Acute/Chronic 1: 26.00%**
Classification and labelling based on calculation method[3]:	Aquatic [Acute 2,][a] Chronic 2 [H401 Toxic to aquatic life] H411 Toxic to aquatic life with long lasting effects	Aquatic Acute 1, Chronic 1 Warning H400 Very toxic to aquatic life H410 Very toxic to aquatic life with long lasting effects 

[3] *Formula for classification of mixture as Aquatic Acute 1 or Chronic 1 based on substances classified as Aquatic Acute 1 or Chronic 1 only is* Σ *(Acute/Chronic 1 x M)* $\geq$ *25%.*

Formula for classification of mixture as Aquatic Acute 1 or Chronic 2 based on substances classified as Aquatic Acute 1 or Chronic 1 only is Σ *(M x 10 x Acute/Chronic 1)* $\geq$ *25%.*

[a] Note: this mixture was placed on the market in the European Union, where Aquatic Acute categories 2 and 3 are not implemented, so in practice it was classified and labelled as Aquatic Chronic 2 only.

Example 4: Not classified vs Acute toxicity (oral) Category 4

Ingredient and Acute Toxicity Estimate (oral)	**Actual concentration in mixture**	**Range specified in Section 3**
Substance N ATE = 500 mg/kg	11%	10-15%
Substance P ATE = 500 mg/kg	12%	10-15%
Calculated ATE_{mix} (oral):	**2174 mg/kg**	**1666 mg/kg** *based on highest concentrations of ranges*
Classification and labelling based on calculation method[4]:	Not classified[b] [or Acute Tox. Cat. 5 (oral) Warning H303 May be harmful if swallowed]	Acute Tox. Cat. 4 (oral) Warning H302 Harmful if swallowed 

[4] *Formula for calculation of Acute Toxicity Estimate for a mixture:* $100 / ATE_{mix} = \Sigma_n (C_i/ATE_i)$

ATE ranges for the oral route (in mg/kg bodyweight):

300 < Category 4 $\leq$ *2000*

2000 < Category 5 $\leq$ *5000 (where implemented).*

[b] Note: this mixture was placed on the market in the European Union, where Acute Toxicity Category 5 is not implemented, so in practice it was not classified or labelled.