



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 2 (k) of the provisional agenda

Work on the Globally Harmonized System of Classification and Labelling of Chemicals:

Other matters

Proposal to amend 4.1.3.6

Transmitted by the United Nations Institute for Training and Research (UNITAR)*

I. Introduction

1. At the forty-sixth session, UNITAR submitted informal document INF.18 with a proposal for amendment to 4.1.3.6. While there was support by some experts for the proposal, others did not support it, thus there was no consensus for replacing “toxicity” with “hazard”.
2. Based on feedback received since the forty-sixth session from several experts, UNITAR revised the proposal for amendment of paragraph 4.1.3.6 by addressing short-term and long-term hazards separately and consequently removing the reference to “acute and/or chronic aquatic toxicity”. Furthermore, the revised proposal now addresses the possibility of using adequate acute toxicity information with respect to long-term hazard classification as a surrogate method, for cases without available adequate chronic toxicity information.

II. Background

3. Paragraph 4.1.3.6 currently reads (**bold added for emphasis**):

“4.1.3.6 Classification of mixtures with ingredients without any useable information

“In the event that **no useable information on acute and/or chronic aquatic toxicity** is available for one or more relevant ingredients, it is concluded that **the mixture cannot be attributed (a) definitive hazard category(ies)**. In this situation the mixture should be classified based on the known ingredients only, with the additional statement that: **“× % of the mixture consists of ingredient(s) of unknown hazards**

* A/78/6 (Sect. 20), table 20.5.

to the aquatic environment". The competent authority can decide to specify that the additional statement is communicated on the label or on the SDS or both, or to leave the choice of where to place the statement to the manufacturer/supplier".

4. The current requirement is not aligned with the criteria in table 4.1.1 according to which classification of chronic hazard is also possible in the absence of adequate chronic toxicity data by using acute toxicity information in a surrogate method.

III. Justification

5. According to 4.1.2.1 "the short-term (acute) and long-term (chronic) classification categories are applied independently". Given that 4.1.2.1 specifically states that short-term (acute) and the long-term (chronic) categories are applied independently, it is now proposed that the % unknowns calculation should also be performed independently for the short-term hazard versus the long-term hazard. When the criteria for the long-term hazard (i.e. based on chronic aquatic toxicity data) were introduced in the third revised edition of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) it became possible that the percentage of ingredients with unknown hazards can be different between the short-term versus long-term hazard.

6. For classification of the short-term hazard, data on acute toxicity are necessary and sufficient. However, for classifying the long-term hazard there are two methods:

(a) chronic toxicity data can be used together with information on degradability; or

(b) in the case that adequate chronic toxicity data are not available, acute toxicity data together with information on degradability and/or bioaccumulation.

7. The current requirement in 4.1.3.6 is not in line with the criteria in table 4.1.1 (b)(iii) according to which classification of chronic hazard is also possible without adequate chronic toxicity data:

(iii) Substances for which adequate chronic toxicity data are not available

Category Chronic 1: (Note 2)

96 hr LC ₅₀ (for fish)	≤ 1 mg/l and/or
48 hr EC ₅₀ (for crustacea)	≤ 1 mg/l and/or
72 or 96hr ErC ₅₀ (for algae or other aquatic plants)	≤ 1 mg/l (Note 3)
and the substance is not rapidly degradable and/or the experimentally determined BCF is ≥ 500 (or, if absent, the log K _{ow} ≥ 4). (Notes 4 and 5)	

Category Chronic 2:

96 hr LC ₅₀ (for fish)	> 1 but ≤ 10 mg/l and/or
48 hr EC ₅₀ (for crustacea)	> 1 but ≤ 10 mg/l and/or
72 or 96hr ErC ₅₀ (for algae or other aquatic plants)	> 1 but ≤ 10 mg/l (Note 3)
and the substance is not rapidly degradable and/or the experimentally determined BCF is ≥ 500 (or, if absent, the log K _{ow} ≥ 4). (Notes 4 and 5)	

Category Chronic 3:

96 hr LC ₅₀ (for fish)	> 10 but ≤ 100 mg/l and/or
48 hr EC ₅₀ (for crustacea)	> 10 but ≤ 100 mg/l and/or
72 or 96hr ErC ₅₀ (for algae or other aquatic plants)	> 10 but ≤ 100 mg/l (Note 3)
and the substance is not rapidly degradable and/or the experimentally determined BCF is ≥ 500 (or, if absent, the log K _{ow} ≥ 4). (Notes 4 and 5).	

8. Thus, valid acute toxicity data together with information concerning degradation and bioaccumulation is usable information and are sufficient "...to attribute a definitive hazard category to a relevant ingredient..." also with respect to chronic hazards in the absence of adequate chronic toxicity data.

9. This procedure is also described in 4.1.2.7: "...Chronic toxicity data are not available for many substances, however, and in those cases, it is necessary to use the available data on acute toxicity to estimate this property."

10. Furthermore, in figure 4.1.1 (Categories for substances long-term hazardous to the aquatic environment) reference is made to table 4.1.1 (b)(iii) in order to classify in the absence of adequate chronic toxicity data by using adequate acute toxicity data.

IV. Proposal

11. Amend 4.1.3.6 as follows (*deleted text is shown in ~~strike through~~ and new text is shown in **bold underlined***):

4.1.3.6 Classification of mixtures with ingredients without any useable information

4.1.3.6.1 In the event that no useable information on ~~acute and/or chronic~~ aquatic toxicity is available for one or more relevant ingredients, it is concluded that the mixture **generally** cannot be attributed ~~(a) a~~ definitive hazard category~~(ies)~~. In this situation the mixture should be classified based on the known ingredients only, with the additional statement that: "× % of the mixture consists of ingredient(s) of unknown **short-term** hazards to the aquatic environment". ~~The competent authority can decide to specify that the additional statement is communicated on the label or on the SDS or both, or to leave the choice of where to place the statement to the manufacturer/supplier.~~

4.1.3.6.2 In the event that no useable information on chronic aquatic toxicity, or in its absence acute aquatic toxicity, is available for one or more relevant ingredients, it is concluded that the mixture generally cannot be attributed a definitive long-term hazard category. In this situation the mixture should be classified based on the known ingredients only, with the additional statement that: "× % of the mixture consists of ingredient(s) of unknown long-term hazards to the aquatic environment".

4.1.3.6.3. In the case where the additional statement on the percent unknowns can be applied for the short-term and for long-term hazard the statement can be combined to read: "The mixture consists of × % of ingredient(s) of unknown short-term and y % of long-term hazards to the aquatic environment.

4.1.3.6.4 The competent authority can decide to specify that the additional statement~~(s)~~ is communicated on the label or on the SDS or both, or to leave the choice of where to place the statement to the manufacturer."

12. To maintain alignment with 4.1.3.6 the following consequential amendments to footnotes 3 and 10 in decision logics 4.1.1 and 4.1.3 (c) are also proposed (*deleted text is shown in ~~strike through~~ and new text is shown in **bold underlined***):

- Decision logic 4.1.1, footnote 3, first sentence (the rest of the text remains unchanged):

³ *If not all ingredients have **useable** information, include the statement "× % of the mixture consists of ingredient(s) of unknown **short-term** hazard to the aquatic environment" **according to 4.1.3.6.**"*

- Decision logic 4.1.3 (c), footnote 10:

¹⁰ In the event that no useable information on ~~acute and/or~~ chronic aquatic toxicity **or in its absence acute aquatic toxicity**, is available for one or more relevant ingredients, it is concluded that the mixture cannot be attributed ~~(a) a~~ definitive **long-term** hazard category~~(ies)~~. In this situation the mixture should be classified based on the known ingredients only, with the additional statement that: "× % of the mixture consists of ingredient(s) of unknown **long-term** hazards to the aquatic environment" **according to 4.1.3.6.** The competent authority can decide to specify that the additional statement be communicated on the label or on the SDS or both, or to leave the choice of where to place the statement to the manufacturer/supplier."

V. Action requested

13. The Sub-Committee is invited to consider the proposals in paragraphs 11 and 12 above.
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