



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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Item 10 (b) of the provisional agenda

**Issues relating to the Globally Harmonized System
of Classification and Labelling of Chemicals (GHS):
clarification of 2.9.3.4.3.4 of the Model Regulations
and 4.1.3.3.4 of the GHS**

Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals

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Item 2 (c) of the provisional agenda

**Classification criteria and related hazard communication:
Clarification of 2.9.3.4.3.4 of the Model Regulations and
4.1.3.3.4 of the GHS**

Clarification of 2.9.3.4.3.4 of Model Regulations and 4.1.3.3.4 of GHS

Transmitted by the expert from China*

Introduction

1. The purpose of this document is to invite the TDG and GHS sub-committees to reconsider the text for the classification of the long-term (chronic) aquatic environmental hazard of mixtures in the Model Regulations and GHS. At the previous session, the expert from China submitted informal documents INF.12 (56th session) and INF.11 (38th session). Following the discussion, the sub-committees invited the expert from China to submit a formal document for this session (57th TDG and 39th GHS).

2. Paragraph 2.9.3.4 of the Model Regulations was paraphrased from section 4.1.3 of GHS. In GHS, the short-term (acute) aquatic hazard (this term is phrased as “acute (short-term) aquatic hazard” in the Model Regulations) of mixtures hazardous to the aquatic environment has three categories, i.e. Acute 1, 2 and 3, while the long-term (chronic) aquatic hazard (this term is phrased as “long-term aquatic hazard” in the Model Regulations.) can be classified as Chronic 1, 2, 3 and 4 (see Table 4.1.1 in GHS). However, in the Model Regulations, only one acute (short-term) aquatic hazard category (category Acute 1) and two long-term aquatic hazard categories (categories Chronic 1 and 2) exist (see Table 2.9.1 in the Model Regulations). In other words, there are no categories corresponding to Chronic 3 and 4 in GHS listed in the Model Regulations.

* 2020 (A/74/6 (Sect.20) and Supplementary, Subprogramme 2).

3. Paragraph 2.9.3.4.3.4 of the Model Regulations describe the classification of Chronic 1 and 2 of mixtures hazardous to the aquatic environment. When there are adequate chronic toxicity data (ECx or NOEC) available for the mixture as a whole, showing ECx or NOEC of the tested mixture less than or equal to 1 mg/l, the mixture can be classified as category Chronic 1 or 2 in accordance with Table 2.9.1 (b) (ii) (rapidly degradable) or Table 2.9.1 (b) (i) (non-rapidly degradable). However, according to Table 2.9.1 (b) (ii) (rapidly degradable), mixtures consisting only of relevant ingredients which are themselves rapidly degradable should be classified as category Chronic 1 or 2, only when ECx or NOEC \leq 0.1 mg/l. The wording in 2.9.3.4.3.4 (a) (i) can easily cause a misunderstanding i.e., that the mixture has to be classified as either category Chronic 1 or 2, as long as ECx or NOEC of the tested mixture is less than or equal to 1 mg/l. We consider that the classification information described in 2.9.3.4.3.4 and that listed in Table 2.9.1 (b) (ii) are not consistent. Mixtures consisting only of relevant ingredients which are themselves rapidly degradable and having ECx or NOEC $>$ 0.1 mg/l but \leq 1 mg/l might not be classified properly based on the current text in 2.9.3.4.3.4.

4. Paragraph 4.1.3.3.4 of the GHS describes the classification for categories chronic 1, 2 and 3 of mixture hazardous to the aquatic environment when there are adequate chronic toxicity data (ECx or NOEC) available for the mixture as a whole showing ECx or NOEC of the tested mixture less than or equal to 1mg/l. In 4.1.3.3.4 (ii), it mentioned that the mixture can be classified as category Chronic 1, 2 or 3 in all other cases in accordance with Table 4.1.1 (b) (i) (non-rapidly degradable). However, according to Table 4.1.1 (b) (i) (non-rapidly degradable), when ECx or NOEC of the tested mixture is less than or equal to 1mg/l, the mixture can only be classified as category Chronic 1 or 2, does not contain category Chronic 3, the classification information is inconsistent and there is no need to mention Chronic 3 in 4.1.3.3.4 (ii).

5. During the discussion of informal document INF.12 (TDG, 56th session)- INF.11 (GHS, 30th session), the expert from the United Kingdom kindly pointed out that the statement of “rapidly degradable mixtures” in the informal document was inaccurate, considering the difficulties in determining whether the whole mixture is rapidly degradable or not. The proposal in paragraph 6 below takes account of this comment.

Proposal

6. The expert from China proposes the following two options to amend 2.9.3.4.3.4 in the Model Regulations (deleted text is ~~struck through~~; new text is underlined):

Option 1

“2.9.3.4.3.4 Classification for categories Chronic 1 and 2

- (a) When there are adequate chronic toxicity data (ECx or NOEC) available for the mixture as a whole showing ECx or NOEC of the tested mixture \leq 1 mg/l:
 - (i) classify the mixture as Chronic 1 or 2 in accordance with Table 2.9.1(b)(ii) (rapidly degradable) if the available information allows the conclusion that all relevant ingredients of the mixture are rapidly degradable;

NOTE: For whole mixture consisting only of relevant ingredients which are themselves rapidly degradable and having ECx or NOEC values $>$ 0.1 mg/l, there is no need to classify the mixture for long-term aquatic hazard under these Regulations.

- (ii) classify the mixture as Chronic 1 or 2 in all other cases in accordance with Table 2.9.1(b)(i) (non-rapidly degradable);
- (b) When there are adequate chronic toxicity data (EC_x or NOEC) available for the mixture as a whole showing EC_x(s) or NOEC(s) of the tested mixture > 1mg/l or above the water solubility:

No need to classify for long-term hazard under these Regulations.”

Option 2

“2.9.3.4.3.4 Classification for categories Chronic 1 and 2

- (a) When there are adequate chronic toxicity data (EC_x or NOEC) available for the mixture as a whole, showing EC_x or NOEC of the tested mixture ≤ 1mg/l:
 - (i) classify the mixture as Chronic 1 or 2 in accordance with Table 2.9.1(b)(ii) (rapidly degradable) if the available information allows the conclusion that all relevant ingredients of the mixture are rapidly degradable;

NOTE: In this situation, when EC_x or NOEC of the tested mixture > 0.1 mg/l, there is no need to classify for long-term hazard under these Regulations.

- (ii) classify the mixture as Chronic 1 or 2 in all other cases in accordance with Table 2.9.1(b)(i) (non-rapidly degradable);
- (b) When there are adequate chronic toxicity data (EC_x or NOEC) available for the mixture as a whole showing EC_x(s) or NOEC(s) of the tested mixture > 1mg/l or above the water solubility:

No need to classify for long-term hazard under these Regulations.”

7. The GHS Sub-Committee is invited to consider if the text of long-term (chronic) hazard classification of mixture in 4.1.3.3.4 of GHS should be revised. We propose to amend paragraph 4.1.3.3.4 of GHS to read as follows (deleted text is ~~struck through~~; new text is underlined):

“4.1.3.3.4 Classification for categories Chronic 1, 2 and 3

- (a) When there are adequate chronic toxicity data (EC_x or NOEC) available for the mixture as a whole showing EC_x or NOEC of the tested mixture ≤ 1 mg/l:
 - (i) Classify the mixture as Chronic 1, 2 or 3 in accordance with Table 4.1.1(b)(ii) (rapidly degradable) if the available information allows the conclusion that all relevant ingredients of the mixture are rapidly degradable;
 - (ii) Classify the mixture as Chronic 1 or 2 ~~or 3~~ in all other cases in accordance with Table 4.1.1 (b)(i) (non-rapidly degradable);
- (b) When there are adequate chronic toxicity data (EC_x or NOEC) available for the mixture as a whole showing EC_x(s) or NOEC(s) of the tested mixture > 1 mg/l or above the water solubility:

No need to classify for long-term (chronic) hazard, unless there are nevertheless reasons for concern.”