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Issues relating to the Globally Harmonized System of Classification and Labelling of Chemicals: Miscellaneous

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

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Classification criteria and related hazard communication: Other issues

Clarification of paragraph 2.9.3.4.3.4 of Model Regulations and paragraph 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 chronic (long-term) aquatic environmental hazard of mixtures in the "Model Regulations" and GHS.
- 2. Paragraph 2.9.3.4 of the "Model Regulations" was paraphrased from section 4.1.3 of GHS. In GHS, the acute (short term) aquatic hazard of mixtures hazardous to the aquatic environment is classified as three categories, i.e. Category Acute 1, 2 and 3, while the long-term (chronic) hazard is classified as Category Chronic 1,2,3 and 4 (see Table 4.1.1 in GHS). However, in the "Model Regulations", only one acute (short term) hazard category (Category Acute 1) and two long-term hazard categories (Category Chronic 1 and 2) exist (see Table 2.9.1 in the "Model Regulations"). In another word, there were no categories corresponding to Chronic 3 and 4 in GHS listed in the "Model Regulations".
- 3. Paragraph 2.9.3.4.3.4 of the "Model Regulations" describes 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 $\leq 1 \text{mg/l}$, 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), rapid degradable mixtures should be classified as Category Chronic 1 or 2, only when ECx or NOEC $\leq 0.1 \text{ mg/l}$. The wording in the 2.9.3.4.3.4(a) (i) can easily cause a misunderstanding, that the mixture has to be classified as either Category Chronic 1 or 2, as long as ECx or NOEC of the tested mixture $\leq 1 \text{mg/l}$. We regarded that the classification information described in paragraph 2.9.3.4.3.4 and that listed in Table 2.9.1 (b) (ii) are not consistent. Rapidly degradable mixtures with ECx or NOEC > 0.1 mg/l but $\leq 1 \text{ mg/l}$ might not be classified properly based on the current text in paragraph 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 $\leq 1 \text{mg/l}$. In (ii) of paragraph 4.1.3.3.4, 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 $\leq 1 \text{mg}$ / 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 paragraph 4.1.3.3.4 (ii).

Proposals

- 5. The expert from China proposes to amend paragraph 2.9.3.4.3.4 in the "Model Regulations" as below (deleted text is struck through; new text is underlined), to eliminate the current inconsistence and ambiguity.
- "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 ≤ 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: For rapidly degradable mixtures with ECx or NOEC > 0.1 mg/l, 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 (ECx or NOEC) available for the mixture as a whole showing ECx(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.

- 6. The GHS Sub-Committee is invited to consider if the text of chronic hazard classification of mixture in paragraph 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 (ECx or NOEC) available for the mixture as a whole showing ECx or NOEC of the tested mixture ≤ 1mg/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<u>or</u>, 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 (ECx or NOEC) available for the mixture as a whole showing ECx(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.".