UPDATING OF THE SECOND REVISED EDITION OF THE GLOBALLY HARMONIZED SYSTEM OF CLASSIFICATION AND LABELLING OF CHEMICALS (GHS)

Health hazards

Proposal for amendment of decision logics 3.8.1 and 3.8.2:
(specific target organ toxicants, single exposure)

Transmitted by the experts from Germany, Australia, and the United States of America

1. The Annex to this paper is a proposed revised Decision Logic for Chapter 3.8 (specific target organ toxicity, single exposure).

2. The purposes of the revisions are:
   
   (a) To clarify that a chemical already classified as Category 1 or 2 for specific target organ toxicity, single exposure (e.g., for liver or kidney damage) should also be evaluated and may be classified as Category 3 for transient narcotic effects and/or respiratory damage. See document ST/SG/AC.10/C.4/2008/3 (Germany).
   
   (b) To clarify that chemical substances and mixtures may be classified as Category 3 for both respiratory irritation and transient narcotic effects, if the relevant criteria are met. See document UN/SCEGHS/15/INF.19 (Australia)
   
   (c) To clarify that more severe respiratory effects and effects on the central nervous system that are not transient should result in classification as Category 1 or 2 for these effects.

The changes are to (1) add “transient” as shown on next page,(2) insert a new footnote 1 to read as follows:

1 Classification in Category 3 would only occur when classification into Category 1 or Category 2 (based on more severe respiratory effects or narcotic effects that are not transient) is not warranted. See 3.8.2.2.1(e) (respiratory effects) and 3.8.2.2.2(b) (narcotic effects).

(Renumber other footnotes accordingly.)
3.8.5.1  Decision logic 3.8.1

**Substance:** Does the substance have data and/or information to evaluate specific target organ toxicity following single exposure?

- Yes
  - **Mixture:** Does the mixture as a whole or its ingredients have data/information to evaluate specific target organ toxicity following single exposure?
    - Yes
      - Following single exposure, can the substance or mixture produce significant toxicity in humans, or can it be presumed to have the potential to produce significant toxicity in humans on the basis of evidence from studies in experimental animals? See 3.8.2 for criteria and guidance values. Application of the criteria needs expert judgment in a weight of evidence approach.
    - No
      - Following single exposure, can the substance or mixture be presumed to have the potential to be harmful to human health on the basis of evidence from studies in experimental animals? See 3.8.2 for criteria and guidance values. Application of the criteria needs expert judgment in a weight of evidence approach.
  - No
    - Following single exposure, can the substance or mixture produce transient narcotic effects or respiratory tract irritation or both? See 3.8.2 and 3.8.3 for criteria. Application of the criteria needs expert judgment in a weight of evidence approach.

**Classification:**
- Category 1: Danger
- Category 2: Warning
- Category 3: Warning
- Not classified

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1. Classification in Category 3 would only occur when classification into Category 1 or Category 2 (based on more severe respiratory effects or narcotic effects that are not transient) is not warranted. See 3.8.2.2.1(e) (respiratory effects) and 3.8.2.2.2(b) (narcotic effects).
3.8.5.2 **Decision logic 3.8.2**

Can bridging principles, as in 3.8.3.3, be applied?

- **No**
  - Does the mixture contain one or more ingredients classified as a Category 1 specific target organ toxicant at a concentration of $\geq 1\%$?
    - Yes
      - Does the mixture contain one or more ingredients classified as a Category 1 specific target organ toxicant at a concentration of $\geq 10\%$?
        - Yes
          - **Category 1 Danger**
        - **No**
          - **Category 2 Warning**
    - **No**
      - Does the mixture contain one or more ingredients classified as a Category 2 specific target organ toxicant at a concentration of $\geq 1.0$ and $< 10\%$?
        - Yes
          - **Category 2 Warning**
        - **No**
          - **Category 3 Warning**
    - **No**
      - **Not classified**

Does the mixture contain one or more ingredients classified as a Category 3 specific target organ toxicant at a concentration $\geq 20\%$? See 3.8.3.4.5. Care should be exercised when classifying such mixtures.

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2.2 See 3.8.2 of this Chapter and “The use of cut-off values/concentration limits” in Chapter 1.3, para 1.3.3.2.
2.3 See 3.8.3.4 and Table 3.8.2 for explanation and guidance.