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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 **6 December 2021**

Forty-first session
Geneva, 8-10 December 2021
Item 2 (f) of the provisional agenda
Work on the Globally Harmonized System (GHS): Practical classification issues (proposed amendments to the GHS)

Status report and proposal to address issues from the programme of work for the practical classification issues informal correspondence group

Transmitted by the expert from the United States of America on behalf of the practical classification issues informal correspondence group

Purpose

1. This informal document provides an update on the work undertaken by the Practical Classification Issues (PCI) informal correspondence group since the July 2021 Sub-Committee meeting and also includes a proposal to address issues from the PCI programme of work.

Status report

2. The PCI has been on hiatus since the July Sub-Committee meeting. However, the working group is now active and looking forward to continuing work on issues from its programme of work.

Proposal to address issues from the programme of work

3. Following up on the status report provided at the 40th session (INF.20), the U.S. has developed guidance and examples to address the conversion of inhalation toxicity values for test data with exposure times other than 1 hour. The guidance is provided in the annex of this document.

4. The following key principles were agreed on by the working group and were used to develop the guidance and examples.

(a) A default value of 2 is specified for n when using the ten Berge equation, but if additional information is available to indicate that 1 or 3 is more appropriate, then that value should be used.

(b) Two equations are included: one for gases and vapours and one for dusts and mists.

(c) The term “fume” is not included in this guidance.

(d) The guidance indicates that generally accepted exposure times for conversion are 30 minutes to 8-hour exposures.

Additionally, the U.S. agreed to examine how formulas and examples are presented in the physical hazard guidance sections and then to follow the same approach when developing this proposal.

5. The PCI informal working group will establish a recuring series of virtual meetings starting in early 2022 to further progress this issue and other items from our program of work.

Annex

Work item (c) from the PCI Programme of work (INF.31, 39th session)

GHS paragraph 3.1.2.6.1 provides guidance on how to convert experimental inhalation toxicity values for tests using a 1-hour exposure to a 4-hour equivalent for gases, vapours, dusts and mists. However, there is no guidance for tests using other exposure times (e.g. studies with 3- or 6-hour exposure times). Consider providing guidance to paragraph 3.1.2.6.1 to address the conversion of inhalation toxicity values for tests using exposure times other than 1 hour.

Proposal

Update to Chapter 3.1

"**3.1.2.6** ***Specific considerations for inhalation toxicity***

3.1.2.6.1 Values for inhalation toxicity are based on 4 hours tests in laboratory animals. When experimental values are taken from tests using a 1-hour exposure, they can be converted to a 4-hour equivalent by dividing the 1-hour value by a factor of 2 for gases and vapours and 4 for dusts and mists. Guidance on the conversion of experimental values for times other than a 1-hour exposure is provided in 3.1.5.3."

New guidance text to be placed after the decision logics

"**3.1.5.3** ***Guidance***

The ATE values used for inhalation toxicity classification in Table 3.1.1 are based on a 4-hour experimental exposure in laboratory animals (3.1.2.6.1). Existing inhalation LC_{50} values obtained in studies using exposure times other than 1 hour (3.1.2.6.1) can be adjusted to a 4-hour exposure using the ten Berge equation (C^n x t = k) for gases and vapors and Haber's law (C x t =k) for dusts and mists, as follows:

Formula for gases and vapours

$$LC_{50}(4\ \text{hours}) = \left(\frac{C^n\ x\ t}{4}\right)^{1/n}$$

where:

C	=	LC_{50} concentration for exposure duration t
n	=	chemical-specific exponent
t	=	exposure duration for C

Formula for dusts and mists

$$LC_{50}(4\ \text{hours}) = \frac{C\ x\ t}{4}$$

where:

C	=	LC_{50} concentration for exposure duration t
n	=	chemical-specific exponent
t	=	exposure duration for C

A default value of 2 is used for n unless additional conclusive information is available to indicate that a value of 1 or 3 is more appropriate. The accepted exposure times for conversion are from 30 minutes to 8-hour exposures. Data with exposure durations greater than 8 hours should not be converted because longer durations are not considered a short-term exposure.

Examples: classification using calculated 4-hour LC_{50} values

Substance (liquid)

1. For the purpose of this example the substance has an experimental 6-hour vapour LC_{50} = 13.6 mg/l
2. No additional information on n is available so the default value (n = 2) will be used.

Criterion:

$$\mathrm{LC}_{50}(4\ \mathrm{hours}) = \left(\frac{C^n\ x\ t}{4}\right)^{\mathbf{1/n}}$$

Calculation

$$\mathrm{LC}_{50}(4\ \mathrm{hours}) = \left(\frac{C^n\ x\ t}{4}\right)^{\frac{\mathbf{1}}{\boldsymbol{n}}} = \left(\frac{13.6^2\ x\ 6}{4}\right)^{\frac{\mathbf{1}}{\mathbf{2}}} = \mathbf{16.7}$$

Therefore, the substance is classified into Category 4 based on the vapours Category 4 criteria (10.0 < ATE ≤ 20.0) from Table 3.1.1.

Substance (solid)

For the purpose of this example the substance has an experimental 2-hour dust LC_{50} = .26 mg/l

Criterion:

$$\mathrm{LC}_{50}(4\ \mathrm{hours}) = \frac{\mathrm{C\ x\ t}}{4}$$

Calculation

$$\mathrm{LC}_{50}(4\ \mathrm{hours}) = \frac{\mathrm{C\ x\ t}}{4} = \frac{.26\ \mathrm{x}\ 2}{4} = 0.13$$

Therefore, the substance is classified into Category 2 based on the dusts and mists Category 2 criteria (0.05 < ATE ≤ 0.5) from Table 3.1.1.