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

Health hazards

Proposal for amendment of Table 3.1.2 (Chapter 3.1)

Transmitted by the expert from Germany

As the GHS is already implemented in some countries and will be implemented in several regions in the year to come, it appears that comprehensibility and feasibility are prerequisites to establish harmonized procedures in classification and labelling.

In the course of gaining experience with the GHS criteria, a problem was identified when applying the criteria supplied with GHS Table 3.1.2. It was recognized that when using the converted acute toxicity point estimate (cATpe) values for calculating the acute toxicity of mixtures Category 1 classification of a mixture containing 100% Category 2 ingredients may result. The same situation is given for Category 3 inhalation of dust/mist, resulting in a Category 2 classification.

This document contains the proposal for an amendment of GHS Table 3.1.2, page 113 of second revised edition of the GHS, as a consequence of analysis of the accompanying NOTE 2.

Background

1. Using the converted acute toxicity point estimate (cATpe) values for calculating the acute toxicity of mixtures provided in the UN GHS (second revised version 2007) the values given for Category 2 substances may result in Category 1 classification of a mixture containing 100% Category 2 ingredients. The same situation is given for Category 3 inhalation of dust/mist, resulting in a Category 2 classification. This is a result of the respective cATpe equalling the upper limit of the next higher category.

2. This problem may be relevant in practice in situations where data from acute toxicity range tests (e.g. Fixed Dose Method, OECD 420) are used. For example, the described problem arises in case there is a 2-ingredient mixture containing one substance with acute toxicity range test data only and another substance contained in a portion of >10% and having an unknown acute toxicity (especially relevant for dermal and inhalative acute toxicity). Moreover, the problem may also be relevant in case there are no ATE values available for the considered exposure route and the respective cATpe is used after route-to-route extrapolation.

Examples: 100% Cat 2 or 3 ingredients in a mixture:

$cATpe_{oral}$ Cat 2 = 5	ATEmix = 100 / (100/5) = 5 → Classification in Cat 1
$cATpe_{dust/mist}$ Cat 3 = 0.5	ATEmix = 100 / (100/0.5) = 0.5 → Classification in Cat 2

3. The accompanying note 2 to table 3.1.2 includes the following text: *"… The values are conservatively set at the lower end of the range of Categories 1 and 2, and at a point approximately 1/10th from the lower end of the range for Categories 3-5."*

4. These values at a point approximately 1/10th from the lower end of the range can be calculated as follows: "the range" equals the difference of the upper (U) and the lower (L) limit, i.e. range = U-L. "At a point 1/10th from the lower end" therefore means L+[(U-L)/10] in mathematical terms.

5. The problem described above could be solved by generally applying the idea of Note 2, i.e. setting values at a point approximately 1/10th from the lower end of the range for all categories (see following table A).

Table A: Following the procedure given in points 4-5 of the background information, the calculation results using the cATpe values in Table 3.1.2 will be:

	lower limit (L)	upper limit (U)	cATpe now	cATpe calculated L+((U-L)/10)
oral 1	0	5	0.5	0.5
oral 2	5	50	5	9.5
oral 3	50	300	100	75
oral 4	300	2000	500	470
oral 5	2000	5000	2500	2300
dermal 1	0	50	5	5
dermal 2	50	200	50	65
dermal 3	200	1000	300	280
dermal 4	1000	2000	1100	1100
dermal 5	2000	5000	2500	2300
gas 1	0	100	10	10
gas 2	100	500	100	140
gas 3	500	2500	700	700
gas 4	2500	20000	4500	4250
vapor 1	0	0.5	0.05	0.05
vapor 2	0.5	2	0.5	0.65
vapor 3	2	10	3	2.8
vapor 4	10	20	11	11
dust/mist 1	0	0.05	0.005	0.005
dust/mist 2	0.05	0.5	0.05	0.095
dust/mist 3	0.5	1	0.5	0.55
dust/mist 4	1	5	1.5	1.4

Proposal for consequential amendments in GHS Table 3.1.2 and Note 2

1. GHS Table 3.1.2; amended according to the proposal: the calculated changed cATpe values (see table A) were rounded for simplicity and are indicated by a circle. cATpe values without circle around represent the current GHS criteria.

2.

Exposure route	Range - Category	cATpe
Oral [mg/kg bw]	0 < Category 1 ≤ 5	0.5
	5 < Category 2 ≤ 50	(10)
	50 < Category 3 ≤ 300	100
	300 < Category 4 ≤ 2000	500
	2000 < Category 5 ≤ 5000	2500
Dermal [mg/kg bw]	0 < Category 1 ≤ 50	5
	50 < Category 2 ≤ 200	(70)
	200 < Category 3 ≤ 1000	300
	1000 < Category 4 ≤ 2000	1100
	2000 < Category 5 ≤ 5000	2500
Gas [ppm]	0 < Category 1 ≤ 100	10
	100 < Category 2 ≤ 500	(140)
	500 < Category 3 ≤ 2500	700
	2500 < Category 4 ≤ 20000	4500
Vapors [mg/l]	0 < Category 1 ≤ 0.5	0.05
	0.5 < Category 2 ≤ 2.0	(0.7)
	2.0 < Category 3 ≤ 10.0	3
	10.0 < Category 4 ≤ 20.0	11
Dust/Mist [mg/l]	0 < Category 1 ≤ 0.05	0.005
	0.05 < Category 2 ≤ 0.50	(0.10
	0.5 < Category 3 ≤ 1.0	0.6)
	1.0 < Category 4 ≤ 5.0	1.5

NOTE 2: *These values are designed to be used in the calculation of the ATE for classification of a mixture based on its components and do not represent test results. The values are conservatively set ~~at the lower end of the range of Categories 1 and 2, and~~ at a point approximately 1/10th from the lower end of the range for each Category ~~ies 3 – 5~~.*