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:

\[\text{cATpe}_{\text{oral}} \text{ Cat 2} = 5 \quad \text{ATEmix} = 100 / (100/5) = 5 \rightarrow \text{Classification in Cat 1}\]
\[\text{cATpe}_{\text{dust/mist}} \text{ Cat 3} = 0.5 \quad \text{ATEmix} = 100 / (100/0.5) = 0.5 \rightarrow \text{Classification in Cat 2}\]
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 $1/10^{th}$ from the lower end of the range for Categories 3-5.”

4. These values at a point approximately $1/10^{th}$ 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 $1/10^{th}$ 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 $1/10^{th}$ 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:

<table>
<thead>
<tr>
<th></th>
<th>lower limit (L)</th>
<th>upper limit (U)</th>
<th>cATpe now</th>
<th>cATpe calculated</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>L+((U-L)/10)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>oral 1</td>
<td>0</td>
<td>5</td>
<td>0.5</td>
<td>0.5</td>
</tr>
<tr>
<td>oral 2</td>
<td>5</td>
<td>50</td>
<td>5</td>
<td>9.5</td>
</tr>
<tr>
<td>oral 3</td>
<td>50</td>
<td>300</td>
<td>100</td>
<td>75</td>
</tr>
<tr>
<td>oral 4</td>
<td>300</td>
<td>2000</td>
<td>500</td>
<td>470</td>
</tr>
<tr>
<td>oral 5</td>
<td>2000</td>
<td>5000</td>
<td>2500</td>
<td>2300</td>
</tr>
<tr>
<td>dermal 1</td>
<td>0</td>
<td>50</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>dermal 2</td>
<td>50</td>
<td>200</td>
<td>50</td>
<td>65</td>
</tr>
<tr>
<td>dermal 3</td>
<td>200</td>
<td>1000</td>
<td>300</td>
<td>280</td>
</tr>
<tr>
<td>dermal 4</td>
<td>1000</td>
<td>2000</td>
<td>1100</td>
<td>1100</td>
</tr>
<tr>
<td>dermal 5</td>
<td>2000</td>
<td>5000</td>
<td>2500</td>
<td>2300</td>
</tr>
<tr>
<td>gas 1</td>
<td>0</td>
<td>100</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>gas 2</td>
<td>100</td>
<td>500</td>
<td>100</td>
<td>140</td>
</tr>
<tr>
<td>gas 3</td>
<td>500</td>
<td>2500</td>
<td>700</td>
<td>700</td>
</tr>
<tr>
<td>gas 4</td>
<td>2500</td>
<td>20000</td>
<td>4500</td>
<td>4250</td>
</tr>
<tr>
<td>vapor 1</td>
<td>0</td>
<td>0.5</td>
<td>0.05</td>
<td>0.05</td>
</tr>
<tr>
<td>vapor 2</td>
<td>0.5</td>
<td>2</td>
<td>0.5</td>
<td>0.65</td>
</tr>
<tr>
<td>vapor 3</td>
<td>2</td>
<td>10</td>
<td>3</td>
<td>2.8</td>
</tr>
<tr>
<td>vapor 4</td>
<td>10</td>
<td>20</td>
<td>11</td>
<td>11</td>
</tr>
<tr>
<td>dust/mist 1</td>
<td>0</td>
<td>0.05</td>
<td>0.005</td>
<td>0.005</td>
</tr>
<tr>
<td>dust/mist 2</td>
<td>0.05</td>
<td>0.5</td>
<td>0.05</td>
<td>0.095</td>
</tr>
<tr>
<td>dust/mist 3</td>
<td>0.5</td>
<td>1</td>
<td>0.5</td>
<td>0.55</td>
</tr>
<tr>
<td>dust/mist 4</td>
<td>1</td>
<td>5</td>
<td>1.5</td>
<td>1.4</td>
</tr>
</tbody>
</table>
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. |
<table>
<thead>
<tr>
<th>Exposure route</th>
<th>Range - Category</th>
<th>cATpe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral [mg/kg bw]</td>
<td>0 &lt; Category 1 ≤ 5</td>
<td>0.5</td>
</tr>
<tr>
<td></td>
<td>5 &lt; Category 2 ≤ 50</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>50 &lt; Category 3 ≤ 300</td>
<td>100</td>
</tr>
<tr>
<td></td>
<td>300 &lt; Category 4 ≤ 2000</td>
<td>500</td>
</tr>
<tr>
<td></td>
<td>2000 &lt; Category 5 ≤ 5000</td>
<td>2500</td>
</tr>
<tr>
<td>Dermal [mg/kg bw]</td>
<td>0 &lt; Category 1 ≤ 50</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>50 &lt; Category 2 ≤ 200</td>
<td>70</td>
</tr>
<tr>
<td></td>
<td>200 &lt; Category 3 ≤ 1000</td>
<td>300</td>
</tr>
<tr>
<td></td>
<td>1000 &lt; Category 4 ≤ 2000</td>
<td>1100</td>
</tr>
<tr>
<td></td>
<td>2000 &lt; Category 5 ≤ 5000</td>
<td>2500</td>
</tr>
<tr>
<td>Gas [ppm]</td>
<td>0 &lt; Category 1 ≤ 100</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>100 &lt; Category 2 ≤ 500</td>
<td>140</td>
</tr>
<tr>
<td></td>
<td>500 &lt; Category 3 ≤ 2500</td>
<td>700</td>
</tr>
<tr>
<td></td>
<td>2500 &lt; Category 4 ≤ 20000</td>
<td>4500</td>
</tr>
<tr>
<td>Vapors [mg/l]</td>
<td>0 &lt; Category 1 ≤ 0.5</td>
<td>0.05</td>
</tr>
<tr>
<td></td>
<td>0.5 &lt; Category 2 ≤ 2.0</td>
<td>0.7</td>
</tr>
<tr>
<td></td>
<td>2.0 &lt; Category 3 ≤ 10.0</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>10.0 &lt; Category 4 ≤ 20.0</td>
<td>11</td>
</tr>
<tr>
<td>Dust/Mist [mg/l]</td>
<td>0 &lt; Category 1 ≤ 0.05</td>
<td>0.005</td>
</tr>
<tr>
<td></td>
<td>0.05 &lt; Category 2 ≤ 0.50</td>
<td>0.10</td>
</tr>
<tr>
<td></td>
<td>0.5 &lt; Category 3 ≤ 1.0</td>
<td>0.6</td>
</tr>
<tr>
<td></td>
<td>1.0 &lt; Category 4 ≤ 5.0</td>
<td>1.5</td>
</tr>
</tbody>
</table>

**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 3–5.