

Concentration cut-offs for disregarding substances in mixture classification

Find the applicable cut-off concentration per hazard class/category in the table below. Please note: There are some substances with a substance-specific cut-off value < 0.1%. These substances are to be treated case by case, and always require an in-depth assessment. The same may apply to substances with identified hazards, for which however classification criteria do not exist.

| Hazard class and category | Concentration cut off % |
|--|-------------------------|
| Acute toxicity, category 1, 2 and 3 | ≥ 0,1 |
| Acute toxicity, category 4 | ≥ 1 |
| Skin corrosion/irritation, category 1, categories 1A, 1B, 1C and category 2 | ≥ 1 |
| Serious damage to eyes/eye irritation, category 1 and 2 | ≥ 1 |
| Respiratory sensitiser category 1 or category 1B | ≥ 1 |
| Respiratory sensitiser category 1A | ≥ 0.1 |
| Skin sensitiser category 1 or category 1B | ≥ 1 |
| Skin sensitiser category 1A | ≥ 0.1 |
| Germ cell mutagenicity category 1A and 1B | ≥ 0,1 |
| Germ cell mutagenicity category 2 | ≥ 1 |
| Carcinogenicity category 1A, 1B and 2 | ≥ 0,1 |
| Reproductive toxicity, category 1A, 1B, 2 and effects on or via lactation | ≥ 0,1 |
| Specific target organ toxicity (STOT) - single exposure, category 1, 2 and 3 | ≥ 1 |
| Specific target organ toxicity (STOT) - repeated exposure, category 1 and 2 | ≥ 1 |
| Aspiration toxicity | ≥ 1 |
| Hazardous to the aquatic environment – Acute, category 1 | ≥ 0,1/M-Factor |
| Hazardous to the aquatic environment – Chronic, category 1 | ≥ 0,1/M-Factor |
| Hazardous to the aquatic environment – Chronic, category 2, 3 and 4 | ≥ 1 |
| Hazardous for the ozone layer | ≥ 0,1 |

Explanation on the origin of the table: The table is copied (with some modification regarding sensitisers and aquatic category 1 toxicants) from REACH Annex II point 3.2.1, which states: *For a mixture meeting the criteria for classification in accordance with Regulation (EC) No 1272/2008, the following substances (see also Table 1.1) shall be indicated.* The table refers to the concentrations above which an ingredient-substance must be taken into account for a mixture classification and safety data provision on request (see specifications referring Regulation (EC) No 1272/2008 under point 3.2.1 of REACH Annex II).

Note 1: *For sensitisers, the table has been modified regarding the cut-offs addressing elicitation. As not directly related to mixture classification, these cut-offs have been removed. The table has been also modified regarding environmental category 1 hazards, for which the M-factor must be applied to determine a substance-specific cut-off.*

Note 2: *for any substance classified for the environment as 'Acute Category 1' or 'Chronic Category 1', 0.1% is to be divided by the M-Factor to determine the substance-specific cut-off.*