Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Health and environmental hazards

Working definitions (substance, mixture and alloy)

Substance

Chemical elements and their compounds in the natural state or obtained by any production process

(The definition of substance includes any additive necessary to preserve the stability of the product and any impurities deriving from the process used, but excludes any solvent which may be separated without affecting the stability of the substance or changing its composition)

Mixture

Mixtures or solutions composed of two or more substances in which they do not react.

Alloy

A metallic material, homogeneous on a macroscopic scale, consisting of two or more elements so combined that they cannot be readily separated by mechanical means.

(Alloys are considered to be mixtures for the purpose of classification under the GHS)

Classification criteria for mixtures

- Based on the classification criteria for substances
- Consider the classification of any impurities, additives or individual constituents of a substance which have been identified, if they exceed the cut-off value/concentration limit for a given hazard class.

Normally,

the harmonized cut-off value/concentration limit is to be applied in all jurisdictions and for all sectors

However…

Classification criteria for mixtures

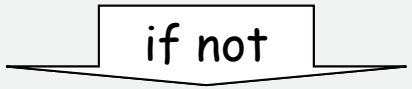
- If there is evidence that the hazard of an ingredient is present below the cut-off/concentration limit, or

- If there is conclusive data that the hazard of an ingredient will not be present at a level above the harmonized cut-off/concentration limit,

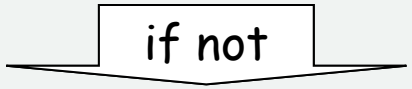
then, the mixture should be classified accordingly

Tiered approach to classification

Generally use test data for the mixture, when available



Use bridging principles, if applicable



Estimate hazards based on the known ingredient information

Classification criteria for mixtures

1. Data are available for the complete mixture
2. Data are not available for the mixture itself => apply bridging principles
   - Dilution
   - Batching
   - Concentration of mixtures of the highest category within one hazard class
   - Interpolation within one toxicity category
   - Substantially similar mixtures
   - Aerosolized mixtures
3. Classification based on ingredients: Apply additivity formula/summation method
   - Data available for all ingredients
   - Data available only for some ingredients

Health and environmental hazards

Health hazards: 10 hazard classes

- Acute toxicity (Chapter 3.1)
- Skin corrosion/irritation (Chapter 3.2)
- Serious eye damage/eye irritation (Chapter 3.3)
- Respiratory or skin sensitization (Chapter 3.4)
- Germ cell mutagenicity (Chapter 3.5)
- Carcinogenicity (Chapter 3.6)
- Reproductive toxicity (Chapter 3.7)
- Specific target organ toxicity-single exposure (Chapter 3.8)
- Specific target organ toxicity-repeated exposure (Chapter 3.9)
- Aspiration hazard (Chapter 3.10)

Environmental hazards: 2 hazard classes

- Hazardous to the aquatic environment (Chapter 4.1)
- Hazardous to the ozone layer (Chapter 4.2)

Health hazards
Acute toxiticy (chapter 3.1)

Acute toxicity refers to serious adverse health effects (i.e. lethality) occurring after a single or short-term oral, dermal or inhalation exposure to a substance or mixture.

5 categories available without subcategorization, based on acute toxicity by the oral, dermal or inhalation route

- **Categories 1, 2, 3, 4, 5**

Classification criteria can be found in chapter 3.1 of the GHS

Health hazards
Skin corrosion/irritation (chapter 3.2)

Skin corrosion refers to the production of irreversible damage to the skin; namely, visible necrosis through the epidermis and into the dermis, occurring after exposure to a substance or mixture

- **1 category** available (**category 1 skin corrosion**) with possibility of subcategorization (**1A, 1B, 1C**)

Skin irritation refers to the production of reversible damage to the skin occurring after exposure to a substance or mixture

- **2 categories** available without subcategorization:
  - **Category 2: Skin irritation**
  - **Category 3: Mild irritation**

Classification criteria can be found in chapter 3.2 of the GHS

Health hazards: Serious eye damage/eye irritation (chapter 3.3)

Serious eye damage refers to the production of tissue damage in the eye, or serious physical decay of vision, which is not fully reversible, occurring after exposure of the eye to a substance or mixture

- **1 category** available (**Category 1 serious eye damage/irreversible effects on the eye**) without subcategorization

Eye irritation refers to the production of changes in the eye, which are fully reversible, occurring after exposure of the eye to a substance or mixture

- **1 category** available (**Category 2 Eye irritation/reversible effects on the eye**) with possibility of subcategorization:
  - **2A eye irritation**
  - **2B mild irritation**

Classification criteria can be found in chapter 3.3 of the GHS

Health hazards
Respiratory/skin sensitization (chapter 3.4)

Respiratory sensitization refers to hypersensitivity of the airways occurring after inhalation of a substance or mixture

- 1 category available (**Category 1 respiratory sensitizer**) with possibility of subcategorization (**1A, 1B**)

Skin sensitization refers to an allergic response occurring after skin contact with a substance or mixture

- 1 category available (**Category 1 skin sensitizer**) with possibility of subcategorization (**1A, 1B**)

Classification criteria can be found in chapter 3.4 of the GHS

Health hazards
Germ cell mutagenicity (chapter 3.5)

Germ cell mutagenicity refers to heritable gene mutations, including heritable structural and numerical chromosome aberrations in germ cells occurring after exposure to a substance or mixture

- 2 categories available :
  - **Category 1** with possibility of subcategorization (**1A, 1B**)
  - **Category 2** without possibility of subcategorization

Classification criteria can be found in chapter 3.5 of the GHS

Health hazards
Carcinogenicity (chapter 3.6)

Carcinogenicity refers to the induction of cancer or an increase in the incidence of cancer occurring after exposure to a substance or mixture. Substances and mixtures which have induced benign and malignant tumors in well performed experimental studies on animals are considered also to be presumed or suspected human carcinogens unless there is strong evidence that the mechanism of tumor formation is not relevant for humans.

2 categories available :

- **Category 1** (**Known or presumed human carcinogens**) with possibility of subcategorization (**1A, 1B**)
- **Category 2** (**Suspected human carcinogens**) without possibility of subcategorization

Classification criteria can be found in chapter 3.6 of the GHS

Health hazards
Reproductive toxicity (chapter 3.7)

Reproductive toxicity refers to adverse effects on sexual function and fertility in adult males and females, as well as developmental toxicity in the offspring, occurring after exposure to a substance or mixture.

3 categories available :

- **Category 1** (**Known or presumed human reproductive toxicant**) with possibility of subcategorization (**1A, 1B**)
- **Category 2** (**Suspected human reproductive toxicant**) without possibility of subcategorization
- **Stand-alone category: Effects on or via lactation**

Classification criteria can be found in chapter 3.7 of the GHS

Health hazards
Specific target organ toxicity-single exposure (chapter 3.8)

Specific target organ toxicity – single exposure (STOT) refers to specific, non-lethal target organ effects occurring after a single exposure to a substance or a mixture.

3 categories available without possibility of subcategorization:

- **Category 1**
- **Category 2**
- **Category 3: Transient target organ effects**

Classification criteria can be found in chapter 3.8 of the GHS

Health hazards
Specific target organ toxicity-repeated exposure (chapter 3.9)

Specific target organ toxicity – repeated exposure refers to specific toxic effects on target organs occurring after aspiration of a substance or mixture repeated exposure.

2 categories available without possibility of subcategorization:

- **Category 1**
- **Category 2**

Classification criteria can be found in chapter 3.9 of the GHS

Health hazards
Aspiration hazard (chapter 3.10)

Aspiration hazard refers to severe acute effects such as chemical pneumonia, pulmonary injury or death occurring after aspiration of a substance or mixture.

Aspiration of a substance or mixture can occur as it is vomited following ingestion. This may have consequences for labelling, particularly where, due to acute toxicity, a recommendation may be considered to induce vomiting after ingestion. However, if the substance/mixture also presents an aspiration toxicity hazard, the recommendation to induce vomiting may need to be modified.

2 categories available without possibility of subcategorization:

- **Category 1**
- **Category 2**

Classification criteria can be found in chapter 3.10 of the GHS

Environmental hazards
Hazardous to the aquatic environment (chapter 4.1)

The core part of the harmonized classification system for substances consists of short-term (acute) classification and long-term (chronic) classification

Short-term (acute toxicity) classification

- **3 categories available (Acute 1, 2 and 3)** without possibility of subcategorization

Long-term (chronic toxicity) classification

- **4 categories available (Chronic 1, 2, 3 and 4)** without possibility of subcategorization

Classification criteria can be found in chapter 4.1 of the GHS

Environmental hazards
Hazardous to the ozone layer (chapter 4.2)

Ozone Depleting Potential (ODP) is an integrative quantity, distinct for each halocarbon source species, that represents the extent of ozone depletion in the stratosphere expected from the halocarbon on a mass-for-mass basis relative to CFC-11. The formal definition of ODP is the ratio of integrated perturbations to total ozone, for a differential mass emission of a particular compound relative to an equal emission of CFC-11

1 category available (Category 1) without possibility of subcategorization

Classification criteria can be found in chapter 4.2 of the GHS

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End “Health and environmental hazards”