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

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Basic concepts

- Substance

  chemical elements and their compounds in the natural state or obtained by any production process, **including** any **additive** necessary to preserve the stability of the product and any **impurities** deriving from the process used, but **excluding any solvent** which may be separated without affecting the stability of the substance or changing its composition

- Mixture

  mixture or a solution composed of two or more substances in which they do not react

- Alloy

  means 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

In the GHS, alloys ≈ mixtures

Who classify?

Manufacturers

Competent authorities

(mandatory/voluntary classification)

Classification process

- 3 steps

1. Identify available data on the substance/mixture
2. Evaluate the data
3. Take a decision on its classification (apply the GHS classification criteria)

Data identification

- GHS does not require generation of test data
- Accepts existing validated data (own or third-party):

  - From the manufacturer
  - From testing results: *in vivo/in vitro*
  - Accidental exposure, clinical/epidemiologic studies…
  - Derived data:
    - Quantitative structure-activity relationships (QSAR) studies *(e.g: "OECD Qsar toolbox for grouping chemicals")*
    - Bridging principles
    - Calculation methods
    - …

Data identification

- Information sources:
  - GHS Sub-Committee secretariat (general information on GHS implementation worldwide with links to existing national/international databases)
  - List of dangerous goods for transport
    - Part 3 of the United Nations Recommendations on the Transport of Dangerous Goods
  - WHO recommended classification of pesticides by hazard
  - International Programme on Chemical Safety
  - OECD ChemPortal (links to more than 25 national/international databases)
  - National/Regional databases:
    - European Unión: Classification and labelling inventory (ECHA)
    - Japan: autoclassification tool
    - New Zealand: Chemical clasification and information database
    - Republic of Korea: classification and labelling list of toxic chemicals
    - Australia: GHS hazardous chemical information list

Data identification

- Tests
  - For physical hazards:
    - o Those specified in the GHS = UN Manual of Tests and Criteria

Physical hazards:
UN Manual of Tests and Criteria

  - For health and environmental hazards:
    - o GHS criteria for health and environmental hazards is test method neutral

Health and environmental hazards:
Any tests conducted according to internationally recognized scientific principles (e.g. OECD guidelines)

Data evaluation

Consider

1. Data quality
2. Weight of evidence
3. Expert judgement

Data evaluation

- Quality

Reliable?	• Was the data generated through validated and internationally recognized tests? • Following Good Laboraty Practices? (GLP)
Pertinent?	• Applicables to the subst./mixture in question? • Referring to the form/state of the subst./mixture in question?
Coherent?	• Is there contradictory information about the tests results when coming from different sources?
Enough?	• Are there enough data to classify the subst./mixture in question?

Data evaluation

- Weight of evidence

Consider all available information together

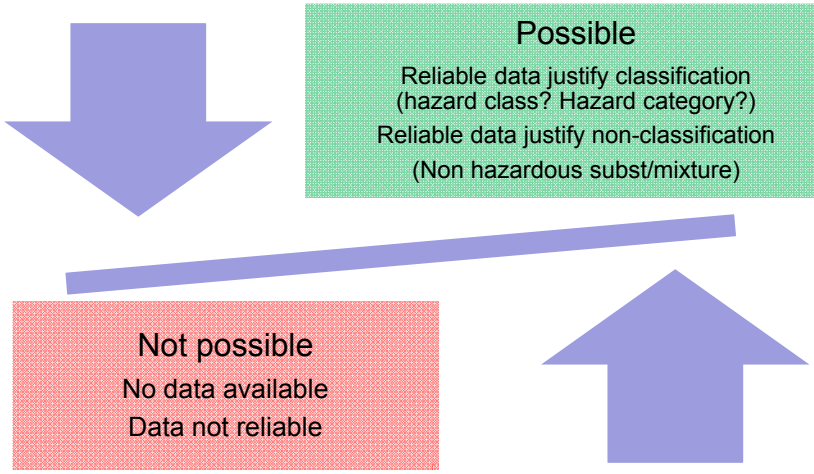
- Results of valid *in vivo/in vitro* tests
- Human experience
- Epidemiological/clinical studies
- Well-documented case reports and observations
- Relevant animal data
- Route of exposure
- Mechanistic information and metabolism studies
- Quality and consistency of data
- Test results (both possitive and negative)

Data evaluation

- Expert judgement

- Evaluation of contradicting or conflicting test results
- Evaluation of data quality (pertinence, reliability…)
- Classification of subst/mixtures posing special problems (e.g. some polymers and metals)
- Difficult to interpret data

Classification



GHS classification criteria

Parts 2, 3 and 4 of the GHS

One chapter for each hazard class

- Definition
- Classification criteria (subst/mixtures)
- Labelling elements
- Decision logics
- Additional guidance

Mixtures classification: tiered approach

1. Data on the mixture as a whole?
   - YES: apply classification criteria
   - NO: go to the next step
2. Data on similar mixtures and individual ingredients of the mixture?
   - YES: Apply bridging principles
   - NO (or bridging principles not applicable): go the the next step
3. Data on all or some of the ingredients of the mixture?
   - YES: Classification based on cut-off values/concentration limits/calculation methods, as specified in the GHS for the relevant hazard class
   - NO: Classification is not possible with the available data (Require further information from the manufacturer/provider on mixture/ingredients)

Classification

Data needed

- Information about the subst/mixture; or
- Information about the ingredients (mixture)
  - identity
  - Concentration in the mixture
  - classification (hazard class/category)
  - Data about impurities, additives (including identity, classification, concentration)
  - Cut-off values/concentration limits
  - Applicable M-factors

Mixtures classification

- Based on available information on similar tested mixtures and individual ingredients
  - Bridging principles:
    - Dilution
    - Batching
    - Concentration of mixtures of the highest category
    - Interpolation within one category/sub-category
    - Substantially similar mixtures
    - Aerosolized form of mixtures
- Based on available information on some or all of the ingredients of the mixture
  - Calculation methods
  - Concentration thresholds (cut-off values/concentration limits, M-factors)

Mixtures classification

Calculation methods:

– Acute toxicity:

$$\frac{100}{ATEmix} = \sum_n \frac{C_i}{ATE_i}$$

where:

C_i = concentration of ingredient i;

n ingredients and i is running from 1 to n;

ATE_i = Acute toxicity estimate of ingredient i;

$$\frac{100 - (\sum C_{unknown} \text{ if } >10\%)}{ATE_{mix}} = \sum_n \frac{C_i}{ATE_i}$$

– Toxicity for the aquatic environment

Based on acute aquatic toxicity:

$$\frac{\sum Ci}{L(E)C_{50_m}} = \sum_n \frac{Ci}{L(E)C_{50_i}}$$

where:

C_i = concentration of ingredient i (weight percentage);

$L(E)C_{50_i}$ = LC_{50} or EC_{50} for ingredient i, in (mg/l);

n = number of ingredients, and i is running from 1 to n;

$L(E)C_{50_m}$ = L(E) C_{50} of the part of the mixture with test data;

Based on chronic aquatic toxicity:

$$\frac{\sum Ci + \sum Cj}{EqNOEC_m} = \sum_n \frac{Ci}{NOECi} + \sum_n \frac{Cj}{0.1 \times NOECj}$$

where:

C_i = concentration of ingredient i (weight percentage) covering the rapidly degradable ingredients;

Cj = concentration of ingredient j (weight percentage) covering the non- rapidly degradable ingredients;

$NOEC_i$ = NOEC (or other recognized measures for chronic toxicity) for ingredient i covering the rapidly degradable ingredients, in mg/l;

NOECj = NOEC (or other recognized measures for chronic toxicity) for ingredient j covering the non-rapidly degradable ingredients, in mg/l;

n = number of ingredients, and i and j are running from 1 to n;

$EqNOEC_m$ = Equivalent NOEC of the part of the mixture with test data;

Mixtures classification

Cut-off values/concentration limits

Values or minimun concentrations of an ingredient or the sum of concentrations of several ingredients in a mixture, that have to be considered for the classification of the mixture

– Generic
  - o Ingredients contributing to the overall toxicity of the mixture («relevant ingredients»)
  - o Concentrations determining the classification of the mixture as hazardous

– Specific
  - o The substance is hazardous in concentrations below the generic cut-off value/concentration limit
  - o The substance is hazardous in concentrations above the generic cut-off value/concentration limit
  - o M-factors for hazardous to the aquatic environment (for mixtures with highly toxic ingredients)

Mixtures classification

- Additivity principle

  Each of the hazardous ingredients contribute to the toxicity of the mixture in proportion to its potency and concentration. Applies to:

  - Skin corrosion/irritation
  - Serious eye damage/irritation
  - Specific target organ toxicity (single exposure), Category 3 (transient target organ effects)
  - Short and long-term toxicity for the aquatic environment

  – Do not apply to:

  - Skin corrosion/irritation (in some cases)
  - Serious eye damage/irritation (in some cases)
  - Respiratory/Skin sensitization
  - Mutagenicity, Carcinogenicty, Reproductive toxicity
  - Specific target organ toxicity (single and repeated exposures), Cat.1 and 2
  - Aspiration hazard

Mixture classification

- Example of application of the additivity principle

Serious eye damage/irritation

Sum of ingredients classified as	Concentration triggering classification of a mixture as	
	Serious eye damage	Eye irritation
	Category 1	Category 2/2A
Skin Category 1 + Eye Category 1[a]	≥ 3%	≥ 1% but < 3%
Eye Category 2		≥ 10%[b]
10 × (skin Category 1 + eye Category 1)[a] + eye Category 2		≥ 10%

[a] *If an ingredient is classified as both skin Category 1 and eye Category 1 its concentration is considered only once in the calculation;*

[b] *A mixture may be classified as eye Category 2B when all relevant ingredients are classified as eye Category 2B.*

For a mixture with 2 ingredients classified as Cat.2 (eyes), the sum of its concentrations would have to be ≥ 10% to have the mixture classified in Cat.2 (eyes)

Mixture classification

- Example of classification when the additivity principle is NOT applicable

Carcinogenicity

Ingredient classified as:	Cut-off/concentration limits triggering classification of a mixture as:		
	Category 1 carcinogen		Category 2 carcinogen
	Category 1A	Category 1B	
Category 1A carcinogen	≥ 0.1 %	--	--
Category 1B carcinogen	--	≥ 0.1 %	
Category 2 carcinogen	--	--	≥ 0.1% (note 1)
			≥ 1.0% (note 2)

A mixture with ingredients classified as Cat.1A or 1B will be classified as Cat.1 when at least one of these ingredients is present in a concentration ≥ 0,1%

Decision on classification and labelling

Does the subs/mixture meet the GHS classification criteria?

- Assing hazard class/category accordingly

Hazard communication elements:

- Assign in accordance with the identified hazards
- Respect precedence rules (e.g. signal words)
- Ensure compatibility with labelling for transport of dangerous goods

Revise classification

- When new information on the subst/mixture is available
- When the manufacturer/provider modifies the composition
  - Changes in concentration
  - Replacement or addition of ingredients
  - Significant variations between production batches
- ….

Classification procedure (summary)

Compile data

Evaluate/examine data

Apply classification criteria

Take a decision on classification

Revise and validate classification result

Questions?

Thank you for your attention!

http://www.unece.org/trans/danger/danger.htm