Classification of hazardous chemicals according to the GHS
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

metallic material, homogeneous on a macroscopic scale, consisting of two or more elements so combined that they cannot be readily separated by mechanical means. In the GHS, alloys ≈ mixtures
Who classifies?

- 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

• Existing validated data:
  – From the manufacturer
  – From tests: 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
    • …

• IF no validated and reliable data available, tests:
  – For physical hazards: those specified in the GHS
  – For health and environmental hazards: “test method neutral”
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 *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 Union: [Classification and labelling inventory](https://echa.europa.eu) (ECHA)
  - Japan: [auto-classification tool](https://www.mlit.go.jp/)
  - New Zealand: [Chemical classification and information database](https://www.chemistry.ifrc.org)
  - Republic of Korea: [classification and labelling list of toxic chemicals](https://www.mohw.go.kr)
  - Australia: [GHS hazardous chemical information list](https://ghs.hazardouschemicals.gov.au)
Data identification

Information sources

The Global Portal to Information on Chemical Substances

eChemPortal

Participating Databases

- Databases currently participating in eChemPortal
- Data sources which can be found through a search by Property
- Data sources which can be found through a search by GHS classification
- Number of substance identity and endpoint records per participating source searchable through eChemPortal

Databases currently participating in eChemPortal

- ACToR
  U.S. EPA Aggregated Computational Toxicology Resource
- AGRITOX
  AGRITOX - Base de données sur les substances actives phytopharmaceutiques
- APVMA-CR
  The Australian Pesticides and Veterinary Medicines Authority (APVMA) database of completed chemical reviews
- CCR
  Canadian Categorization Results
- CESAR
  Canada’s Existing Substances Assessment Repository
- Combined Exposures
  Collection of Case Studies on Risk Assessments of Combined Exposures to Multiple Chemicals
- ECHA C&L inventory
  Public Classification and Labelling (C&L) Inventory according to the European Union (EU) CLP Regulation (EC) No 1272/2008
- ECHA CHEM
  European Chemicals Agency’s Dissemination portal with information on chemical substances registered under REACH.
- EFSA Open Food Tox
  Chemical Hazards Database of the European Food Safety Authority
- EnviChem
  Data Bank of Environmental Properties of Chemicals
- EPA HHBP
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 Laboratory Practices? (GLP)

Pertinent?
- Applicable to the subst./mixture in question?
- Referring to the form/state of the subst./mixture in question?

Coherent?
- Is there contradictory information about the test 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 positive and negative)
Data evaluation
Expert judgement

- Evaluation of contradictory 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

Possible
Reliable data justify classification
(hazard class? Hazard category?)
Reliable data justify non-classification
(Non-hazardous subst/mixture)

Not possible
No data available
Data not reliable
## Classification of mixtures: 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 (dilution, batching, interpolation…)
   - **NO** (or bridging principles not applicable): go the next step

3. Data on all or some of the ingredients of the mixture?
   - **YES**: Classify based on cut-off values/concentration limits, additivity principle, calculation methods…, as specified in GHS for the relevant hazard class
   - **NO**: Classification is not possible with the available data. Further information on the mixtures or its ingredients is needed
Decision on classification and labelling

Does the subs/mixture meet the GHS classification criteria?

- Assign 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
Revision of classification and labelling

• 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
Thank you!

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