CEFIC/EUROMETAUX/FECC/DUCC Workshop

How to classify MIXTURES under CLP

The Bridging Principle

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General Procedure for HEALTH & ENV (1)

Tiered approach (decision tree):

Method dependent on:

- Type of effect (hazard class, if applicable category)
- Amount of information for the mixture itself and/or for **similar tested** mixtures, and/or for its ingredients

General Procedure for HEALTH &ENV (2)

Hierarchy

- **A**. Generally use test data for the mixtures, when available*. Then apply classification criteria for substances.

- **B**. Use “bridging principles”, if applicable

- **C**. Estimate hazards using ingredient information

* Exceptions CMRs, Bio-degradability & -accumulation

B. Philosophy of Bridging
(Annex I 1.1.3)

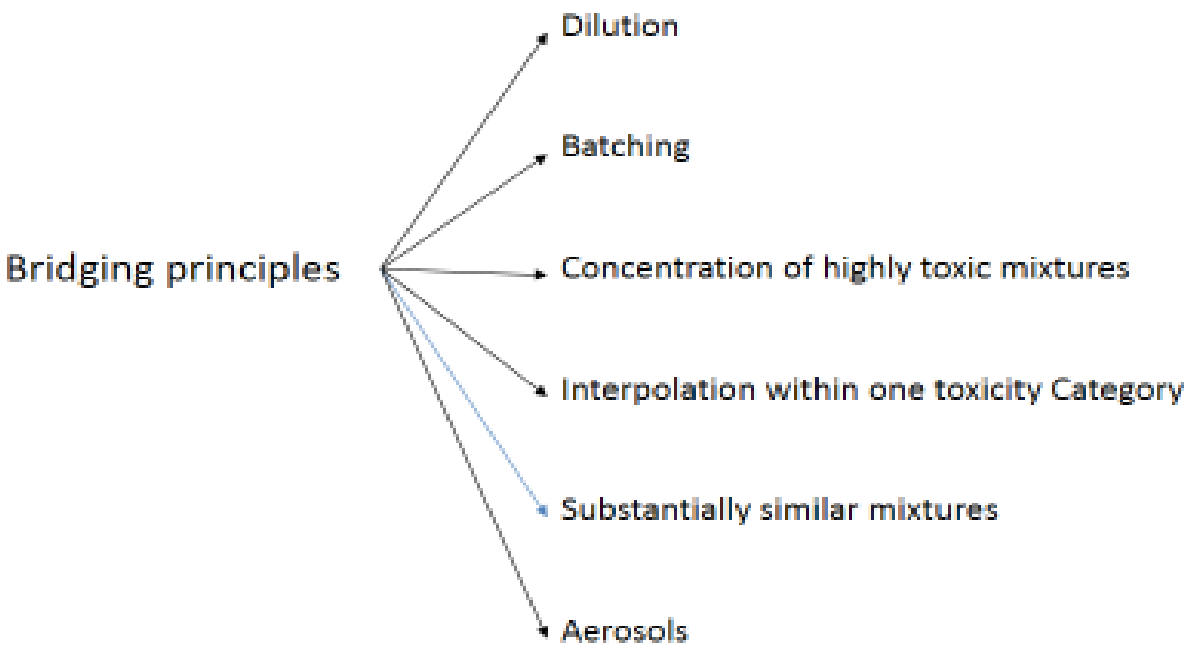
- **Principle**: A mechanism for extrapolating data for the determination of the hazards/classification of a mixture not tested as a whole concerning the hazardous properties posed by the ingredients.
- **Approach**: Conclusion based on information about a tested mixture/ingredients to an untested mixture with similarities
- Requirement: Certain conditions have to be fulfilled

⇨ Transfer of the classification of the tested mixture(s) to the untested mixture

Remark: cf. SARs/Category approach for properties of substances with similarities

B. Bridging Principles

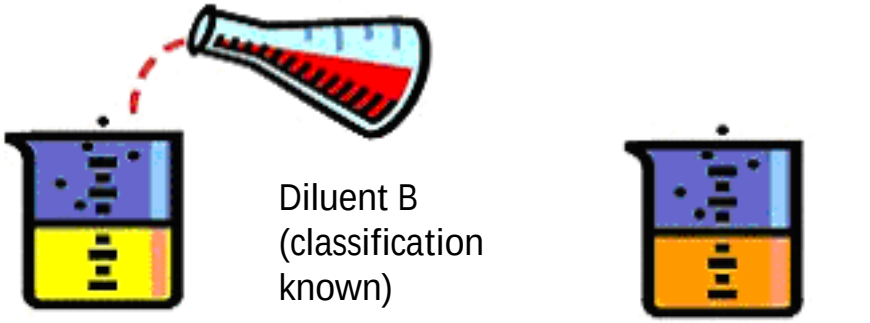
GHS- vs. CLP-Bridging Principles



CLP in addition: Changes in the composition of a mixture (cf. DPD)

Dilution

Principle: Dilution with a substance in the equivalent or in a lower hazard category as the least hazardous ingredient of the mixture



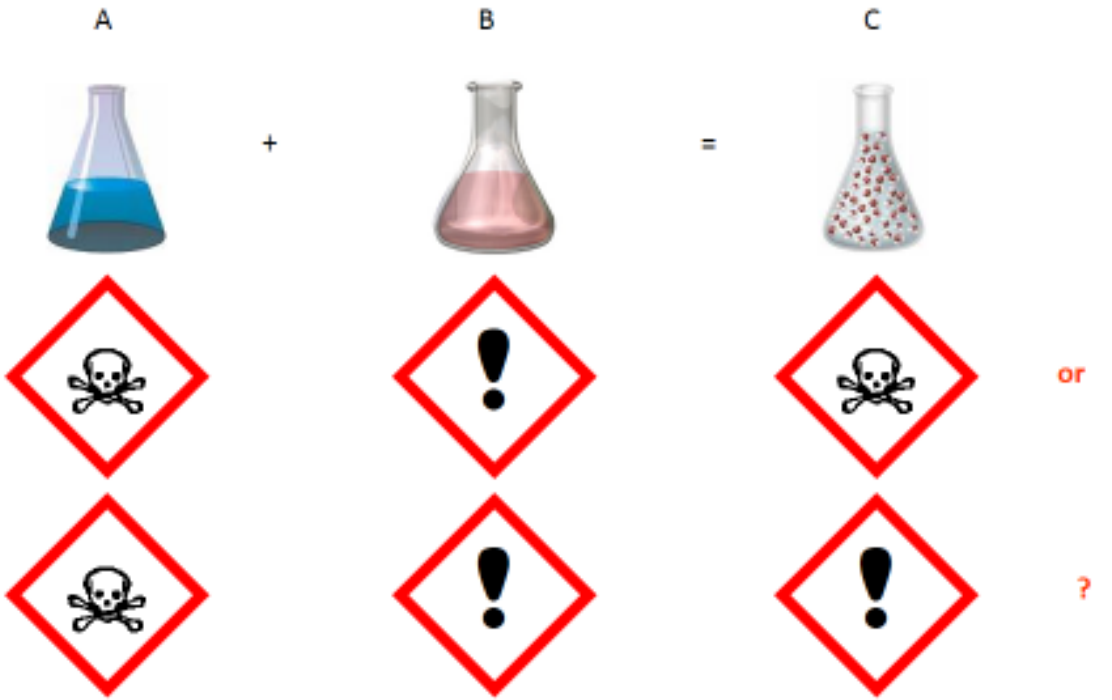
Diluent B: a substance with equal or lower toxicity (e.g. in Acute toxicity) than the least toxic ingredient in mixture A (Source ECHA CLP-Guidance)

Two options for classification:

- Equivalent classification to original mixture, **or**
- Use of specific criterion specified in applicable hazard classes

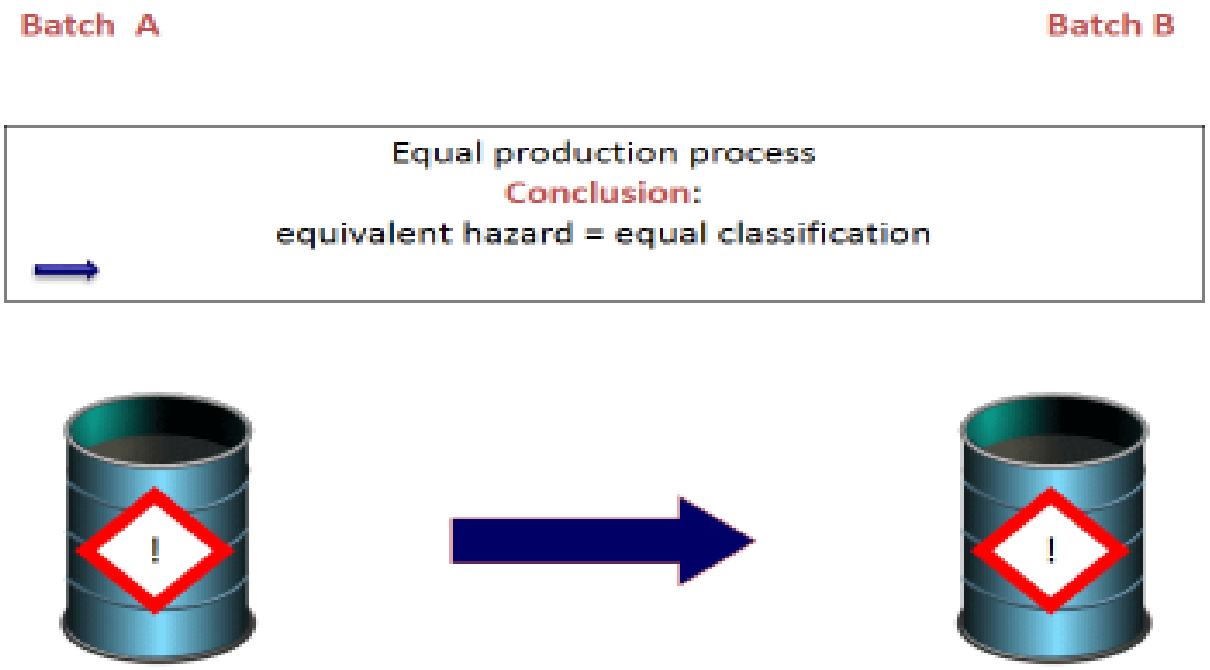
Remark: Discrepancy between US and Germany in a UNSCEGHS test run with glutaraldehyde: US Acute Tox.3 vs. Germany Cat.4

Dilution



Batching

Conclusion of the hazards/classification from a tested production batch (mixture) to an equivalent non tested batch of the same commercial product/manufacturer, unless there is reason for significant variations .



Interpolation within one Hazard Category

- Three mixtures A, B and C, all containing identical ingredient 1 which is hazardous.
- Mixtures A and B in same hazard category based on test data
- Mixture C not tested, thus classification using substance criteria not possible (s. decision tree)
- Concentration of ingredient 1 in mixture C intermediate to the concentrations of A and B

à **Assumption: Identical classification of mixture C as A and B.**

Example

Database:

- Mixtures A, B and C containing ingredient 1, which is classified as Eye Dam.1
- All other ingredients are neither classified in Skin Corr. 1 nor in Eye Dam. 1

Mixture A	Mixture C	Mixture B
6 % Ingredient 1: Test OECD 405 à Eye Irrit.2	11% No testdata Classification ?	15% Ingredient 1: Test OECD 405 à Eye Irrit. 2

à Classification **C: Eye Irrit. 2**

Rationale :

- - No test data for mixture C à Application of substance criteria not possible
  - Bridging applicable? Yes, interpolation within one hazard category-
  - Mixtures A and B were tested and are in the same hazard category, i.e. Eye Irrit. 2
  - Mixture C contains the identical ingredient 1with a concentration intermediate to the concentrations in A and in B.
- **Remark**:

  According to the CLP criteria based on Generic concentration limit (3%) a classification for mixture C in **Eye Dam.1** would have been warranted. (Table 3.3.3)

  According to DPD the classification **Xi; R 41** would be obligatory(DPD Annex I Part B Table IV: Cut-off limit 10%)

Substantially similar Mixtures

Given the following:

(a) two mixtures each containing two ingredients:

(i) A + B

(ii) C + B;

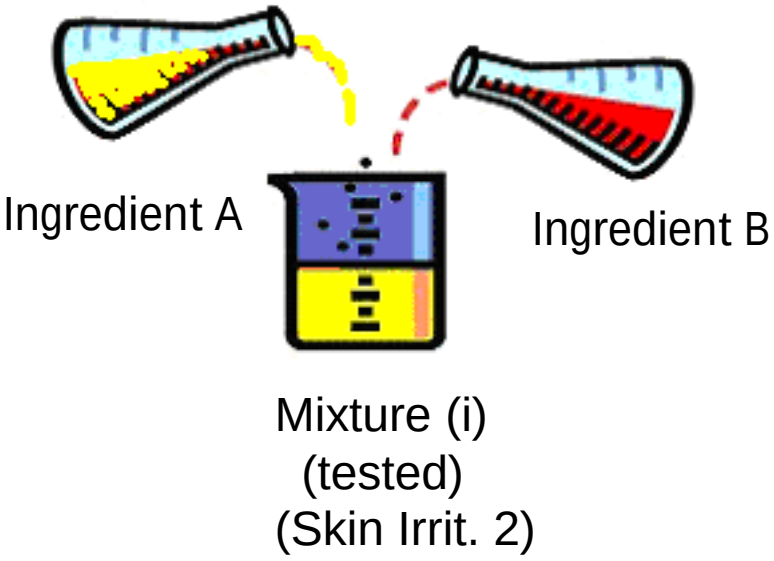
(b) the **concentration of ingredient B is essentially the same** in both mixtures;

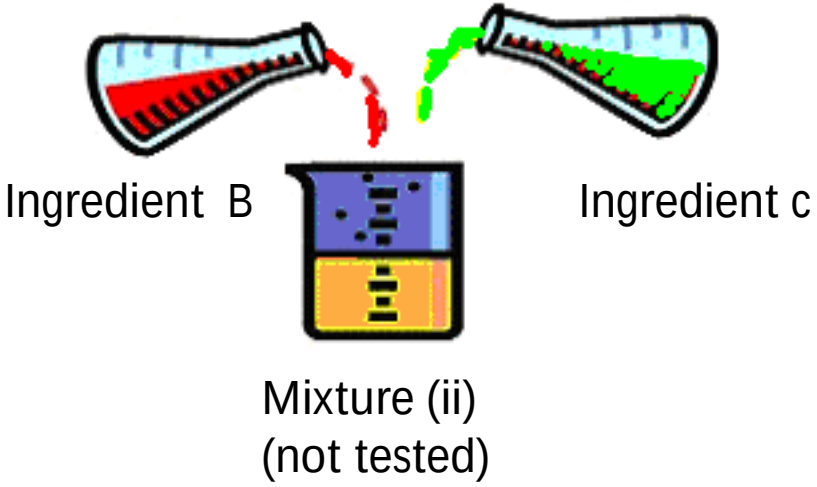
(c) the concentration of **ingredient A in mixture (i) equals that of ingredient C** in mixture (ii);

(d) hazard data for **A and C** are available and substantially equivalent, i.e. they **are in the same hazard category** and are not expected to affect the hazard classification of B.

- **If mixture (i) or (ii) is already classified based on test data, then the other mixture shall be assigned the same hazard category.**

Substantially similar Mixtures





Source: ECHA CLP-Guidance

Changes in the Composition of a Mixture
(CLP Annex I Table 1.2; cf. DPD Article 7.3)

Initial concentration range of the constituent	**Permitted variation in initial concentration of the constituent**
$\leq$ 2.5%	$\pm$ 30%
2.5 < C $\leq$ 10%	$\pm$ 20%
10 < C $\leq$ 25%	$\pm$ 10%
25 < C $\leq$ 100%	$\pm$ 5%

Examples

The composition of Mixture A is changed by varying the concentration of the constituent 1 which has given rise to the classification

Classification of Mixture A (initial)	**Mixture A: initial concentration of constituent 1 (%)**	**Mixture B: concentration of constituent 1 after change (%)**
Acute Tox. 3 (oral)	15%	16,4%
Acute Tox.4 (dermal)	60%	65%

Mixture B Classification after change:

- Acute Tox. 3 (oral) Variation permitted since (variation: 1,4/15=9,3%< 10%)

- Acute Tox. 4 (dermal) bridging not possible (variation:5/60=8,3% > 5%)

à Necessary estimation via additivity formula on basis of ATE values

Aerosols

Principle: Same hazard classification in aerosol form as in non-aerosolised form, provided no affect through added propellant

Applicable for mixtures covered by Acute Tox., Skin Corr./Irrit., Serious Eye Dam./Irrit., Resp./Skin Sens., STOT-SE and STOT-RE

Example:

Non-aerosolised mixture A : Test data according to OECD 405 result in Skin Irrit.2.

The aerosol form is mixture A (50%) and propane/butane (20%/30%).

à **Classification of the aerosolised form: Skin Irrit.2.**

Rationale: The classification of the non-aersolised form can be used, since propane and butane have no skin corrosion property

Conclusion

- Only little correspondence with DPD criteria.
- Several optional approaches.
- With a robust data base a more severe classification due to the more stringent GHS cut-off values for mixture classification can sometimes be avoided via application of Bridging principles.