

Concentration of highly toxic mixtures bridging principle example using acute toxicity data

While this specific example uses acute toxicity data, the reader is reminded that the concentration of highly toxic mixtures bridging principle can be applied to other hazard classes as prescribed in the purple book.

Concentration of highly toxic mixtures

If a tested mixture is classified in Category 1, and the concentration of the ingredients of the tested mixture that are in Category 1 is increased, the resulting untested mixture should be classified in Category 1 without additional testing.

Tested mixture information:

Acute toxicity classification and test data	
Oral	Dermal
Category 1 (LD ₅₀ : 3 mg/kg)	Category 2 (LD ₅₀ : 85 mg/kg)

Information on ingredients in the tested mixture:

Ingredient	Wt%	Acute toxicity Classification and Test Data	
		Oral	Dermal
Ingredient 1	75	Category 1 (LD ₅₀ : 1 mg/kg)	Category 2 (LD ₅₀ : 195 mg/kg)
Ingredient 2	25	Category 2 (LD ₅₀ : 6 mg/kg)	Category 1 (LD ₅₀ : 40 mg/kg)

Information on an untested mixture:

Ingredient	Wt%
Ingredient 1	80
Ingredient 2	20

Answer:

- Oral route – Applying the concentration of highly toxic mixtures bridging principle, the untested mixture can be classified as Oral Acute Toxicity; Category 1 without additional testing
- Dermal route – Concentration of highly toxic mixtures bridging principle cannot be applied.

Rationale:

- Classification via application of substance criteria is not possible since acute toxicity test data was not provided for the untested mixture;
- Classification via the application of bridging principles can be considered since there are sufficient data on both the individual ingredients and a similar tested mixture;
- Classification of the mixture based on ingredient information should be considered if the classifier chooses not to apply the bridging principle or sufficient data had not been available to apply the bridging principle;

Oral route

- (d) The concentration of highly toxic mixtures bridging principle can be applied because the tested mixture is classified in Category 1 and the concentration of ingredient 1 (i.e., a Category 1 ingredient) has increased in the untested mixture.

Dermal route

- (e) The concentration of highly toxic mixtures bridging principle cannot be applied because the tested mixture is not classified into Category 1.

(Ref. Doc: ST/SG/AC.10/C.4/2010/15, Annex 2 example 3)