Interpolation within one hazard category uses skin corrosion/irritation data

The purpose of this example is to illustrate how the interpolation within one toxicity category bridging principle criteria can be applied. While this specific example uses skin corrosion/irritation data, the reader is reminded that the interpolation within one toxicity category bridging principle can be applied to other hazard classes as prescribed in the purple book.

Interpolation within one toxicity category

For three mixtures (A, B and C) with identical ingredients, where mixtures A and B have been tested and are in the same irritation/corrosion toxicity category, and where untested mixture C has the same toxicologically active ingredients as mixtures A and B but has concentrations of toxicologically active ingredients intermediate to the concentrations in mixtures A and B, then mixture C is assumed to be in the same irritation/corrosion category as A and B.

Tested mixture information:

Skin corrosion/irritation classification and test data	
Mixture A	**Mixture B**
Skin Irritation; Category 2	**Skin Irritation; Category 2**
Animal 1: Mean Erythema/eschar: 2.5 Mean Oedema: 1.5	Animal 1: Mean Erythema/eschar: 3.8 Mean Oedema: 2.5
Animal 2: Mean Erythema/eschar: 2.3 Mean Oedema: 1.3	Animal 2: Mean Erythema/eschar: 3.5 Mean Oedema: 2.9
Animal 3: Mean Erythema/eschar: 2.2 Mean Oedema: 1	Animal 3: Mean Erythema/eschar: 4.0 Mean Oedema: 3.2

Information on ingredients in the tested mixture:

Ingredient	**Ingredient classification**	**Weight %**	
		Mixture A	**Mixture B**
Ingredient 1	Skin Corrosive; Category 1C	1	5
Ingredient 2	Skin Irritant Category 2	15	30
Water	Not Classified	84	65

Untested mixture information:

Ingredient	**Weight %**		
	Mixture A	**Mixture C**	**Mixture B**
Ingredient 1	1	4	5
Ingredient 2	15	20	30
Water	84	76	65

Answer:

Applying the interpolation within one toxicity category bridging principle the untested Mixture C can be classified as Skin Irritant; Category 2 without additional testing.

Rationale:

(a) Classification via application of substance criteria is not possible since skin corrosion/irritation test data was not provided for the untested mixture;

(b) 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;

(c) 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;

(d) The interpolation within one toxicity category bridging principle can be applied because:

(i) Mixtures A and B have both been tested and are in the same irritation/corrosion toxicity category (i.e., Skin Irritant; Category 2); AND

(ii) Untested Mixture C has the same toxicologically active ingredients (i.e., ingredients 1 and 2) as tested Mixtures A and B; AND

(iii) The concentrations of ingredients 1 and 2 in Mixture C are both intermediate to the concentrations of ingredients 1 and 2 in Mixtures A and B.

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