Application of the criteria in paragraph 3.1.3.6.1 (c)

Acute toxicity – Oral

Ingredient information:

Ingredient	Wt%	Classification	Test data
Ingredient 1	4	Oral Category 4	LD_{50}: 1,737 mg/kg
Ingredient 2	5	-	LD_{50}: > 5,000 mg/kg
Ingredient 3	5	-	LD_{50}: 5,400 mg/kg
Ingredient 4	86	-	Oral limit dose > 2,000 mg/kg (No signs of toxicity)

Answer:

Apply the equation in paragraph 3.1.3.6.1:

$$\frac{100}{ATE_{mixture}} = \sum_n \frac{Ci}{ATEi}$$

$$\frac{100}{ATE_{mixture}} = \frac{4}{1,737}$$

Therefore: $ATE_{mixture}$ = 43,425 mg/kg, Not Classified

Rationale:

(a)   Classification via application of substance criteria is not possible since acute toxicity test data was not provide for the mixture (paragraph 3.1.3.4).

(b)   Classification via the application of bridging principles is not possible since data on a similar mixture (paragraph 3.1.3.5.1) was not provided.

(c)   Classification of mixture based ingredient data can be considered (paragraph 3.1.3.6).

(d)   Applying the "relevant ingredients" concept from paragraph 3.1.3.3(a) means that all ingredients will be considered when applying criteria in paragraph 3.1.3.6.

(e)   Data is available for all ingredients so criteria in paragraph 3.1.3.6.1 apply.

(f)   Applying sub-paragraph 3.1.3.6.1 (a):

    (i)   Ingredient 1 is included in the $ATE_{mixture}$ calculation because it falls into a GHS acute toxicity category;

    (ii)   Ingredients 2 and 3 can be ignored in the $ATE_{mixture}$ calculation because they do not fall within a GHS acute toxicity category.

(g)   Applying paragraph 3.1.3.6.1 (c):

Ingredient 4 can be ignored in the $ATE_{mixture}$ calculation because it has oral limit dose test data that does not show acute toxicity at 2,000 mg/kg.

(Ref Doc: ST/SG/AC.10/C.4/2008/23, Annex 2, Example 3)