

Application of the tiered approach to determining the mixture's classification where acute toxicity data is available on the mixture as a whole as well as on the ingredients, and long-term (chronic) aquatic hazard classification information is only available on the ingredients

Ingredient information:

Ingredient	Wt%	Acute toxicity data	L(E)C ₅₀ mg/l	Long-term (chronic) aquatic hazard classification
Ingredient 1	5	LC ₅₀ (for fish)	12	Chronic 1 (M Factor: 1)
		EC ₅₀ (for crustacea)	18	
		ErC ₅₀ (algae)	0.9	
Ingredient 2	1.5	LC ₅₀ (for fish)	40	Chronic 2
		EC ₅₀ (for crustacea)	25	
		ErC ₅₀ (algae)	9.5	
Ingredient 3	93.5	LC ₅₀ (for fish)	> 100	Not classified
		EC ₅₀ (for crustacea)	> 100	
		ErC ₅₀ (algae)	> 100	

Information on tested mixture:

Acute toxicity data of the mixture as a whole	L(E)C ₅₀ mg/l
LC ₅₀ (for fish)	68
EC ₅₀ (for crustacea)	90
ErC ₅₀ (algae)	12.5

Answer:

Short-term (acute) aquatic hazard –classified in Category Acute 3 because:

Acute toxicity data for the mixture as a whole are available for all three trophic levels in the range of 10-100 mg/l.

Long-term (chronic) aquatic hazard– classified in Category Chronic 2 because:

Chronic 1: (Chronic 1) x M ≥ 25%

5% x 1 = 5% (Not classified)

Chronic 2: (M x 10 x Chronic 1) + Chronic 2 ≥ 25%

using data from the ingredients of the mixture:

(1 x 10 x 5%) + 1.5% = 51.5% (Classified)

Rationale:

Short-term (acute) aquatic hazard classification:

- Classification via application of substance criteria is possible for acute toxicity since acute aquatic toxicity test data was provided for the mixture as a whole (paragraph 4.1.3.3);
- The higher toxicity value (from the most sensitive test organism) which in this case is Algae or other aquatic plants is used to classify the tested mixture (paragraph 4.1.3.3 (a));

Long-term (chronic) aquatic hazard classification:

- (c) Classification via application of substance criteria is not possible since chronic aquatic toxicity test data was not provided for the mixture as a whole (paragraph 4.1.3.3.4 (a));
- (d) Classification via the application of bridging principles is not possible since data on a similar mixture was not provided (paragraph 4.1.3.4);
- (e) Long-term (chronic) aquatic hazard classification data is available for some or in this case all of the ingredients of the mixture and the percentage of these ingredients will feed straight into the summation method (paragraph 4.1.3.5.1);
- (f) Adequate chronic toxicity data is not available so the additivity formula cannot be considered (paragraph 4.1.3.5.2);
- (g) Applying the “relevant ingredients” concept from paragraph 4.1.3.1 means that ingredients 1, 2, and 3 will be considered when applying criteria in paragraph 4.1.3.5.5;
- (h) The summation method described in paragraph 4.1.3.5.5.4 applies and the cut-off value/concentration limits provided in Table 4.1.4 are used for classification.

(Ref. Doc: ST/SG/AC.10/C.4/2012/25, Annex 4, Example 3)