

**Long-term (chronic) aquatic hazard classification: application of a stepped approach where the additivity formula is used for the part of the mixture that has chronic toxicity data and passing that result into the summation method**

**Ingredient information:**

Ingredient	Wt%	Chronic toxicity data	NOEC or EC <sub>x</sub>	Rapidly degradable	Long-term (chronic) aquatic hazard classification
Ingredient 1	15	NOEC (28 day for fish)	4.1	Yes	-
		NOEC (21 day for crustacea)	0.13		
Ingredient 2	5	NOEC (for algae)	0.8	No	-
Ingredient 3	80	-	-	-	Chronic 3

**Answer:**

Long-term (chronic) aquatic hazard – classified in Category Chronic 3 because:

**Step 1:**

Applying the additivity formula based on chronic toxicity from 4.1.3.5.2 (b):

$$\frac{\sum C_i + \sum C_j}{EqNOEC_m} = \sum_n \frac{C_i}{NOEC_i} + \sum_n \frac{C_j}{0.1 \times NOEC_j}$$

where:

- C<sub>i</sub> = concentration of ingredient i (weight percentage) covering the rapidly degradable ingredients;
- C<sub>j</sub> = concentration of ingredient j (weight percentage) covering the non- rapidly degradable ingredients;
- NOEC<sub>i</sub> = NOEC (or other recognized measures for chronic toxicity) for ingredient i covering the rapidly degradable ingredients, in mg/l;
- NOEC<sub>j</sub> = NOEC (or other recognized measures for chronic toxicity) for ingredient j covering the non-rapidly degradable ingredients, in mg/l;
- N = number of ingredients, and i and j are running from 1 to n;
- EqNOEC<sub>m</sub> = Equivalent NOEC of the part of the mixture with test data;

$$EqNOEC_m = 20 / ((15/0.13) + 5/(0.1 \times 0.8)) = 0.11 \text{ mg/l}$$

The part of the mixture (i.e., 20%) with chronic toxicity data (i.e., ingredients 1 and 2) has an EqNOEC<sub>m</sub> of 0.11 mg/l. As the NOEC of the ingredients that are considered non-rapidly degradable have already been multiplied with the factor 0.1 the EqNOEC<sub>m</sub> can now be applied to table 4.1 b (ii) resulting in a classification of Chronic 3.

## Step 2:

### Ingredient information going into the summation method calculations:

Ingredient	Wt %	Long-term (chronic) aquatic hazard classification
Additivity result – part of mixture with only toxicity data	20	Chronic 3
Ingredient 3	80	Chronic 3

Chronic 1:  $(\text{Chronic 1}) \times M \geq 25\%$

0% (Not classified)

Chronic 2:  $(M \times 10 \times \text{Chronic 1}) + \text{Chronic 2} \geq 25\%$

using data from the additivity result & ingredients of the mixture:

$(10 \times 0\%) + 0\% = 0\%$  (Not classified)

Chronic 3:  $(M \times 100 \times \text{Chronic 1}) + (10 \times \text{Chronic 2}) + \text{Chronic 3} \geq 25\%$

using data from the additivity result & ingredients of the mixture:

$(100 \times 0\%) + (10 \times 0\%) + 20\% + 80\% = 100\%$  (Classified)

Alternatively apply summation method straight away.

### Rationale:

- (a) Classification via application of substance criteria is not possible since acute aquatic toxicity test data was not provided for the mixture (paragraph 4.1.3.3);
- (b) Classification via the application of bridging principles is not possible since data on a similar mixture was not provided (paragraph 4.1.3.4);
- (c) Classification based on ingredient data for the mixture can be considered (paragraph 4.1.3.5);
- (d) The percentage of the ingredient classified as Chronic 3 will feed straight into the summation method (paragraph 4.1.3.5.1);
- (e) Adequate toxicity data for the other ingredients are available so the additivity formula in combination with the summation method can be considered (paragraphs 4.1.3.5.2 and 4.1.3.5.4);
- (f) Applying the “relevant ingredients” concept from paragraph 4.1.3.1 means that ingredients 1, 2, and 3 will be considered in the calculations (paragraph 4.1.3.5.2 (b));
- (g) When applying the additivity formula the preferred method is to calculate the toxicity of this part of the mixture for each ingredient toxicity values that relate to the same taxonomic group (i.e. fish, crustacean or algae) and then to use the highest toxicity obtained (i.e., use the most sensitive of the three groups). However, when toxicity data for each ingredient are not available in the same taxonomic group the data from the most sensitive test organism should be used (paragraph 4.1.3.5.3). In this case ingredient 1’s toxicity data for Crustacea is used because it has the lowest value (i.e. highest toxicity) and ingredient 2’s Algae data is used;
- (h) Application of the chronic additivity formula results in 20% of the mixture being classified as Chronic 3, which is used in the summation method with the classification information provided for ingredient 3;

- (i) If the mixture is classified in more than one way, the method yielding the more conservative result is valid (GHS 4.1.3.5.4);

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*(Ref.Doc: ST/SG/AC.10/C.4/2012/25, Annex 4, example 2)*