(Short-term (acute) aquatic hazard classification): Classification when there are acute toxicity data as well as hazard classification information available for all relevant components of an untested mixture

Ingredient information:

Ingredient	Wt%	Acute toxicity data	$L(E)C_{50}$	Short-term (acute) aquatic hazard classification
Ingredient 1	20	Fish (96 hr LC_{50})	0.15	Acute 1 M-Factor = 1
		Crustacea (48 hr EC_{50})	11	
		Algae /aquatic plants (72 or 96 hr ErC_{50})	33	
Ingredient 2	20	Fish (96 hr LC_{50})	12	Acute 2
		Crustacea (48 hr EC_{50})	1.2	
		Algae /aquatic plants (72 or 96 hr ErC_{50})	43	
Ingredient 3	60	Fish (96 hr LC_{50})	98	Acute 3
		Crustacea (48 hr EC_{50})	91	
		Algae /aquatic plants (72 or 96 hr ErC_{50})	95	

NOTE: There are two interpretations of the GHS criteria with respect to whether classification should always be based on the summation method whenever information on the classification categories of the ingredients of an untested mixture is available, or whether it is preferable to make the maximum use of actual data on the toxicity of the ingredients through use of the additivity formula when both toxicity data and aquatic hazard classification information are available. For example, the European Union guidance document on the application of the GHS-criteria as implemented in the EU Classification, Labelling, and Packaging (CLP) Regulation states that the information on classification categories of the ingredients should be used to apply the summation method and where classification on the ingredients are available the additivity formula should not be used. Another interpretation is that it is preferable to make maximum use of available scientific data on the toxicity of the ingredients through use of the additivity formula. In the example presented here, according to this interpretation, toxicity data are available for all ingredients. However, if data were only available on some ingredients and information on other ingredients was limited to the classification category, data could be used in the formula to assign a classification category to the portion of the mixture for which data are available. This result could then be combined with the classification category information on the remainder of the ingredients using the summation method. The example will be worked out according to both interpretations.

Answer according to the first interpretation, without use of the additivity formula:

Short-term (acute) aquatic hazard classification:

Acute 1: (Acute 1) x M ≥ 25%

using data from ingredients of the mixture:

(20% x 1) = 20% (Not classified)

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

using data from ingredients of the mixture:

(1 x 10 x 20%) + 20% = 220% (Classified)

The mixture is classified as Acute 2 using the summation method in section 4.1.3.5.5.

Rationale:

(a) Classification via application of substance criteria is not possible since aquatic toxicity test data were 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 were not provided (paragraph 4.1.3.4);

(c) Classification based on ingredient data for the mixture can be considered using the summation method (paragraph 4.1.3.5);

Short-term (acute) aquatic hazard classification:

(d) Acute classification data are available for the ingredients of the mixture and the percentage of these ingredients will feed straight into the summation method (paragraph 4.1.3.5. 1);

(e) The summation method described in paragraph 4.1.3.5.5.3 applies and the cut-off value/concentration limits provided in Table 4.1.3 are used for classification.

Answer according to the second interpretation, available toxicity data in the additivity formula:

Short-term (acute) aquatic hazard classification

Applying the acute additivity formula from 4.1.3.5.2 (a):

$$\frac{\sum Ci}{L(E)C_{50_m}} = \sum_n \frac{Ci}{L(E)C_{50_i}}$$

Where:

C_i	=	concentration of ingredient i (weight percentage);
$L(E)C_{50}$	=	LC_{50} or EC_{50} for ingredient i, in (mg/l);
N	=	number of ingredients, and i is running from 1 to n;
$L(E)C_{50_m}$	=	$L(E)C_{50}$ of the part of the mixture with test data;

Fish $LC_{50Mixture}$ = 100/(20/0.15 + 20/12 + 60/98) = 0.74 mg/l
Crustacea $EC_{50Mixture}$ = 100/(20/11 + 20/1.2 + 60/91) = 5.22 mg/l
Algae $ErC_{50Mixture}$ = 100/(20/33 + 20/43 = 60/95) = 58.73 mg/l

The mixture is classified as Category Acute 1, since the fish LC50 is < 1 mg/l.

Rationale:

In addition to the rationale given for the answer using the summation method:

(a) Adequate toxicity data are available for more than one ingredient so the additivity formulas can be considered (paragraph 4.1.3.5.2);

(b) If the mixture is classified in more than one way (e.g. with or without the use of the additivity formula), the method yielding the more protective/conservative result should be used (paragraph 4.1.3.5.4). Since use of the additivity formula produces a more conservative result, the mixture would be classified as a short-term (acute) aquatic hazard Category 1.

(Reference document: ST/SG/AC.10/C.4/2012/25, Annex 4, example 1)