Application of the summation methods when classification information is available for some or all of the ingredients of a mixture

Ingredient information:

Ingredient	Wt%	Short-term (acute) aquatic hazard classification (M-factor)	Long-term (chronic) aquatic hazard classification (M-factor)
Ingredient 1	0.01	Acute 1 (M-factor: 10)	Chronic 1 (M-factor: 10)
Ingredient 2	1.0	Acute 2	Chronic 2
Ingredient 3	25.0	Not classified	Chronic 4
Ingredient 4	73.99	Not classified	Not classified

Answer:

Short-term (acute) aquatic hazard - Not classified because:

Acute 1: (Acute 1) x M $\geq$ 25%

        using data from ingredients of the mixture:

        (0.01% x 10) = 0.1% (Not classified)

Acute 2: (M x 10 x Acute 1) + Acute 2 $\geq$ 25%

        using data from ingredients of the mixture:

        (10 x 10 x 0.01%) + 1.0% = 2.0% (Not classified)

Acute 3: (M x 100 x Acute 1) + (10 x Acute 2) + Acute 3 $\geq$ 25%

        using data from ingredients of the mixture:

        (10 x 100 x 0.01%) + (10 x 1.0) = 20% (Not classified)

Long-term (chronic) aquatic hazard – classified in Category Chronic 4 because:

Chronic 1: (Chronic 1) x M $\geq$ 25%

        using data from ingredients of the mixture:

        0.01% x 10 = 0.1% (Not classified)

Chronic 2: (M x 10 x Chronic 1) + Chronic 2 $\geq$ 25%

        using data from ingredients of the mixture:

        (10 x 10 x 0.01%) + 1.0% = 2% (Not classified)

Chronic 3: (M x 100 x Chronic 1) + (10 x Chronic 2) + Chronic 3 $\geq$ 25%

        using data from ingredients of the mixture:

        (10 x 100 x 0.01%) + (10 x 1.0%) = 20% (Not classified)

Chronic 4: Chronic 1 + Chronic 2 + Chronic 3 + Chronic 4 $\geq$ 25%

        using data from ingredients of the mixture:

        0.01% + 1.0% + 25.0% = 26.01% (Classified)

Rationale:

(a) Classification via application of substance criteria is not possible since 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) Short-term (acute) and long-term (chronic) aquatic hazard classification data is available for some of the ingredients of the mixture and the percentage of these ingredients classified as "Acute" or "Chronic" will feed straight into the summation method (paragraph 4.1.3.5.51);

(e) Adequate toxicity data is not available so the additivity formula cannot be considered (paragraph 4.1.3.5.2)

Short-term (acute) aquatic hazard classification:

(f) Applying the "relevant ingredients" concept from paragraph 4.1.3.1 means that:

    (i) The use of expert judgment is necessary to make the "relevant ingredient" decision for ingredient 1 since it is a highly toxic ingredient with an M-factor of 10. In this case it was decided to include the ingredient because its concentration in the mixture (i.e. 0.01%) is still significant given the M-factor and the constants used in the Acute 2 and 3 calculations for Acute 1 ingredients;

    (ii) Ingredient 2 will be included in the calculation because it is in the mixture at a concentration $\geq 1\%$;

(g) 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.

Long-term (chronic) aquatic hazard classification:

(h) Applying the "relevant ingredients" concept from paragraph 4.1.3.1 means that:

    (i) The use of expert judgment is necessary to make the "relevant ingredient" decision for ingredient 1 since it is a highly toxic ingredient with an M-factor of 10. In this case it was decided to include the ingredient because its concentration in the mixture (i.e., 0.01%) is still significant given the M factor and the constants used in the Chronic 2 and 3 calculations for Chronic 1 ingredients.

    (ii) Ingredients 2 and 3 will be included in the calculation because they are in the mixture at a concentration $\geq 1\%$.

(i) 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.

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