Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals

Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals **26 June 2012**

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Item 4 (a) of the provisional agenda
Implementation of the GHS –Implementation issues

Update on the work of the informal correspondence group on Practical Classification Issues

Transmitted by the expert from the United States of America on behalf of the informal correspondence group on practical classification issues

A. Purpose

1. The purpose of this document is to provide an update on the work undertaken by the Informal Correspondence Group on Practical Classification Issues (PCI).

B. Background

2. This document presents proposals that were the basis of discussions by the PCI group during the 21st and 22nd sessions and from on-going work to resolve an outstanding issue from the 20th session.

3. During the 20th session, the PCI group submitted a working paper (ST/SG/AC.10/C.4/2010/15) with four worked examples demonstrating the application of the classification criteria for mixtures hazardous to the aquatic environment. During this meeting the expert from Sweden submitted an informal paper (UN/SCEGHS/20/INF.12) raising some concerns, especially regarding the interpretation of when the additivity method can be applied for an ingredient with adequate toxicity data and a classification. Accordingly, the PCI group withdrew one example and agreed to propose an update in this biennium. After discussions amongst the experts in this area, it was agreed that a worked example should be progressed to illustrate the two interpretations.

C. Proposed recommendations

4. The proposed recommendations in this document are presented in three annexes:

   (a) Annex 1 sets forth the recommended editorial amendments to the GHS text.

   (b) Annex 2 provides worked examples illustrating the use of in vitro data.

   (c) Annex 3 provides a new worked example illustrating the application of mixture classification criteria for hazardous to the aquatic environment, as

well as some minor editorial revisions to correct terminology issues for three examples previously approved by the Subcommittee.

D. Next steps

5. Pending feedback from this document, the PCI group plans to submit an official document for the 24th session.

Annex 1

Proposed editorial amendments to the GHS text

1. PCI Correspondence group item:

Propose editorial revisions and/or definitions, as appropriate, to clarify the use of terms such as "no data available", "not applicable", and "not classified", which are used in the decision logics and SDS guidance in Annex 4.

Proposed recommendations:

Amend paragraph A4.3.11.1 as follows:

"These hazards should always be listed on the SDS. ~~If~~ Where data for any of these hazards are not available or are insufficient for classification, ~~they~~ this should ~~still~~ be clearly ~~listed~~ stated on the SDS. ~~with a statement that data is not available~~".

Amend paragraph A4.3.11.4 as follows:

"A4.3.11.4 General statements such as "Toxic" with no supporting data or "Safe if properly used" are not acceptable as they may be misleading and do not provide a description of health effects. Phrases such as "not applicable", "not relevant", or leaving blank spaces in the health effects section can lead to confusion and misunderstanding and should not be used. ~~For health effects and where information is not available, this should be clearly stated.~~ Health effects should be described accurately and relevant distinctions made. For example, allergic contact dermatitis and irritant contact dermatitis should be distinguished from each other."

Amend paragraph A4.3.11.6 as follows:

"Also provide information on the relevant negative data (see A4.2.2.3). ~~Information to support negative test results should be provided~~ If data are available ~~and~~ showing that the substance or mixture does not meet the criteria for classification, it should be stated on the SDS that the substance or mixture has been evaluated and, based on available data, does not meet the classification criteria. (e.g. "carcinogenicity studies in the rat have shown no significant increase in the incidence of cancer")."

Amend paragraph A4.3.12.1 as follows:

"Provide information to evaluate the environmental impact of the substance or mixture if it were released to the environment. This information can assist in handling spills, and evaluating waste treatment practices and should clearly indicate species, media, units, test duration and test conditions. Where ~~information~~ data is not available or insufficient for classification, this should be clearly stated on the SDS. Additionally, if data is available ~~and~~ showing that the substance or mixture does not meet the criteria for classification, it should be stated on the SDS that the substance or mixture has been evaluated and, based on available data, does not meet the classification criteria. Provide also a short summary of the data given under A4.3.12.3 and A4.3.12.7."

2. Chapter 1.2

Propose definitions in Chapter 1.2 to conform with paragraphs A4.3.11.1, A4.3.11.4, A4.3.11.6 and A4.3.12.1 as amended above.

Proposed recommendation:

Amend Chapter 1.2 to include the definitions below in alphabetical order:

"No data available means when data on the hazards of a substance or mixture are not available or are insufficient for classification;

Not classified means when data on the hazards of a substance or mixture have been evaluated and based on the available data does not meet the classification criteria;"

Annex 2

Examples using *in vitro* data

The following example of the application of bridging principle "interpolation within one hazard category" below will be suggested for inclusion in UNITAR's advanced training document, which is under development.

Example 1

Interpolation within one hazard category bridging principle example

The following example uses skin corrosion *in vitro* data from a Human Skin Model (HSM) test (OECD TG 431) to demonstrate the application of the interpolation within one hazard category bridging principle.

OECD TG 431 indicates that the HSM test:

(i) allows the identification of corrosive substances and mixtures; and

(ii) it further enables the identification of non-corrosive substance and mixtures when supported by a weight of evidence determination using other existing information (e.g. pH).

Interpolation within one hazard category

For three mixtures (A, B and C) with identical ingredients, where mixtures A and B have been tested and are in the same irritation/corrosion hazard category, and where untested mixture C has the same toxicologically active ingredients as mixtures A and B but has concentrations of toxicologically active ingredients intermediate to the concentrations in mixtures A and B, then mixture C is assumed to be in the same irritation/corrosion hazard category as A and B.

Tested mixture information:

Mixture A – pH (neat liquid): 1.3; Acid reserve: 6.8; Consideration of pH and acid reserve according to Young *et al.* method[1,2] indicates the mixture may not be corrosive

Mixture B – pH (neat liquid): 1.8; Acid reserve: 2.5; Consideration of pH and acid reserve according to Young *et al.* method [1,2] indicates the mixture may not be corrosive

[1] Young J.R., How M.J., Walker A.P., Worth W.M.H. (1988): Classification as corrosive or irritant to skin of preparations containing acidic or alkaline substances, without test on animals. *Toxicology in Vitro* 2, 19-26.

[2] Young J.R., How M.J. (1994), Product classification as corrosive or irritant by measuring pH and acid/alkali reserve. In Alternative Methods in Toxicology vol. 10 - *In Vitro* Skin Toxicology: Irritation, Phototoxicity, Sensitization, eds. A.Rougier, A.M. Goldberg and H.I Maibach, Mary Ann Liebert, Inc. 23-27.

Skin corrosion/irritation classification and test data			
Test substance	% Viability 3 mins	% Viability 60 mins	Classification
Mixture A	**100**	**30**	**Not Skin Cat. 1**
positive control	23	12	
Mixture B	**88**	**77**	**Not Skin Cat. 1**
positive control	20	12	

The test substance is considered to be non-corrosive to skin:

(i) if the viability after three minutes exposure is ≥ 50% and the viability after 1 hour exposure is ≥ 15%.

Mixtures A and B are not classified as Skin Corrosion Category 1 based on test data and consideration of pH/acid reserve.

Information on ingredients in the tested mixtures:

Ingredient	**Ingredient Skin/Eye classification**	**Weight %**	
		Mixture A	**Mixture B**
Ingredient 1[*]	Eye Irritant Category 2	25	10
Ingredient 2	Not Classified[**]	0.5	7
Ingredient 3	Not Classified[**]	2	6
Ingredient 4	Not Classified[**]	0.2	0.2
Ingredient 5	Not Classified[**]	2	2
Water	Not Classified	70.3	74.8

[*] Ingredient 1 is not classified for skin corrosion/irritation based on the results of an OECD TG 404 study

[**] Not classified for skin corrosion/irritation or serious eye damage/eye irritation based on test data

Untested mixture information:

Ingredient	**Weight %**		
	Mixture A	**Mixture C**	**Mixture B**
Ingredient 1	25	15	10
Ingredient 2	0.5	5.6	7
Ingredient 3	2	6	6
Ingredient 4	0.2	0.2	0.2
Ingredient 5	2	2	2
Water	70.3	71.2	74.8

Mixture C – pH (neat liquid): 1.8; Acid reserve: 3.8; Consideration of pH and acid reserve according to Young *et al.* [1,2] method indicates the mixture may not be corrosive

Answer:

Applying the Interpolation within one hazard category bridging principle, the untested Mixture C is not classified as Skin Corrosion Category 1 based on test data and consideration of pH/acid reserve.

Further information and evaluation will be required to determine the classification of untested Mixture C regarding Skin Irritation.

Rationale:

(a) Classification via application of substance criteria is not possible since skin corrosion/irritation test data was not provided for the untested mixture;

(End of example 1)

Example 2

This example uses Serious Eye Damage/Eye Irritation *in vitro* data from a Bovine Corneal Opacity and Permeability (BCOP) test (OECD TG 437) to illustrate classification of a mixture following the proposed tiered evaluation approach in GHS Chapter 3.3.

Information on Mixture A

Composition:

Ingredient	Weight %	Skin/Eye classification
Ingredient 1	22.06	Eye Cat. 1; Skin Cat. 2
Ingredient 2	4.00	Eye Cat. 1; Skin Cat. 2
Ingredient 3	5.50	Eye Cat. 2A
Ingredient 4	8.00	Not classified *
Ingredient 5	0.05	Not classified *
Ingredient 6	0.2	Not classified *
Water	60.19	Not classified

* Not classified for skin corrosion/irritation or serious eye damage/eye irritation based on test data

pH of mixture (neat liquid): 7 – 8

Mixture is not classified as Skin Corrosion Cat. 1 based on test data

Test data:

BCOP test data			
	Mean opacity value	Mean permeability OD_{490} value	IVIS
Mixture	15	5	90
Concurrent positive and negative controls acceptable			

IVIS: *In Vitro* Irritancy Score

IVIS = mean opacity value + (15 x mean permeability OD_{490} value)

A test sample that induces an IVIS $\geq$ 55.1 is defined as a corrosive or severe irritant.

Classification of Mixture A

Answer:

Applying the proposed tiered evaluation approach in GHS Chapter 3.3, Mixture A is classified as Serious Eye Damage Category 1 based on test data.

Rationale:

(a) Classification based on existing human eye data is not possible since such data are not available;

(b) Classification via application of substance criteria in GHS Table 3.3.1 and Table 3.3.2 is not possible since existing animal data are not available;

(c) Test results derived using the BCOP test method indicate Mixture A is a corrosive or severe eye irritant and takes precedence over information on the classification of ingredients.

(End of example 2)

Annex 3

Examples 1-3 are marked with the proposed editorial revisions to consistently apply terminology for Acute aquatic hazard classification and Long-term aquatic hazard classification.

Example 4 is an updated version of the example submitted in working paper ST/SG/AC.10/C.4/2010/15 that explains and illustrates the two interpretations of when the additivity method can be applied for an ingredient with adequate toxicity data and a classification.

Hazardous to the aquatic environment examples

These examples will be proposed for inclusion in the training document which is being developed by the United Nations Institute for Training and Research (UNITAR).

Example 1

The following example demonstrates application of the summation methods when classification information is available for some or all of the ingredients of a mixture.

Ingredient information:

Ingredient	Wt%	Acute classification (M-factor)	Chronic 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:

Acute aquatic hazard Classification - Not classified because:

Acute 1: (Acute 1) x M ≥ 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 ≥ 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 ≥ 25%

using data from ingredients of the mixture:

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

Long-term aquatic hazard ~~Chronic~~ Classification - Category Chronic 4 because:

Chronic 1: (Chronic 1) x M ≥ 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 ≥ 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 ≥ 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 ≥ 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) Acute and long-term aquatic hazard ~~chronic~~ 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)

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 ≥ 1%;

(g) The summation method ~~approach~~ 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 aquatic hazard ~~Chronic~~ 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 ≥ 1%.

(i) The summation method ~~approach~~ 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.

(End of example 1)

Example 2

For the purpose of long-term aquatic hazard classification the ~~The~~ following example demonstrates 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_x	Rapidly degradable	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 aquatic hazard Classification – Category ~~Mixture is~~ Chronic ~~Category~~3 because:

Step 1:

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

$$\frac{\sum Ci + \sum Cj}{EqNOEC_m} = \sum_n \frac{Ci}{NOECi} + \sum_n \frac{Cj}{0.1 \times NOECj}$$

where:

C_i = concentration of ingredient i (weight percentage) covering the rapidly degradable ingredients;

Cj = concentration of ingredient j (weight percentage) covering the non- rapidly degradable ingredients;

$NOEC_i$ = NOEC (or other recognized measures for chronic toxicity) for ingredient i covering the rapidly degradable ingredients, in mg/l;

NOECj = 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;

$EqNOEC_m$ = Equivalent NOEC of the part of the mixture with test data;

EqNOECm = 20/((15/0.13) + 5/(0.1x 0.8)) = 0.11 mg/l

The part of the mixture (i.e., 20%) with chronic toxicity data (i.e., ingredients 1 and 2) has an EqNOECm of 0.11 mg/l. As the NOEC of the ingredients that are considered not-rapidly degradable have already been multiplied with the factor 0.1 the EqNOECm 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 %	Classification
Additivity result – part of mixture with only toxicity data	20	Chronic 3
Ingredient 3	80	Chronic 3

Chronic 1: (Chronic 1) x M ≥ 25%

0% (Not classified)

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

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

(10 x 0%) + 0% = 0% (Not classified)

Chronic 3: (M x 100 x Chronic 1) + (10 x Chronic 2) + Chronic 3 ≥ 25%

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

(100 x 0%) + (10 x 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 & 4.1.3.5.5.4);

(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 is 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 ~~Category~~ 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);

(End of example 2)

Example 3

The following example demonstrates 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 ~~chronic~~ long-term aquatic hazard classification information is only available on the ingredients.

Ingredient information:

Ingredient	Wt%	Acute toxicity data	$L(E)C_{50}$ mg/l	Chronic 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 ~~Chronic 4~~
		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:

Acute aquatic hazard classification - Category Chronic 3 because:

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

Long-term aquatic hazard ~~Chronic~~ classification - 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:

Acute aquatic hazard classification:

(a) 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);

(b) 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 4.1.3.3.3 (a));

Long-term aquatic hazard ~~Chronic~~ 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 aquatic hazard ~~Chronic~~ 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 ~~chronic~~ summation method ~~approach~~ 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.

(End of example 3)

Example 4 [the new example]

The following example demonstrates the classification when there are toxicity data as well as hazard classification information available for all relevant components of an untested mixture. Ingredients 1, 2, and 3 in this mixture are not classified for long-term aquatic hazard because Ingredients 1, 2, and 3 are readily biodegradable and have experimentally determined bioconcentration factors (BCF) < 500.

Ingredient information:

Ingredient	Wt%	Acute toxicity data	L(E)C_{50}	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 that 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:

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 aquatic hazard Category 2 using the summation method in section 4.1.3.5.5.

Long-term aquatic hazard classification

Not classified for long-term aquatic hazard, since the ingredients are not classified for long-term aquatic hazard.

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);

Acute aquatic hazard classification:

(d) Acute classification data are available for the ingredients of the mixture and the classification category for each ingredient in the summation method (paragraph 4.1.3.5.51);

(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.

Long-term aquatic hazard classification:

(f) The ingredients are assessed as *not* long-term aquatic hazardous and there is therefore no need to consider long-term aquatic hazard classification of the mixture further.

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

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 $EC5_{0Mixture}$ = 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 acute aquatic hazard Category 1, since the fish LC50 is < 1 mg/l.

Rationale:

In addition to the rational 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 the additivity method produces a more conservative result, the mixture would be classified as an acute aquatic hazard Category 1.

(End of example 4)