United Nations ST/SG/AC.10/C.4/2012/25

Secretariat

Distr.: General
25 September 2012

Original: English

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

Twenty-fourth session
Geneva, 12 – 14 December 2012
Item 4 (a) of the provisional agenda
Implementation of the GHS: implementation issues

Proposals to address issues from the programme of work for the practical classification issues correspondence group

Transmitted by the expert from the United States of America on behalf of the informal correspondence group on practical classification issues[1]

Purpose

1. The informal correspondence working group on practical classification issues (PCI) provides in this document recommendations to clarify classification criteria in the GHS as well as a set of worked examples on applying GHS criteria.

Background

2. During the twenty-third session, the PCI informal group submitted informal document INF.20 to the Sub-Committee, providing an update on its work. The PCI group also met surrounding the Sub-Committee meeting to further discuss the proposals presented in INF.20, as well as several other thought starters. Based on feedback on the information document and the thought starters, the PCI has developed the proposed editorial changes to the GHS and worked examples as provided in this document.

[1] In accordance with the programme of work of the Sub-Committee for 2011-2012 approved by the Committee at its fifth session (refer to ST/SG/AC.10/38, par. 16 and ST/SG/AC.10/C.4/40, Annex II, item 3).

Proposal

3. The correspondence group submits the following recommendations to the Sub-Committee for consideration and approval:

(a) Adoption of the recommended editorial amendments to the GHS set forth in Annex 1, to be incorporated into the next revised edition of the GHS;

(b) Adoption of the worked examples illustrating:

(i) the use of the bridging principle interpolation within one hazard category (Annex 2);

(ii) classification of a mixture following the tiered evaluation approach in GHS Chapters 3.3 (Annex 3); and

(iii) application of mixture classification criteria for hazardous to the aquatic environment (Annex 4).

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

Annex 1

Proposed editorial amendments to the GHS

1. Annex 4

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 in Annex 4 (Guidance on the preparation of Safety Data Sheets).

Proposed recommendations:

A4.3.11.1 Amend the sentence following sub-paragraphs (a) to (j) to read: "These hazards should always be listed on the SDS."

A4.3.11.2 to A4.3.11.5 Renumber as follows:

- Current A4.3.11.3 becomes new A4.3.11.2
- Current A4.3.11.5 becomes new A4.3.11.3
- Current A4.3.11.2 becomes new A4.3.11.4
- Current A4.3.11.4 becomes new A4.3.11.5

A4.3.11.6 Amend to read as follows:

"A4.3.11.6 If data for any of these hazards are not available, they should still be listed on the SDS with a statement that data are not available. Also provide information on the relevant negative data (see A4.2.2.3). If data are available 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. Additionally, if a substance or mixture is found to be not classified for other reasons, for example, due to technical impossibility to obtain data, or inconclusive data, this should be clearly stated on the SDS."

A4.3.12.1 Amend to read as follows:

"A4.3.12.1 The information that shall be provided in this section is to enable evaluation of 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, control of release, accidental release measures, and transport."

A4.3.12.2 Insert a new paragraph A4.3.12.2 to read as follows:

"A4.3.12.2 A concise but complete and comprehensible description of the various ecotoxicological (environment) properties, and the available data used to identify those properties, should be provided. The basic properties, for which data should be provided, are:

(a) Toxicity;

(b) Persistence and degradability;

(c) Bioaccumulative potential;

(d) Mobility in soil;

(e) Other adverse effects.

These properties should always be listed on the SDS. Species, media, units, test duration and test conditions should be clearly indicated. (If data for any of these properties are not available, they should still be listed on the SDS with a statement that data are not available).".

A4.3.12.3 Current paragraph A4.3.12.2 becomes new paragraph A4.3.12.3.

Amend the end of the second sentence to read: "…and appropriate, for each relevant substance of the mixture (i.e. those which are required to be listed in Section 3 of the SDS)."

A4.3.12.4 Insert a new paragraph A4.3.12.4 to read as follows:

"A4.3.12.4 Provide also a short summary of the data given under A4.3.12.5 and A4.3.12.9 in relation to the hazard classification criteria. Where data are not available for classification, this should be clearly stated on the SDS for each basic property concerned. Additionally, if data are available 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. Additionally, if a substance or mixture is found to be not classified for other reasons, for example, due to technical impossibility to obtain the data, or inconclusive data, this should be clearly stated on the SDS.".

Renumber current paragraphs A4.3.12.3 to A4.3.12.7 as new paragraphs A4.3.12.5 to A4.3.12.9.

2. Chapter 1.2

PCI correspondence group item: Propose definitions in Chapter 1.2 to provide guidance around the terms used in the decision logics.

Proposed recommendation

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

"No data available means when it is not possible to assess the hazards of a substance or mixture because no data/information are available;

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 criteria for classification;"

3. Chapter 1.5

PCI correspondence group item: Propose editorial amendments to Chapter 1.5 (Hazard Communication: Safety Data Sheets (SDS)) to provide a reference to IMO Resolution MSC.286(86).

Proposed recommendation

1.5.1.3 Add a new paragraph 1.5.1.3 to read as follows:

"1.5.1.3 To address the needs of seafarers and other transport workers in the bulk transport of dangerous goods in sea-going or inland navigation bulk carriers or tank-vessels subject to IMO or national regulations, additional safety and environmental information is required. Paragraph A4.3.14.7 of Annex 4 recommends the inclusion of basic classification information when such cargoes are transported as liquids in bulk according to Annex II of MARPOL and the IBC Code. In addition, ships carrying oil or oil fuel, as defined in Annex I of MARPOL, in bulk or bunkering of oil fuel are required before loading to be provided with a 'material safety data sheet.' in accordance with the IMO's Maritime Safety Committee (MSC) resolution "Recommendations for Material Safety Data Sheets (MSDS) for MARPOL Annex I Oil Cargo and Oil Fuel" (MSC.286(86)). Therefore, in order to have one harmonized SDS for maritime and non-maritime use, the additional provisions of MSC.286(86) may be included in the GHS SDS, where appropriate, for marine transport of MARPOL Annex I cargoes and marine fuel oils to allow for the generation of one harmonized safety data sheet." .

Annex 2

[English only]

Example illustrating a use of the bridging principle interpolation within one hazard category

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 program, which is under development.

This 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) 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 corrosion/irritation 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 corrosion/irritation hazard category as A and B (GHS 3.2.3.2.5).

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[2, 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, 3] indicates the mixture may not be corrosive

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 or mixture is considered to be non-corrosive to skin:

[2] 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.

[3] 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.

(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. The classification of Mixtures A and B, based on the generic concentration limits of the ingredients, is Eye Irritation Category 2.

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:

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

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

***NOTE**: In Chapter 1.3 Classification of Hazardous Substances and Mixtures, the principle that the GHS itself does not include requirements for testing substances or mixtures is clearly stated. However, the GHS also recognizes that some parts of regulatory systems (e.g., pesticides) may require data to be generated. In reviewing this example there were different interpretations on whether negative in vitro data in combination with pH ≤ 2 could be used to justify not being classified as a Skin corrosion Category 1. Where a competent authority requires additional test data, testing and classification should be undertaken in accordance with the competent authority's requirements.*

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 of Mixtures A and B and consideration of pH/acid reserve.

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

The classification of Mixture C is Eye Irritation Category 2.

Rationale:

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

(b) Classification via the application of bridging principles can be considered since there are sufficient data on both the individual ingredients and similar tested mixtures;

(c) Classification of the mixture based on ingredient information should be considered if the classifier chooses not to apply the bridging principle or sufficient data had not been available to apply the bridging principle;

(d) The interpolation within one hazard category bridging principle can be applied because:

(i) Mixtures A and B have both been tested and are in the same corrosion/irritation hazard category (i.e. Not classified as Skin Corrosion Category 1); AND

(ii) Untested mixture C has the same toxicologically active ingredient (i.e. Ingredient 1) as tested mixtures A and B; AND

(iii) The concentration of ingredient 1 in mixture C is intermediate to the concentration of ingredient 1 in mixtures A and B.

(e) Classification of the mixture based on ingredient information should be considered for eye irritation (GHS paragraph 3.3.3.3.2 and Table 3.3.3).

(End of example)

Annex 3

[English only]

Classification of a mixture for skin corrosion/irritation and serious eye damage/irritation following the tiered evaluation approach

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

pH of mixture (neat liquid): 7 – 8

Mixture is not classified for skin corrosion/irritation based on test data

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*

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 to eyes.

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.

Based on the information of the ingredients of the mixture and generic concentration limits Mixture A is classified as Skin Irritation Category 2.

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.

(d) Classification of the mixture based on ingredient information should be considered for skin irritation (GHS paragraph 3.2.3.3.2 and Table 3.2.3).

(End of example)

Annex 4

[English only]

Hazardous to the aquatic environment examples

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

Examples 1-3 are marked with the proposed editorial revisions to consistently apply terminology for Short-term (acute) aquatic hazard classification and Long-term (chronic) aquatic hazard classification.

Example 4 is an updated version of the example submitted in document ST/SG/AC.10/C.4/2010/15 that explains and illustrates the 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.

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%**	**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**~~ **(acute) aquatic hazard** - 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 (chronic) aquatic hazard ~~Chronic~~ – classified in 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) Short-term (acute) ~~Acute~~ and long-term (chronic) 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)

Short-term ~~Acute~~(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 (chronic) 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 (chronic) 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	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 ~~Mixture is~~ Chronic ~~Category~~3 because:

Step 1:

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

$$\frac{\sum \mathrm{Ci} + \sum \mathrm{Cj}}{\mathrm{EqNOEC_m}} = \sum_{\mathrm{n}} \frac{\mathrm{Ci}}{\mathrm{NOECi}} + \sum_{\mathrm{n}} \frac{\mathrm{Cj}}{0.1 \times \mathrm{NOECj}}$$

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 %**	**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: (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 and 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 (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 ~~Chronic 4~~
		EC_{50} (for crustacea)	> 100	
		ErC_{50} (algae)	> 100	

Information on tested mixture:

Acute toxicity data <u>of the mixture as a whole</u>	**$L(E)C_{50}$ mg/l**
LC_{50} (for fish)	68
EC_{50} (for crustacea)	90
ErC_{50} (algae)	12.5

Answer:

~~**Acute**~~ **<u>Short-term (acute) aquatic hazard</u>** –classified in Category <u>Acute</u> 3 <u>because</u>:

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

<u>Long-term (chronic) aquatic hazard</u> ~~**Chronic**~~ – classified in Category <u>Chronic</u> 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~~ <u>Short-term (acute) aquatic hazard</u> 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));

<u>Long-term (chronic) aquatic hazard</u> ~~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) <u>Long-term (chronic) aquatic hazard</u> ~~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 (Short-term (acute) aquatic hazard classification)

The following example demonstrates the 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 $EC5_{0Mixtur}e$ = 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 an short-term (acute) aquatic hazard Category 1.

(End of example 4)