



**Comité d'experts du transport des marchandises dangereuses
et du Système général harmonisé de classification
et d'étiquetage des produits chimiques****Sous-Comité d'experts du Système général harmonisé
de classification et d'étiquetage des produits chimiques****Vingt-quatrième session**

Genève, 12-14 décembre 2012

Point 4 a) de l'ordre du jour provisoire

Mise en œuvre du SGH: questions relatives à l'état de la mise en œuvre**Propositions visant à résoudre les problèmes recensés
dans le programme de travail du groupe de travail
par correspondance chargé des questions pratiques
de classification****Communication de l'expert des États-Unis d'Amérique au nom
du groupe de travail informel par correspondance chargé
des questions pratiques de classification¹****Objet**

1. Par le biais du présent document, le groupe de travail informel par correspondance chargé des questions pratiques de classification formule des recommandations devant permettre de préciser les critères de classification dans le SGH et fournit une série d'exemples concrets d'application des critères du SGH.

Historique de la question

2. À la vingt-troisième session, le groupe de travail informel par correspondance chargé des questions pratiques de classification a soumis au Sous-Comité le document informel INF.20, qui faisait le point sur les travaux menés par le groupe. Le groupe informel s'est aussi réuni en parallèle de la session du Sous-Comité afin d'examiner plus

¹ Conformément au programme de travail du Sous-Comité pour la période 2011-2012, adopté par le Comité à sa cinquième session (voir ST/SG/AC.10/38, par. 16, et ST/SG/AC.10/C.4/40, annexe II, point 3).

avant les propositions formulées dans le document INF.20 ainsi que plusieurs idées pilotes. Sur la base des réactions suscitées par le document d'information et par les discussions, le groupe de travail a élaboré les propositions de modifications d'ordre rédactionnel à apporter au SGH et les exemples pratiques qui figurent dans le présent document.

Proposition

3. Le groupe de travail par correspondance soumet les recommandations suivantes au Sous-Comité pour examen et approbation:

- a) Adoption des amendements de forme au SGH proposés dans l'annexe 1, aux fins de leur incorporation dans la prochaine édition révisée du SGH;
- b) Adoption des exemples concrets illustrant:
 - i) L'utilisation du principe d'extrapolation au sein d'une catégorie de danger (annexe 2);
 - ii) La classification d'un mélange selon la méthode d'évaluation par paliers au chapitre 3.3 du SGH (annexe 3);
 - iii) Application des critères de classification aux mélanges dangereux pour l'environnement aquatique (annexe 4).

Ces exemples concrets seraient proposés pour intégration dans le programme de formation que l'Institut des Nations Unies pour la formation et la recherche (UNITAR) élabore actuellement.

Annexe 1

Propositions d'amendements de forme au SGH

1. Annexe 4

Point relatif au groupe de travail par correspondance chargé des questions pratiques de classification: Proposer des corrections de forme et/ou des définitions, le cas échéant, afin de clarifier l'emploi de termes tels que «aucune donnée disponible», «sans objet (s.o.)» et «non classé», qui figurent dans les diagrammes de décision et dans l'annexe 4 (Document guide sur l'élaboration des fiches de données de sécurité).

Propositions de recommandations:

A4.3.11.1 Modifier la phrase qui suit l'alinéa j) de sorte qu'elle se lise comme suit:
«Ces dangers devraient toujours figurer sur la FDS.».

A4.3.11.2 à A4.3.11.5 Renuméroter comme suit:

- L'actuel paragraphe A4.3.11.3 devient le paragraphe A4.3.11.2;
- L'actuel paragraphe A4.3.11.5 devient le paragraphe A4.3.11.3;
- L'actuel paragraphe A4.3.11.2 devient le paragraphe A4.3.11.4;
- L'actuel paragraphe A4.3.11.4 devient le paragraphe A4.3.11.5.

A4.3.11.6 Modifier de sorte qu'il se lise comme suit:

«A4.3.11.6 Si les données ne sont pas disponibles pour l'un de ces dangers, il devrait néanmoins figurer sur la FDS accompagné d'une mention indiquant que les données ne sont pas disponibles. Fournir aussi des informations sur les données négatives pertinentes (voir A4.2.2.3). Si des données indiquant que la substance ou le mélange ne répondent pas aux critères de classification sont disponibles, il doit être indiqué sur la FDS que la substance ou le mélange ont été évalués et que, compte tenu des données disponibles, ils ne répondent pas aux critères de classification. En outre, si une substance ou un mélange ne sont pas classés pour d'autres raisons, par exemple, en raison de l'impossibilité technique d'obtenir les données ou du caractère peu concluant des données, il convient de l'indiquer clairement sur la FDS.».

A4.3.12.1 Modifier de sorte qu'il se lise comme suit:

«A4.3.12.1 Les informations à fournir dans cette section visent à permettre l'évaluation des effets environnementaux de la substance ou du mélange s'ils ont été libérés dans l'environnement. Ces données peuvent aider à faire face aux déversements et à évaluer les pratiques en matière de traitement des déchets, de contrôle du déversement, de mesures à prendre en cas de déversement accidentel et de transport.».

A4.3.12.2 Ajouter un nouveau paragraphe A4.3.12.2, libellé comme suit:

«A4.3.12.2 Il faudrait présenter de manière concise, mais complète et compréhensible, les diverses propriétés écotoxicologiques (environnementales) et les données disponibles utilisées pour identifier ces propriétés. Les propriétés de base pour lesquelles il faudrait fournir des données sont les suivantes:

- a) Toxicité;
- b) Persistance et dégradabilité;
- c) Potentiel de bioaccumulation;
- d) Mobilité dans le sol;
- e) Autres effets nocifs.

Ces propriétés devraient toujours figurer sur la FDS. Il faudrait indiquer clairement les espèces, les milieux, les unités, la durée des essais et les conditions dans lesquelles ils ont été effectués. (Si les données ne sont pas disponibles pour l'une de ces propriétés, elle devrait néanmoins figurer sur la FDS accompagnée d'une mention indiquant que les données ne sont pas disponibles.)».

A4.3.12.3 L'actuel paragraphe A4.3.12.2 devient le paragraphe A4.3.12.3.

Modifier la fin de la deuxième phrase de sorte qu'elle se lise comme suit: «... et appropriées, pour chaque substance pertinente du mélange (à savoir celles qui doivent obligatoirement figurer dans la section 3 de la FDS).

A4.3.12.4 Ajouter un nouveau paragraphe A4.3.12.4, libellé comme suit:

«A4.3.12.4 Fournir aussi un bref résumé des données fournies sous A4.3.12.5 et A4.3.12.9 concernant les critères de classification des dangers. Si les données ne sont pas disponibles pour la classification, cela devrait être indiqué clairement dans la FDS pour chaque propriété de base concernée. De plus, si des données indiquant que la substance ou le mélange ne répondent pas aux critères de classification sont disponibles, il doit être indiqué sur la FDS que la substance ou le mélange ont été évalués et que, compte tenu des données disponibles, ils ne répondent pas aux critères de classification. En outre, si une substance ou un mélange ne sont pas classés pour d'autres raisons, par exemple, en raison de l'impossibilité technique d'obtenir les données ou du caractère peu concluant des données, il convient de l'indiquer clairement sur la FDS.».

Renommer les actuels paragraphes A4.3.12.3 à A4.3.12.7, qui deviennent les paragraphes A4.3.12.5 à A4.3.12.9.

2. Chapitre 1.2

Point relatif au groupe de travail par correspondance chargé des questions pratiques de classification: Proposer des définitions à ajouter au chapitre 1.2 afin de clarifier les termes utilisés dans les diagrammes de décision.

Proposition de recommandation

Modifier le chapitre 1.2 en y ajoutant les définitions ci-après dans l'ordre alphabétique:

«*Aucune donnée disponible*, l'impossibilité d'évaluer les dangers que présentent une substance ou un mélange en raison de l'absence de données ou d'informations;

Non classé, le fait que des données concernant les dangers que présentent une substance ou un mélange ont été évaluées et que, compte tenu des données disponibles, la substance ou le mélange ne répondent pas aux critères de classification;».

3. Chapitre 1.5

Point relatif au groupe de travail par correspondance chargé des questions pratiques de classification: Proposer des amendements de forme au chapitre 1.5 (Communication des dangers: fiches de données de sécurité (FDS)) afin d'y ajouter une référence à la résolution MSC.286(86) de l'OMI.

Proposition de recommandation

1.5.1.3 Ajouter un nouveau paragraphe 1.5.1.3, libellé comme suit:

«1.5.1.3 Pour répondre aux besoins des gens de mer et des autres ouvriers participant au transport en vrac de marchandises dangereuses par vraquier ou bateau-citerne de navigation maritime ou intérieure soumis à la réglementation de l'OMI ou des autorités nationales, des informations supplémentaires sur la sécurité et l'environnement sont nécessaires. Le paragraphe A4.3.14.7 de l'annexe 4 recommande d'indiquer des informations de classification de base lorsque ces cargaisons sont transportées sous forme de liquides en vrac conformément à l'annexe II de MARPOL et au Recueil IBC. En outre, les navires qui transportent des hydrocarbures ou des combustibles liquides, tels que définis dans l'annexe I de MARPOL, en vrac ou en soute, doivent obtenir une fiche de données de sécurité pour matière dangereuse conformément à la résolution du Comité de la sécurité maritime de l'OMI intitulée «Recommandations relatives aux fiches de données de sécurité pour matière dangereuse (MSDS) concernant les cargaisons d'hydrocarbures et les combustibles liquides visés par l'annexe I de MARPOL» (MSC.286(86)). Par conséquent, afin de permettre l'établissement d'une fiche de données de sécurité harmonisée pour les usages maritimes et non maritimes, les dispositions additionnelles de la résolution MSC.286(86) peuvent être incluses dans la FDS du SGH, le cas échéant, pour le transport maritime des cargaisons d'hydrocarbures et des combustibles liquides visés par l'annexe I de MARPOL.».

Annexe 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:

- (i) if the viability after three minutes exposure is $\geq 50\%$ and the viability after 1 hour exposure is $\geq 15\%$.

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.

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 $\text{pH} \leq 2$ 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)

Annexe 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 OD₄₉₀ value)

A test sample that induces an IVIS ≥ 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:

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

Annexe 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%	<u>Short-term (acute) aquatic hazard classification (M-factor)</u>	<u>Long-term (chronic) aquatic hazard classification (M-factor)</u>
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: $(\text{Acute 1}) \times M \geq 25\%$

using data from ingredients of the mixture:

$(0.01\% \times 10) = 0.1\%$ (Not classified)

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

using data from ingredients of the mixture:

$(10 \times 10 \times 0.01\%) + 1.0\% = 2.0\%$ (Not classified)

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

using data from ingredients of the mixture:

$(10 \times 100 \times 0.01\%) + (10 \times 1.0) = 20\%$ (Not classified)

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

- Chronic 1: $(\text{Chronic 1}) \times M \geq 25\%$
 using data from ingredients of the mixture:
 $0.01\% \times 10 = 0.1\%$ (Not classified)
- Chronic 2: $(M \times 10 \times \text{Chronic 1}) + \text{Chronic 2} \geq 25\%$
 using data from ingredients of the mixture:
 $(10 \times 10 \times 0.01\%) + 1.0\% = 2\%$ (Not classified)
- Chronic 3: $(M \times 100 \times \text{Chronic 1}) + (10 \times \text{Chronic 2}) + \text{Chronic 3} \geq 25\%$
 using data from ingredients of the mixture:
 $(10 \times 100 \times 0.01\%) + (10 \times 1.0\%) = 20\%$ (Not classified)
- Chronic 4: $\text{Chronic 1} + \text{Chronic 2} + \text{Chronic 3} + \text{Chronic 4} \geq 25\%$
 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) ~~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 4.1.3.5.1);
- (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 $\geq 1\%$;
- (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 $\geq 1\%$.
- (i) The summation method ~~approach~~ described in paragraph 4.1.3.5.4 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 3 ~~Mixture is Chronic Category 3~~
because:

Step 1:

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

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

where:

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

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

The part of the mixture (i.e., 20%) with chronic toxicity data (i.e., ingredients 1 and 2) has an $EqNOEC_m$ 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 $EqNOEC_m$ 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:

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

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:

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

Alternatively apply summation method straight away.

Rationale:

- 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);
- 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 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	<u>Not classified</u> 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)C₅₀ mg/l
LC ₅₀ (for fish)	68
EC ₅₀ (for crustacea)	90
ErC ₅₀ (algae)	12.5

Answer:

Acute Short-term (acute) aquatic hazard –classified in Category Acute 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 (chronic) aquatic hazard Chronic – classified in Category Chronic 2 because:

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

$$5\% \times 1 = 5\% \text{ (Not classified)}$$

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

using data from the ingredients of the mixture:

$$(1 \times 10 \times 5\%) + 1.5\% = 51.5\% \text{ (Classified)}$$

Rationale:

Acute-Short-term (acute) aquatic hazard classification:

- 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);
- 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 (chronic) aquatic hazard Chronic-classification:

- 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));
- Classification via the application of bridging principles is not possible since data on a similar mixture was not provided (paragraph 4.1.3.4);
- Long-term (chronic) 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);
- Adequate chronic toxicity data is not available so the additivity formula cannot be considered (paragraph 4.1.3.5.2);
- 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 \geq 25%
 using data from ingredients of the mixture:
 (20% x 1) = 20% (Not classified)

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

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

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;

$$\text{Fish } LC_{50\text{Mixture}} = 100/(20/0.15 + 20/12 + 60/98) = 0.74 \text{ mg/l}$$

$$\text{Crustacea } EC_{50\text{Mixture}} = 100/(20/11 + 20/1.2 + 60/91) = 5.22 \text{ mg/l}$$

$$\text{Algae } ErC_{50\text{Mixture}} = 100/(20/33 + 20/43 + 60/95) = 58.73 \text{ mg/l}$$

The mixture is classified as Category Acute 1, since the fish LC_{50} 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)
