

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

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Item 4 (a) of the provisional agenda

Implementation of the GHS –Implementation issues

Report of the informal working group on Practical Classification Issues

Transmitted by the expert from the United States of America on behalf of the informal working group

The Informal Correspondence Working Group on Practical Classification Issues (PCI) held a meeting on 7 and 8 December 2010 to discuss additional comments received on documents ST/SG/AC.10/C.4//2010/15 and ST/SG/AC.10/C.4//2010/16. The PCI Correspondence Group recommends adoption of working papers ST/SG/AC.10/C.4//2010/15 and ST/SG/AC.10/C.4//2010/16 with the amendments provided below:

Amendments to ST/SG/AC.10/C.4/2010/15

Annex 1

Chapter 3.1: Acute toxicity (amend as indicated)

3.1.3.6.2.3 Insert “relevant” before “ingredient(s)” (~~twice~~) (first two times) and delete “total” before “percentage”.

Annex 4: Guidance on the preparation of Safety Data Sheets (SDS)

A4.3.2.1.2 (amend as indicated)

“If the substance or mixture is classified in accordance with Parts 2, 3 and/or 4 of the GHS generally the classification is communicated by providing the appropriate hazard class and category/subcategory to indicate the hazard. For example, flammable liquid Category 1, and skin corrosive category 1A. However, when classification is differentiated within a hazard class and results in unique hazard statements, then the classification should also reflect that differentiation. For example, the route of exposure differentiates the Acute Toxicity classification as follows: acute oral toxicity Category 1, acute dermal toxicity Category 1 and acute inhalation toxicity Category 1. If a substance or mixture is classified into more than one category in a hazard class that is differentiated, then all classifications should be communicated.”

Annex 2

2. Batching bridging principle example

Background - Paragraph 3 (amend as indicated):

3. Mixtures containing various concentrations of ingredient A have been tested over the course of many years in animal studies. The results of these studies show a direct correlation of Ingredient A's ortho-isomers concentration in the mixture to statistically significant effects in the animal studies. Based on all available data ~~a conservative guideline-specific concentration limit~~ is established (i.e. using a safety factor of 1000x) that any mixture containing greater than or equal to 0.5% of the ortho-isomers of ingredient A must be classified as Specific target organ toxicity – single exposure; Category 2 1. Mixtures containing less than 0.5% of the ortho-isomers of ingredient A are not classified as STOT category 1.

5. Substantially similar mixtures bridging principle example

Background information (amend as indicated):

~~1. Ingredient 1 has been used in products ranging from 1.2 to 6.0 weight percent for years without reports of sensitization.~~

~~1-2. Existing animal test data on ingredient 1 indicates that it is a Category 1 skin sensitizer.~~

2. Ingredient 1 has been used in products ranging from 1.2 to 6.0 weight percent for years with lack of evidence of skin sensitising properties (see table below "tested mixture information".)

Answer: (amended as indicated):

The untested mixture (Product 6) is not classified for skin sensitisation based on the test data available for the similar tested mixture (Product 1).

Rationale: Insert the figure below after paragraph (d) and before sub-paragraph (i).

Test Mixture (i) Product 1			Untested Mixture (ii) Product 6		
Ingredient	Wt %		Ingredient	Wt %	
Ingredient 1	5	→ (ii) B	(ii) B ←	Ingredient 1	4.8
Ingredient 2(a)	91	} (ii) A	} (ii) C	Ingredient 2(b)	91.2
Ingredient 3	3			Ingredient 3	3
Ingredient 4	0.9			Ingredient 4	0.9
Ingredient 5	0.1			Ingredient 5	0.1

Annex 3:

The correspondence group agreed that further discussion was necessary to resolve differences in interpretation of when the additivity method can be applied for ingredients with adequate toxicity data and a classification. Which was illustrated in Example 1. Accordingly, Example 1 is being withdrawn for consideration by the sub-committee. The PCI agreed to continue discussion and will propose updated example(s) in the next biennium.

Replace Annex 3 with the following examples that incorporate agreed editorial revisions.

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) (see UN/SCEGHS/19/INF.24, Annex 3):

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	68.76	Not classified	Not classified

Answer:

Acute Classification - 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)

Chronic Classification - Category 4 because:

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

using data from ingredients of the mixture:

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

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

using data from ingredients of the mixture:

$$(10 \times 10 \times 0.01\%) + 1.0\% = 2\% \text{ (Not classified)}$$

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

using data from ingredients of the mixture:

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

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

using data from ingredients of the mixture:

$$0.01\% + 1.0\% + 25.0\% = 26.01\% \text{ (Classified)}$$

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 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)

Acute 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 4.1.3.5.3 applies and the cut-off value/concentration limits provided in Table 4.1.3 are used for classification.

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 4.1.3.5.5.4 applies and the cut-off value/concentration limits provided in Table 4.1.4 are used for classification.

(End of example 1)

Example 2

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:

Mixture is Chronic Category 3

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 %	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:
 $(10 \times 0\%) + 0\% = 0\%$ (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:
 $(100 \times 0\%) + (10 \times 0\%) + 20\% + 80\% = 100\%$ (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);
- Classification based on ingredient data for the mixture can be considered (paragraph 4.1.3.5);
- The percentage of the ingredient classified as Chronic 3 will feed straight into the summation method (paragraph 4.1.3.5.1);
- 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 & 4.1.3.5.4);
- 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));
- 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 at 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 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	Chronic 4
		EC ₅₀ (for crustacea)	> 100	
		ErC ₅₀ (algae)	> 100	

Information on tested mixture:

Acute toxicity data	L(E)C ₅₀ mg/l
LC ₅₀ (for fish)	68
EC ₅₀ (for crustacea)	90
ErC ₅₀ (algae)	12.5

Answer:

Acute classification - Category 3

Chronic classification - Category 2 because:

Chronic 1: (Chronic 1) x M ≥ 25%

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

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

using data from the ingredients of the mixture:

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

Rationale:

Acute 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));

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) 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)

Amendments to ST/SG/AC.10/C.4/2010/16

Updates agreed to during the PCI's meeting are indicated below:

Chapter 2.5

(see INF.24 (19th session), Annex I, item 3):

2.5.2 Insert 2.5.2.1 before the first paragraph.

2.5.2.2 Insert a new paragraph 2.5.2.2 as follows:

“2.5.2.2 *Simple asphyxiants*

2.5.2.2.1 In addition to classification into one of the four gases under pressure groups, if data are available that indicates that a substance or mixture may result in simple asphyxiation, certain authorities may also choose to require it to be labelled as a *simple asphyxiant*.

2.5.2.2.2 *Simple asphyxiants* are substances or mixtures that displace oxygen in the ambient atmosphere, and can thus cause oxygen deprivation (without other significant health and physical hazards) in those who are exposed, leading to unconsciousness and death. The effects of simple asphyxiants are well known in the workplace and are of particular concern in more or less confined spaces. Well known examples of simple asphyxiants include: nitrogen, helium, neon, argon, krypton, and xenon. Evaluation of other gases as simple asphyxiants requires expert judgment to evaluate evidence such as human experience, information from similar substances, and other pertinent data (e.g. classification for acute inhalation toxicity).

2.5.3 Insert a Note under table 2.5.2 as follows:

“NOTE: If a compressed gas substance/mixture is determined to be a simple asphyxiant, competent authorities may choose to require the asphyxiation ~~hazard~~ effect be communicated by adding the statement using the signal word “warning” and hazard “May displace oxygen and cause suffocation” ~~“Release of gas will displace oxygen and cause rapid suffocation”~~ “Release of gas will displace oxygen and cause rapid suffocation” on the label.

Consequential amendments to Chapter 1.2

Insert the following new definition:

“**Simple asphyxiant** means a substance or mixture that that displaces oxygen in the ambient atmosphere, and can thus cause oxygen deprivation (without other significant health and physical hazards), in those who are exposed, leading to unconsciousness and death. See Chapter 2.5 of the GHS”.