# UN/SCEGHS/16/INF.5

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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# DEVELOPMENT OF GUIDANCE ON THE APPLICATION OF GHS CRITERIA

Amendments to the bridging principles in chapters 3.1 to 3.10 and 4.1 of the GHS as amended in accordance with ST/SG/AC.10/C.4/2008/23, annex 1

# Note by the secretariat

This document contains the full text of the relevant sections of chapters 3.1 to 3.10 and 4.1 of the GHS dealing with bridging principles, as amended in accordance with the draft amendments listed in ST/SG/AC.10/C.4/2008/23, annex 1.

All changes to current text of the GHS are indicated.

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- 3.1.3.5 Classification of mixtures where acute toxicity test data are not available for the complete mixture: bridging principles
- 3.1.3.5.1 Where the mixture itself has not been tested to determine its acute toxicity, but there are sufficient data on **both** the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data will be used in accordance with the following agreed bridging principles. This ensures that the classification process uses the available data to the greatest extent possible in characterizing the hazards of the mixture without the necessity for additional testing in animals.

### 3.1.3.5.2 *Dilution*

If a <u>tested</u> mixture is diluted with a diluent that has an equivalent or lower toxicity classification than the least toxic original ingredient, and which is not expected to affect the toxicity of other ingredients, then the new <u>diluted</u> mixture may be classified as equivalent to the original <u>tested</u> mixture. Alternatively, the formula explained in 3.1.3.6.1 could be applied.

If a mixture is diluted with water or other totally non toxic material, the toxicity of the mixture can be calculated from test data on the undiluted mixture. For example, if a mixture with an  $LD_{50}$  of 1000 mg/kg bodyweight were diluted with an equal volume of water, the  $LD_{50}$  of the diluted mixture would be 2000 mg/kg bodyweight.

# 3.1.3.5.3 *Batching*

The toxicity of one a tested production batch of a complex mixture can be assumed to be substantially equivalent to that of another untested production batch of the same commercial product, and when produced by or under the control of the same manufacturer, unless there is reason to believe there is significant variation such that the toxicity of the untested batch has changed. If the latter occurs, new classification is necessary.

Note: The text in red was not included in your original document but I think that it should be included (see amendments to paras. 3.2.3.2.3, 3.3.3.2.3, 3.8.3.3.3 and 3.9.3.3.3.

# 3.1.3.5.4 *Concentration of highly toxic mixtures*

If a <u>tested</u> mixture is classified in Category 1, and the concentration of the ingredients of the <u>tested</u> mixture that are in Category 1 is increased, the <u>new-resulting untested</u> mixture should be classified in Category 1 without additional testing.

# 3.1.3.5.5 *Interpolation within one toxicity category*

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

# 3.1.3.5.6 *Substantially similar mixtures*

Given the following:

- (a) Two mixtures: (i) A + B;
  - (ii) C + B;
- (b) The concentration of ingredient B is essentially the same in both mixtures;
- (c) The concentration of ingredient A in mixture (i) equals that of ingredient C in mixture (ii);
- (d) Data on toxicity for A and C are available and substantially equivalent, i.e. they are in the same hazard category and are not expected to affect the toxicity of B;

If mixture (i) or (ii) is already classified based on test data, then mixture (ii) the other mixture can be assigned the same hazard category.

3.1.3.5.7 *(unchanged)* 

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# **Amendments to Chapter 3.2**

- 3.2.3.2 Classification of mixtures when data are not available for the complete mixture: bridging principles
- 3.2.3.2.1 Where the mixture itself has not been tested to determine its skin irritation/corrosion, but there are sufficient data on <u>both</u> the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data will be used in accordance with the following agreed bridging principles. This ensures that the classification process uses the available data to the greatest extent possible in characterizing the hazards of the mixture without the necessity for additional testing in animals.

# 3.2.3.2.2 *Dilution*

If a <u>tested</u> mixture is diluted with a diluent which has an equivalent or lower corrosivity/irritancy classification than the least corrosive/irritant original ingredient and which is not expected to affect the corrosivity/irritancy of other ingredients, then the new <u>diluted</u> mixture may be classified as equivalent to the original <u>tested</u> mixture. Alternatively, the method explained in 3.2.3.3 could be applied.

# 3.2.3.2.3 *Batching*

The irritation/corrosion potential of <u>one-a tested production</u> batch of a <u>complex-mixture</u> can be assumed to be substantially equivalent to that of another <u>untested production</u> batch of the same commercial product, <u>and-when produced</u> by or under the control of the same manufacturer, unless there is reason to believe there is significant variation such that the toxicity of the <u>untested batch has changed</u>. If the latter occurs, new classification is necessary.

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# 3.2.3.2.4 Concentration of mixtures of the highest corrosion/irritation category

If a tested mixture classified in the highest sub-category for corrosion is concentrated, a-the more concentrated untested mixture should be classified in the highest corrosion sub-category without additional testing. If a tested mixture classified in the highest category for skin irritation is concentrated and does not contain corrosive ingredients, a-the more concentrated untested mixture should be classified in the highest irritation category without additional testing.

# 3.2.3.2.5 *Interpolation within one toxicity category*

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

# 3.2.3.2.6 *Substantially similar mixtures*

Given the following:

- (a) Two mixtures:
- (i) A + B;
- (ii) C + B;
- (b) The concentration of ingredient B is essentially the same in both mixtures;
- (c) The concentration of ingredient A in mixture (i) equals that of ingredient C in mixture (ii);
- (d) Data on irritation/corrosion for A and C are available and substantially equivalent, i.e. they are in the same hazard category and are not expected to affect the toxicity of B.

If mixture (i) or (ii) is already classified based on test data, then mixture (ii) the other mixture can be classified in the same hazard category.

3.2.3.2.7 *(unchanged)* 

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- 3.3.3.2 Classification of mixtures when data are not available for the complete mixture: bridging principles
- 3.3.3.2.1 Where the mixture itself has not been tested to determine its skin corrosivity or potential to cause serious eye damage or irritation, but there are sufficient data on **both** the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data will be used in accordance with the following agreed bridging principles. This ensures that the classification process uses the available data to the greatest extent possible in characterizing the hazards of the mixture without the necessity for additional testing in animals.

### 3.3.3.2.2 *Dilution*

If a <u>tested</u> mixture is diluted with a diluent which has an equivalent or lower classification for serious eye damage/irritancy classification than the least damaging/irritant original ingredient and which is not expected to affect the corrosivity/irritancy of other ingredients, then the new <u>diluted</u> mixture may be classified as equivalent to the original <u>tested</u> mixture. Alternatively, the method explained in 3.3.3.3 could be applied.

# 3.3.3.2.3 *Batching*

The irritation/serious eye damage potential of <u>one-a tested production</u> batch of a <u>complex</u> mixture can be assumed to be substantially equivalent to that of another <u>untested production</u> batch of the same commercial product, <u>and when produced</u> by or under the control of the same manufacturer, unless there is reason to believe there is significant variation such that the toxicity of the <u>untested batch</u> has changed. If the latter occurs, new classification is necessary.

3.3.3.2.4 Concentration of mixtures of the highest serious eye damage/irritation category

If a tested mixture classified in the highest category for serious eye damage is concentrated, a the more concentrated untested mixture should be classified in the highest serious eye damage category without additional testing. If a tested mixture classified in the highest sub-category for skin/eye irritation is concentrated and does not contain serious eye damage ingredients, a the more concentrated untested mixture should be classified in the highest irritation category without additional testing.

3.3.3.2.5 *Interpolation within one toxicity 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/serious eye damage toxicity category, and where untested mixture C has the same toxicologically active ingredients as mixtures A and B but has with concentrations of toxicologically active ingredients intermediate to the concentrations of those ingredients in mixtures A and B, then mixture C is assumed to be in the same irritation/serious eye damage category as A and B.

3.3.3.2.6 Substantially similar mixtures

Given the following:

- (a) Two mixtures: (i) A + B (ii) C + B:
- (b) The concentration of ingredient B is essentially the same in both mixtures;

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- (c) The concentration of ingredient A in mixture (i) equals that of ingredient C in mixture (ii);
- (d) Data on irritation/serious eye damage for A and C are available and substantially equivalent, i.e. they are in the same hazard category and are not expected to affect the toxicity of B.

If mixture (i) or (ii) is already classified by testing, mixture (ii) the other mixture can be assigned in the same hazard category.

3.3.3.2.7 *(unchanged)* 

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# **Amendments to Chapter 3.4**

- 3.4.3.2 Classification of mixtures when data are not available for the complete mixture: bridging principles
- 3.4.3.2.1 Where the mixture itself has not been tested to determine its sensitizing properties, but there are sufficient data on **both** the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data will be used in accordance with the following agreed bridging principles. This ensures that the classification process uses the available data to the greatest extent possible in characterizing the hazards of the mixture without the necessity for additional testing in animals.

### 3.4.3.2.2 *Dilution*

If a <u>tested</u> mixture is diluted with a diluent which is not a sensitizer and which is not expected to affect the sensitization of other ingredients, then the new <u>diluted</u> mixture may be classified as equivalent to the original <u>tested</u> mixture.

# 3.4.3.2.3 *Batching*

The sensitizing properties of <u>one-a tested production</u> batch of a <u>complex-mixture</u> can be assumed to be substantially equivalent to that of another <u>untested production</u> batch of the same commercial product <u>and-when produced</u> by or under the control of the same manufacturer, unless there is reason to believe there is significant variation such that the sensitization <u>potential</u> of the <u>untested batch</u> has changed. If the latter occurs, new classification is necessary.

# 3.4.3.2.4 Substantially similar mixtures

Given the following:

- (a) Two mixtures: (i) A + B; (ii) C + B;
- (b) The concentration of ingredient B is essentially the same in both mixtures;
- (c) The concentration of ingredient A in mixture (i) equals that of ingredient C in mixture (ii);

- (d) Ingredient B is a sensitizer and ingredients A and C are not sensitizers;
- (e) A and C are not expected to affect the sensitizing properties of B.

If mixture (i) or (ii) is already classified by testing, then the other mixture (ii) can be assigned the same hazard category.

3.4.3.2.5 *(unchanged)* 

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# **Amendments to Chapter 3.5**

- 3.5.3.2 Classification of mixtures when data are not available for the complete mixture: bridging principles
- 3.5.3.2.1 Where the mixture itself has not been tested to determine its germ cell mutagenicity hazard, but there are sufficient data on **both** the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data will be used in accordance with the following agreed bridging principles. This ensures that the classification process uses the available data to the greatest extent possible in characterizing the hazards of the mixture without the necessity for additional testing in animals.

### 3.5.3.2.2 *Dilution*

If a <u>tested</u> mixture is diluted with a diluent which is not expected to affect the germ cell mutagenicity of other ingredients, then the new <u>diluted</u> mixture may be classified as equivalent to the original <u>tested</u> mixture.

# 3.5.3.2.3 *Batching*

The germ cell mutagenic potential of <u>one-a tested</u> production batch of a <u>complex-mixture</u> can be assumed to be substantially equivalent to that of another <u>untested</u> production batch of the same commercial product, <u>when produced</u> by <u>and-or under the control of the same manufacturer unless there is reason to believe there is significant variation in composition such that the germ cell mutagenic potential of the <u>untested</u> batch has changed. If the latter occurs, a new classification is necessary.</u>

# 3.5.3.2.4 Substantially similar mixtures

Given the following:

- (a) Two mixtures: (i) A + B;
  - (ii) C + B;
- (b) The concentration of mutagen ingredient B is the same in both mixtures;
- (c) The concentration of ingredient A in mixture (i) equals that of ingredient C in mixture (ii);
- (d) Data on toxicity for A and C are available and substantially equivalent, i.e. they are in the same hazard category and are not expected to affect the germ cell mutagenicity of B.

If mixture (i) or (ii) is already classified by testing, then mixture (ii) the other mixture can be classified in the same hazard category.

- 3.6.3.2 Classification of mixtures when data are not available for the complete mixture: bridging principles
- 3.6.3.2.1 Where the mixture itself has not been tested to determine its carcinogenic hazard, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data will be used in accordance with the following agreed bridging principles. This ensures that the classification process uses the available data to the greatest extent possible in characterizing the hazards of the mixture without the necessity for additional testing in animals.

#### 3.6.3.2.2 Dilution

If a tested mixture is diluted with a diluent that is not expected to affect the carcinogenicity of other ingredients, then the new diluted mixture may be classified as equivalent to the original tested mixture.

#### 3.6.3.2.3 **Batching**

The carcinogenic potential of one a tested production batch of a complex mixture can be assumed to be substantially equivalent to that of another untested production batch of the same commercial product, when produced by and or under the control of the same manufacturer unless there is reason to believe there is significant variation in composition such that the carcinogenic potential of the untested batch has changed. If the latter occurs, a new classification is necessary.

#### 3.6.3.2.4 Substantially similar mixtures

Given the following:

- (a) Two mixtures:
  - (i) A + B;
  - (ii) C + B;
- The concentration of carcinogen ingredient B is the same in both mixtures; (b)
- The concentration of ingredient A in mixture (i) equals that of ingredient C in (c) mixture (ii);
- (d) Data on toxicity for A and C are available and substantially equivalent, i.e. they are in the same hazard category and are not expected to affect the carcinogenicity of B.

If mixture (i) or (ii) is already classified by testing, then mixture (ii) the other mixture can be assigned the same **hazard** category.

- 3.7.3.2 Classification of mixtures when data are not available for the complete mixture: bridging principles
- 3.7.3.2.1 Where the mixture itself has not been tested to determine its reproductive toxicity, but there are sufficient data on **both** the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data will be used in accordance with the following agreed bridging rules. This ensures that the classification process uses the available data to the greatest extent possible in characterizing the hazards of the mixture without the necessity for additional testing in animals.

### 3.7.3.2.2 *Dilution*

If a <u>tested</u> mixture is diluted with a diluent which is not expected to affect the reproductive toxicity of other ingredients, then the new <u>diluted</u> mixture may be classified as equivalent to the original <u>tested</u> mixture.

# 3.7.3.2.3 *Batching*

The reproductive toxicity potential of <u>one-a tested</u> production batch of a <u>complex-mixture</u> can be assumed to be substantially equivalent to that of another <u>untested</u> production batch of the same commercial product, <u>when</u> produced by <u>and-or</u> under the control of the same manufacturer unless there is reason to believe there is significant variation in composition such that the reproductive toxicity potential of the <u>untested</u> batch has changed. If the latter occurs, a new classification is necessary.

# 3.7.3.2.4 Substantially similar mixtures

Given the following:

- (a) Two mixtures: (i) A + B;
  - (ii) C + B;
- (b) The concentration of Ingredient B, toxic to reproduction, is the same in both mixtures;
- (c) The concentration of ingredient A in mixture (i) equals that of ingredient C in mixture (ii);
- (d) Data on toxicity for A and C are available and substantially equivalent, i.e. they are in the same hazard category and are not expected to affect the reproductive toxicity of B.

If mixture (i) or (ii) is already classified by testing, then mixture (ii) the other mixture can be assigned the same hazard category.

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- 3.8.3.3 Classification of mixtures when data are not available for the complete mixture: bridging principles
- 3.8.3.3.1 Where the mixture itself has not been tested to determine its specific target organ toxicity, but there are sufficient data on **both** the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data can be used in accordance with the following bridging principles. This ensures that the classification process uses the available data to the greatest extent possible in characterizing the hazards of the mixture without the necessity of additional testing in animals.

### 3.8.3.3.2 *Dilution*

If a <u>tested</u> mixture is diluted with a diluent which has the same or a lower toxicity classification as the least toxic original ingredient and which is not expected to affect the toxicity of other ingredients, then the new <u>diluted</u> mixture may be classified as equivalent to the original <u>tested</u> mixture.

# 3.8.3.3.3 *Batching*

The toxicity of one a tested production batch of a complex mixture can be assumed to be substantially equivalent to that of another untested production batch of the same commercial product, and when produced by or under the control of the same manufacturer, unless there is reason to believe there is significant variation such that the toxicity of the untested batch has changed. If the latter occurs, a new classification is necessary.

# 3.8.3.3.4 *Concentration of highly toxic mixtures*

If in a <u>tested</u> mixture of Category 1, the concentration of a toxic ingredient is increased, the <u>resulting</u> concentrated mixture should be classified in Category 1 without additional testing.

### 3.8.3.3.5 *Interpolation within one toxicity category*

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

# 3.8.3.3.6 Substantially similar mixtures

Given the following:

- (a) Two mixtures: (i) A + B;
  - (ii) C + B;
- (b) The concentration of ingredient B is essentially the same in both mixtures;
- (c) The concentration of ingredient A in mixture (i) equals that of ingredient C in mixture (ii);
- (d) Data on toxicity for A and C are available and substantially equivalent, i.e. they are in the same hazard category and are not expected to affect the toxicity of B.

If mixture (i) or (ii) is already classified by testing, then mixture (ii) the other mixture can be assigned the same hazard category.

3.8.3.3.7 *(unchanged)* 

# 3.9.3.3 Classification of mixtures when data are not available for the complete mixture: bridging principles

3.9.3.3.1 Where the mixture itself has not been tested to determine its specific target organ toxicity, but there are sufficient data on **both** the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data can be used in accordance with the following bridging principles. This ensures that the classification process uses the available data to the greatest extent possible in characterizing the hazards of the mixture without the necessity of additional testing in animals.

### 3.9.3.3.2 *Dilution*

If a <u>tested</u> mixture is diluted with a diluent which has the same or a lower toxicity classification as the least toxic original ingredient and which is not expected to affect the toxicity of other ingredients, then the new <u>diluted</u> mixture may be classified as equivalent to the original <u>tested</u> mixture.

# 3.9.3.3.3 *Batching*

The toxicity of one-a tested production batch of a complex mixture can be assumed to be substantially equivalent to that of another untested production batch of the same commercial product, and when produced by or under the control of the same manufacturer, unless there is reason to believe there is significant variation such that the toxicity of the untested batch has changed. If the latter occurs, new classification is necessary.

# 3.9.3.3.4 *Concentration of highly toxic mixtures*

If in a <u>tested</u> mixture of Category 1, the concentration of a toxic ingredient is increased, the <u>resulting</u> concentrated mixture should be classified in Category 1 without additional testing.

### 3.9.3.3.5 *Interpolation within one toxicity category*

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

# 3.9.3.3.6 *Substantially similar mixtures*

Given the following:

- (a) Two mixtures: (i) A + B;
  - (ii) C + B;
- (b) The concentration of ingredient B is essentially the same in both mixtures;
- (c) The concentration of ingredient A in mixture (i) equals that of ingredient C in mixture (ii);
- (d) Data on toxicity for A and C are available and substantially equivalent, i.e. they are in the same hazard category and are not expected to affect the toxicity of B.

If mixture (i) or (ii) is already classified by testing, then mixture (ii) the other mixture can be assigned the same hazard category.

# 3.9.3.3.7 *(unchanged)*

- 3.10.3.2 Classification of mixtures when data are not available for the complete mixture: bridging principles
- 3.10.3.2.1 Where the mixture itself has not been tested to determine its aspiration toxicity, but there are sufficient data on **both** the individual ingredients and similar tested mixtures to adequately characterize the hazard of the mixture, these data will be used in accordance with the following bridging principles. This ensures that the classification process uses the available data to the greatest extent possible in characterizing the hazards of the mixture without the necessity of additional testing in animals.

### 3.10.3.2.2 *Dilution*

If a <u>tested</u> mixture is diluted with a diluent that does not pose an aspiration toxicity hazard, and which is not expected to affect the aspiration toxicity of other ingredients or the mixture, then the new <u>diluted</u> mixture may be classified as equivalent to the original <u>tested</u> mixture. However, the concentration of aspiration toxicant(s) should not drop below 10%.

# 3.10.3.2.3 Batching

The aspiration toxicity of <u>one-a tested</u> production batch of a <u>complex-mixture</u> can be assumed to be substantially equivalent to that of another <u>untested</u> production batch of the same commercial product, <u>and-when</u> produced by or under the control of the same manufacturer, unless there is reason to believe there is significant variation such that the aspiration toxicity, reflected by viscosity or concentration, of the <u>untested</u> batch has changed. If the latter occurs, new classification is necessary.

# 3.10.3.2.4 *Concentration of Category 1 mixtures*

If a <u>tested</u> mixture is classified in Category 1, and the concentration of the ingredients of the <u>tested</u> mixture that are in Category 1 is increased, the <u>new-resulting untested</u> mixture should be classified in Category 1 without additional testing.

3.10.3.2.5 *Interpolation within one toxicity category* 

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

### 3.10.3.2.6 *Substantially similar mixtures*

Given the following:

- (a) Two mixtures: (i) A + B;
  - (ii) C + B;
- (b) The concentration of ingredient B is essentially the same in both mixtures;
- (c) The concentration of ingredient A in mixture (i) equals that of ingredient C in mixture (ii);
- (d) Aspiration toxicity for A and C is substantially equivalent, i.e. they are in the same hazard category and are not expected to affect the aspiration toxicity of B.

If mixture (i) or (ii) is already classified based on the criteria in table 3.10.1, then mixture (ii) the other mixture can be assigned the same hazard category.

- 4.1.3.4 Classification of mixtures when data are not available for the complete mixture: bridging principles
- 4.1.3.4.1 *(unchanged)*
- 4.1.3.4.2 *Dilution*

If <u>Where</u> a <u>new</u> mixture is formed by diluting <u>another classifieda</u> <u>tested</u> mixture or a substance with a diluent which has an equivalent or lower aquatic hazard classification than the least toxic original ingredient and which is not expected to affect the aquatic hazards of other ingredients, then the <u>resulting</u> mixture may be classified as equivalent to the original <u>tested</u> mixture or substance. <u>Alternatively</u>, the method explained in 4.1.3.5 could be applied.

If a mixture is formed by diluting another classified mixture or a substance with water or other totally non toxic material, the toxicity of the mixture can be calculated from the original mixture or substance.

### 4.1.3.4.3 *Batching*

The aquatic hazard classification of one a tested production batch of a complex mixture can be assumed to be substantially equivalent to that of another untested production batch of the same commercial product, and when produced by or under the control of the same manufacturer, unless there is reason to believe there is significant variation such that the aquatic hazard classification of the untested batch has changed. If the latter occurs, new classification is necessary.

4.1.3.4.4 *Concentration of mixtures which are classified with the most severe classification categories (Chronic 1 and Acute 1)* 

If a <u>tested</u> mixture is classified as Chronic 1 and/or Acute 1, and <u>the</u> ingredients of the mixture which are classified as Chronic 1 and/or Acute 1 are further concentrated, the more concentrated <u>untested</u> mixture should be classified with the same classification category as the original <u>tested</u> mixture without additional testing.

4.1.3.4.5 *Interpolation within one toxicity category* 

For three mixtures (A, B and C) with identical ingredients, where mixtures A and B have been tested and are in the same toxicity 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 toxicity category as A and B. If mixtures A and B are in the same classification category and mixture C is made in which the toxicologically active ingredients have concentrations intermediate to those in mixtures A and B, then mixture C is assumed to be in the same category as A and B. Note that the identity of the ingredients is the same in all three mixtures.

4.1.3.4.6 Substantially similar mixtures

Given the following:

(a) Two mixtures: (i) A + B;

(ii) C + B;

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- (b) The concentration of ingredient B is <u>essentially</u> the same in both mixtures;
- (c) The concentration of ingredient A in mixture (i) equals that of ingredient C in mixture (ii);
- (d) Classification Data on aquatic toxicity for A and C are available and are the same substantially equivalent, i.e. they are in the same hazard category and are not expected to affect the aquatic toxicity of B.

Then there is no need to test <u>If</u> mixture (i) or (ii) if mixture (i) is already characterized classified based on test data, then the other mixture can be by testing and both mixtures would be classified assigned in the same <u>hazard</u> category.

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