

## CHAPTER 2.9

### CLASS 9 – MISCELLANEOUS DANGEROUS SUBSTANCES AND ARTICLES

#### 2.9.1 Definitions

2.9.1.1 *Class 9 substances and articles (miscellaneous dangerous substances and articles)* are substances and articles which, during transport present a danger not covered by other classes.

2.9.1.2 *Genetically modified microorganisms (GMMOs) and genetically modified organisms (GMOs)* are microorganisms and organisms in which genetic material has been purposely altered through genetic engineering in a way that does not occur naturally.

#### 2.9.2 Assignment to Class 9

2.9.2.1 Class 9 includes, inter alia:

- a) environmentally hazardous substances which are not covered by other classes;
- b) elevated temperature substances (i.e. substances that are transported or offered for transport at temperatures equal to or exceeding 100 °C in a liquid state or at temperatures equal or exceeding 240 °C in a solid state);
- c) GMMOs or GMOs which do not meet the definition of infectious substances (see 2.6.3) but which are capable of altering animals, plants or microbiological substances in a way not normally the result of natural reproduction. They shall be assigned to UN 3245.

GMMOs or GMOs are not subject to these Regulations when authorized for use by the competent authorities of the Governments of the countries of origin, transit and destination.

#### 2.9.3 Environmentally hazardous substances (aquatic environment)

##### 2.9.3.1 General definitions

2.9.3.1.1 Environmentally hazardous substances include, inter alia, liquid or solid substances pollutant to the aquatic environment and solutions and mixtures of such substances (such as preparations and wastes).

2.9.3.1.2 The aquatic environment may be considered in terms of the aquatic organisms that live in the water, and the aquatic ecosystem of which they are part<sup>1</sup>. The basis, therefore, of the identification of hazard is the aquatic toxicity of the substance or mixture, although this may be modified by further information on the degradation and bioaccumulation behaviour.

2.9.3.1.3 While the following classification procedure is intended to apply to all substances and mixtures, it is recognised that in some cases, e.g. metals or poorly soluble inorganic compounds, special guidance will be necessary<sup>2</sup>.

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<sup>1</sup> This does not address aquatic pollutants for which there may be a need to consider effects beyond the aquatic environment such as the impacts on human health etc.

<sup>2</sup> This can be found in Annex 10 of the GHS.

2.9.3.1.4 The following definitions apply for acronyms or terms used in this section:

- BCF: Bioconcentration Factor;
- BOD: Biochemical Oxygen Demand;
- COD: Chemical Oxygen Demand;
- GLP: Good Laboratory Practices;
- EC<sub>50</sub>: the effective concentration of substance that causes 50% of the maximum response;
- ErC<sub>50</sub>: EC<sub>50</sub> in terms of reduction of growth;
- K<sub>ow</sub>: octanol/water partition coefficient;
- LC<sub>50</sub> (50% lethal concentration): the concentration of a substance in water which causes the death of 50% (one half) in a group of test animals;
- L(E)C<sub>50</sub>: LC<sub>50</sub> or EC<sub>50</sub>;
- NOEC: No Observed Effect Concentration;
- OECD Test Guidelines: Test guidelines published by the Organization for Economic Cooperation and Development (OECD);

### 2.9.3.2 *Definitions and data requirements*

2.9.3.2.1 The basic elements for classification of environmentally hazardous substances (aquatic environment) are:

- acute aquatic toxicity;
- potential for or actual bioaccumulation;
- degradation (biotic or abiotic) for organic chemicals; and
- chronic aquatic toxicity.

2.9.3.2.2 While data from internationally harmonised test methods are preferred, in practice, data from national methods may also be used where they are considered as equivalent. In general, freshwater and marine species toxicity data can be considered as equivalent data and are preferably to be derived using OECD Test Guidelines or equivalent according to the principles of Good Laboratory Practices (GLP). Where such data are not available, classification shall be based on the best available data.

2.9.3.2.3 **Acute aquatic toxicity** shall normally be determined using a fish 96 hour LC<sub>50</sub> (OECD Test Guideline 203 or equivalent), a crustacea species 48 hour EC<sub>50</sub> (OECD Test Guideline 202 or equivalent) and/or an algal species 72 or 96 hour EC<sub>50</sub> (OECD Test Guideline 201 or equivalent). These species are considered as surrogates for all aquatic organisms. Data on other species such as Lemna may also be considered if the test methodology is suitable.

2.9.3.2.4 **Bioaccumulation** means net result of uptake, transformation and elimination of a substance in an organism due to all routes of exposure (i.e. air, water, sediment/soil and food).

**The potential for bioaccumulation** shall normally be determined by using the octanol/water partition coefficient, usually reported as a log K<sub>ow</sub> determined according to OECD Test Guideline 107 or 117. While this represents a potential to bioaccumulate, an experimentally determined Bioconcentration Factor (BCF)

provides a better measure and shall be used in preference when available. A BCF shall be determined according to OECD Test Guideline 305.

2.9.3.2.5 **Environmental degradation** may be biotic or abiotic (eg. hydrolysis) and the criteria used reflect this fact. Ready biodegradation is most easily defined using the OECD biodegradability tests (OECD Test Guideline 301 (A - F)). A pass level in these tests may be considered as indicative of rapid degradation in most aquatic environments. As these are freshwater tests, use of results from OECD Test Guideline 306, which is more suitable for the marine environment, is also included. Where such data are not available, a BOD(5 days)/COD ratio > 0.5 is considered as indicative of rapid degradation. Abiotic degradation such as hydrolysis, primary degradation, both abiotic and biotic, degradation in non-aquatic media and proven rapid degradation in the environment may all be considered in defining rapid degradability<sup>3</sup>.

Substances are considered rapidly degradable in the environment if the following criteria are met:

- (a) In 28-day ready biodegradation studies, the following levels of degradation are achieved:
  - (i) Tests based on dissolved organic carbon: 70%;
  - (ii) Tests based on oxygen depletion or carbon dioxide generation: 60% of theoretical maxima;

These levels of biodegradation shall be achieved within 10 days of the start of degradation which point is taken as the time when 10% of the substance has been degraded; or
- (b) In those cases where only BOD and COD data are available, when the ratio of BOD<sub>5</sub>/COD is ≥ 0.5; or
- (c) If other convincing scientific evidence is available to demonstrate that the substance or mixture can be degraded (biotically and/or abiotically) in the aquatic environment to a level above 70% within a 28 day period.

2.9.3.2.6 **Chronic toxicity** data are less available than acute data and the range of testing procedures less standardised. Data generated according to the OECD Test Guidelines 210 (Fish Early Life Stage) or 211 (Daphnia Reproduction) and 201 (Algal Growth Inhibition) may be accepted. Other validated and internationally accepted tests may also be used. The “No Observed Effect Concentrations” (NOECs) or other equivalent L(E)Cx shall be used.

### 2.9.3.3 *Substance classification categories and criteria*

2.9.3.3.1 Substances shall be classified as “environmentally hazardous substances (aquatic environment)”, if they satisfy the criteria for Acute I, Chronic I or Chronic II, according to the following tables:

#### **Acute toxicity**

<b><u>Category: Acute I</u></b>	
Acute toxicity:	
96 hr LC <sub>50</sub> (for fish)	≤ 1 mg/l and/or
48 hr EC <sub>50</sub> (for crustacea)	≤ 1 mg/l and/or
72 or 96hr ErC <sub>50</sub> (for algae or other aquatic plants)	≤ 1 mg/l

<sup>3</sup> *Special guidance on data interpretation is provided in Chapter 4.1 and Annex 9 of the GHS.*

## Chronic toxicity

### **Category: Chronic I**

Acute toxicity:

96 hr LC <sub>50</sub> (for fish)	≤ 1 mg/l and/or
48 hr EC <sub>50</sub> (for crustacea)	≤ 1 mg/l and/or
72 or 96hr ErC <sub>50</sub> (for algae or other aquatic plants)	≤ 1 mg/l

and the substance is not rapidly degradable and/or the log K<sub>ow</sub> ≥ 4 (unless the experimentally determined BCF < 500)

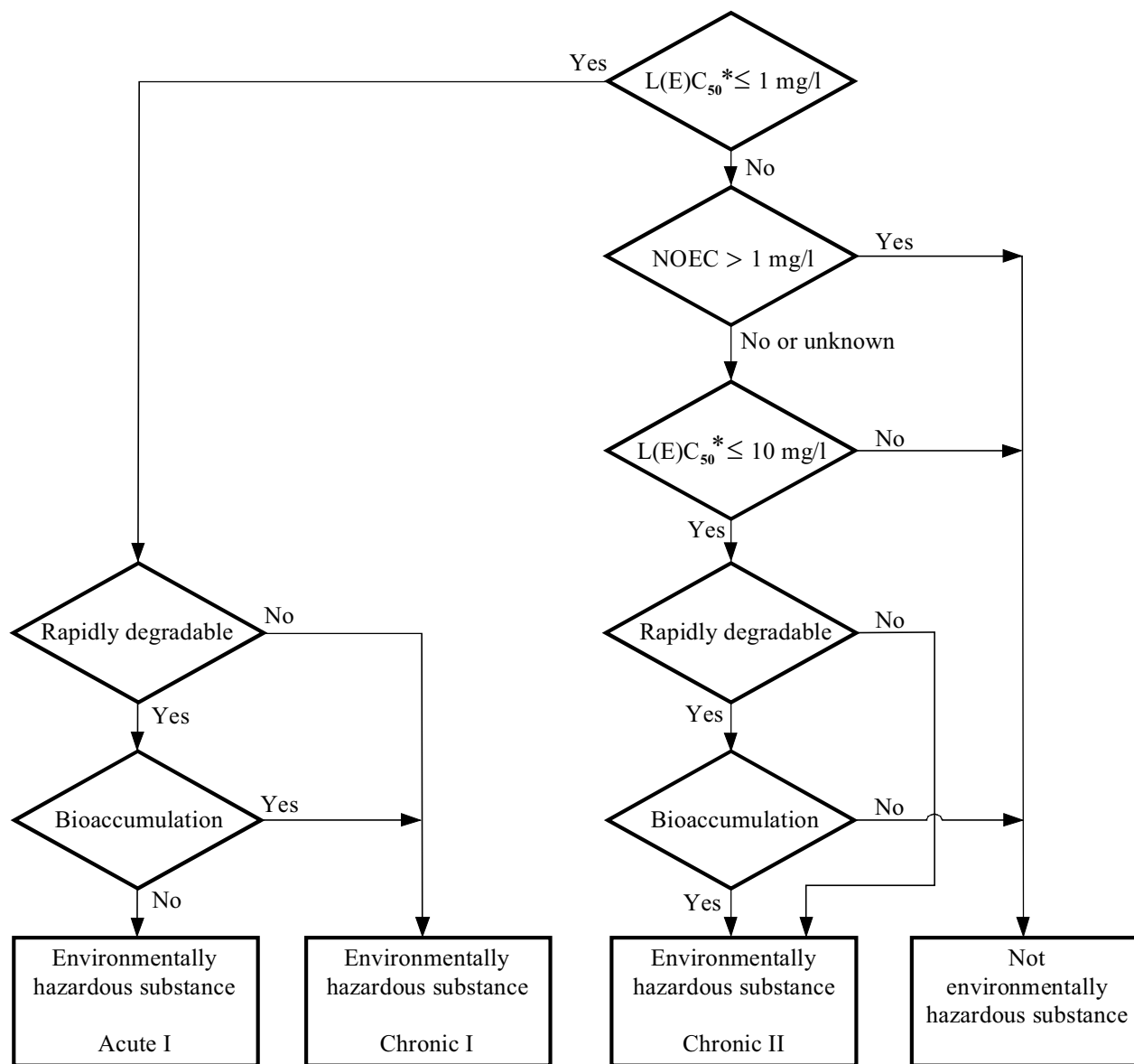
### **Category: Chronic II**

Acute toxicity:

96 hr LC <sub>50</sub> (for fish)	>1 to ≤ 10 mg/l and/or
48 hr EC <sub>50</sub> (for crustacea)	>1 to ≤ 10 mg/l and/or
72 or 96hr ErC <sub>50</sub> (for algae or other aquatic plants)	>1 to ≤ 10 mg/l

and the substance is not rapidly degradable and/or the log K<sub>ow</sub> ≥ 4 (unless the experimentally determined BCF < 500), unless the chronic toxicity NOECs are > 1 mg/l

The classification flowchart below outlines the process to be followed.



\* Lowest value of 96-hour  $LC_{50}$ , 48-hour  $EC_{50}$  or 72 or 96-hour  $ErC_{50}$ , as appropriate.

### 2.9.3.4 Mixtures classification categories and criteria

2.9.3.4.1 The classification system for mixtures covers the classification categories which are used for substances meaning acute category I and chronic categories I and II. In order to make use of all available data for purposes of classifying the aquatic environmental hazards of the mixture, the following assumption is made and is applied where appropriate:

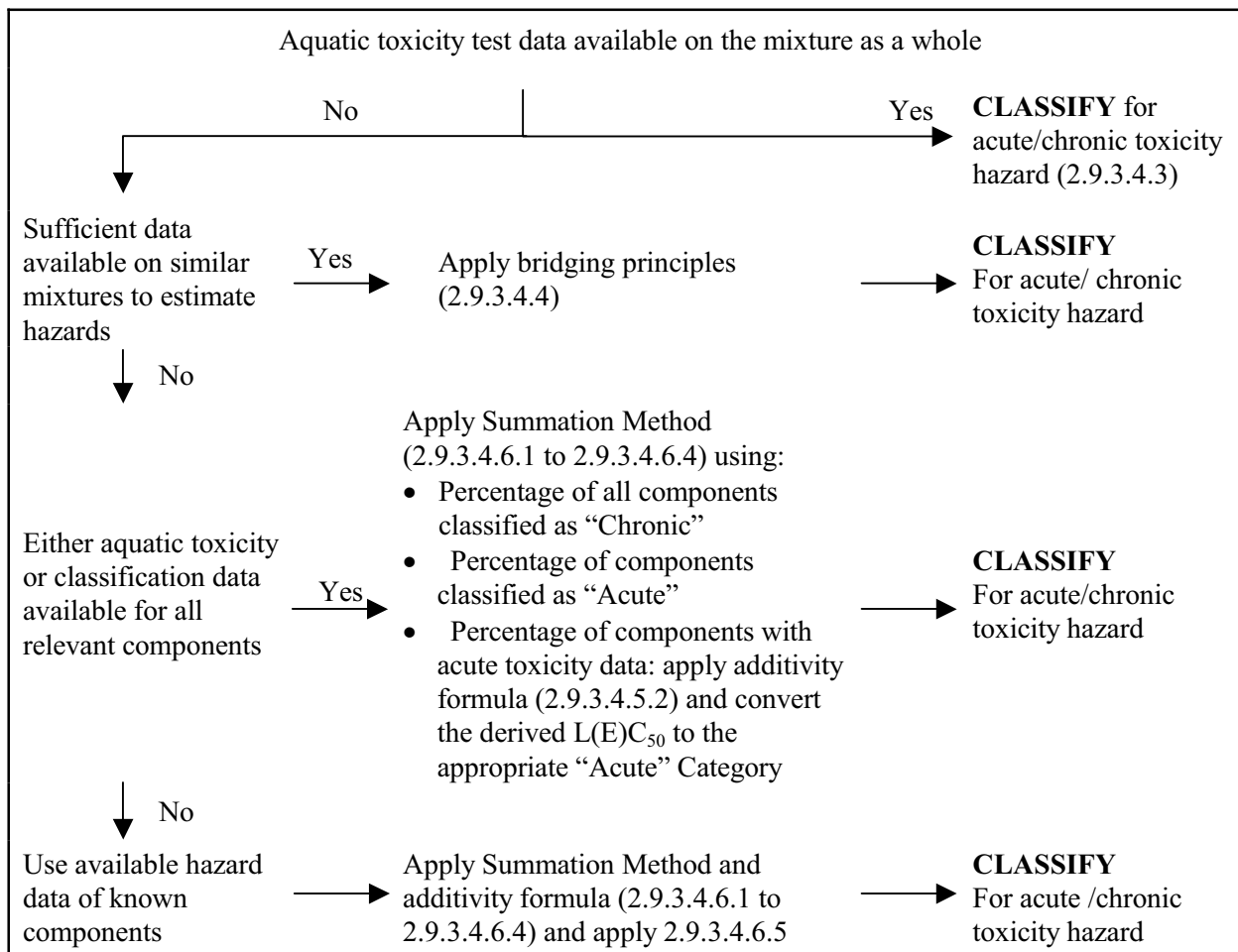
The “relevant components” of a mixture are those which are present in a concentration of 1% (by mass) or greater, unless there is a presumption (e.g. in the case of highly toxic components) that a component present at less than 1% can still be relevant for classifying the mixture for aquatic environmental hazards.

2.9.3.4.2 The approach for classification of aquatic environmental hazards is tiered, and is dependent upon the type of information available for the mixture itself and for its components. Elements of the tiered approach include:

- (a) classification based on tested mixtures;
- (b) classification based on bridging principles;
- (c) the use of “summation of classified components” and /or an “additivity formula”.

Figure 2.9.1 below outlines the process to be followed.

**Figure 2.9.1: Tiered approach to classification of mixtures for acute and chronic aquatic environmental hazards**



#### 2.9.3.4.3 *Classification of mixtures when data are available for the complete mixture*

2.9.3.4.3.1 When the mixture as a whole has been tested to determine its aquatic toxicity, it shall be classified according to the criteria that have been agreed for substances, but only for acute toxicity. The classification is based on the data for fish, crustacea and algae/plants. Classification of mixtures by using LC<sub>50</sub> or EC<sub>50</sub> data for the mixture as a whole is not possible for chronic categories since both toxicity data and environmental fate data are needed, and there are no degradability and bioaccumulation data for mixtures as a whole. It is not possible to apply the criteria for chronic classification because the data from degradability and bio-accumulation tests of mixtures cannot be interpreted; they are meaningful only for single substances.

2.9.3.4.3.2 When there is acute toxicity test data (LC<sub>50</sub> or EC<sub>50</sub>) available for the mixture as a whole, this data as well as information with respect to the classification of components for chronic toxicity shall be used to complete the classification for tested mixtures as follows. When chronic (long term) toxicity data (NOEC) is also available, this shall be used in addition.

- (a) L(E)C<sub>50</sub> (LC<sub>50</sub> or EC<sub>50</sub>) of the tested mixture ≤ 1mg/l and NOEC of the tested mixture ≤ 1.0 mg/l or unknown:
  - classify mixture as category acute I;
  - apply summation of classified components approach (see 2.9.3.4.6.3 and 2.9.3.4.6.4) for chronic classification (chronic I, II, or no need of chronic classification);
- (b) L(E)C<sub>50</sub> of the tested mixture ≤ 1 mg/l and NOEC of the tested mixture > 1.0 mg/l:
  - classify mixture as category acute I;
  - apply summation of classified components approach (see 2.9.3.4.6.3 and 2.9.3.4.6.4) for classification as Category Chronic I. If the mixture is not classified as Category Chronic I, then there is no need for chronic classification;
- (c) L(E)C<sub>50</sub> of the tested mixture > 1 mg/l, or above the water solubility, and NOEC of the tested mixture ≤ 1.0 mg/l or unknown:
  - no need to classify for acute toxicity;
  - apply summation of classified components approach (see 2.9.3.4.6.3 and 2.9.3.4.6.4) for chronic classification or no need for chronic classification;
- (d) L(E)C<sub>50</sub> of the tested mixture > 1 mg/l, or above the water solubility, and NOEC of the tested mixture > 1.0 mg/l:
  - No need to classify for acute or chronic toxicity.

#### 2.9.3.4.4 *Bridging principles*

2.9.3.4.4.1 Where the mixture itself has not been tested to determine its aquatic environmental hazard, but there are sufficient data on the individual components and similar tested mixtures to adequately characterise the hazards of the mixture, this data shall 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 characterising the hazards of the mixture without the necessity for additional testing in animals.

#### 2.9.3.4.4.2 Dilution

2.9.3.4.4.2.1 If a mixture is formed by diluting another classified mixture or a substance with a diluent which has an equivalent or lower aquatic hazard classification than the least toxic original component and which is not expected to affect the aquatic hazards of other components, then the mixture shall be classified as equivalent to the original mixture or substance.

2.9.3.4.4.2.2 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 shall be calculated from the original mixture or substance.

#### 2.9.3.4.4.3 Batching

2.9.3.4.4.3.1 The aquatic hazard classification of one production batch of a complex mixture shall be assumed to be substantially equivalent to that of another production batch of the same commercial product and 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 batch has changed. If the latter occurs, new classification is necessary.

2.9.3.4.4.4 Concentration of mixtures which are classified with the most severe classification categories (chronic I and acute I)

2.9.3.4.4.4.1 If a mixture is classified as chronic I and/or acute I, and components of the mixture which are classified as chronic I and/or acute I are further concentrated, the more concentrated mixture shall be classified with the same classification category as the original mixture without additional testing.

#### 2.9.3.4.4.5 Interpolation within one toxicity category

2.9.3.4.4.5.1 If mixtures A and B are in the same classification category and mixture C is made in which the toxicologically active components have concentrations intermediate to those in mixtures A and B, then mixture C shall be in the same category as A and B. Note that the identity of the components is the same in all three mixtures.

#### 2.9.3.4.4.6 Substantially similar mixtures

2.9.3.4.4.6.1 Given the following:

(a) Two mixtures:

(i) A + B

(ii) C + B;

(b) The concentration of component B is the same in both mixtures;

(c) The concentration of component A in mixture (i) equals that of component C in mixture (ii);

(d) Classification for A and C are available and are the same, i.e. they are in the same hazard category and are not expected to affect the aquatic toxicity of B,

then there shall be no need to test mixture (ii) if mixture (i) is already characterised by testing and both mixtures are classified in the same category.

2.9.3.4.5 *Classification of mixtures when data are available for all components or only for some components of the mixture*

2.9.3.4.5.1 The classification of a mixture shall be based on summation of the classification of its components. The percentage of components classified as “Acute” or “Chronic” will feed straight into the summation method. Details of the summation method are described in 2.9.3.4.6.1 to 2.9.3.4.6.4.1.

2.9.3.4.5.2 Mixtures are often made of a combination of both components that are classified (as Acute I and/or Chronic I, II) and those for which adequate test data is available. When adequate toxicity data is available for more than one component in the mixture, the combined toxicity of those components shall be calculated using the following additivity formula, and the calculated toxicity shall be used to assign that portion of the mixture an acute toxicity hazard which is then subsequently used in applying the summation method.

$$\frac{\sum C_i}{L(E)C_{50m}} = \sum_n \frac{C_i}{L(E)C_{50i}}$$

where:

$C_i$  = concentration of component i (mass percentage);  
 $L(E)C_{50i}$  = (mg/L)  $LC_{50}$  or  $EC_{50}$  for component i;  
 $n$  = number of components, and i is running from 1 to n;  
 $L(E)C_{50m}$  =  $L(E)C_{50}$  of the part of the mixture with test data

2.9.3.4.5.3 When applying the additivity formula for part of the mixture, it is preferable to calculate the toxicity of this part of the mixture using for each substance toxicity values that relate to the same species (i.e. fish, daphnia or algae) and then to use the highest toxicity (lowest value) obtained (i.e. use the most sensitive of the three species). However, when toxicity data for each component are not available in the same species, the toxicity value of each component shall be selected in the same manner that toxicity values are selected for the classification of substances, i.e. the higher toxicity (from the most sensitive test organism) is used. The calculated acute toxicity shall then be used to classify this part of the mixture as Acute I using the same criteria described for substances.

2.9.3.4.5.4 If a mixture is classified in more than one way, the method yielding the more conservative result shall be used.

2.9.3.4.6 *Summation method*

2.9.3.4.6.1 Classification procedure

2.9.3.4.6.1.1 In general a more severe classification for mixtures overrides a less severe classification, e.g. a classification with chronic I overrides a classification with chronic II. As a consequence the classification procedure is already completed if the results of the classification is chronic I. A more severe classification than chronic I is not possible and it is not necessary therefore to undergo the further classification procedure.

2.9.3.4.6.2 Classification for the acute category I

2.9.3.4.6.2.1 All components classified as acute I shall be considered. If the sum of these components is greater than or equal to 25% the whole mixture shall be classified as category acute I. If the result of the calculation is a classification of the mixture as category acute I, the classification process is completed.

2.9.3.4.6.2.2 The classification of mixtures for acute hazards based on this summation of classified components, is summarised in Table 2.9.1 below.

**Table 2.9.1: Classification of a mixture for acute hazards, based on summation of classified components**

Sum of components classified as:	Mixture is classified as:
Acute I $\times$ M <sup>a</sup> $\geq$ 25%	Acute I

<sup>a</sup> For explanation of the M factor, see 2.9.3.4.6.4.

#### 2.9.3.4.6.3 Classification for the chronic categories I, II

2.9.3.4.6.3.1 First, all components classified as chronic I are considered. If the sum of these components is greater than or equal to 25% the mixture shall be classified as category chronic I. If the result of the calculation is a classification of the mixture as category chronic I the classification procedure is completed.

2.9.3.4.6.3.2 In cases where the mixture is not classified as chronic I, classification of the mixture as chronic II is considered. A mixture shall be classified as chronic II if 10 times the sum of all components classified as chronic I plus the sum of all components classified as chronic II is greater than or equal to 25%. If the result of the calculation is classification of the mixture as chronic II, the classification process is completed.

2.9.3.4.6.3.3 The classification of mixtures for chronic hazards, based on this summation of classified components, is summarised in Table 2.9.2 below.

**Table 2.9.2: Classification of a mixture for chronic hazards, based on summation of classified components**

Sum of components classified as:	Mixture is classified as:
Chronic I $\times$ M <sup>a</sup> $\geq$ 25%	Chronic I
(M $\times$ 10 $\times$ Chronic I)+Chronic II $\geq$ 25%	Chronic II

<sup>a</sup> For explanation of the M factor, see 2.9.3.4.6.4.

#### 2.9.3.4.6.4 Mixtures with highly toxic components

2.9.3.4.6.4.1 Acute category 1 components with toxicities well below 1 mg/l may influence the toxicity of the mixture and are given increased weight in applying the summation of classification approach. When a mixture contains components classified as acute or chronic category I, the tiered approach described in 2.9.3.4.6.2 and 2.9.3.4.6.3 shall be applied using a weighted sum by multiplying the concentrations of acute category 1 components by a factor, instead of merely adding up the percentages. This means that the concentration of “Acute I” in the left column of Table 2.9.1 and the concentration of “Chronic I” in the left column of Table 2.9.2 are multiplied by the appropriate multiplying factor. The multiplying factors to be applied to these components are defined using the toxicity value, as summarised in Table 2.9.3 below. Therefore, in order to classify a mixture containing acute I and/or chronic I components, the classifier needs to be informed of the value of the M factor in order to apply the summation method. Alternatively, the additivity formula (2.9.3.4.5.2) may be used when toxicity data are available for all highly toxic components in the mixture and there is convincing evidence that all other components, including those for which specific acute toxicity data are not available, are of low or no toxicity and do not significantly contribute to the environmental hazard of the mixture.

**Table 2.9.3: Multiplying factors for highly toxic components of mixtures**

L(E)C <sub>50</sub> value	Multiplying factor (M)
$0.1 < L(E)C_{50} \leq 1$	1
$0.01 < L(E)C_{50} \leq 0.1$	10
$0.001 < L(E)C_{50} \leq 0.01$	100
$0.0001 < L(E)C_{50} \leq 0.001$	1 000
$0.00001 < L(E)C_{50} \leq 0.0001$	10 000
(continue in factor 10 intervals)	

2.9.3.4.6.5 Classification of mixtures with components without any useable information

2.9.3.4.6.5.1 In the event that no useable information on acute and/or chronic aquatic hazard is available for one or more relevant components, it is concluded that the mixture cannot be attributed (a) definitive hazard category(ies). In this situation the mixture shall be classified based on the known components only with the additional statement that: “× percent of the mixture consists of component(s) of unknown hazards to the aquatic environment.”.

**2.9.3.5 *Substances or mixtures dangerous to the aquatic environment not otherwise classified under these Regulations***

2.9.3.5.1 Substances or mixtures dangerous to the aquatic environment not otherwise classified under these Regulations shall be designated:

UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. or

UN 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.

They shall be assigned to packing group III.