

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 Transport of Dangerous Goods

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ISSUES RELATING TO THE GLOBALLY HARMONIZED SYSTEM OF CLASSIFICATION AND LABELLING OF CHEMICALS (GHS)

Consolidated version of Chapter 2.9 of the Model Regulations

Harmonization with the amendments to the 2nd revised edition of the GHS

Note by the secretariat

1. The secretariat reproduces below the text of Chapter 2.9 of the Model Regulations, as it will appear in the 16th revised edition. It includes the amendments adopted by the Sub-Committee at its 31st, 32nd and 33rd sessions (ST/SG/AC.10/C.3/2008/97) and corrections to the 15th revised edition (ST/SG/AC.10/1/Rev.15/Corr.1 and UN/SCETDG/33/INF.58).
2. In addition, the secretariat has incorporated new amendments that should be made to ensure continuous harmonization with the GHS in the light of the work currently carried out by the GHS Sub-Committee.
3. The amendments shown in [track changes](#) reflect the amendments to the 2nd revised edition of the GHS adopted by the GHS Sub-Committee at its 13th, 14th and 15th sessions (ST/SG/AC.10/C.4/2008/14). The corrections and amendments [between square brackets and shown in track changes](#) are proposed by the secretariat and will be discussed at the 16th session of the GHS Sub-Committee in December 2008 (ST/SG/AC.10/C.4/2008/14/Add.1).
4. When incorporating the changes into the Model Regulations, the secretariat noted that some figures and tables of the GHS are not included in the Model Regulations. As these illustrate the classification process, the Sub-Committee may wish to consider if they should be included in the Model Regulations or if reference should be made to the GHS.
5. The Sub-Committee is invited to consider the following issues:
 - 2.9.3.3.1 (b): reference is made to figure 4.1.1 of the GHS, which is not included in the Model Regulations.
 - End of section 2.9.3.3: the classification flowchart in the Model Regulations needs to be updated. An alternative could be to replace it with the new table 4.1.2 of the GHS.
 - 2.9.3.4.3.1: reference is made to decision logic 4.1.5.2.2 of the GHS, which is not included in the Model Regulations.

CHAPTER 2.9

CLASS 9 – MISCELLANEOUS DANGEROUS SUBSTANCES AND ARTICLES, INCLUDING ENVIRONMENTALLY HAZARDOUS SUBSTANCES

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 *Deleted.*

2.9.2 Assignment to Class 9

The substances and articles of Class 9 are subdivided as follows:

Substances which, on inhalation as fine dust, may endanger health

- 2212 BLUE ASBESTOS (crocidolite) or
- 2212 BROWN ASBESTOS (amosite, mysorite)
- 2590 WHITE ASBESTOS (chrysotile, actinolite, anthophyllite, tremolite)

Substances evolving flammable vapour

- 2211 POLYMERIC BEADS, EXPANDABLE, evolving flammable vapour
- 3314 PLASTICS MOULDING COMPOUND in dough, sheet or extruded rope form evolving flammable vapour

Lithium batteries

- 3090 LITHIUM METAL BATTERIES (including lithium alloy batteries)
- 3091 LITHIUM METAL BATTERIES CONTAINED IN EQUIPMENT (including lithium alloy batteries) or
- 3091 LITHIUM METAL BATTERIES PACKED WITH EQUIPMENT (including lithium alloy batteries)
- 3480 LITHIUM ION BATTERIES (including lithium ion polymer batteries)
- 3481 LITHIUM ION BATTERIES CONTAINED IN EQUIPMENT (including lithium ion polymer batteries)
- or
- 3481 LITHIUM ION BATTERIES PACKED WITH EQUIPMENT (including lithium ion polymer batteries)

Live-saving appliances

- 2990 LIFE-SAVING APPLIANCES, SELF-INFLATING
- 3072 LIFE-SAVING APPLIANCES NOT SELF-INFLATING containing dangerous goods as equipment
- 3268 AIR BAG INFLATORS or
- 3268 AIR BAG MODULES or
- 3268 SEAT-BELT PRETENSIONERS

Substances and articles which, in the event of fire, may form dioxins

This group of substances includes:

- 2315 POLYCHLORINATED BIPHENYLS, LIQUID
- 3432 POLYCHLORINATED BIPHENYLS, SOLID
- 3151 POLYHALOGENATED BIPHENYLS, LIQUID or

- 3151 POLYHALOGENATED TERPHENYLS, LIQUID
- 3152 POLYHALOGENATED BIPHENYLS, SOLID or
- 3152 POLYHALOGENATED TERPHENYLS, SOLID

Examples of articles are transformers, condensers and apparatus containing those substances.

Substances transported or offered for transport at elevated temperatures

- (a) Liquid

3257 ELEVATED TEMPERATURE LIQUID, N.O.S., at or above 100 °C and below its flash-point (including molten metal, molten salts, etc.)

- (b) Solid

3258 ELEVATED TEMPERATURE SOLID, N.O.S., at or above 240 °C

Environmentally hazardous substances

- (a) Solid

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

- (b) Liquid

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

These designations are used for substances and mixtures which are dangerous to the aquatic environment that do not meet the classification criteria of any other class or another substance within Class 9. These designations may also be used for wastes not otherwise subject to these Regulations but which are covered under the *Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal* and for substances designated to be environmentally hazardous substances by the competent authority of the country of origin, transit or destination which do not meet the criteria for an environmentally hazardous substance according to these Regulations or for any other hazard Class. The criteria for substances which are hazardous to the aquatic environment are given in 2.9.3.

Genetically modified micro-organisms (GMMOs) and genetically modified organisms (GMOs)

- 3245 GENETICALLY MODIFIED MICRO-ORGANISMS or
- 3245 GENETICALLY MODIFIED ORGANISMS

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

GMMOs and 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 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 countries of origin, transit and destination.

Other substances or articles presenting a danger during transport, but not meeting the definitions of another class

- 1841 ACETALDEHYDE AMMONIA
- 1845 CARBON DIOXIDE, SOLID (DRY ICE)
- 1931 ZINC DITHIONITE (ZINC HYDROSULPHITE)
- 1941 DIBROMODIFLUOROMETHANE
- 1990 BENZALDEHYDE
- 2071 AMMONIUM NITRATE BASED FERTILISER
- 2216 FISH MEAL (FISH SCRAP), STABILIZED
- 2807 MAGNETIZED MATERIAL
- 2969 CASTOR BEANS or
- 2969 CASTOR MEAL or
- 2969 CASTOR POMACE or
- 2969 CASTOR FLAKE
- 3166 ENGINE, INTERNAL COMBUSTION or
- 3166 VEHICLE, FLAMMABLE GAS POWERED or
- 3166 VEHICLE, FLAMMABLE LIQUID POWERED or
- 3166 FUEL CELL ENGINE or
- 3166 VEHICLE, FUEL CELL POWERED WITH FLAMMABLE GAS or
- 3166 VEHICLE, FUEL CELL POWERED WITH FLAMMABLE LIQUID
- 3171 BATTERY-POWERED VEHICLE or
- 3171 BATTERY-POWERED EQUIPMENT
- 3316 CHEMICAL KIT or
- 3316 FIRST AID KIT
- 3334 AVIATION REGULATED LIQUID, N.O.S.
- 3335 AVIATION REGULATED SOLID, N.O.S.
- 3359 FUMIGATED CARGO TRANSPORT UNIT
- 3363 DANGEROUS GOODS IN MACHINERY or
- 3363 DANGEROUS GOODS IN APPARATUS

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).

For the purposes of this section,

“Substance” means chemical elements and their compounds in the natural state or obtained by any production process, including any additive necessary to preserve the stability of the product and any impurities deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.

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 part¹. 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.

¹ 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.

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 necessary².

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_x: the concentration associated with x% response;
- EC₅₀: the effective concentration of substance that causes 50% of the maximum response;
- ErC₅₀: EC₅₀ in terms of reduction of growth;
- K_{ow}: octanol/water partition coefficient;
- LC₅₀ (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)C₅₀: LC₅₀ or EC₅₀;
- NOEC: ~~(No Observed Effect Concentration);~~ the test concentration immediately below the lowest tested concentration with statistically significant adverse effect. The NOEC has not statistically significant adverse effect compared to the control;
- 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:

- ~~-(a)~~ acute aquatic toxicity;
- (b) chronic aquatic toxicity;
- ~~-(c)~~ potential for or actual bioaccumulation; and
- ~~-(d)~~ 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, it has been agreed that 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 This can be found in Annex 10 of the GHS.

2.9.3.2.3 [Acute aquatic toxicity means the intrinsic property of a substance to be injurious to an organism in a short-term aquatic exposure to that substance.](#)

[Note by the secretariat: this definition is included in the 2nd revised edition of the GHS but is missing in the Model Regulations.]

[For classification purposes, Acute \(short-term\) hazard is the hazard of a chemical caused by its acute toxicity to an organism during short-term aquatic exposure to that chemical.](#)

[\[Acute \(short-term\) hazard, for classification purposes, means the hazard of a chemical caused by its acute toxicity to an organism during short-term aquatic exposure to that chemical.\]](#)

Acute aquatic toxicity shall normally be determined using a fish 96 hour LC₅₀ (OECD Test Guideline 203 or equivalent), a crustacea species 48 hour EC₅₀ (OECD Test Guideline 202 or equivalent) and/or an algal species 72 or 96 hour EC₅₀ (OECD Test Guideline 201 or equivalent). These species are considered as surrogate for all aquatic organisms and data on other species such as Lemna may also be considered if the test methodology is suitable.

2.9.3.2.64 [Chronic aquatic toxicity means the intrinsic property of a substance to cause adverse effects to aquatic organisms during aquatic exposures which are determined in relation to the life-cycle of the organism.](#)

[Note by the secretariat: this definition is included in the 2nd revised edition of the GHS but is missing in the Model Regulations.]

[For classification purposes, Long-term hazard, is the hazard of a chemical caused by its chronic toxicity following long-term exposure in the aquatic environment.](#)

[\[Long-term hazard, for classification purposes, means the hazard of a chemical caused by its chronic toxicity following long-term exposure in the aquatic environment.\]](#)

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.

2.9.3.2.45 **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_{ow} 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.

2.9.3.2.56 [Degradation means the decomposition of organic molecules to smaller molecules and eventually to carbon dioxide, water and salts.](#)

[Note by the secretariat: this definition is included in the 2nd revised edition of the GHS but is missing in the Model Regulations.]

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 environments. These are freshwater tests and thus the use of the results from OECD Test Guideline 306, which is more suitable for marine environments, has also been 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 degradability³.

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 BOD₅/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.

2.9.3.3 *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 1, Chronic 1 or Chronic 2, according to the following tables:

Table 2.9.1: Categories for substances hazardous to the aquatic environment (Note 1)

(a) Acute (short-term) aquatic hazard toxicity

Category: Acute 1 (Note 2)	
<u>Acute toxicity:</u>	
96 hr LC ₅₀ (for fish)	≤ 1 mg/l and/or
48 hr EC ₅₀ (for crustacea)	≤ 1 mg/l and/or
72 or 96hr ErC ₅₀ (for algae or other aquatic plants)	≤ 1 mg/l (<u>Note 3</u>)

³ Special guidance on data interpretation is provided in Chapter 4.1 and Annex 9 of the GHS.

Chronic toxicity**(b) Long-term aquatic hazard** *(see also figure 4.1.1)*

[Note by the secretariat: reference is made to figure 4.1.1 of the GHS. See comments on following page]

(i) Non-rapidly degradable substances (Note 4) for which there are adequate chronic toxicity data available

Category Chronic 1: <i>(Note 2)</i>	
Chronic NOEC or EC _x (for fish)	≤ 0.1 mg/l and/or
Chronic NOEC or EC _x (for crustacea)	≤ 0.1 mg/l and/or
Chronic NOEC or EC _x (for algae or other aquatic plants)	≤ 0.1 mg/l
Category Chronic 2:	
Chronic NOEC or EC _x (for fish)	≤ 1 mg/l and/or
Chronic NOEC or EC _x (for crustacea)	≤ 1 mg/l and/or
Chronic NOEC or EC _x (for algae or other aquatic plants)	≤ 1 mg/l

(ii) Rapidly degradable substances for which there are adequate chronic toxicity data available

Category Chronic 1: <i>(Note 2)</i>	
Chronic NOEC or EC _x (for fish)	≤ 0.01 mg/l and/or
Chronic NOEC or EC _x (for crustacea)	≤ 0.01 mg/l and/or
Chronic NOEC or EC _x (for algae or other aquatic plants)	≤ 0.01 mg/l
Category Chronic 2:	
Chronic NOEC or EC _x (for fish)	≤ 0.1 mg/l and/or
Chronic NOEC or EC _x (for crustacea)	≤ 0.1 mg/l and/or
Chronic NOEC or EC _x (for algae or other aquatic plants)	≤ 0.1 mg/l

(iii) Substances for which adequate chronic toxicity data are not available

Category Chronic 1 <i>(Note 2):</i>	
96 hr LC ₅₀ (for fish)	≤ 1 mg/l and/or
48 hr EC ₅₀ (for crustacea)	≤ 1 mg/l and/or
72 or 96hr ErC ₅₀ (for algae or other aquatic plants)	≤ 1 mg/l <i>(Note 3)</i>
and the substance is not rapidly degradable and/or the <u>experimentally determined BCF is ≥ 500 (or, if absent the log K_{ow} ≥ 4) (Notes 4 and 5)</u> (unless the experimentally determined BCF < 500)	
Category Chronic 2:	
96 hr LC ₅₀ (for fish)	>1 to but ≤ 10 mg/l and/or
48 hr EC ₅₀ (for crustacea)	>1 to but ≤ 10 mg/l and/or
72 or 96hr ErC ₅₀ (for algae or other aquatic plants)	>1 to but ≤ 10 mg/l <i>(Note 3)</i>
and the substance is not rapidly degradable and/or the <u>experimentally determined BCF is ≥ 500 (or, if absent the log K_{ow} ≥ 4) (Notes 4 and 5)</u> (unless the experimentally determined BCF < 500), unless the chronic toxicity NOECs are > 1 mg/l	

NOTE 1: *The organisms fish, crustacea and algae are tested as surrogate species covering a range of trophic levels and taxa, and the test methods are highly standardized. Data on other organisms may also be considered, however, provided they represent equivalent species and test endpoints.*

NOTE 2: When classifying substances as Acute 1 and/or Chronic 1 it is necessary at the same time to indicate an appropriate M factor (see 2.9.3.4.6.4) to apply the summation method.

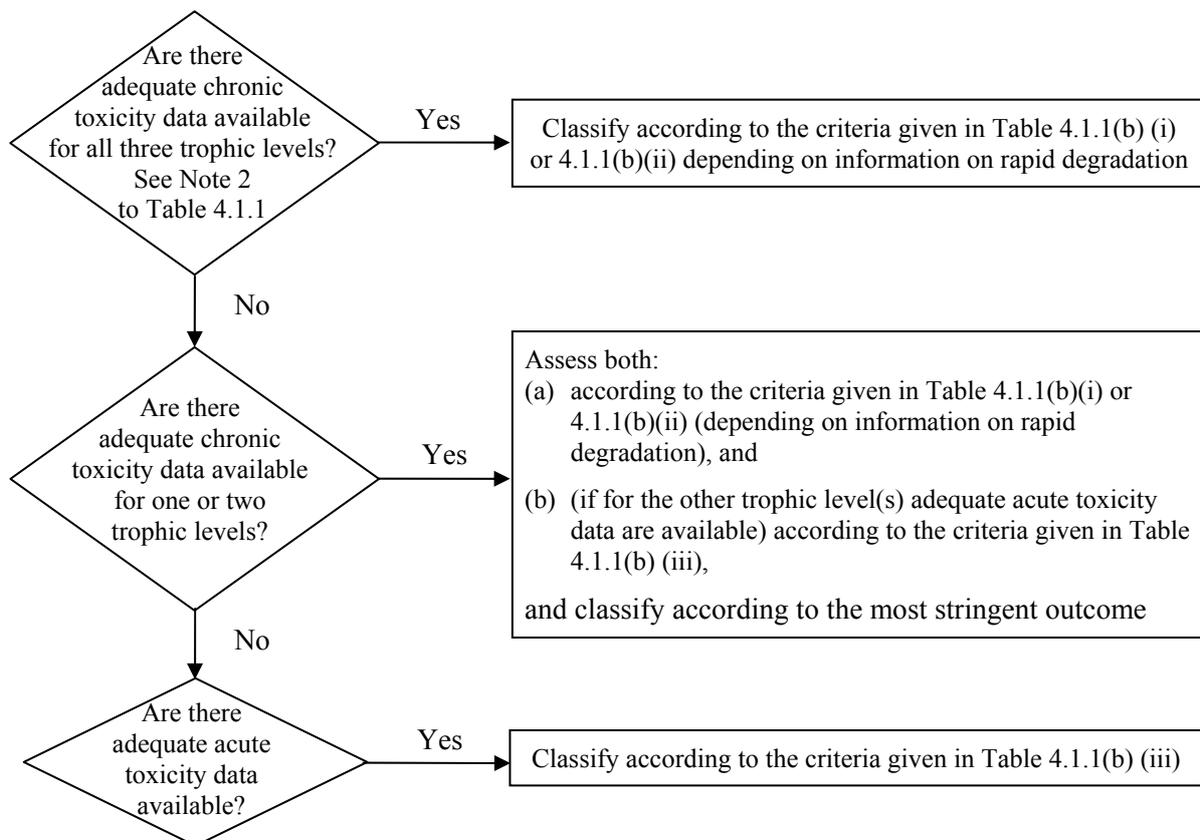
NOTE 3: Where the algal toxicity ErC_{50} [$= EC_{50}$ (growth rate)] falls more than 100 times below the next most sensitive species and results in a classification based solely on this effect, consideration should be given to whether this toxicity is representative of the toxicity to aquatic plants. Where it can be shown that this is not the case, professional judgment should be used in deciding if classification should be applied. Classification should be based on the ErC_{50} . In circumstances where the basis of the EC_{50} is not specified and no ErC_{50} is recorded, classification should be based on the lowest EC_{50} available.

NOTE 4. Lack of rapid degradability is based on either a lack of ready biodegradability or other evidence of lack of rapid degradation. When no useful data on degradability are available, either experimentally determined or estimated data, the substance should be regarded as not rapidly degradable.

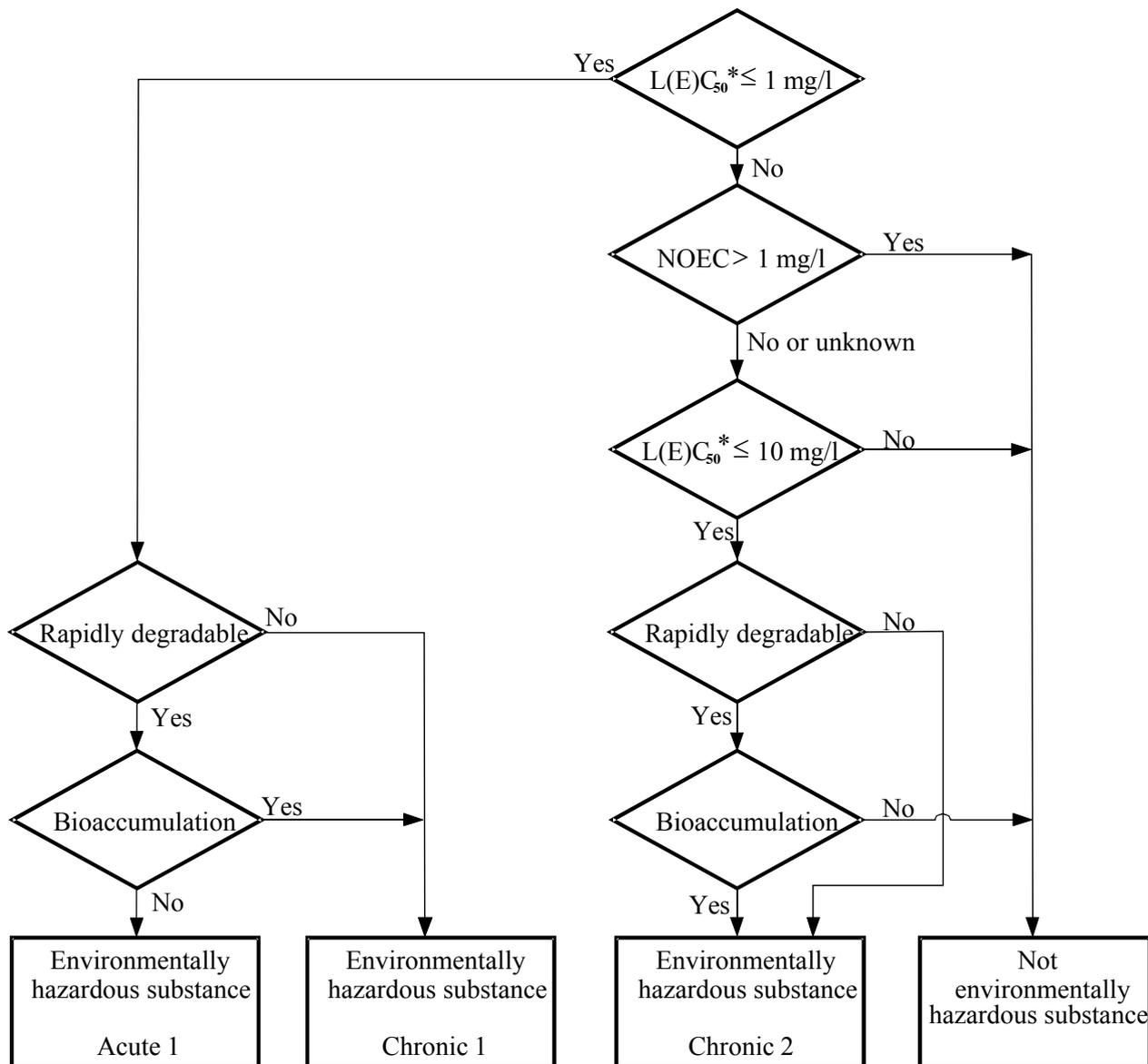
NOTE 5: Potential to bioaccumulate, based on an experimentally derived $BCF \geq 500$ or, if absent, a $\log K_{ow} \geq 4$ provided $\log K_{ow}$ is an appropriate descriptor for the bioaccumulation potential of the substance. Measured $\log K_{ow}$ values take precedence over estimated values and measured BCF values take precedence over $\log K_{ow}$ values.

Note by the secretariat: figure 4.1.1 of the GHS is not included in the Model Regulations. It reads as follows:

Figure 4.1.1: Categories for substances long-term hazardous to the aquatic environment



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.

Note by the secretariat: the above classification flowchart is not included in the GHS but should be updated to ensure harmonization. In the GHS, the same process is outlined with Table 4.1.2. The Sub-Committee may wish to consider which option should be used in the Model Regulations.

Table 4.1.2 of the GHS reads as follows:

Table 4.1.2: Classification scheme for substances hazardous to the aquatic environment

Classification categories			
Acute hazard (Note 1)	Long-term hazard (Note 2)		
	Adequate chronic toxicity data available		Adequate chronic toxicity data not available (Note 1)
	Non-rapidly degradable substances (Note 3)	Rapidly degradable substances (Note 3)	
Category: Acute 1 L(E)C ₅₀ ≤ 1.00	Category: Chronic 1 NOEC or EC _x ≤ 0.1	Category: Chronic 1 NOEC or EC _x ≤ 0.01	Category: Chronic 1 L(E)C ₅₀ ≤ 1.00 and lack of rapid degradability and/or BCF ≥ 500 or, if absent log K _{ow} ≥ 4
	Category: Chronic 2 0.1 < NOEC or EC _x ≤ 1	Category: Chronic 2 0.01 < NOEC or EC _x ≤ 0.1	Category: Chronic 2 1.00 < L(E)C ₅₀ ≤ 10.0 and lack of rapid degradability and/or BCF ≥ 500 or, if absent log K _{ow} ≥ 4

NOTE 1: Acute toxicity band based on L(E)C₅₀ values in mg/l for fish, crustacea and/or algae or other aquatic plants (or QSAR estimation if no experimental data).

NOTE 2: Substances are classified in the various chronic categories unless there are adequate long-term toxicity data available for all three trophic levels above the water solubility or above 1 mg/l. ("Adequate" means that the data sufficiently cover the endpoint of concern. Generally this would mean measured test data, but in order to avoid unnecessary testing it can on a case by case basis also be estimated data, e.g. (Q)SAR, or for obvious cases expert judgment).

NOTE 3: Chronic toxicity band based on NOEC or equivalent EC_x values in mg/l for fish or crustacea or other recognized measures for long-term toxicity.

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 1 and chronic categories 1 and 2. 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:

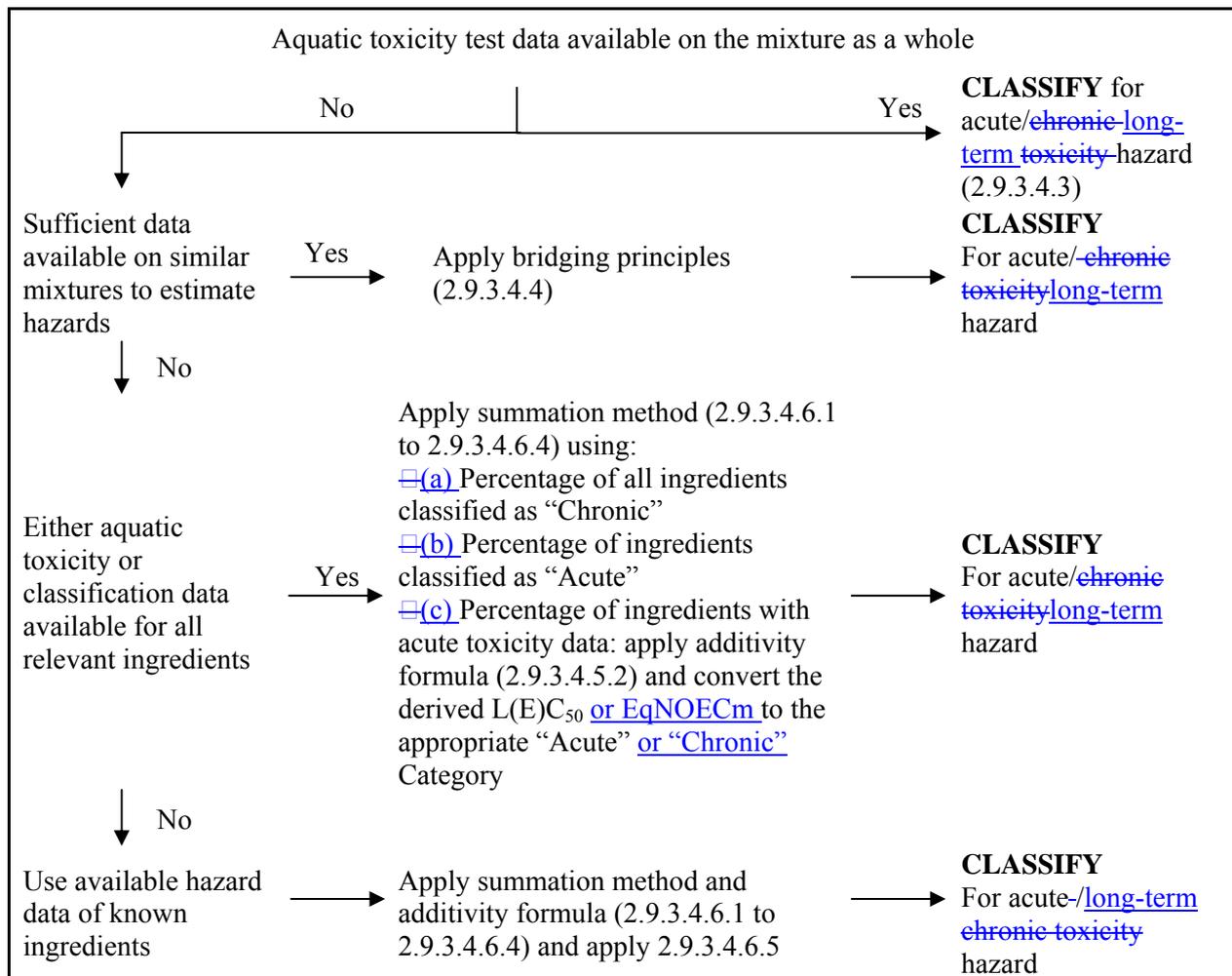
The "relevant ingredients" of a mixture are those which are present in a concentration of equal to or greater than 0.1% (by mass) ~~or greater for ingredients classified as acute 1 and/or Chronic 1 and equal to or greater than 1% for other ingredients~~, unless there is a presumption (e.g. in the case of highly toxic ingredients) that an ingredient present at less than 0.1% 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 ingredients. 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 ingredients” 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-long-term aquatic environmental hazards

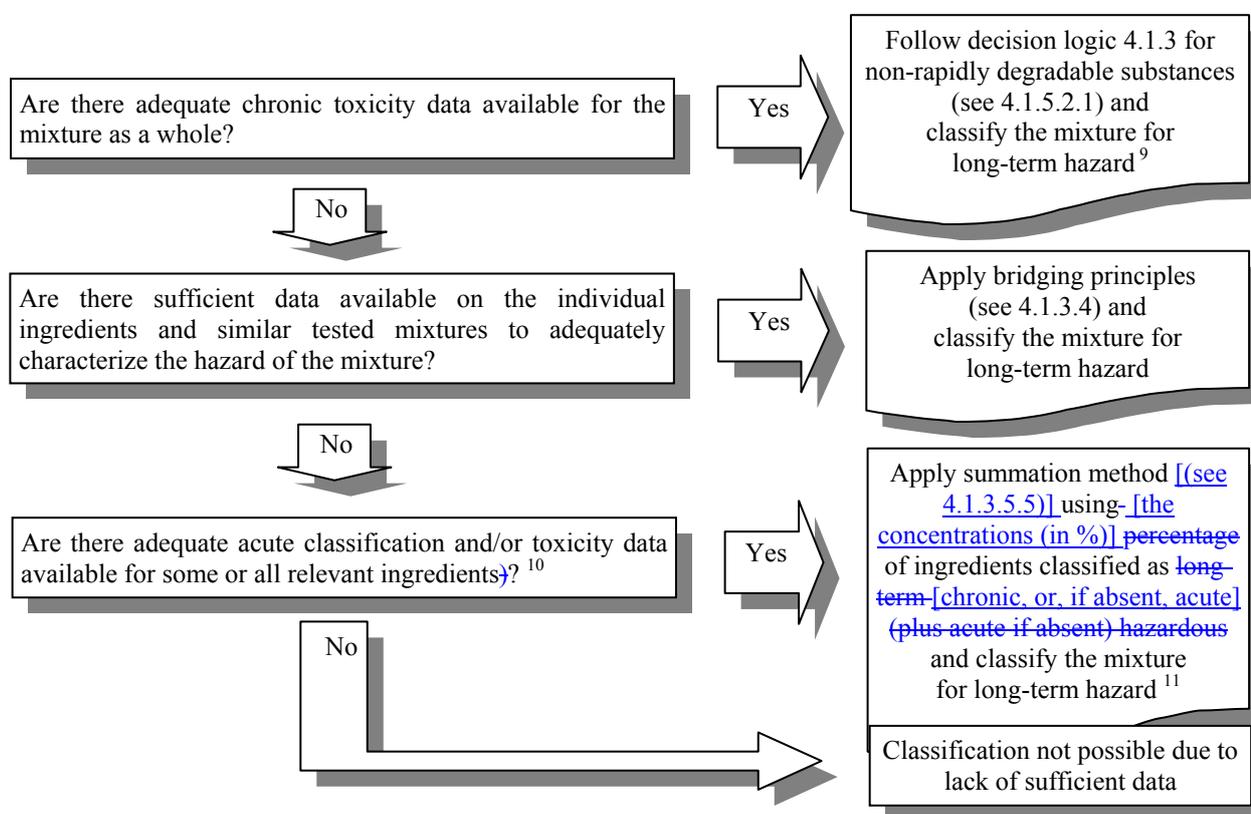


2.9.3.4.3 *Classification of mixtures when toxicity data are available for the complete mixture*

2.9.3.4.3.1 When the mixture as a whole has been tested to determine its aquatic toxicity, ~~it~~ this information shall be used for classifying the mixture according to the criteria that have been agreed for substances; but only for acute toxicity. The classification is normally based on the data for fish, crustacea and algae/plants (see 2.9.3.2.3 and 2.9.3.2.4). When adequate acute or chronic data for the mixture as a whole are lacking, “bridging principles” or “summation method” should be applied (see decision logic 4.1.5.2.2 and paragraphs 2.9.3.4.4 and 2.9.3.4.5).

Note by the secretariat: decision logic 4.1.5.2.2 is not included in the Model Regulations. It reads as follows:

4.1.5.2.2 Decision logic 4.1.4 for mixtures



⁹ Degradability and bioaccumulation tests ~~of~~ for mixtures are not used as they are usually difficult to interpret, and such tests may be meaningful only for single substances. The mixture is therefore by default regarded as non-rapidly degradable. However, if the available information allows the conclusion that all relevant ingredients of the mixture are rapidly degradable) the mixture can, for classification purposes, be regarded as rapidly degradable.

¹⁰ In the event that no useable information on acute and/or chronic aquatic ~~hazard~~ [toxicity] is available for one or more relevant ingredients, it is concluded that the mixture cannot be attributed (a) definitive hazard category(ies). In this situation the mixture should be classified based on the known ingredients only, with the additional statement that: “× % of the mixture consists of ingredient(s) of unknown hazards to the aquatic environment”.

¹¹ When adequate toxicity data are available for more than one ingredient in the mixture, the combined toxicity of those ingredients may be calculated using the additivity formula s ~~(a)~~ or (b) in 4.1.3.5.2 ~~(a)~~ , depending on the nature of the toxicity data. The calculated toxicity may be used to assign that portion of the mixture an acute or long-term hazard category which is then subsequently used in applying the summation method. (It is preferable to calculate the toxicity of this part of the mixture using for each ingredient a toxicity value that relate to the same ~~species group~~ [taxonomic group] (e.g. fish, crustacea or algae) and then to use the highest toxicity (lowest value) obtained (i.e. use the most sensitive of the three groups) (see 4.1.3.5.3)).

2.9.3.4.3.2 The long-term hazard classification of mixtures requires additional information on degradability and in certain cases bioaccumulation. Classification of mixtures by using LC₅₀ or EC₅₀ 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 for mixtures cannot are not used as they are usually difficult to interpret, and such tests may be interpreted; they are meaningful only for single substances.

2.9.3.4.3.23 *Classification for category Acute 1*

When there are acute toxicity test data (LC₅₀ or EC₅₀) available for the mixture as a whole, these data as well as information with respect to the classification of ingredients for chronic toxicity shall be used to complete the classification for tested mixtures as follows. When chronic (long term) toxicity data (NOEC) are also available, they shall be used as well.

- (a) When there are adequate acute toxicity test data (LC₅₀ or EC₅₀) available for the mixture as a whole showing L(E)C₅₀ ≤ 100mg/l:

Classify the mixture as Acute 1 in accordance with Table 2.9.1 (a)

- (b) When there are acute toxicity test data (LC₅₀(s) or EC₅₀(s) available for the mixture as a whole showing L(E)C₅₀(s) >100mg/l, or above the water solubility:

No need to classify for acute hazard

2.9.3.4.3.4 *Classification for categories Chronic 1 and 2*

- (a) When there are adequate chronic toxicity data (EC_x or NOEC) available for the mixture as a whole showing EC_x or NOEC of the tested mixture ≤ 1mg/l:

(i) Classify the mixture as Chronic 1 or 2 in accordance with Table 2.9.1 (b)(ii) (rapidly degradable) if the available information allows the conclusion that all relevant ingredients of the mixture are rapidly degradable;

(ii) Classify the mixture as Chronic 1 or 2 in all other cases in accordance with Table 2.9.1 (b)(i) (non rapidly degradable);

- (b) When there are adequate chronic toxicity data (EC_x or NOEC) available for the mixture as a whole showing EC_x (s) or NOEC(s) of the tested mixture > 1mg/l or above the water solubility:

No need to classify for long-term hazard, unless there are nevertheless reasons for concern

- ~~(a) L(E)C₅₀ (LC₅₀ or EC₅₀) of the tested mixture ≤ 1mg/l and NOEC of the tested mixture ≤ 1.0 mg/l or unknown:~~

~~— classify mixture as category acute 1;~~

~~— apply summation of classified ingredients approach (see 2.9.3.4.6.3 and 2.9.3.4.6.4) for chronic classification (chronic 1, 2, or no need of chronic classification);~~

- ~~(b) L(E)C₅₀ of the tested mixture ≤ 1 mg/l and NOEC of the tested mixture > 1.0 mg/l:~~

~~— classify mixture as category acute 1;~~

~~— apply summation of classified ingredients approach (see 2.9.3.4.6.3 and 2.9.3.4.6.4) for classification as Category Chronic 1. If the mixture is not classified as Category Chronic 1, then there is no need for chronic classification;~~

~~(c) $L(E)C_{50}$ 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 ingredients 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) $L(E)C_{50}$ 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 ingredients and similar tested mixtures to adequately [characterise](#) the hazards of the mixture, these 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 ingredient and which is not expected to affect the aquatic hazards of other ingredients, 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 1 and acute 1)

2.9.3.4.4.4.1 If a mixture is classified as chronic 1 and/or acute 1, and ingredients of the mixture which are classified as chronic 1 and/or acute 1 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 ingredients 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 ingredients 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 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) 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 [\[toxicity\]](#) data are available for all ingredients or only for some ingredients of the mixture*

2.9.3.4.5.1 The classification of a mixture shall be based on summation of the concentrations of its classified ingredients. The percentage of ingredients 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 may be made of a combination of both ingredients that are classified (as Acute 1 and/or Chronic 1, 2) and those for which adequate [\[toxicity\]](#) test data are available. When adequate toxicity data are available for more than one ingredient in the mixture, the combined toxicity of those ingredients shall be calculated using the following additivity formulas [\(a\) or \(b\)](#), ~~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~~ depending on the nature of the toxicity data:-

[\(a\) Based on \[acute\] aquatic toxicity:](#)

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

where:

- C_i = concentration of ingredient i (mass percentage);
- $L(E)C_{50i}$ = ~~(mg/L)~~LC₅₀ or EC₅₀ for ingredient i, ~~(mg/l)~~;
- n = number of ingredients, and i is running from 1 to n;
- $L(E)C_{50m}$ = L(E)C₅₀ of the part of the mixture with test data

[The calculated toxicity shall be used to assign that portion of the mixture an acute hazard category which is then subsequently used in applying the summation method.;](#)

(b) Based on chronic aquatic toxicity:

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

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 long-term toxicity [long-term hazard] [chronic toxicity]) for ingredient i covering the rapidly degradable ingredients, in mg/l;

$NOEC_j$ = NOEC (or other recognized measures for long-term toxicity [long-term hazard] [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;

The equivalent toxicity thus reflects the fact that non-rapidly degrading substances are classified one hazard category level more “severe” than rapidly degrading substances.

The calculated equivalent toxicity shall be used to assign that portion of the mixture a long-term hazard category, in accordance with the criteria for rapidly degradable substances (Table 2.9.1 (b) (ii)), which is then subsequently used in applying the summation method.

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 taxonomic group (i.e. fish, daphnia crustacea or algae) and then to use the highest toxicity (lowest value) obtained (i.e. use the most sensitive of the three species groups). However, when toxicity data for each ingredient are not available in the same [species taxonomic group], the toxicity value of each ingredient 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 and chronic toxicity shall then be used to classify this part of the mixture as Acute 1 and/or chronic 1 or 2 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 1 overrides a classification with chronic 2. As a consequence the classification procedure is already completed if the results of the classification is chronic 1. A more severe classification than chronic 1 is not possible; therefore, it is not necessary to pursue the classification procedure further.

2.9.3.4.6.2 Classification for ~~the~~ acute category 1

2.9.3.4.6.2.1 ~~First, A~~ll ingredients classified as acute 1 shall be considered. If the sum of [the concentrations (in %) of] these ingredients is greater than or equal to 25% the whole mixture shall be classified as ~~category~~ acute 1. If the result of the calculation is a classification of the mixture as ~~category~~ acute 1, the classification process is completed.

2.9.3.4.6.2.2 The classification of mixtures for acute hazards based on this summation of [the concentrations of] classified ingredients, is ~~summarised~~ summarized in Table 2.9.~~1-2~~ below.

Table 2.9.~~12~~: Classification of a mixture for acute hazards, based on summation of [the concentrations of] classified ingredients

Sum of <u>[the concentrations (in %) of]</u> ingredients classified as:	Mixture is classified as:
Acute 1 × M ^a ≥ 25%	Acute 1

^a For explanation of the M factor, see 2.9.3.4.6.4.

2.9.3.4.6.3 Classification for ~~the~~ chronic categories 1, 2

2.9.3.4.6.3.1 First, all ingredients classified as chronic 1 are considered. If the sum of the concentrations (in %) of these ingredients is greater than or equal to 25% the mixture shall be classified as ~~category~~ chronic 1. If the result of the calculation is a classification of the mixture as ~~category~~ chronic 1 the classification procedure is completed.

2.9.3.4.6.3.2 In cases where the mixture is not classified as chronic 1, classification of the mixture as chronic 2 is considered. A mixture shall be classified as chronic 2 if 10 times the sum of [the concentrations (in %) of] all ingredients classified as chronic 1 plus the sum of [the concentrations (in %) of] all ingredients classified as chronic 2 is greater than or equal to 25%. If the result of the calculation is classification of the mixture as chronic 2, the classification process is completed.

2.9.3.4.6.3.3 The classification of mixtures for ~~chronic~~ long-term hazards, based on this summation of [the concentrations of] classified ingredients, is summarised in Table 2.9.~~2-3~~ below.

Table 2.9.~~23~~: Classification of a mixture for ~~chronic~~ long-term hazards, based on summation of [the concentrations of] classified ingredients

Sum of <u>[the concentrations (in %) of]</u> ingredients classified as:	Mixture is classified as:
Chronic 1 × M ^a ≥ 25%	Chronic 1
(M × 10 × Chronic 1) <u>+</u> Chronic 2 ≥ 25%	Chronic 2

^a For explanation of the M factor, see 2.9.3.4.6.4.

2.9.3.4.6.4 Mixtures with highly toxic ingredients

2.9.3.4.6.4.1 ~~Category a~~ Acute 1 or Chronic 1 ingredients with acute toxicities well below 1 mg/l and/or chronic toxicities well below 0.1 mg/l (if non-rapidly degradable) and 0.01 mg/l (if rapidly degradable) may influence the toxicity of the mixture and are given increased weight in applying the summation method. When a mixture contains ingredients classified as acute 1 or chronic 1, 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 1 and chronic 1 ingredients by a factor, instead of merely adding up the percentages. This means that the concentration of “Acute 1” in the left column of Table 2.9.~~1-2~~ and the concentration of “Chronic 1” in the left column of Table

2.9.2-3 are multiplied by the appropriate multiplying factor. The multiplying factors to be applied to these ingredients are defined using the toxicity value, as ~~summarised~~ summarized in Table 2.9.3-4 below. Therefore, in order to classify a mixture containing acute 1 and/or chronic 1 ingredients, 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 ingredients in the mixture and there is convincing evidence that all other ingredients, including those for which specific acute and/or chronic toxicity data are not available, are of low or no toxicity and do not significantly contribute to the environmental hazard of the mixture.

Table 2.9.34: Multiplying factors for highly toxic ingredients of mixtures

<u>Acute toxicity</u>	<u>M factor</u>	<u>Chronic toxicity</u>	<u>M factor</u>	
<u>L(E)C₅₀ value</u>		<u>NOEC value</u>	<u>NRD^a</u> <u>ingredients</u>	<u>RD^b</u> <u>ingredients</u>
$0.1 < L(E)C_{50} \leq 1$	1	$0.01 < NOEC \leq 0.1$	<u>1</u>	<u>-</u>
$0.01 < L(E)C_{50} \leq 0.1$	10	$0.001 < NOEC \leq 0.01$	<u>10</u>	<u>1</u>
$0.001 < L(E)C_{50} \leq 0.01$	100	$0.0001 < NOEC \leq 0.001$	<u>100</u>	<u>10</u>
$0.0001 < L(E)C_{50} \leq 0.001$	1000	$0.00001 < NOEC \leq 0.0001$	<u>1000</u>	<u>100</u>
$0.00001 < L(E)C_{50} \leq 0.0001$	10000	$0.000001 < NOEC \leq 0.00001$	<u>10000</u>	<u>1000</u>
(continue in factor 10 intervals)		(continue in factor 10 intervals)		

^a Non-rapidly degradable

^b Rapidly degradable

2.9.3.4.6.5 Classification of mixtures with ingredients 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-toxicity]~~ is available for one or more relevant ingredients, 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 ingredients only with the additional statement that: “× percent of the mixture consists of ingredient(s) of unknown hazards to the aquatic environment.”.