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COMMISSION REGULATION (EU) No 286/2011

of 10 March 2011

amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures

(Text with EEA relevance)

(OJ L 83, 30.3.2011, p. 1)

Corrected by:

►**C1** Corrigendum, OJ L 138, 26.5.2011, p. 66 (286/2011)

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COMMISSION REGULATION (EU) No 286/2011

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amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 ([1]), and in particular Article 53 thereof,

Whereas:

(1) Regulation (EC) No 1272/2008 harmonises the provisions and criteria for the classification and labelling of substances, mixtures and certain specific articles within the European Union.

(2) That Regulation takes into account the Globally Harmonised System of Classification and Labelling of Chemicals (hereinafter referred to as 'the GHS') of the United Nations (UN).

(3) The classification criteria and labelling rules of the GHS are periodically reviewed at UN level. The third revised edition of the GHS was adopted in December 2008 by the United Nations Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonised System of Classification and Labelling of Chemicals (UNCETDG/GHS). It contains amendments concerning, inter alia, the provisions for the allocation of hazard statements and for the labelling of small packaging, new sub-categories for respiratory and skin sensitisation, the revision of the classification criteria for long-term hazards (chronic toxicity) to the aquatic environment and a new hazard class for substances and mixtures hazardous to the ozone layer. It is therefore necessary to adapt the technical provisions and criteria in the Annexes to Regulation (EC) No 1272/2008 to the third revised edition of the GHS.

(4) The GHS allows authorities to adopt supplemental labelling provisions to protect individuals already sensitised to a specific chemical that may elicit a response at very low concentration. Requirements should be introduced to add the name of such chemical on the label even if present at very low concentration in a mixture.

(5) The terminology of different provisions in the Annexes and certain technical criteria should also be amended to facilitate implementation by operators and enforcement authorities, to improve consistency of the legal text and to enhance clarity.

([1]) OJ L 353, 31.12.2008, p. 1.

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(6) To ensure that suppliers of substances can adapt to the new classification, labelling and packaging provisions introduced by this Regulation, a transitional period should be foreseen and the application of this Regulation should be deferred. This should allow for the possibility to apply the provisions laid down in this Regulation on a voluntary basis before the transitional period is over.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Committee established pursuant to Article 133 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council ([1]),

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 1272/2008 is amended as follows:

(1) Article 25(5) is deleted;

(2) the following new section (e) is inserted in Article 26(1):

'(e) if the hazard pictogram "GHS02" or "GHS06" applies, the use of the hazard pictogram "GHS04" shall be optional.';

(3) Annex I is amended in accordance with Annex I to this Regulation;

(4) Annex II is amended in accordance with Annex II to this Regulation;

(5) Annex III is amended in accordance with Annex III to this Regulation;

(6) Annex IV is amended in accordance with Annex IV to this Regulation;

(7) Annex V is amended in accordance with Annex V to this Regulation;

(8) Annex VI is amended in accordance with Annex VI to this Regulation;

(9) Annex VII is amended in accordance with Annex VII to this Regulation.

Article 2

Transitional provisions

1. By way of derogation from the second paragraph of Article 3, substances and mixtures may, before 1 December 2012 and 1 June 2015 respectively, be classified, labelled and packaged in accordance with Regulation (EC) No 1272/2008 as amended by this Regulation.

2. By way of derogation from the second paragraph of Article 3, substances classified, labelled and packaged in accordance with Regulation (EC) No 1272/2008 and placed on the market before 1 December 2012, are not required to be relabelled and repackaged in accordance with this Regulation until 1 December 2014.

([1]) OJ L 396, 30.12.2006, p. 1.

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3. By way of derogation from the second paragraph of Article 3, mixtures classified, labelled and packaged in accordance with Directive 1999/45/EC of the European Parliament and of the Council [1] or Regulation (EC) No 1272/2008 and placed on the market before 1 June 2015, are not required to be relabelled and repackaged in accordance with this Regulation until 1 June 2017.

Article 3

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

It shall apply in respect of substances from 1 December 2012 and in respect of mixtures from 1 June 2015.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

[1] OJ L 200, 30.7.1999, p. 1.

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ANNEX I

A. Part 1 of Annex I to Regulation (EC) No 1272/2008 is amended as follows:

(1) in section 1.1.2.2.2, the Note under Table 1.1 is replaced by the following:

'Note:

Generic cut-off values are in weight percentages except for gaseous mixtures for those hazard classes where the generic cut-off values may be best described in volume percentages.';

(2) in section 1.1.3.1, the beginning of the first sentence is replaced by 'If a tested mixture';

(3) sections 1.1.3.2, 1.1.3.3 and 1.1.3.4 are replaced by the following:

'1.1.3.2. *Batching*

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

1.1.3.3. *Concentration of highly hazardous mixtures*

In the case of the classification of mixtures covered by sections 3.1, 3.2, 3.3, 3.8, 3.9, 3.10 and 4.1, if a tested mixture is classified in the highest hazard category or sub-category, and the concentration of the components of the tested mixture that are in that category or sub-category is increased, the resulting untested mixture shall be classified in that category or sub-category without additional testing.

1.1.3.4. *Interpolation within one toxicity category*

In the case of the classification of mixtures covered by sections 3.1, 3.2, 3.3, 3.8, 3.9, 3.10 and 4.1, for three mixtures (A, B and C) with identical components, where mixtures A and B have been tested and are in the same hazard category, and where untested mixture C has the same hazardous components as mixture A and B but has concentrations of those hazardous components intermediate to the concentrations in mixtures A and B, then mixture C is assumed to be in the same hazard category as A and B.';

(4) in section 1.1.3.5, the last sentence is replaced by the following:

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

(5) sections 1.2, 1.2.1, 1.2.1.1, 1.2.1.2 and 1.2.1.3 are replaced by the following:

'1.2. **Labelling**

1.2.1. ***General rules for the application of labels required by Article 31***

1.2.1.1. Hazard pictograms shall be in the shape of a square set at a point.

1.2.1.2. Hazard pictograms as laid down in Annex V shall have a black symbol on a white background with a red frame sufficiently wide to be clearly visible.

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1.2.1.3. Each hazard pictogram shall cover at least one fifteenth of the minimum surface area of the label dedicated to the information required by Article 17. The minimum area of each hazard pictogram shall not be less than 1 cm^2.

1.2.1.4. The dimensions of the label and of each pictogram shall be as follows:

Table 1.3

Minimum dimensions of labels and pictograms

Capacity of the package	Dimensions of the label (in millimetres) for the information required by Article 17	Dimensions of each pictogram (in millimetres)
Not exceeding 3 litres:	If possible, at least 52 × 74	Not smaller than 10 × 10 If possible, at least 16 × 16
Greater than 3 litres but not exceeding 50 litres:	At least 74 × 105	At least 23 × 23
Greater than 50 litres but not exceeding 500 litres:	At least 105 × 148	At least 32 × 32
Greater than 500 litres:	At least 148 × 210	At least 46 × 46’

(6) the introductory sentence in section 1.5.2.1.3 is replaced by the following:

‘The pictogram, the signal word, the hazard statement, and the precautionary statement linked to the hazard categories listed below may be omitted from the label elements required by Article 17 where:’;

(7) in section 1.5.2.2, point (b) is replaced by the following:

‘(b) The classification of the contents of the soluble packaging is exclusively one or more of the hazard categories in 1.5.2.1.1 (b), 1.5.2.1.2 (b) or 1.5.2.1.3 (b); and’.

B. Part 2 of Annex I to Regulation (EC) No 1272/2008 is amended as follows:

(1) section 2.1.4.1 is amended as follows:

(a) the footnote under Figure 2.1.1 is replaced by the following:

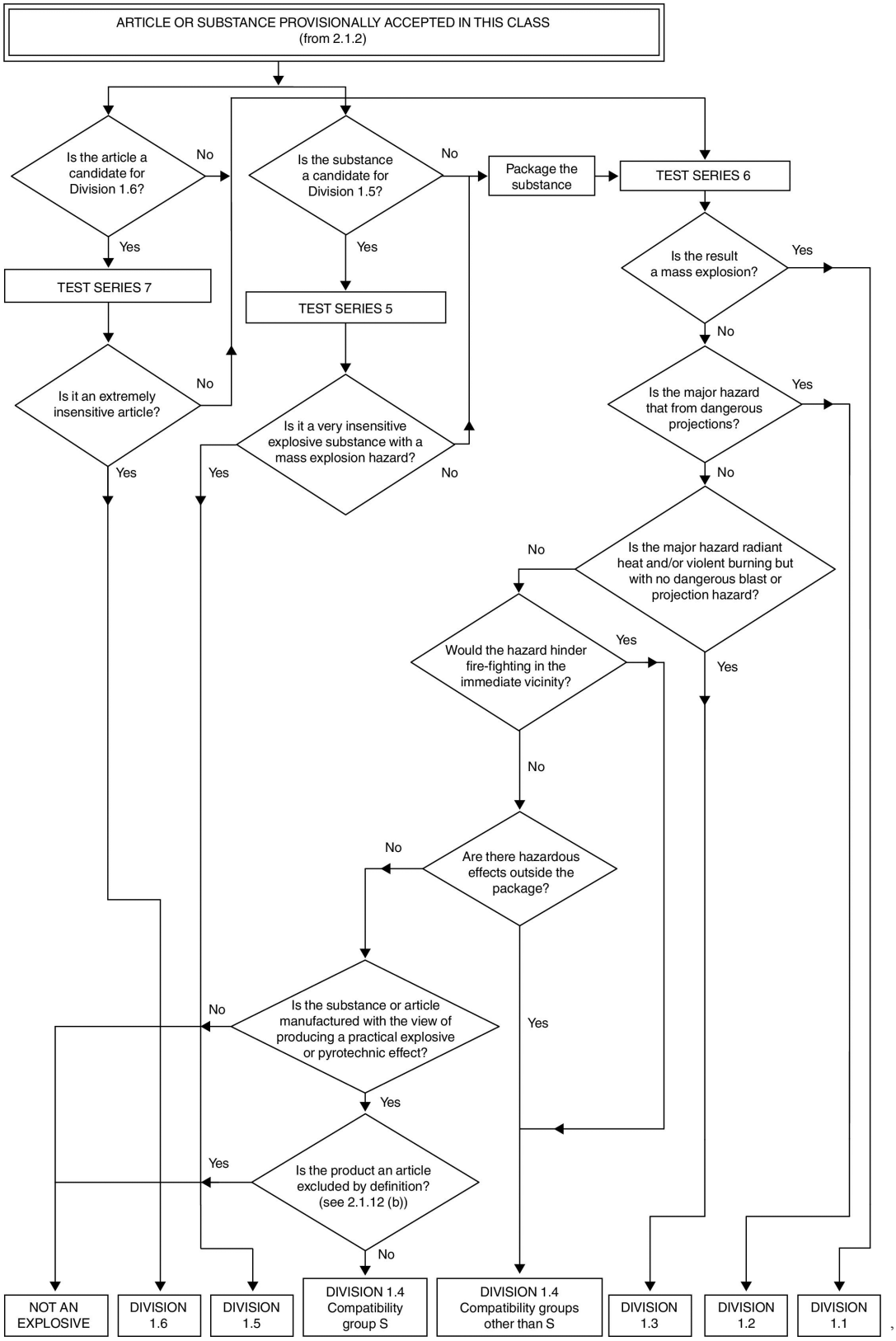
‘(*) See UN Recommendations on the Transport of Dangerous Goods, Model Regulations, 16th rev. ed, sub-section 2.1.2.’;

(b) Figure 2.1.3 is replaced by the following:

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'Figure 2.1.3

Procedure for assignment to a division in the class of explosives (Class 1 for transport)



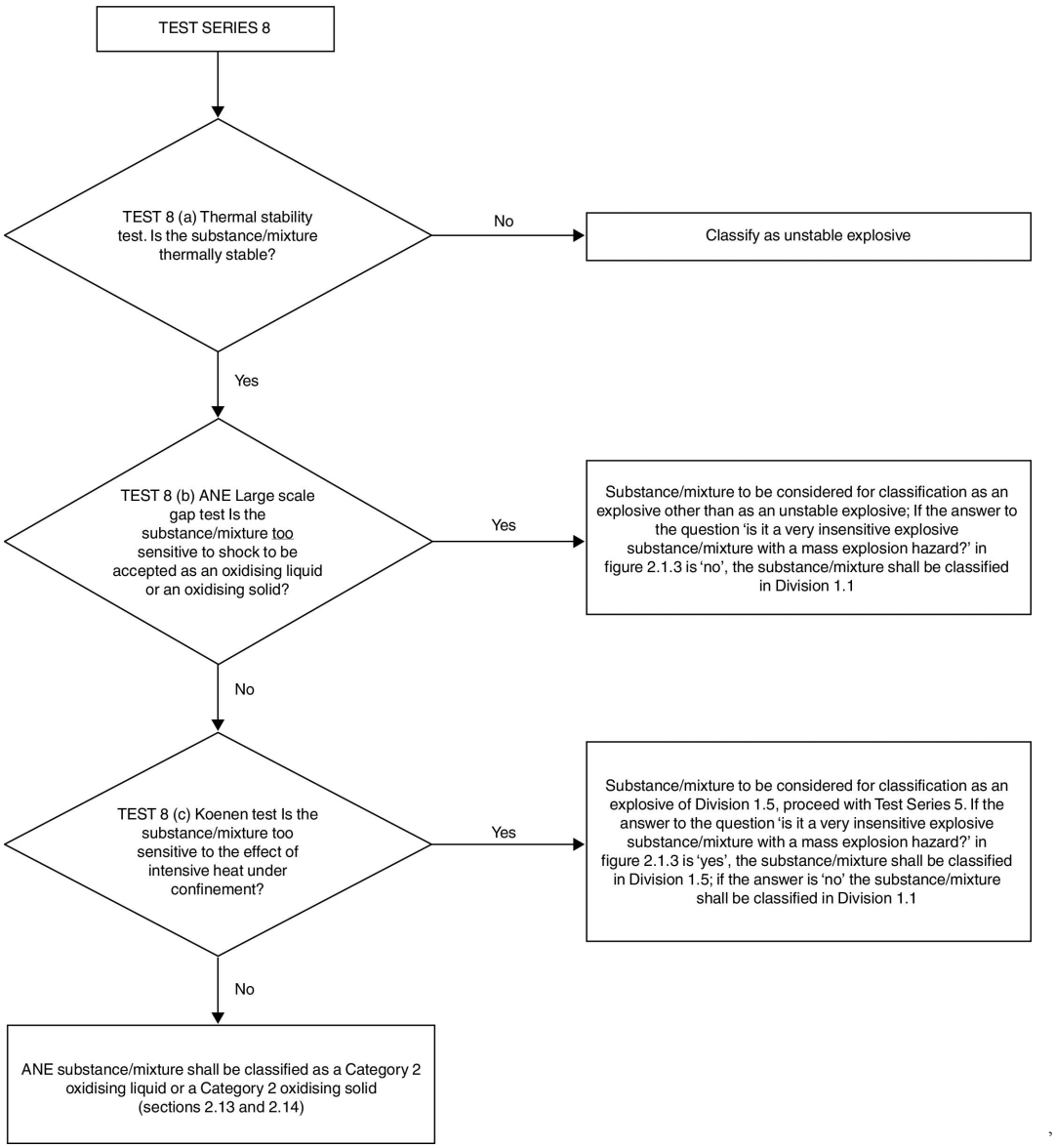
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(c) Figure 2.1.4, is replaced by the following:

'Figure 2.1.4

Procedure for the classification of ammonium nitrate emulsion, suspension or gel (ANE)



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(2) in section 2.1.4.2, the Note is replaced by the following:

'*Note:*

Neither a series 1 type (a) propagation of detonation test nor a series 2 type (a) test of sensitivity to detonative shock is required if the exothermic decomposition energy of organic materials is less than 800 J/g. For organic substances and mixtures of organic substances with a decomposition energy of 800 J/g or more, tests 1 (a) and 2 (a) need not be performed if the outcome of the ballistic mortar Mk.IIId test (F.1), or the ballistic mortar test (F.2) or the BAM Trauzl test (F.3) with initiation by a standard No 8 detonator (see Appendix 1 to the UN RTDG, Manual of Tests and Criteria) is "no". In this case, the results of test 1 (a) and 2 (a) are deemed to be "-".';

(3) in section 2.2.2.1, the Note under Table 2.2.1 is replaced by the following:

'*Note:*

Aerosols shall not be classified as flammable gases; see section 2.3.';

(4) in section 2.3.2.1, the Note is replaced by the following notes:

'*Note 1:*

Flammable components do not cover pyrophoric, self-heating or water-reactive substances and mixtures because such components are never used as aerosol contents.

Note 2:

Flammable aerosols do not fall additionally within the scope of sections 2.2 (flammable gases), 2.6 (flammable liquids) or 2.7 (flammable solids).';

(5) in section 2.3.2.2, the following Note is inserted at the end of the paragraph:

'*Note:*

Aerosols not submitted to the flammability classification procedures in this section shall be classified as flammable aerosols, Category 1.';

(6) in section 2.4.2.1, the Note under Table 2.4.1 is replaced by the following:

'*Note:*

"Gases which cause or contribute to the combustion of other material more than air does" mean pure gases or gas mixtures with an oxidising power greater than 23,5 % as determined by a method specified in ISO 10156 as amended or 10156-2 as amended.';

(7) in section 2.5.3, the following Note is inserted under Table 2.5.2:

'*Note:*

Pictogram GHS04 is not required for gases under pressure where pictogram GHS02 or pictogram GHS06 appears.';

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(8) in section 2.6.2.1 the following Note is inserted under Table 2.6.1:

'*Note:*

Aerosols shall not be classified as flammable liquids; see section 2.3.';

(9) section 2.6.4.2 is amended as follows:

(a) the first paragraph is replaced by the following:

'In the case of mixtures (*) containing known flammable liquids in defined concentrations, although they may contain non-volatile components e.g. polymers, additives, the flash point need not be determined experimentally if the calculated flash point of the mixture, using the method given in 2.6.4.3, is at least 5 °C (**) greater than the relevant classification criterion (23 °C and 60 °C, respectively) and provided that:

(*) To date, the calculation method has been validated for mixtures containing up to 6 volatile components. These components may be flammable liquids like hydrocarbons, ethers, alcohols, esters (except acrylates), and water. It is however not yet validated for mixtures containing halogenated sulphurous, and/or phosphoric compounds as well as reactive acrylates.

(**) If the calculated flash point is less than 5 °C greater than the relevant classification criterion, the calculation method may not be used and the flash point should be determined experimentally.';

(b) in point (b), the words 'of the mixture' shall be added;

(10) in section 2.6.4.4, Table 2.6.3, the complete row 'British Standard Institute, BS 2000 Part 170 as amended (identical to EN ISO 13736)' is deleted;

(11) section 2.6.4.5 is replaced by the following:

'2.6.4.5 Liquids with a flash point of more than 35 °C and not more than 60 °C need not be classified in Category 3 if negative results have been obtained in the sustained combustibility test L.2, Part III, section 32 of the UN RTDG, Manual of Tests and Criteria.';

(12) the following new section 2.6.4.6 is inserted:

'2.6.4.6. Possible test methods for determining the initial boiling point of flammable liquids are listed in Table 2.6.4.

Table 2.6.4

Methods for determining the initial boiling point of flammable liquids

European standards:	EN ISO 3405 as amended Petroleum products — Determination of distillation characteristics at atmospheric pressure
	EN ISO 3924 as amended Petroleum products — Determination of boiling range distribution — Gas chromatography method
	EN ISO 4626 as amended Volatile organic liquids — Determination of boiling range of organic solvents used as raw materials
Regulation (EC) No 440/2008 (*)	Method A.2 as described in Part A of the Annex to Regulation (EC) No 440/2008

(*) OJ L 142, 31.5.2008, p. 1.'

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(13) in section 2.7.2.3, the Note under Table 2.7.1 is replaced by the following:

'*Note 1:*

The test shall be performed on the substance or mixture in its physical form as presented. If, for example, for the purposes of supply or transport, the same chemical is to be presented in a physical form different from that which was tested and which is considered likely to materially alter its performance in a classification test, the substance shall also be tested in the new form.

Note 2:

Aerosols shall not be classified as flammable solids; see section 2.3.';

(14) in section 2.8.4.2, Figure 2.8.1, points 7.4, 8.4 and 9.4, the word 'No' is replaced by 'None';

(15) section 2.11.1.2 is replaced by the following:

'2.11.1.2. Self-heating of a substance or a mixture is a process where the gradual reaction of that substance or mixture with oxygen (in the air) generates heat. If the rate of heat production exceeds the rate of heat loss, then the temperature of the substance or mixture will rise which, after an induction time, may lead to self-ignition and combustion.';

(16) in section 2.15.4.2, Figure 2.15.1, points 7.4, 8.4 and 9.4, the word 'No' is replaced by 'None'.

C. Part 3 of Annex I to Regulation (EC) No 1272/2008 is amended as follows:

(1) section 3.1.2.1 is replaced by the following:

'3.1.2.1. Substances can be allocated to one of four toxicity categories based on acute toxicity by the oral, dermal or inhalation route according to the numeric criteria shown in Table 3.1.1. Acute toxicity values are expressed as (approximate) LD_{50} (oral, dermal) or LC_{50} (inhalation) values or as acute toxicity estimates (ATE). Explanatory notes are shown following Table 3.1.1.

Table 3.1.1

Acute toxicity hazard categories and acute toxicity estimates (ATE) defining the respective categories

Exposure route	Category 1	Category 2	Category 3	Category 4
Oral (mg/kg bodyweight) See: Note (a) Note (b)	ATE ≤ 5	5 < ATE ≤ 50	50 < ATE ≤ 300	300 < ATE ≤ 2 000
Dermal (mg/kg bodyweight) See: Note (a) Note (b)	ATE ≤ 50	50 < ATE ≤ 200	200 < ATE ≤ 1 000	1 000 < ATE ≤ 2 000
Gases (ppmV (*)) see: Note (a) Note (b) Note (c)	ATE ≤ 100	100 < ATE ≤ 500	500 < ATE ≤ 2 500	2 500 < ATE ≤ 20 000

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Exposure route	Category 1	Category 2	Category 3	Category 4
Vapours (mg/l) see: Note (a) Note (b) Note (c) Note (d)	ATE ≤ 0,5	0,5 < ATE ≤ 2,0	2,0 < ATE ≤ 10,0	10,0 < ATE ≤ 20,0
Dusts and mists (mg/l) see: Note (a) Note (b) Note (c)	ATE ≤ 0,05	0,05 < ATE ≤ 0,5	0,5 < ATE ≤ 1,0	1,0 < ATE ≤ 5,0

(*) Gas concentrations are expressed in parts per million per volume (ppmV).

Notes to Table 3.1.1:

(a) The acute toxicity estimate (ATE) for the classification of a substance is derived using the LD_{50}/LC_{50} where available.

(b) The acute toxicity estimate (ATE) for the classification of a substance in a mixture is derived using:

— the LD_{50}/LC_{50} where available,

— the appropriate conversion value from Table 3.1.2 that relates to the results of a range test, or

— the appropriate conversion value from Table 3.1.2 that relates to a classification category.

(c) Generic concentration limits for inhalation toxicity in the table are based on 4-hour testing exposures. Conversion of existing inhalation toxicity data which have been generated using a 1-hour exposure can be carried out by dividing by a factor of 2 for gases and vapours and 4 for dusts and mists.

(d) For some substances the test atmosphere will not just be a vapour but will consist of a mixture of liquid and vapour phases. For other substances the test atmosphere may consist of a vapour which is near the gaseous phase. In these latter cases, classification shall be based on ppmV as follows: Category 1 (100 ppmV), Category 2 (500 ppmV), Category 3 (2 500 ppmV), Category 4 (20 000 ppmV).

The terms “dust”, “mist” and “vapour” are defined as follows:

— dust: solid particles of a substance or mixture suspended in a gas (usually air),

— mist: liquid droplets of a substance or mixture suspended in a gas (usually air),

— vapour: the gaseous form of a substance or mixture released from its liquid or solid state.

Dust is generally formed by mechanical processes. Mist is generally formed by condensation of supersaturated vapours or by physical shearing of liquids. Dusts and mists generally have sizes ranging from less than 1 to about 100 μm.’;

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(2) section 3.1.3.2 is replaced by the following:

‘3.1.3.2. For acute toxicity each route of exposure shall be considered for the classification of mixtures, but only one route of exposure is needed as long as this route is followed (estimated or tested) for all components and there is no relevant evidence to suggest acute toxicity by multiple routes. When there is relevant evidence of toxicity by multiple routes of exposure, classification is to be conducted for all appropriate routes of exposure. All available information shall be considered. The pictogram and signal word used shall reflect the most severe hazard category and all relevant hazard statements shall be used.’;

(3) in section 3.1.3.3, points (c) and (d) are added:

‘(c) If the converted acute toxicity point estimates for all components of a mixture are within the same category, then the mixture should be classified in that category.

(d) When only range data (or acute toxicity hazard category information) are available for components in a mixture, they may be converted to point estimates in accordance with Table 3.1.2 when calculating the classification of the new mixture using the formulas in sections 3.1.3.6.1 and 3.1.3.6.2.3.’;

(4) section 3.1.3.5.2 is replaced by the following:

‘3.1.3.5.2. If a tested mixture is diluted with a diluent that has an equivalent or lower toxicity classification than the least toxic original components, and which is not expected to affect the toxicity of other components, then the new diluted mixture may be classified as equivalent to the original tested mixture. Alternatively, the formula explained in section 3.1.3.6.1 can be applied.’;

(5) section 3.1.3.6.1, is amended as follows:

(a) point (c) is replaced by the following:

‘(c) ignore components if the data available are from a limit dose test (at the upper threshold for Category 4 for the appropriate route of exposure as provided in Table 3.1.1) and do not show acute toxicity.’;

(b) the first sentence beneath point (c) is replaced by the following:

‘Components that fall within the scope of this section are considered to be components with a known acute toxicity estimate (ATE). See note (b) to Table 3.1.1 and section 3.1.3.3 for appropriate application of available data to the equation below, and section 3.1.3.6.2.3.’;

(6) in section 3.1.3.6.2.1, point (a), the footnote is replaced by the following:

‘([1]) When mixtures contain components that do not have acute toxicity data for each route of exposure, acute toxicity estimates may be extrapolated from the available data and applied to the appropriate routes (see section 3.1.3.2). However, specific legislation may require testing for a specific route. In those cases, classification shall be performed for that route based upon the legal requirements.’;

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(7) section 3.1.3.6.2.2 is replaced by the following:

‘3.1.3.6.2.2. In the event that a component without any useable information for classification is used in a mixture at a concentration of 1 % or greater, it is concluded that the mixture cannot be attributed a definitive acute toxicity estimate. In this situation the mixture shall be classified based on the known components only, with the additional statement on the label and in the SDS that: “× percent of the mixture consists of component(s) of unknown toxicity”.’;

(8) in section 3.1.3.6.2.3, the title of Table 3.1.2 is replaced by the following:

‘Conversion from experimentally obtained acute toxicity range values (or acute toxicity hazard categories) to acute toxicity point estimates for use in the formulas for the classification of mixtures’;

(9) the following sentence is added to section 3.1.4.1:

‘Without prejudice to Article 27, combined hazard statements may be used in accordance with Annex III.’;

(10) in Tables 3.1.3, 3.2.5, 3.3.5, 3.4.4 and 3.8.4, the pictogram with the exclamation mark is replaced by the following pictogram:

‘’;

(11) in section 3.4.1.5 the words ‘at section 3.4.4.’ are replaced by ‘in Annex II, section 2.8.’;

(12) in section 3.4.1.6 the word ‘and’ is inserted after ‘Respiratory Sensitisation’;

(13) sections from 3.4.2 to 3.4.2.2.4.1 are replaced by the following:

‘3.4.2. ***Classification criteria for substances***

3.4.2.1. *Respiratory sensitisers*

3.4.2.1.1. Hazard categories

3.4.2.1.1.1. Respiratory sensitisers shall be classified in Category 1 where data are not sufficient for sub-categorisation.

3.4.2.1.1.2. Where data are sufficient a refined evaluation according to 3.4.2.1.1.3 shall allow the allocation of respiratory sensitisers into sub-category 1A, strong sensitisers, or sub-category 1B for other respiratory sensitisers.

3.4.2.1.1.3. Effects seen in either humans or animals will normally justify classification in a weight of evidence approach for respiratory sensitisers. Substances may be allocated to one of the two sub-categories 1A or 1B using a weight of evidence approach in accordance with the criteria given in Table 3.4.1 and on the basis of reliable and good quality evidence from human cases or epidemiological studies and/or observations from appropriate studies in experimental animals.

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3.4.2.1.1.4. Substances shall be classified as respiratory sensitisers in accordance with the criteria in Table 3.4.1:

Table 3.4.1

Hazard category and sub-categories for respiratory sensitisers

Category	Criteria
Category 1	Substances shall be classified as respiratory sensitisers (Category 1) where data are not sufficient for sub-categorisation in accordance with the following criteria: (a) if there is evidence in humans that the substance can lead to specific respiratory hypersensitivity; and/or (b) if there are positive results from an appropriate animal test.
Sub-category 1A:	Substances showing a high frequency of occurrence in humans; or a probability of occurrence of a high sensitisation rate in humans based on animal or other tests (*). Severity of reaction may also be considered.
Sub-category 1B:	Substances showing a low to moderate frequency of occurrence in humans; or a probability of occurrence of a low to moderate sensitisation rate in humans based on animal or other tests (*). Severity of reaction may also be considered.

(*) At present, recognised and validated animal models for the testing of respiratory hypersensitivity are not available. Under certain circumstances, data from animal studies may provide valuable information in a weight of evidence assessment.

3.4.2.1.2. Human evidence

3.4.2.1.2.1. Evidence that a substance can lead to specific respiratory hypersensitivity will normally be based on human experience. In this context, hypersensitivity is normally seen as asthma, but other hypersensitivity reactions such as rhinitis/conjunctivitis and alveolitis are also considered. The condition will have the clinical character of an allergic reaction. However, immunological mechanisms do not have to be demonstrated.

3.4.2.1.2.2. When considering the human evidence, it is necessary for a decision on classification to take into account, in addition to the evidence from the cases:

(a) the size of the population exposed;

(b) the extent of exposure.

The use of human data is discussed in sections 1.1.1.3, 1.1.1.4 and 1.1.1.5.

3.4.2.1.2.3. The evidence referred to above could be:

(a) clinical history and data from appropriate lung function tests related to exposure to the substance, confirmed by other supportive evidence which may include:

(i) in vivo immunological test (e.g. skin prick test);

(ii) in vitro immunological test (e.g. serological analysis);

(iii) studies that indicate other specific hypersensitivity reactions where immunological mechanisms of action have not been proven, e.g. repeated low-level irritation, pharmacologically mediated effects;

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(iv) a chemical structure related to substances known to cause respiratory hypersensitivity;

(b) data from one or more positive bronchial challenge tests with the substance conducted according to accepted guidelines for the determination of a specific hypersensitivity reaction.

3.4.2.1.2.4. Clinical history shall include both medical and occupational history to determine a relationship between exposure to a specific substance and development of respiratory hypersensitivity. Relevant information includes aggravating factors both in the home and workplace, the onset and progress of the disease, family history and medical history of the patient in question. The medical history shall also include a note of other allergic or airway disorders from childhood, and smoking history.

3.4.2.1.2.5. The results of positive bronchial challenge tests are considered to provide sufficient evidence for classification on their own. It is however recognised that in practice many of the examinations listed above will already have been carried out.

3.4.2.1.3. Animal studies

3.4.2.1.3.1. Data from appropriate animal studies (*) which may be indicative of the potential of a substance to cause sensitisation by inhalation in humans (**) may include:

(a) measurements of Immunoglobulin E (IgE) and other specific immunological parameters in mice;

(b) specific pulmonary responses in guinea pigs.

3.4.2.2. *Skin sensitisers*

3.4.2.2.1. Hazard categories

3.4.2.2.1.1. Skin sensitisers shall be classified in Category 1 where data are not sufficient for sub-categorisation.

3.4.2.2.1.2. Where data are sufficient a refined evaluation according to section 3.4.2.2.1.3 allows the allocation of skin sensitisers into sub-category 1A, strong sensitisers, or sub-category 1B for other skin sensitisers.

3.4.2.2.1.3. Effects seen in either humans or animals will normally justify classification in a weight of evidence approach for skin sensitisers as described in section 3.4.2.2.2. Substances may be allocated to one of the two sub-categories 1A or 1B using a weight of evidence approach in accordance with the criteria given in Table 3.4.2 and on the basis of reliable and good quality evidence from human cases or epidemiological studies and/or observations from appropriate studies in experimental animals according to the guidance values provided in sections 3.4.2.2.2.1 and 3.4.2.2.3.2 for sub-category 1A and in sections 3.4.2.2.2.2 and 3.4.2.2.3.3 for sub-category 1B.

3.4.2.2.1.4. Substances shall be classified as skin sensitisers in accordance with the criteria in Table 3.4.2:

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Table 3.4.2

Hazard category and sub-categories for skin sensitisers

Category	Criteria
Category 1	Substances shall be classified as skin sensitisers (Category 1) where data are not sufficient for sub-categorisation in accordance with the following criteria: (a) if there is evidence in humans that the substance can lead to sensitisation by skin contact in a substantial number of persons; or (b) if there are positive results from an appropriate animal test (see specific criteria in section 3.4.2.2.4.1).
Sub-category 1A:	Substances showing a high frequency of occurrence in humans and/or a high potency in animals can be presumed to have the potential to produce significant sensitisation in humans. Severity of reaction may also be considered.
Sub-category 1B:	Substances showing a low to moderate frequency of occurrence in humans and/or a low to moderate potency in animals can be presumed to have the potential to produce sensitisation in humans. Severity of reaction may also be considered.

3.4.2.2.2. Human evidence

3.4.2.2.2.1. Human evidence for sub-category 1A can include:

(a) positive responses at ≤ 500 μg/cm^2 (HRIPT, HMT — induction threshold);

(b) diagnostic patch test data where there is a relatively high and substantial incidence of reactions in a defined population in relation to relatively low exposure;

(c) other epidemiological evidence where there is a relatively high and substantial incidence of allergic contact dermatitis in relation to relatively low exposure.

3.4.2.2.2.2. Human evidence for sub-category 1B can include:

(a) positive responses at > 500 μg/cm2 (HRIPT, HMT — induction threshold);

(b) diagnostic patch test data where there is a relatively low but substantial incidence of reactions in a defined population in relation to relatively high exposure;

(c) other epidemiological evidence where there is a relatively low but substantial incidence of allergic contact dermatitis in relation to relatively high exposure.

The use of human data is discussed in sections 1.1.1.3, 1.1.1.4 and 1.1.1.5.

3.4.2.2.3. Animal studies

3.4.2.2.3.1. For Category 1, when an adjuvant type test method for skin sensitisation is used, a response of at least 30 % of the animals is considered as positive. For a non-adjuvant Guinea pig test method a response of at least 15 % of the animals is considered positive. For Category 1, a stimulation index of three or more is considered a positive response in the local lymph node assay. Test methods for skin sensitisation are described in the OECD Guideline 406

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(the Guinea Pig Maximisation test and the Buehler guinea pig test) and Guideline 429 (Local Lymph Node Assay). Other methods may be used provided that they are well-validated and scientific justification is given. For example, the mouse ear swelling test (MEST) could be a reliable screening test to detect moderate to strong sensitisers, and could be used as a first stage in the assessment of skin sensitisation potential.

3.4.2.2.3.2. Animal test results for sub-category 1A can include data with values indicated in Table 3.4.3

Table 3.4.3

Animal test results for sub-category 1A

Assay	Criteria
Local lymph node assay	EC3 value ≤ 2 %
Guinea pig maximisation test	≥ 30 % responding at ≤ 0,1 % intradermal induction dose or ≥ 60 % responding at > 0,1 % to ≤ 1 % intradermal induction dose
Buehler assay	≥ 15 % responding at ≤ 0,2 % topical induction dose or ≥ 60 % responding at > 0,2 % to ≤ 20 % topical induction dose

3.4.2.2.3.3. Animal test results for sub-category 1B can include data with values indicated in Table 3.4.4 below:

Table 3.4.4

Animal test results for sub-category 1B

Assay	Criteria
Local lymph node assay	EC3 value > 2 %
Guinea pig maximisation test	≥ 30 % to < 60 % responding at > 0,1 % to ≤ 1 % intradermal induction dose or ≥ 30 % responding at > 1 % intradermal induction dose
Buehler assay	≥ 15 % to < 60 % responding at > 0,2 % to ≤ 20 % topical induction dose or ≥ 15 % responding at > 20 % topical induction dose

3.4.2.2.4. Specific considerations

3.4.2.2.4.1. For classification of a substance, evidence should include any or all of the following using a weight of evidence approach:

(a) positive data from patch testing, normally obtained in more than one dermatology clinic;

(b) epidemiological studies showing allergic contact dermatitis caused by the substance. Situations in which a high proportion of those exposed exhibit characteristic symptoms are to be looked at with special concern, even if the number of cases is small;

(c) positive data from appropriate animal studies;

(d) positive data from experimental studies in man (see section 1.3.2.4.7);

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(e) well documented episodes of allergic contact dermatitis, normally obtained in more than one dermatology clinic;

(f) severity of reaction may also be considered.

3.4.2.2.4.2. Evidence from animal studies is usually much more reliable than evidence from human exposure. However, in cases where evidence is available from both sources, and there is conflict between the results, the quality and reliability of the evidence from both sources must be assessed in order to resolve the question of classification on a case-by-case basis. Normally, human data are not generated in controlled experiments with volunteers for the purpose of hazard classification but rather as part of risk assessment to confirm lack of effects seen in animal tests. Consequently, positive human data on skin sensitisation are usually derived from case-control or other, less defined studies. Evaluation of human data must therefore be carried out with caution as the frequency of cases reflect, in addition to the inherent properties of the substances, factors such as the exposure situation, bioavailability, individual predisposition and preventive measures taken. Negative human data should not normally be used to negate positive results from animal studies. For both animal and human data, consideration should be given to the impact of vehicle.

3.4.2.2.4.3. If none of the abovementioned conditions are met, the substance need not be classified as a skin sensitiser. However, a combination of two or more indicators of skin sensitisation as listed below may alter the decision. This shall be considered on a case-by-case basis.

(a) Isolated episodes of allergic contact dermatitis;

(b) epidemiological studies of limited power, e.g. where chance, bias or confounders have not been ruled out fully with reasonable confidence;

(c) data from animal tests, performed according to existing guidelines, which do not meet the criteria for a positive result described in section 3.4.2.2.3, but which are sufficiently close to the limit to be considered significant;

(d) positive data from non-standard methods;

(e) positive results from close structural analogues.

3.4.2.2.4.4. Immunological contact urticaria

Substances meeting the criteria for classification as respiratory sensitisers may in addition cause immunological contact urticaria. Consideration should be given to classifying these substances also as skin sensitisers. Substances which cause immunological contact urticaria without meeting the criteria for respiratory sensitisers should also be considered for classification as skin sensitisers.

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There is no recognised animal model available to identify substances which cause immunological contact urticaria. Therefore, classification will normally be based on human evidence which will be similar to that for skin sensitisation.

(*) At present, recognised and validated animal models for the testing of respiratory hypersensitivity are not available. Under certain circumstances, data from animal studies may provide valuable information in a weight of evidence assessment.

(**) The mechanisms by which substances induce symptoms of asthma are not yet fully known. For preventative measures, these substances are considered respiratory sensitisers. However, if on the basis of the evidence, it can be demonstrated that these substances induce symptoms of asthma by irritation only in people with bronchial hyper reactivity, they should not be considered as respiratory sensitisers.';

(14) in section 3.4.3.3.1 the reference to 'Table 3.4.3' is replaced by 'Table 3.4.5';

(15) section 3.4.3.3.2 is amended as follows:

(a) the reference to 'Table 3.4.1' is replaced by 'Table 3.4.5';

(b) the reference to 'Table 3.4.3' is replaced by 'Table 3.4.6';

(c) Table 3.4.3 and Notes 1, 2 and 3 are replaced by the following:

'Table 3.4.5

Generic concentration limits of components of a mixture classified as either respiratory sensitisers or skin sensitisers that trigger classification of the mixture

Component classified as:	Generic concentration limits triggering classification of a mixture as:		
	Respiratory sensitiser Category 1		Skin sensitiser Category 1
	Solid/liquid	Gas	All physical states
Respiratory sensitiser Category 1	≥ 1,0 %	≥ 0,2 %	
Respiratory sensitiser Sub-category 1A	≥ 0,1 %	≥ 0,1 %	
Respiratory sensitiser Sub-category 1B	≥ 1,0 %	≥ 0,2 %	
Skin sensitiser Category 1			≥ 1,0 %
Skin sensitiser Sub-category 1A			≥ 0,1 %
Skin sensitiser Sub-category 1B			≥ 1,0 %'

(d) a new Table 3.4.6 is inserted after the new Table 3.4.5:

'Table 3.4.6

Concentration limits for elicitation of components of a mixture

Component classified as:	Concentration limits for elicitation		
	Respiratory sensitiser Category 1		Skin sensitiser Category 1
	Solid/liquid	Gas	All physical states
Respiratory sensitiser Category 1	≥ 0,1 % (Note 1)	≥ 0,1 % (Note 1)	

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Component classified as:	Concentration limits for elicitation		
	Respiratory sensitiser Category 1		Skin sensitiser Category 1
	Solid/liquid	Gas	All physical states
Respiratory sensitiser Sub-category 1A	≥ 0,01 % (Note 1)	≥ 0,01 % (Note 1)	
Respiratory sensitiser Sub-category 1B	≥ 0,1 % (Note 1)	≥ 0,1 % (Note 1)	
Skin sensitiser Category 1			≥ 0,1 % (Note 1)
Skin sensitiser Sub-category 1A			≥ 0,01 % (Note 1)
Skin sensitiser Sub-category 1B			≥ 0,1 % (Note 1)

Note 1:

This concentration limit for elicitation is used for the application of the special labelling requirements of Annex II section 2.8 to protect already sensitised individuals. A SDS is required for the mixture containing a component above this concentration. For sensitising substances with specific concentration limit lower than 0,1 %, the concentration limit for elicitation should be set at one tenth of the specific concentration limit.';

(16) section 3.4.4.1 is replaced by the following:

'3.4.4.1. Label elements shall be used for substances or mixtures meeting the criteria for classification in this hazard class in accordance with Table 3.4.7.

Table 3.4.7

Respiratory or skin sensitisation label elements

Classification	Respiratory sensitisation	Skin sensitisation
	Category 1 and sub-categories 1A and 1B	Category 1 and sub-categories 1A and 1B
GHS pictograms		
Signal word	Danger	Warning
Hazard statement	H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled	H317: May cause an allergic skin reaction
Precautionary statement prevention	P261 P285	P261 P272 P280
Precautionary statement response	P304 + P341 P342 + P311	P302 + P352 P333 + P313 P321 P363

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Classification	Respiratory sensitisation	Skin sensitisation
	Category 1 and sub-categories 1A and 1B	Category 1 and sub-categories 1A and 1B
Precautionary statement storage		
Precautionary statement disposal	P501	P501’

(17) in section 3.8.3.4.5, the following sentence is added at the end:

‘Respiratory tract irritation and narcotic effects are to be evaluated separately in accordance with the criteria given in section 3.8.2.2. When conducting classifications for these hazards, the contribution of each component should be considered additive, unless there is evidence that the effects are not additive.’;

(18) in section 3.9.1.2, the words ‘or mixture’ are added after the word ‘substance’;

(19) the following section 3.10.1.6.2a. is inserted:

‘3.10.1.6.2a Although the definition of aspiration in section 3.10.1.2 includes the entry of solids into the respiratory system, classification according to point (b) in Table 3.10.1 for Category 1 is intended to apply to liquid substances and mixtures only.’;

D. Part 4 of Annex I to Regulation (EC) No 1272/2008 is replaced by the following text:

‘4. PART 4: ENVIRONMENTAL HAZARDS

4.1. **Hazardous to the aquatic environment**

4.1.1. ***Definitions and general considerations***

4.1.1.1. *Definitions*

(a) “acute aquatic toxicity” means the intrinsic property of a substance to be injurious to an aquatic organism in a short-term aquatic exposure to that substance.

(b) “acute (short-term) hazard” means for classification purposes the hazard of a substance or mixture caused by its acute toxicity to an organism during short-term aquatic exposure to that substance or mixture.

(c) “availability of a substance” means the extent to which this substance becomes a soluble or disaggregate species. For metal availability, the extent to which the metal ion portion of a metal (M°) compound can disaggregate from the rest of the compound (molecule).

(d) “bioavailability” or “biological availability” means the extent to which a substance is taken up by an organism, and distributed to an area within the organism. It is dependent upon physico-chemical properties of the substance, anatomy and physiology of the organism, pharmacokinetics, and route of exposure. Availability is not a prerequisite for bioavailability.

(e) “bioaccumulation” means the 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).

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(f) “bioconcentration” means the net result of uptake, transformation and elimination of a substance in an organism due to waterborne exposure.

(g) “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.

(h) “degradation” means the decomposition of organic molecules to smaller molecules and eventually to carbon dioxide, water and salts.

(i) “EC_x” means the effect concentration associated with x% response.

(j) “long-term hazard” means for classification purposes the hazard of a substance or mixture caused by its chronic toxicity following long-term exposure in the aquatic environment.

(k) “no observed effect concentration (NOEC)” means the test concentration immediately below the lowest tested concentration with statistically significant adverse effect. The NOEC has no statistically significant adverse effect compared to the control.

4.1.1.2. *Basic elements*

4.1.1.2.0. Hazardous to the aquatic environment is differentiated into:

— acute aquatic hazard,

— long-term aquatic hazard.

4.1.1.2.1. The basic elements used for classification for aquatic environmental hazards are:

— acute aquatic toxicity,

— chronic aquatic toxicity,

— potential for or actual bioaccumulation, and

— degradation (biotic or abiotic) for organic chemicals.

4.1.1.2.2. Preferably data shall be derived using the standardised test methods referred to in Article 8(3). In practice data from other standardised test methods such as national methods shall also be used where they are considered as equivalent. Where valid data are available from non-standard testing and from non-testing methods, these shall be considered in classification provided they fulfil the requirements specified in section 1 of Annex XI to Regulation (EC) No 1907/2006. In general, both freshwater and marine species toxicity data are considered suitable for use in classification provided the test methods used are equivalent. Where such data are not available classification shall be based on the best available data. See also Part 1 of Annex I to Regulation (EC) No 1272/2008.

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4.1.1.3. *Other considerations*

4.1.1.3.1. Classification of substances and mixtures for environmental hazards requires the identification of the hazards they present to the aquatic environment. The aquatic environment is considered in terms of the aquatic organisms that live in the water, and the aquatic ecosystem of which they are part. The basis, therefore, of the identification of acute (short-term) and long-term hazards is the aquatic toxicity of the substance or mixture, although this shall be modified by taking account of further information on the degradation and bioaccumulation behaviour, if appropriate.

4.1.1.3.2. While the classification system applies to all substances and mixtures, it is recognised that for special cases (e.g. metals) the European Chemicals Agency has issued guidance.

4.1.2. ***Classification criteria for substances***

4.1.2.1. The system for classification recognises that the intrinsic hazard to aquatic organisms is represented by both the acute and long-term hazard of a substance. For the long-term hazard, separate hazard categories are defined representing a gradation in the level of hazard identified. The lowest of the available toxicity values between and within the different trophic levels (fish, crustacean, algae/aquatic plants) shall normally be used to define the appropriate hazard category(ies). There are circumstances, however, when a weight of evidence approach is appropriate.

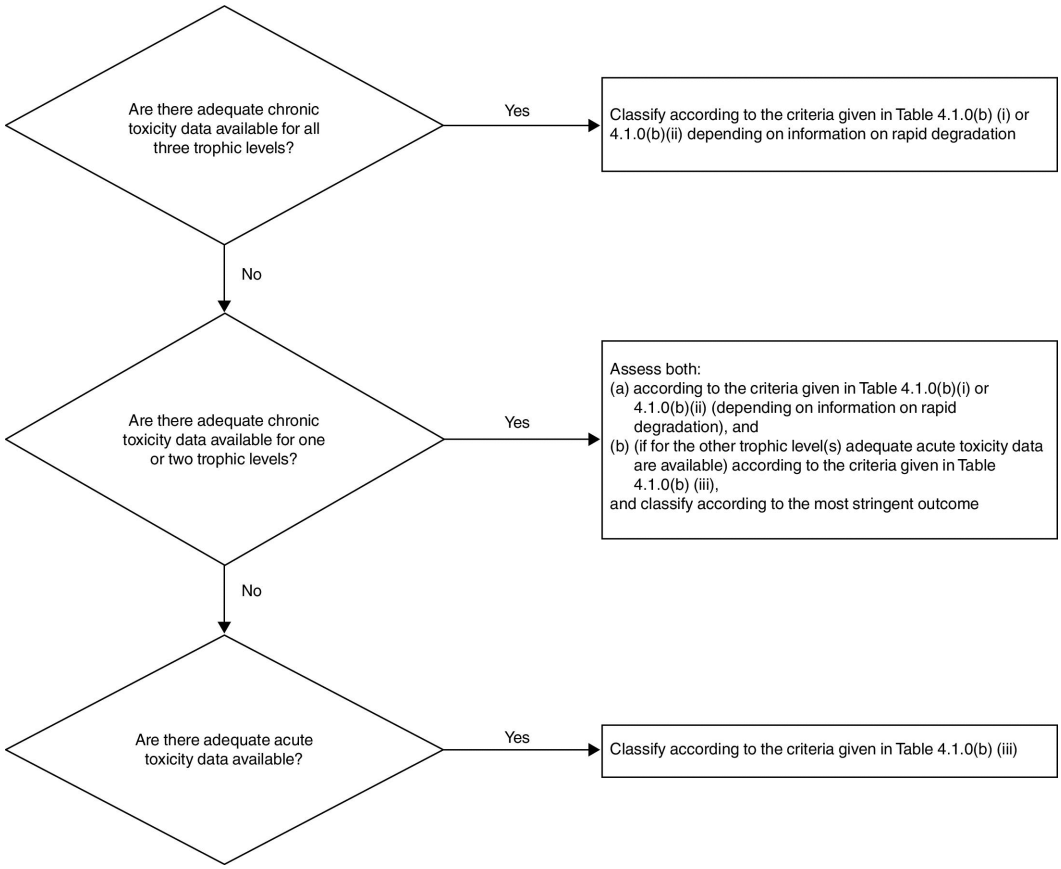
4.1.2.2. The core classification system for substances consists of one acute hazard classification category and three long-term hazard classification categories. The acute and the long-term hazard classification categories are applied independently.

4.1.2.3. The criteria for classification of a substance in category Acute 1 are defined on the basis of acute aquatic toxicity data only (EC_{50} or LC_{50}). The criteria for classification of a substance into the categories Chronic 1 to 3 follow a tiered approach where the first step is to see if available information on chronic toxicity merits long-term hazard classification. In absence of adequate chronic toxicity data, the subsequent step is to combine two types of information, i.e. acute aquatic toxicity data and environmental fate data (degradability and bioaccumulation data) (see figure 4.1.1).

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Figure 4.1.1

Categories for substances long-term hazardous to the aquatic environment



4.1.2.4. The system also introduces a "safety net" classification (referred to as category Chronic 4) for use when the data available do not allow classification under the formal criteria for acute 1 or chronic 1 to 3 but there are nevertheless some grounds for concern (see example in Table 4.1.0).

4.1.2.5. Substances with acute toxicities below 1 mg/l or chronic toxicities below 0,1 mg/l (if non-rapidly degradable) and 0,01 mg/l (if rapidly degradable) contribute as components of a mixture to the toxicity of the mixture even at a low concentration and shall normally be given increased weight in applying the summation of classification approach (see note 1 of Table 4.1.0 and section 4.1.3.5.5).

4.1.2.6. The criteria for classifying and categorising substances as "hazardous to the aquatic environment" are summarised in Table 4.1.0.

Table 4.1.0

Classification categories for hazardous to the aquatic environment

(a) Acute (short-term) aquatic hazard	
Category Acute 1: (Note 1)	
96 hr LC_{50} (for fish)	≤ 1 mg/l and/or
48 hr EC_{50} (for crustacea)	≤ 1 mg/l and/or
72 or 96 hr ErC_{50} (for algae or other aquatic plants)	≤ 1 mg/l. (Note 2)

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(b) Long-term aquatic hazard

(i) Non-rapidly degradable substances (Note 3) for which there are adequate chronic toxicity data available

Category Chronic 1: (Note 1)

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)	> 0,1 to ≤ 1 mg/l and/or
Chronic NOEC or EC_x (for crustacea)	> 0,1 to ≤ 1 mg/l and/or
Chronic NOEC or EC_x (for algae or other aquatic plants)	> 0,1 to ≤ 1 mg/l.

(ii) Rapidly degradable substances (Note 3) for which there are adequate chronic toxicity data available

Category Chronic 1: (Note 1)

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)	> 0,01 to ≤ 0,1 mg/l and/or
Chronic NOEC or EC_x (for crustacea)	> 0,01 to ≤ 0,1 mg/l and/or
Chronic NOEC or EC_x (for algae or other aquatic plants)	> 0,01 to ≤ 0,1 mg/l.

Category Chronic 3:

Chronic NOEC or EC_x (for fish)	> 0,1 to ≤ 1 mg/l and/or
Chronic NOEC or EC_x (for crustacea)	> 0,1 to ≤ 1 mg/l and/or
Chronic NOEC or EC_x (for algae or other aquatic plants)	> 0,1 to ≤ 1 mg/l.

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

Category Chronic 1: (Note 1)

96 hr LC_{50} (for fish)	≤ 1 mg/l and/or
48 hr EC_{50} (for crustacea)	≤ 1 mg/l and/or
72 or 96 hr ErC_{50} (for algae or other aquatic plants)	≤ 1 mg/l. (Note 2)

and the substance is not rapidly degradable and/or the experimentally determined BCF ≥ 500 (or, if absent, the log K_{ow}≥ 4). (Note 3).

Category Chronic 2:

96 hr LC_{50} (for fish)	> 1 to ≤10 mg/l and/or

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48 hr EC_{50} (for crustacea)	> 1 to ≤10 mg/l and/or
72 or 96 hr ErC_{50} (for algae or other aquatic plants)	> 1 to ≤10 mg/l (Note 2)
and the substance is not rapidly degradable and/or the experimentally determined BCF ≥ 500 (or, if absent, the log K_{ow}≥ 4). (Note 3).	
Category Chronic 3:	
96 hr LC_{50} (for fish)	> 10 to ≤ 100 mg/l and/or
48 hr EC_{50} (for crustacea)	> 10 to ≤ 100 mg/l and/or
72 or 96 hr ErC_{50} (for algae or other aquatic plants)	> 10 to ≤ 100 mg/l. (Note 2)
and the substance is not rapidly degradable and/or the experimentally determined BCF ≥ 500 (or, if absent, the log K_{ow}≥ 4). (Note 3).	
"Safety net" classification	
Category Chronic 4	
Cases when data do not allow classification under the above criteria but there are nevertheless some grounds for concern. This includes, for example, poorly soluble substances for which no acute toxicity is recorded at levels up to the water solubility (note 4), and which are not rapidly degradable in accordance with section 4.1.2.9.5 and have an experimentally determined BCF ≥ 500 (or, if absent, a log K_{ow} ≥ 4), indicating a potential to bioaccumulate, which will be classified in this category unless other scientific evidence exists showing classification to be unnecessary. Such evidence includes chronic toxicity NOECs > water solubility or > 1 mg/l, or other evidence of rapid degradation in the environment than the ones provided by any of the methods listed in section 4.1.2.9.5.	

Note 1:

When classifying substances as Acute Category 1 and/or Chronic Category 1 it is necessary at the same time to indicate the appropriate M-factor(s) (see Table 4.1.3).

Note 2:

Classification shall be based on the ErC_{50} [= EC_{50} (growth rate)]. In circumstances where the basis of the EC_{50} is not specified or no ErC_{50} is recorded, classification shall be based on the lowest EC_{50} available.

Note 3:

When no useful data on degradability are available, either experimentally determined or estimated data, the substance should be regarded as not rapidly degradable.

Note 4:

"No acute toxicity" is taken to mean that the L(E)C_{50}(s) is/are above the water solubility. Also for poorly soluble substances, (water solubility < 1 mg/l), where there is evidence that the acute test does not provide a true measure of the intrinsic toxicity.

4.1.2.7. *Aquatic toxicity*

4.1.2.7.1. Acute aquatic toxicity is normally determined using a fish 96-hour LC_{50}, a crustacea species 48-hour EC_{50} and/or an algal species 72- or 96-hour EC_{50}. These species cover a range of trophic levels and taxa and are considered as surrogate for all aquatic organisms. Data on other species (e.g. Lemna spp.) shall also be considered if the test methodology is suitable. The aquatic plant growth inhibition tests are normally considered as chronic tests but the EC_{50}s are treated as acute values for classification purposes (see note 2).

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4.1.2.7.2. For determining chronic aquatic toxicity for classification purposes data generated according to the standardised test methods referred to in Article 8(3) shall be accepted, as well as results obtained from other validated and internationally accepted test methods. The NOECs or other equivalent EC_x (e.g. EC_{10}) shall be used.

4.1.2.8. *Bioaccumulation*

4.1.2.8.1. Bioaccumulation of substances within aquatic organisms can give rise to toxic effects over longer time scales even when actual water concentrations are low. For organic substances the potential for bioaccumulation shall normally be determined by using the octanol/water partition coefficient, usually reported as a log K_{ow}. The relationship between the log K_{ow} of an organic substance and its bioconcentration as measured by the bioconcentration factor (BCF) in fish has considerable scientific literature support. Using a cut-off value of log $K_{ow} \geq 4$ is intended to identify only those substances with a real potential to bioconcentrate. While this represents a potential to bioaccumulate, an experimentally determined BCF provides a better measure and shall be used in preference if available. A BCF in fish of ≥ 500 is indicative of the potential to bioconcentrate for classification purposes. Some relationships can be observed between chronic toxicity and bioaccumulation potential, as toxicity is related to the body burden.

4.1.2.9. *Rapid degradability of organic substances*

4.1.2.9.1. Substances that rapidly degrade can be quickly removed from the environment. While effects of such substances can occur, particularly in the event of a spillage or accident, they are localised and of short duration. In the absence of rapid degradation in the environment a substance in the water has the potential to exert toxicity over a wide temporal and spatial scale.

4.1.2.9.2. One way of demonstrating rapid degradation utilises the biodegradation screening tests designed to determine whether an organic substance is "readily biodegradable". Where such data are not available, a BOD(5 days)/COD ratio $\geq 0{,}5$ is considered as indicative of rapid degradation. Thus, a substance which passes this screening test is considered likely to biodegrade "rapidly" in the aquatic environment, and is thus unlikely to be persistent. However, a fail in the screening test does not necessarily mean that the substance will not degrade rapidly in the environment. Other evidence of rapid degradation in the environment may therefore also be considered and are of particular importance where the substances are inhibitory to microbial activity at the concentration levels used in standard testing. Thus, a further classification criterion is included which allows the use of data to show that the substance did actually degrade biotically or abiotically in the aquatic environment by > 70 % in 28 days. Thus, if degradation is demonstrated under environmentally realistic conditions, then the criterion of "rapid degradability" is met.

4.1.2.9.3. Many degradation data are available in the form of degradation half-lives and these can be used in defining rapid degradation provided that ultimate biodegradation of the substance, i.e. full mineralisation, is achieved. Primary biodegradation does not normally suffice in the assessment of rapid degradability unless it can be demonstrated that the degradation products do not fulfil the criteria for classification as hazardous to the aquatic environment.

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4.1.2.9.4. The criteria used reflect the fact that environmental degradation may be biotic or abiotic. Hydrolysis can be considered if the hydrolysis products do not fulfil the criteria for classification as hazardous to the aquatic environment.

4.1.2.9.5. Substances are considered rapidly degradable in the environment if one of the following criteria holds true:

(a) if, in 28-day ready biodegradation studies, at least 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 maximum.

These levels of biodegradation must 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, unless the substance is identified as an UVCB or as a complex, multi-constituent substance with structurally similar constituents. In this case, and where there is sufficient justification, the 10-day window condition may be waived and the pass level applied at 28 days; or

(b) if, in those cases where only BOD and COD data are available, when the ratio of BOD_5/COD is ≥ 0,5; or

(c) if other convincing scientific evidence is available to demonstrate that the substance can be degraded (biotically and/or abiotically) in the aquatic environment to a level > 70 % within a 28-day period.

4.1.2.10. *Inorganic compounds and metals*

4.1.2.10.1. For inorganic compounds and metals, the concept of degradability as applied to organic compounds has limited or no meaning. Rather, such substances may be transformed by normal environmental processes to either increase or decrease the bioavailability of the toxic species. Equally the use of bioaccumulation data shall be treated with care (*).

(*) Specific guidance has been issued by the European Chemicals Agency on how these data for such substances may be used in meeting the requirements of the classification criteria.

4.1.2.10.2. Poorly soluble inorganic compounds and metals may be acutely or chronically toxic in the aquatic environment depending on the intrinsic toxicity of the bioavailable inorganic species and the rate and amount of this species which enter solution. All evidence must be weighed in a classification decision. This would be especially true for metals showing borderline results in the Transformation/Dissolution Protocol.

4.1.3. ***Classification criteria for mixtures***

4.1.3.1. The classification system for mixtures covers all classification categories which are used for substances, i.e. categories Acute 1 and Chronic 1 to 4. In order to make use of all available data for purposes of classifying the aquatic environmental hazards of the mixture, the following is applied where appropriate:

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The “relevant components” of a mixture are those which are classified “Acute 1”or “Chronic 1” and present in a concentration of 0,1 % (w/w) or greater, and those which are classified “Chronic 2”, “Chronic 3” or “Chronic 4” and present in a concentration of 1 % (w/w) or greater, unless there is a presumption (such as in the case of highly toxic components (see section 4.1.3.5.5.5)) that a component present in a lower concentration can still be relevant for classifying the mixture for aquatic environmental hazards. Generally, for substances classified as “Acute 1” or “Chronic 1” the concentration to be taken into account is (0,1/M) %. (For explanation M-factor see section 4.1.3.5.5.5.)

4.1.3.2. 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. Figure 4.1.2 outlines the process to be followed.

Elements of the tiered approach include:

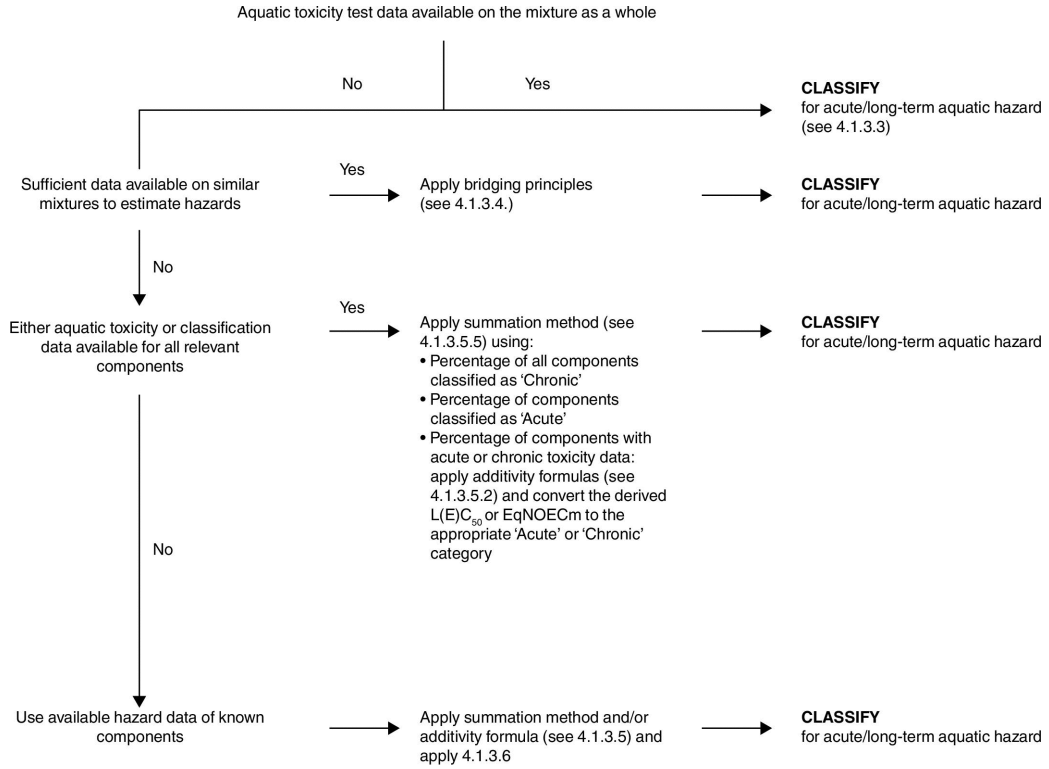
— classification based on tested mixtures,

— classification based on bridging principles,

— the use of “summation of classified components” and/or an “additivity formula”.

Figure 4.1.2

Tiered approach to classification of mixtures for acute and long-term aquatic environmental hazards



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

4.1.3.3.1. When the mixture as a whole has been tested to determine its aquatic toxicity, this information can be used for classifying the mixture according to the criteria that have been agreed for substances. The classification is normally based on the data for fish, crustacea and algae/plants (see sections 4.1.2.7.1 and 4.1.2.7.2). When adequate acute or chronic toxicity data for the mixture as a whole are lacking, "bridging principles" or "summation method" should be applied (see sections 4.1.3.4 and 4.1.3.5).

4.1.3.3.2. The long-term hazard classification of mixtures requires additional information on degradability and in certain cases bioaccumulation. Degradability and bioaccumulation tests for mixtures are not used as they are usually difficult to interpret, and such tests may be meaningful only for single substances.

4.1.3.3.3. Classification for category Acute 1

(a) When there are adequate acute toxicity test data (LC_{50} or EC_{50}) available for the mixture as a whole showing $L(E)C_{50} \leq 1$ mg/l:

Classify mixture as Acute 1 in accordance with point (a) of Table 4.1.0.

(b) When there are acute toxicity test data (LC_{50}(s) or EC_{50}(s)) available for the mixture as a whole showing $L(E)C_{50}(s) > 1$ mg/l for normally all trophic levels:

No need to classify for acute hazard.

4.1.3.3.4. Classification for categories Chronic 1, 2 and 3

(a) When there are adequate chronic toxicity data (EC_xx 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, 2 or 3 in accordance with point (b)(ii) of Table 4.1.0 as rapidly degradable if the available information allows the conclusion that all relevant components of the mixture are rapidly degradable;

(ii) Classify the mixture as Chronic 1 or 2 in all other cases in accordance with point (b)(i) of Table 4.1.0 as 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 > 1 mg/l for normally all trophic levels:

No need to classify for long-term hazard in categories Chronic 1, 2 or 3.

4.1.3.3.5. Classification for category Chronic 4

If there are nevertheless reasons for concern:

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Classify the mixture as Chronic 4 (safety net classification) in accordance with Table 4.1.0.

4.1.3.4. *Classification of mixtures when toxicity data are not available for the complete mixture: bridging principles*

4.1.3.4.1. 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 bridging rules set out in section 1.1.3. However, in relation to application of the bridging rule for dilution, sections 4.1.3.4.2 and 4.1.3.4.3 shall be used.

4.1.3.4.2. Dilution: if a mixture is formed by diluting another tested mixture or a substance classified for its aquatic environmental hazard 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 resulting mixture may be classified as equivalent to the original tested mixture or substance. Alternatively, the method explained in section 4.1.3.5 may be applied.

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

4.1.3.5. *Classification of mixtures when toxicity data are available for some or all components of the mixture*

4.1.3.5.1. The classification of a mixture is based on summation of the concentration of its classified components. The percentage of components classified as "Acute" or "Chronic" is fed straight in to the summation method. Details of the summation method are described in section 4.1.3.5.5.

4.1.3.5.2. Mixtures can be made of a combination of both components that are classified (as Acute 1 and/or Chronic 1, 2, 3, 4) and others for which adequate toxicity test data is available. When adequate toxicity data are available for more than one component in the mixture, the combined toxicity of those components is calculated using the following additivity formulas (a) or (b), depending on the nature of the toxicity data:

(a) Based on acute aquatic toxicity:

$$\frac{\sum Ci}{L(E)C_{50m}} = \sum_{n} \frac{Ci}{L(E)C_{50i}}$$

where:

C_i = concentration of component i (weight percentage);

$L(E)C_{50i}$ = (mg/l) LC_{50} or EC_{50} for component i;

η = 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.

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The calculated toxicity may 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:

$$\frac{\sum Ci + \sum Cj}{EqNOECm} = \sum_{n} \frac{Ci}{NOECi} + \sum_{n} \frac{Cj}{0,1 \times NOECj}$$

where:

C_i = concentration of component i (weight percentage) covering the rapidly degradable components;

Cj = concentration of component j (weight percentage) covering the non- rapidly degradable components;

NOECi = NOEC (or other recognised measures for chronic toxicity) for component i covering the rapidly degradable components, in mg/l;

NOECj = NOEC (or other recognised measures for chronic toxicity) for component j covering the non-rapidly degradable components, in mg/l;

n = number of components, and i and j are running from 1 to n;

EqNOECm = 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 may be used to assign that portion of the mixture a long-term hazard category, in accordance with the criteria for rapidly degradable substances (point (b)(ii) of Table 4.1.0), which is then subsequently used in applying the summation method.

4.1.3.5.3. 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 taxonomic group (i.e. fish, crustacean, algae or equivalent) and then to use the highest toxicity (lowest value) obtained (i.e. use the most sensitive of the three taxonomic groups). However, when toxicity data for each component are not available in the same taxonomic group, the toxicity value of each component is 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 is then used to assess whether this part of the mixture shall be classified as Acute 1 and/or Chronic 1, 2 or 3 using the same criteria described for substances.

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

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4.1.3.5.5. Summation method

4.1.3.5.5.1. *Rationale*

4.1.3.5.5.1.1. In case of the substance classification categories Chronic 1 to Chronic 3, the underlying toxicity criteria differ by a factor of 10 in moving from one category to another. Substances with a classification in a high toxicity band therefore contribute to the classification of a mixture in a lower band. The calculation of these classification categories therefore needs to consider the contribution of any substance classified as Chronic 1, 2 or 3.

4.1.3.5.5.1.2. When a mixture contains components classified as Acute 1 or Chronic 1, attention must be paid to the fact that such components, when their acute toxicity is below 1 mg/l and/or chronic toxicity is below 0,1 mg/l (if non rapidly degradable) and 0,01 mg/l (if rapidly degradable) contribute to the toxicity of the mixture even at a low concentration. Active ingredients in pesticides often possess such high aquatic toxicity but also some other substances like organometallic compounds. Under these circumstances the application of the normal generic concentration limits leads to an "under-classification" of the mixture. Therefore, multiplying factors shall be applied to account for highly toxic components, as described in section 4.1.3.5.5.5.

4.1.3.5.5.2. *Classification procedure*

4.1.3.5.5.2.1. 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, in this example, the classification procedure is already completed if the result of the classification is Chronic 1. A more severe classification than Chronic 1 is not possible. Therefore it is not necessary to undergo the further classification procedure.

4.1.3.5.5.3. *Classification for category Acute 1*

4.1.3.5.5.3.1. First all components classified as Acute 1 are considered. If the sum of the concentrations (in %) of these components multiplied by their corresponding M-factors is greater than 25 % the whole mixture is classified as Acute 1.

4.1.3.5.5.3.2. The classification of mixtures for acute hazards based on this summation of classified components is summarised in Table 4.1.1.

Table 4.1.1

Classification of a mixture for acute hazards, based on summation of classified components

Sum of components classified as:	Mixture is classified as:
Acute 1 × M (v) ≥ 25 %	Acute 1

(v) For explanation of the M-factor, see 4.1.3.5.5.5.

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4.1.3.5.5.4. *Classification for the categories Chronic 1, 2, 3 and 4*

4.1.3.5.5.4.1. First all components classified as Chronic 1 are considered. If the sum of the concentrations (in %) of these components multiplied by their corresponding M-factors is equal to or greater than 25 %, the mixture is classified as Chronic 1. If the result of the calculation is a classification of the mixture as Chronic 1, the classification procedure is completed.

4.1.3.5.5.4.2. In cases where the mixture is not classified as Chronic 1, classification of the mixture as Chronic 2 is considered. A mixture is classified as Chronic 2 if 10 times the sum of the concentrations (in %) of all components classified as Chronic 1 multiplied by their corresponding M-factors plus the sum of the concentrations (in %) of all components classified as Chronic 2 is equal to or greater than 25 %. If the result of the calculation is classification of the mixture as Chronic 2, the classification process is completed.

4.1.3.5.5.4.3. In cases where the mixture is not classified either as Chronic 1 or Chronic 2, classification of the mixture as Chronic 3 is considered. A mixture is classified as Chronic 3 if 100 times the sum of the concentrations (in %) of all components classified as Chronic 1 multiplied by their corresponding M-factors plus 10 times the sum of the concentrations (in %) of all components classified with Chronic 2 plus the sum of the concentrations (in %) of all components classified as Chronic 3 is $\geq$ 25 %.

4.1.3.5.5.4.4. If the mixture is still not classified in Chronic 1, 2 or 3, classification of the mixture as Chronic 4 shall be considered. A mixture is classified as Chronic 4 if the sum of the concentrations (in %) of components classified as Chronic 1, 2, 3 and 4 is equal to or greater than 25 %.

4.1.3.5.5.4.5. The classification of mixtures for long-term hazards, based on this summation of the concentrations of classified components, is summarised in Table 4.1.2.

Table 4.1.2

Classification of a mixture for long-term hazards, based on summation of the concentrations of classified components

Sum of components classified as:	Mixture is classified as:
Chronic 1 × M ([a]) $\geq$ 25 %	Chronic 1
(M × 10 × Chronic 1) + Chronic 2 $\geq$ 25 %	Chronic 2
(M × 100 × Chronic 1) + (10 × Chronic 2) + Chronic 3 $\geq$ 25 %	Chronic 3
Chronic 1 + Chronic 2 + Chronic 3 + Chronic 4 $\geq$ 25 %	Chronic 4

([a]) For explanation of the M-factor, see 4.1.3.5.5.5.

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4.1.3.5.5.5. *Mixtures with highly toxic components*

4.1.3.5.5.5.1. Acute 1 and Chronic 1 components with toxicities below 1 mg/l and/or chronic toxicities below 0,1 mg/l (if non-rapidly degradable) and 0,01 mg/l (if rapidly degradable) contribute to the toxicity of the mixture even at a low concentration and shall normally be given increased weight in applying the summation of classification approach. When a mixture contains components classified as Acute or Chronic 1, one of the following shall be applied:

— the tiered approach described in sections 4.1.3.5.5.3 and 4.1.3.5.5.4 using a weighted sum by multiplying the concentrations of Acute 1 and Chronic 1 components by a factor, instead of merely adding up the percentages. This means that the concentration of "Acute 1" in the left column of Table 4.1.1 and the concentration of "Chronic 1" in the left column of Table 4.1.2 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 4.1.3. Therefore, in order to classify a mixture containing Acute/Chronic 1 components, the classifier needs to be informed of the value of the M-factor in order to apply the summation method,

— the additivity formula (see section 4.1.3.5.2) provided that 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 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 4.1.3

Multiplying factors for highly toxic components of mixtures

Acute toxicity	M factor	Chronic toxicity	M factor	
$L(E)C_{50}$ value mg/l		NOEC value mg/l	NRD [a] components	RD [b] components
$0,1 < L(E)C_{50} \leq 1$	1	$0,01 < NOEC \leq 0,1$	1	—
$0,01 < L(E)C_{50} \leq 0,1$	10	$0,001 < NOEC \leq 0,01$	10	1
$0,001 < L(E)C_{50} \leq 0,01$	100	$0,0001 < NOEC \leq 0,001$	100	10
$0,0001 < L(E)C_{50} \leq 0,001$	1 000	$0,00001 < NOEC \leq 0,0001$	1 000	100
$0,00001 < L(E)C_{50} \leq 0,0001$	10 000	$0,000001 < NOEC \leq 0,00001$	10 000	1 000
(continue in factor 10 intervals)		(continue in factor 10 intervals)		

[a] Non-rapidly degradable.
[b] Rapidly degradable.

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4.1.3.6. *Classification of mixtures with components without any useable information*

4.1.3.6.1. In the event that no useable information on acute and/or long-term aquatic hazard is available for one or more relevant components, it is concluded that the mixture cannot be attributed to one or more definitive hazard category(ies). In this situation the mixture shall be classified based on the known components only, with the additional statement on the label and in the SDS that: "Contains x % of components with unknown hazards to the aquatic environment".

4.1.4. ***Hazard communication***

4.1.4.1. Label elements shall be used for substances or mixtures meeting the criteria for classification in this hazard class in accordance with Table 4.1.4.

Table 4.1.4

Label elements for hazardous to the aquatic environment

ACUTE AQUATIC HAZARD	
	Acute 1
GHS pictogram	
Signal word	Warning
Hazard statement	H400: Very toxic to aquatic life
Precautionary statement prevention	P273
Precautionary statement response	P391
Precautionary statement storage	
Precautionary statement disposal	P501

LONG-TERM AQUATIC HAZARD				
	Chronic 1	Chronic 2	Chronic 3	Chronic 4
GHS pictograms			No pictogram is used	No pictogram is used
Signal word	Warning	No signal word is used	No signal word is used	No signal word is used

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LONG-TERM AQUATIC HAZARD				
	Chronic 1	Chronic 2	Chronic 3	Chronic 4
Hazard statement	H410: Very toxic to aquatic life with long lasting effects	H411: Toxic to aquatic life with long lasting effects	H412: Harmful to aquatic life with long lasting effects	H413: May cause long lasting harmful effects to aquatic life
Precautionary statement prevention	P273	P273	P273	P273
Precautionary statement response	P391	P391		
Precautionary statement storage				
Precautionary statement disposal	P501	P501	P501	P501’

E. Part 5 of Annex I to Regulation (EC) No 1272/2008 is replaced by the following text:

‘5. PART 5: ADDITIONAL HAZARDS

5.1. **Hazardous to the ozone layer**

5.1.1. ***Definitions and general considerations***

5.1.1.1. Ozone depleting potential (ODP) is an integrative quantity, distinct for each halocarbon source species, that represents the extent of ozone depletion in the stratosphere expected from the halocarbon on a mass-for-mass basis relative to CFC-11. The formal definition of ODP is the ratio of integrated perturbations to total ozone, for a differential mass emission of a particular compound relative to an equal emission of CFC-11.

Substance hazardous to the ozone layer means a substance which, on the basis of the available evidence concerning its properties and its predicted or observed environmental fate and behaviour may present a danger to the structure and/or the functioning of the stratospheric ozone layer. This includes substances which are listed in Annex I to Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer (*).

5.1.2. ***Classification criteria for substances***

5.1.2.1. A substance shall be classified as hazardous to the ozone layer (Category 1) if the available evidence concerning its properties and its predicted or observed environmental fate and behaviour indicate that it may present a danger to the structure and/or the functioning of the stratospheric ozone layer.

5.1.3. ***Classification criteria for mixtures***

5.1.3.1. Mixtures shall be classified as hazardous to the ozone layer (Category 1) on the basis of the individual concentration of the substance(s) contained therein that are also classified as hazardous to the ozone layer (Category 1), in accordance with Table 5.1.

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Table 5.1

Generic concentration limits for substances (in a mixture), classified as hazardous to the ozone layer (Category 1), that trigger classification of the mixture as hazardous to the ozone layer (Category 1)

Classification of the substance	Classification of the mixture
Hazardous to the ozone layer (Category 1)	C ≥ 0,1 %

5.1.4. ***Hazard communication***

5.1.4.1. Label elements shall be used for substances or mixtures meeting the criteria for classification in this hazard class in accordance with Table 5.2.

Table 5.2

Label elements for hazardous to the ozone layer

Symbol/pictogram	
Signal word	Warning
Hazard statement	H420: Harms public health and the environment by destroying ozone in the upper atmosphere
Precautionary statements	P502

(*) OJ L 286, 31.10.2009, p. 1.'.

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ANNEX II

Annex II to Regulation (EC) No 1272/2008 is amended as follows:

(1) Part 2 is amended as follows:

(a) section 2.8 is replaced by the following:

‘2.8. **Mixtures containing at least one sensitising substance**

The label on the packaging of mixtures not classified as sensitising but containing at least one substance classified as sensitising and present in a concentration equal to or greater than that specified in Table 3.4.6 of Annex I shall bear the statement:

EUH208 — “Contains (name of sensitising substance). May produce an allergic reaction”.

Mixtures classified as sensitising containing other substance(s) classified as sensitising (in addition to the one that leads to the classification of the mixture) and present in a concentration equal to or greater than that specified in Table 3.4.6 of Annex I shall bear the name(s) of that/those substance(s) on the label.’;

(b) in section 2.10, the first indent is replaced by the following:

‘— ≥ 0,1 % of a substance classified as skin sensitiser category 1, 1B, respiratory sensitiser category 1, 1B, or carcinogenic category 2, or

— ≥ 0,01 % of a substance classified as skin sensitiser category 1A, respiratory sensitiser category 1A, or

— ≥ one tenth of the specific concentration limit for a substance classified as skin sensitiser or respiratory sensitiser with specific concentration limit lower than 0,1 %, or’;

(2) in Part 3, section 3.2.2.1, is replaced by the following:

‘3.2.2.1. This provision does not apply to aerosols which are only classified and labelled as “flammable aerosols, Category 1” or “flammable aerosols, Category 2”. It does not apply either to transportable gas receptacles.’.

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ANNEX III

Annex III to Regulation (EC) No 1272/2008 is amended as follows:

(1) Part 1 shall be amended as follows:

(a) the introductory sentence is replaced by the following:

'The hazard statements shall be applied in accordance with Parts 2, 3, 4 and 5 of Annex I.

In selecting the hazard statements in accordance with Articles 21 and 27, suppliers may use the combined hazard statements provided for in this Annex.

In accordance with Article 27 the following principles of precedence for hazard statements may apply to labelling:

(a) if the hazard statement H410 "Very toxic to aquatic life with long lasting effects" is assigned, the statement H400 "Very toxic to aquatic life" may be omitted;

(b) if the statement H314 "Causes severe skin burns and eye damage" is assigned, the statement H318 "Causes serious eye damage" may be omitted.

In order to indicate the route of administration or exposure the combined hazard statements in Table 1.2 may be used.';

(b) in Table 1.1, the footnote to code H200 is deleted;

(c) Table 1.2 is amended as follows:

(i) in Code H317, the title of the 3rd column is replaced by the following:

'3.4 — Sensitisation — Skin, hazard category 1, 1A, 1B';

(ii) in Code H334, the title of the 3rd column is replaced by the following:

'3.4 — Sensitisation — Respiratory, hazard category 1, 1A, 1B';

(iii) the following combined hazard statements are added to the Table after Code H373:

H300 + H310	Language	3.1 — Acute toxicity (oral) and acute toxicity (dermal), hazard category 1, 2
	'BG	Смъртоносен при поглъщане или при контакт с кожата
	ES	Mortal en caso de ingestión o en contacto con la piel
	CS	Při požití nebo při styku s kůží může způsobit smrt
	DA	Livsfarlig ved indtagelse eller hudkontakt
	DE	Lebensgefahr bei Verschlucken oder Hautkontakt
	ET	Allaneelamisel või nahale sattumisel surmav
	EL	Θανατηφόρο σε περίπτωση κατάποσης ή σε επαφή με το δέρμα
	EN	Fatal if swallowed or in contact with skin
	FR	Mortel par ingestion ou par contact cutané
	GA	Ábhar marfach é seo má shlogtar é nó má theagmhaíonn leis an gcraiceann
	IT	Mortale in caso di ingestione o a contatto con la pelle

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H300 + H310	Language	3.1 — Acute toxicity (oral) and acute toxicity (dermal), hazard category 1, 2
	LV	Var izraisīt nāvi, ja norīts vai saskaras ar ādu
	LT	Mirtina prarijus arba susilietus su oda
	HU	Lenyelve vagy bőrrel érintkezve halálos
	MT	Fatali jekk tinbela' jew tmiss mal-ġilda
	NL	Dodelijk bij inslikken en bij contact met de huid
	PL	Grozi śmiercią po połknięciu lub w kontakcie ze skórą
	PT	Mortal por ingestão ou contacto com a pele
	RO	Mortal în caz de înghiţire sau în contact cu pielea
	SK	Pri požití alebo styku s kožou môže spôsobiť smrť
	SL	Smrtno pri zaužitju ali v stiku s kožo
	FI	Tappavaa nieltynä tai joutuessaan iholle
	SV	Dödligt vid förtäring eller vid hudkontakt

H300 + H330	Language	3.1 — Acute toxicity (oral) and acute toxicity (inhalation), hazard category 1, 2
	BG	Смъртоносен при поглъщане или при вдишване
	ES	Mortal en caso de ingestión o inhalación
	CS	Při požití nebo při vdechování může způsobit smrt
	DA	Livsfarlig ved indtagelse eller indånding
	DE	Lebensgefahr bei Verschlucken oder Einatmen
	ET	Allaneelamisel või sissehingamisel surmav
	EL	Θανατηφόρο σε περίπτωση κατάποσης ή σε περίπτωση εισπνοής
	EN	Fatal if swallowed or if inhaled
	FR	Mortel par ingestion ou par inhalation
	GA	Ábhar marfach é seo má shlogtar nó má ionanálaítear é
	IT	Mortale se ingerito o inalato
	LV	Var izraisīt nāvi, ja norīts vai iekļūst elpceļos
	LT	Mirtina prarijus arba įkvėpus
	HU	Lenyelve vagy belélegezve halálos
	MT	Fatali jekk tinbela' jew tittieħed bin-nifs
	NL	Dodelijk bij inslikken en bij inademing
	PL	Grozi śmiercią po połknięciu lub w następstwie wdychania
	PT	Mortal por ingestão ou inalação
	RO	Mortal în caz de înghiţire sau inhalare

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H300 + H330	Language	3.1 — Acute toxicity (oral) and acute toxicity (inhalation), hazard category 1, 2
	SK	Pri požití alebo vdýchnutí môže spôsobiť smrť
	SL	Smrtno pri zaužitju ali vdihavanju
	FI	Tappavaa nieltynä tai hengitettynä
	SV	Dödligt vid förtäring eller inandning

H310 + H330	Language	3.1 — Acute toxicity (dermal) and acute toxicity (inhalation), hazard category 1, 2
	BG	Смъртоносен при контакт с кожата или при вдишване
	ES	Mortal en contacto con la piel o si se inhala
	CS	Při styku s kůží nebo při vdechování může způsobit smrt
	DA	Livsfarlig ved hudkontakt eller indånding
	DE	Lebensgefahr bei Hautkontakt oder Einatmen
	ET	Nahale sattumisel või sissehingamisel surmav
	EL	Θανατηφόρο σε επαφή με το δέρμα ή σε περίπτωση εισπνοής
	EN	Fatal in contact with skin or if inhaled
	FR	Mortel par contact cutané ou par inhalation
	GA	Ábhar marfach é seo má theagmhaíonn leis an gcraiceann nó má ionanálaítear é
	IT	Mortale a contatto con la pelle o in caso di inalazione
	LV	Var izraisīt nāvi, ja saskaras ar ādu vai nonāk elpceļos
	LT	Mirtina susilietus su oda arba įkvėpus
	HU	Bőrrel érintkezve vagy belélegezve halálos
	MT	Fatali f'kuntatt mal-ġilda jew jekk tittieħed binifs
	NL	Dodelijk bij contact met de huid en bij inademing
	PL	Grozi śmiercią w kontakcie ze skórą lub w następstwie wdychania
	PT	Mortal por contacto com a pele ou inalação
	RO	Mortal în contact cu pielea sau prin inhalare
	SK	Pri styku s kožou alebo pri vdýchnutí môže spôsobiť smrť
	SL	Smrtno v stiku s kožo ali pri vdihavanju
	FI	Tappavaa joutuessaan iholle tai hengitettynä
	SV	Dödligt vid hudkontakt eller inandning

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H300 + H310 + H330	Language	3.1 — Acute toxicity (oral), acute toxicity (dermal) and acute toxicity (inhalation), hazard category 1, 2
	BG	Смъртоносен при поглъщане, при контакт с кожата или при вдишване
	ES	Mortal en caso de ingestión, contacto con la piel o inhalación
	CS	Při požití, při styku s kůží nebo při vdechování může způsobit smrt
	DA	Livsfarlig ved indtagelse, hudkontakt eller indånding
	DE	Lebensgefahr bei Verschlucken, Hautkontakt oder Einatmen
	ET	Allaneelamisel, nahale sattumisel või sissehingamisel surmav
	EL	Θανατηφόρο σε περίπτωση κατάποσης, σε επαφή με το δέρμα ή σε περίπτωση εισπνοής
	EN	Fatal if swallowed, in contact with skin or if inhaled
	FR	Mortel par ingestion, par contact cutané ou par inhalation
	GA	Ábhar marfach é seo má shlogtar, má theagmhaíonn leis an gcraiceann nó má ionanálaítear é
	IT	Mortale se ingerito, a contatto con la pelle o se inalato
	LV	Var izraisīt nāvi, ja norīts, saskaras ar ādu vai iekļūst elpceļos
	LT	Mirtina prarijus, susilietus su oda arba įkvėpus
	HU	Lenyelve, bőrrel érintkezve vagy belélegezve halálos
	MT	Fatali jekk tinbela', tmiss mal-ġilda jew tittieħed bin-nifs
	NL	Dodelijk bij inslikken, bij contact met de huid en bij inademing
	PL	Grozi śmiercią po połknięciu, w kontakcie ze skórą lub w następstwie wdychania
	PT	Mortal por ingestão, contacto com a pele ou inalação
	RO	Mortal în caz de înghiţire, în contact cu pielea sau prin inhalare
	SK	Pri požití, pri styku s kožou alebo pri vdýchnutí môže spôsobiť smrť
	SL	Smrtno pri zaužitju, v stiku s kožo ali pri vdihavanju
	FI	Tappavaa nieltynä, joutuessaan iholle tai hengitettynä
	SV	Dödligt vid förtäring, hudkontakt eller inandning

▼B

H301 + H311	Language	3.1 — Acute toxicity (oral) and acute toxicity (dermal), hazard category 3
	BG	Токсичен при поглъщане или при контакт с кожата
	ES	Tóxico en caso de ingestión o en contacto con la piel
	CS	Toxický při požití a při styku s kůží
	DA	Giftig ved indtagelse eller hudkontakt
	DE	Giftig bei Verschlucken oder Hautkontakt
	ET	Allaneelamisel või nahale sattumisel mürgine
	EL	Τοξικό σε περίπτωση κατάποσης ή σε επαφή με το δέρμα
	EN	Toxic if swallowed or in contact with skin
	FR	Toxique par ingestion ou par contact cutané
	GA	Ábhar tocsaineach má shlogtar é nó má theagmhaíonn leis an gcraiceann
	IT	Tossico se ingerito o a contatto con la pelle
	LV	Toksisks, ja norīts vai saskaras ar ādu
	LT	Toksiška prarijus arba susilietus su oda
	HU	Lenyelve vagy bőrrel érintkezve mérgező
	MT	Tossika jekk tinbela' jew tmiss mal-ġilda
	NL	Giftig bij inslikken en bij contact met de huid
	PL	Działa toksycznie po połknięciu lub w kontakcie ze skórą
	PT	Tóxico por ingestão ou contacto com a pele
	RO	Toxic în caz de înghițire sau în contact cu pielea
	SK	Toxický pri požití a pri styku s kožou
	SL	Strupeno pri zaužitju ali v stiku s kožo
	FI	Myrkyllistä nieltynä tai joutuessaan iholle
	SV	Giftigt vid förtäring eller hudkontakt

H301 + H331	Language	3.1 — Acute toxicity (oral) and acute toxicity (inhalation), hazard category 3
	BG	Токсичен при поглъщане или при вдишване
	ES	Tóxico en caso de ingestión o inhalación
	CS	Toxický při požití a při vdechování
	DA	Giftig ved indtagelse eller indånding
	DE	Giftig bei Verschlucken oder Einatmen
	ET	Allaneelamisel või sissehingamisel mürgine
	EL	Τοξικό σε περίπτωση κατάποσης ή σε περίπτωση εισπνοής
	EN	Toxic if swallowed or if inhaled
	FR	Toxique par ingestion ou par inhalation

▼B

H301 + H331	Language	3.1 — Acute toxicity (oral) and acute toxicity (inhalation), hazard category 3
	GA	Ábhar tocsaineach má shlogtar nó má ionanálaítear é
	IT	Tossico se ingerito o inalato
	LV	Toksisks, ja norīts vai iekļūst elpceļos
	LT	Toksiška prarijus arba įkvėpus
	HU	Lenyelve vagy belélegezve mérgező
	MT	Tossika jekk tinbela' jew tittieħed bin-nifs
	NL	Giftig bij inslikken en bij inademing
	PL	Działa toksycznie po połknięciu lub w następstwie wdychania
	PT	Tóxico por ingestão ou inalação
	RO	Toxic în caz de înghițire sau prin inhalare
	SK	Toxický pri požití alebo vdýchnutí
	SL	Strupeno pri zaužitju ali vdihavanju
	FI	Myrkyllistä nieltynä tai hengitettynä
	SV	Giftigt vid förtäring eller inandning

H311 + H331	Language	3.1 — Acute toxicity (dermal) and acute toxicity (inhalation), hazard category 3
	BG	Токсичен при контакт с кожата или при вдишване
	ES	Tóxico en contacto con la piel o si se inhala
	CS	Toxický při styku s kůží a při vdechování
	DA	Livsfarlig ved hudkontakt eller indånding
	DE	Giftig bei Hautkontakt oder Einatmen
	ET	Nahale sattumisel või sissehingamisel mürgine
	EL	Τοξικό σε επαφή με το δέρμα ή σε περίπτωση εισπνοής
	EN	Toxic in contact with skin or if inhaled
	FR	Toxique par contact cutané ou par inhalation
	GA	Ábhar tocsaineach má theagmhaíonn leis an gcraiceann nó má ionanálaítear é
	IT	Tossico a contatto con la pelle o se inalato
	LV	Toksisks saskarē ar ādu vai ja iekļūst elpceļos
	LT	Toksiška susilietus su oda arba įkvėpus
	HU	Bőrrel érintkezve vagy belélegezve mérgező
	MT	Tossika jekk tmiss mal-ġilda jew tittieħeb bin-nifs
	NL	Giftig bij contact met de huid en bij inademing
	PL	Działa toksycznie w kontakcie ze skórą lub w następstwie wdychania
	PT	Tóxico em contacto com a pele ou por inalação
	RO	Toxic în contact cu pielea sau prin inhalare

▼B

H311 + H331	Language	3.1 — Acute toxicity (dermal) and acute toxicity (inhalation), hazard category 3
	SK	Toxický pri styku s kožou alebo pri vdýchnutí
	SL	Strupeno v stiku s kožo ali pri vdihavanju
	FI	Myrkyllistä joutuessaan iholle tai hengitettynä
	SV	Giftigt vid hudkontakt eller förtäring

H301 + H311 + H331	Language	3.1 — Acute toxicity (oral), acute toxicity (dermal) and acute toxicity (inhalation), hazard category 3
	BG	Токсичен при поглъщане, при контакт с кожата или при вдишване
	ES	Tóxico en caso de ingestión, contacto con la piel o inhalación
	CS	Toxický při požití, při styku s kůží a při vdechování
	DA	Giftig ved indtagelse, hudkontakt eller indånding
	DE	Giftig bei Verschlucken, Hautkontakt oder Einatmen
	ET	Allaneelamisel, nahale sattumisel või sissehingamisel mürgine
	EL	Τοξικό σε περίπτωση κατάποσης, σε επαφή με το δέρμα ή σε περίπτωση κατάποσης
	EN	Toxic if swallowed, in contact with skin or if inhaled
	FR	Toxique par ingestion, par contact cutané ou par inhalation
	GA	Ábhar tocsaineach má shlogtar, má theagmhaíonn leis an gcraiceann nó má ionanálaítear é
	IT	Tossico se ingerito, a contatto con la pelle o se inalato
	LV	Toksisks, ja norīts, saskaras ar ādu vai iekļūst elpceļos
	LT	Toksiška prarijus, susilietus su oda arba įkvėpus
	HU	Lenyelve, bőrrel érintkezve vagy belélegezve mérgező
	MT	Tossika jekk tinbela', tmiss mal-ġilda jew tittieħed bin-nifs
	NL	Giftig bij inslikken, bij contact met de huid en bij inademing
	PL	Działa toksycznie po połknięciu, w kontakcie ze skórą lub w następstwie wdychania
	PT	Tóxico por ingestão, contacto com a pele ou inalação
	RO	Toxic în caz de înghițire, în contact cu pielea sau prin inhalare
	SK	Toxický pri požití, styku s kožou alebo pri vdýchnutí
	SL	Strupeno pri zaužitju, v stiku s kožo ali pri vdihavanju

▼B

H301 + H311 + H331	Language	3.1 — Acute toxicity (oral), acute toxicity (dermal) and acute toxicity (inhalation), hazard category 3
	FI	Myrkyllistä nieltynä, joutuessaan iholle tai hengitettynä
	SV	Giftigt vid förtäring, hudkontakt eller inandning

H302 + H312	Language	3.1 — Acute toxicity (oral) and acute toxicity (dermal), hazard category 4
	BG	Вреден при поглъщане или при контакт с кожата
	ES	Nocivo en caso de ingestión o en contacto con la piel
	CS	Zdraví škodlivý při požití a při styku s kůží
	DA	Livsfarlig ved indtagelse eller hudkontakt
	DE	Gesundheitsschädlich bei Verschlucken oder Hautkontakt
	ET	Allaneelamisel või nahale sattumisel kahjulik
	EL	Επιβλαβές σε περίπτωση κατάποσης ή σε επαφή με το δέρμα
	EN	Harmful if swallowed or in contact with skin
	FR	Nocif en cas d'ingestion ou de contact cutané
	GA	Ábhar dochrach má shlogtar é nó má theagmhaíonn leis an gcraiceann
	IT	Nocivo se ingerito o a contatto con la pelle
	LV	Kaitīgs, ja norīts vai saskaras ar ādu
	LT	Kenksminga prarijus arba susilietus su oda
	HU	Lenyelve vagy bőrrel érintkezve ártalmas
	MT	Tagħmel ħsara jekk tinbela' jew jekk tmiss mal-ġilda
	NL	Schadelijk bij inslikken en bij contact met de huid
	PL	Działa szkodliwie po połknięciu lub w kontakcie ze skórą
	PT	Nocivo por ingestão ou contacto com a pele
	RO	Nociv în caz de înghițire sau în contact cu pielea
	SK	Zdraviu škodlivý pri požití alebo pri styku s kožou
	SL	Zdravju škodljivo pri zaužitju ali v stiku s kožo
	FI	Haitallista nieltynä tai joutuessaan iholle
	SV	Skadligt vid förtäring eller hudkontakt

H302 + H332	Language	3.1 — Acute toxicity (oral) and acute toxicity (inhalation), hazard category 4
	BG	Вреден при поглъщане или при вдишване
	ES	Nocivo en caso de ingestión o inhalación

▼B

H302 + H332	Language	3.1 — Acute toxicity (oral) and acute toxicity (inhalation), hazard category 4
	CS	Zdraví škodlivý při požití a při vdechování
	DA	Farlig ved indtagelse eller indånding
	DE	Gesundheitsschädlich bei Verschlucken oder Einatmen
	ET	Allaneelamisel või sissehingamisel kahjulik
	EL	Επιβλαβές σε περίπτωση κατάποσης ή σε περίπτωση εισπνοής
	EN	Harmful if swallowed or if inhaled
	FR	Nocif en cas d'ingestion ou d'inhalation
	GA	Ábhar dochrach má shlogtar nó má ionanálaítear é
	IT	Nocivo se ingerito o inalato
	LV	Kaitīgs, ja norīts vai iekļūst elpceļos
	LT	Kenksminga prarijus arba įkvėpus
	HU	Lenyelve vagy belélegezve ártalmas
	MT	Tagħmel ħsara jekk tinbela' jew tittieħed binnifs
	NL	Schadelijk bij inslikken en bij inademing
	PL	Działa szkodliwie po połknięciu lub w następstwie wdychania
	PT	Nocivo por ingestão ou inalação
	RO	Nociv în caz de înghiţire sau inhalare
	SK	Zdraviu škodlivý pri požití alebo vdýchnutí
	SL	Zdravju škodljivo pri zaužitju in vdihavanju
	FI	Haitallista nieltynä tai hengitettynä
	SV	Skadligt vid förtäring eller inandning

H312 + H332	Language	3.1 — Acute toxicity (dermal) and acute toxicity (inhalation), hazard category 4
	BG	Вреден при контакт с кожата или при вдишване
	ES	Nocivo en contacto con la piel o si se inhala
	CS	Zdraví škodlivý při styku s kůží a při vdechování
	DA	Farlig ved hudkontakt eller indånding
	DE	Gesundheitsschädlich bei Hautkontakt oder Einatmen
	ET	Nahale sattumisel või sissehingamisel kahjulik
	EL	Επιβλαβές σε επαφή με το δέρμα ή σε περίπτωση εισπνοής
	EN	Harmful in contact with skin or if inhaled
	FR	Nocif en cas de contact cutané ou d'inhalation
	GA	Ábhar dochrach má theagmhaíonn leis an gcraiceann nó má ionanálaítear é

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H312 + H332	Language	3.1 — Acute toxicity (dermal) and acute toxicity (inhalation), hazard category 4
	IT	Nocivo a contatto con la pelle o se inalato
	LV	Kaitīgs saskarē ar ādu vai ja iekļūst elpceļos
	LT	Kenksminga susilietus su oda arba įkvėpus
	HU	Bőrrel érintkezve vagy belélegezve ártalmas
	MT	Tagħmel ħsara jekk tmiss mal-ġilda jew jekk tittieħed bin-nifs
	NL	Schadelijk bij contact met de huid en bij inademing
	PL	Działa szkodliwie w kontakcie ze skórą lub w następstwie wdychania
	PT	Nocivo em contacto com a pele ou por inalação
	RO	Nociv în contact cu pielea sau prin inhalare
	SK	Zdraviu škodlivý pri styku s kožou alebo pri vdýchnutí
	SL	Zdravju škodljivo v stiku s kožo in pri vdihavanju
	FI	Haitallista joutuessaan iholle tai hengitettynä
	SV	Skadligt vid hudkontakt eller inandning

H302 + H312 + H332	Language	3.1 — Acute toxicity (oral), acute toxicity (dermal) and acute toxicity (inhalation), hazard category 4
	BG	Вреден при поглъщане, при контакт с кожата или при вдишване
	ES	Nocivo en caso de ingestión, contacto con la piel o inhalación
	CS	Zdraví škodlivý při požití, při styku s kůží a při vdechování
	DA	Farlig ved indånding, hudkontakt eller indånding
	DE	Gesundheitsschädlich bei Verschlucken, Hautkontakt oder Einatmen
	ET	Allaneelamisel, nahale sattumisel või sissehingamisel kahjulik
	EL	Επιβλαβές σε περίπτωση κατάποσης, σε επαφή με το δέρμα ή σε περίπτωση εισπνοής
	EN	Harmful if swallowed, in contact with skin or if inhaled
	FR	Nocif en cas d'ingestion, de contact cutané ou d'inhalation
	GA	Ábhar dochrach má shlogtar, má theagmhaíonn leis an gcraiceann nó má ionanálaítear é
	IT	Nocivo se ingerito, a contatto con la pelle o se inalato
	LV	Kaitīgs, ja norīts, saskaras ar ādu vai nonāk elpceļos
	LT	Kenksminga prarijus, susilietus su oda arba įkvėpus

▼B

H302 + H312 + H332	Language	3.1 — Acute toxicity (oral), acute toxicity (dermal) and acute toxicity (inhalation), hazard category 4
	HU	Lenyelve, bőrrel érintkezve vagy belélegezve ártalmas
	MT	Tagħmel il-ħsara jekk tinbela', tmiss mal-ġilda jew tittiħed bin-nifs
	NL	Schadelijk bij inslikken, bij contact met de huid en bij inademing
	PL	Działa szkodliwie po połknięciu, w kontakcie ze skórą lub w następstwie wdychania
	PT	Nocivo por ingestão, contacto com a pele ou inalação
	RO	Nociv în caz de înghițire, în contact cu pielea sau prin inhalare
	SK	Zdraviu škodlivý pri požití, styku s kožou alebo pri vdýchnutí
	SL	Zdravju škodljivo pri zaužitju, v stiku s kožo ali pri vdihavanju
	FI	Haitallista nieltynä, joutuessaan iholle tai hengitettynä
	SV	Skadligt vid förtäring, hudkontakt eller inandning’

(d) Table 1.3 is amended as follows:

(i) the following new hazard statement is added to the Table after Code H413:

‘H420	Language	5.1– Hazardous to the ozone layer — hazard category 1
	BG	Вреди на общественото здраве и на околната среда, като разрушава озона във високите слоеве на атмосферата
	ES	Causa daños a la salud pública y el medio ambiente al destruir el ozono en la atmósfera superior
	CS	Poškozuje veřejné zdraví a životní prostředí tím, že ničí ozon ve svrchních vrstvách atmosféry
	DA	Skader folkesundheden og miljøet ved at ødelægge ozon i den øvre atmosfære
	DE	Schädigt die öffentliche Gesundheit und die Umwelt durch Ozonabbau in der äußeren Atmosphäre
	ET	Kahjustab rahvatervist ja keskkonda, hävitades kõrgatmosfääris asuvat osoonikihti
	EL	Βλάπτει τη δημόσια υγεία και το περιβάλλον καταστρέφοντας το όζον στην ανώτερη ατμόσφαιρα
	EN	Harms public health and the environment by destroying ozone in the upper atmosphere
	FR	Nuit à la santé publique et à l'environnement en détruisant l'ozone dans la haute atmosphère
	GA	Déanann an t-ábhar seo díobháil don tsláinte phoiblí agus don chomhshaol trí ózón san atmaisféar uachtarach a scriosadh

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‘H420	Language	5.1– Hazardous to the ozone layer — hazard category 1
	IT	Nuoce alla salute pubblica e all'ambiente distruggendo l'ozono dello strato superiore dell'atmosfera
	LV	Bīstams sabiedrības veselībai un videi, jo iznīcina ozonu atmosfēras augšējā slānī
	LT	Kenkia visuomenės sveikatai ir aplinkai, nes naikina ozono sluoksnį viršutinėje atmosferoje
	HU	Károsítja a közegészséget és a környezetet, mert a légkör felső rétegeiben lebontja az ózont
	MT	Tagħmel ħsara lis-saħħa tal-pubbliku u lill-ambjent billi teqred l-ożonu fl-atmosfera ta' fuq
	NL	Schadelijk voor de volksgezondheid en het milieu door afbraak van ozon in de bovenste lagen van de atmosfeer
	PL	Szkodliwe dla zdrowia publicznego i środowiska w związku z niszczącym oddziaływaniem na ozon w górnej warstwie atmosfery
	PT	Prejudica a saúde pública e o ambiente ao destruir o ozono na alta atmosfera
	RO	Dăunează sănătății publice și mediului înconjurător prin distrugerea ozonului în atmosfera superioară
	SK	Poškodzuje verejné zdravie a životné prostredie tým, že ničí ozón vo vrchných vrstvách atmosféry
	SL	Škodljivo za javno zdravje in okolje zaradi uničevanja ozona v zgornji atmosferi
	FI	Vahingoittaa kansanterveyttä ja ympäristöä tuhoamalla otsonia ylemmässä ilmakehässä
	SV	Skadar folkhälsan och miljön genom förstöring av ozonet i övre delen av atmosfären’

(2) in Part 2, Table 2.3 is deleted;

(3) Part 3 is amended as follows:

(a) in the title the words ‘substances and’ are deleted;

(b) in Code EUH201/201A, first column, all references to ‘201/201A’ are deleted;

(c) in Code EUH209/209A, first column, all references to ‘209/209A’ are deleted.

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ANNEX IV

Annex IV to Regulation (EC) No 1272/2008 is amended as follows:

(1) Part 1 is amended as follows:

(a) Table 6.2 is amended as follows:

(i) Code P261 is replaced by the following:

‘P261	Avoid breathing dust/ fume/gas/mist/ vapours/spray.	Acute toxicity — inhalation (section 3.1)	3, 4	Manufacturer/supplier to specify applicable conditions.’
		Respiratory sensitisation (section 3.4)	1, 1A, 1B	
		Skin sensitisation (section 3.4)	1, 1A, 1B	
		Specific target organ toxicity — single exposure; respiratory tract irritation (section 3.8)	3	
		Specific target organ toxicity — single exposure; narcosis (section 3.8)	3	

(ii) Code P272 is replaced by the following:

‘P272	Contaminated work clothing should not be allowed out of the workplace.	Skin sensitisation (section 3.4)	1, 1A, 1B’	

(iii) Code P280 is replaced by the following:

‘P280	Wear protective gloves/protective clothing/eye protection/face protection.	Explosives (section 2.1)	Divisions 1.1, 1.2, 1.3, 1.4, 1.5	Manufacturer/supplier to specify type of equipment. — *Specify face protection.*
		Flammable liquids (section 2.6)	1, 2, 3	Manufacturer/supplier to specify type of equipment. — *Specify protective gloves and eye/ face protection.*
		Flammable solids (section 2.7)	1, 2	
		Self-reactive substances and mixtures (section 2.8)	Types A, B, C, D, E, F	
		Pyrophoric liquids (section 2.9)	1	
		Pyrophoric solids (section 2.10)	1	
		Self-heating substances and mixtures (section 2.11)	1, 2	
		Substances and mixtures which, in contact with water, emit flammable gases (section 2.12)	1, 2, 3	
		Oxidising liquids (section 2.13)	1, 2, 3	
		Oxidising solids (section 2.14)	1, 2, 3	
		Organic peroxides (section 2.15)	Types A, B, C, D, E, F	

▼B

		Acute toxicity — dermal (section 3.1)	1, 2, 3, 4	Manufacturer/supplier to specify type of equipment. — *Specify protective gloves/clothing.*
		Skin corrosion (section 3.2)	1A, 1B, 1C	Manufacturer/supplier to specify type of equipment. — *Specify protective gloves/clothing and eye/face protection.*
		Skin irritation (section 3.2)	2	Manufacturer/supplier to specify type of equipment. — *Specify protective gloves.*
		Skin sensitisation (section 3.4)	1, 1A, 1B	
		Severe eye damage (section 3.3)	1	Manufacturer/supplier to specify type of equipment. — *Specify eye/face protection.*'
		Eye irritation (section 3.3)	2	

(iv) Code P285 is replaced by the following:

'P285	In case of inadequate ventilation wear respiratory protection.	Respiratory sensitisation (section 3.4)	1, 1A, 1B	Manufacturer/supplier to specify equipment.'

(v) Code P273 is amended as follows:

— in column 3, row 2, the words 'chronic aquatic hazard (section 4.1)' are replaced by 'long-term aquatic hazard (section 4.1)',

— the last row is deleted;

(b) Table 6.3 is amended as follows:

(i) Code P302 is replaced by the following:

'P302	IF ON SKIN:	Pyrophoric liquids (section 2.9)	1	
		Acute toxicity — dermal (section 3.1)	1, 2, 3, 4	
		Skin irritation (section 3.2)	2	
		Skin sensitisation (section 3.4)	1, 1A, 1B'	

(ii) Code P304 is replaced by the following:

'P304	IF INHALED:	Acute toxicity — inhalation (section 3.1)	1, 2, 3, 4	
		Skin corrosion (section 3.2)	1A, 1B, 1C	
		Respiratory sensitisation (section 3.4)	1, 1A, 1B	

▼B

		Specific target organ toxicity — single exposure; respiratory tract irritation (section 3.8)	3	
		Specific target organ toxicity — single exposure; narcosis (section 3.8)	3’	

(iii) Code P311 is replaced by the following:

‘P311	Call a POISON CENTRE or doctor/ physician.	Acute toxicity — inhalation (section 3.1)	3	
		Respiratory sensitisation (section 3.4)	1, 1A, 1B	
		Specific target organ toxicity — single exposure (section 3.8)	1, 2’	

(iv) Code P313 is replaced by the following:

‘P313	Get medical advice/ attention.	Skin irritation (section 3.2)	2, 3	
		Eye irritation (section 3.3)	2	
		Skin sensitisation (section 3.4)	1, 1A, 1B	
		Germ cell mutagenicity (section 3.5)	1A, 1B, 2	
		Carcinogenicity (section 3.6)	1A, 1B, 2	
		Reproductive toxicity (section 3.7)	1A, 1B, 2	
		Reproductive toxicity — effects on or via lactation (section 3.7)	Additional category’	

(v) Code P321 is replaced by the following:

‘P321	Specific treatment (see … on this label).	Acute toxicity — oral (section 3.1)	1, 2, 3	… Reference to supplemental first aid instruction. — *if immediate administration of antidote is required.*
		Acute toxicity — inhalation (section 3.1)	3	… Reference to supplemental first aid instruction. — *if immediate specific measures are required.*
		Specific target organ toxicity — single exposure (section 3.8)	1	… Reference to supplemental first aid instruction.

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				— *if immediate measures are required.*
		Skin sensitisation (section 3.4)	1, 1A, 1B	… Reference to supplemental first aid instruction. — *manufacturer/ supplier may specify a cleansing agent if appropriate.*’
		Skin corrosion (section 3.2)	1A, 1B, 1C	
		Skin irritation (section 3.2)	2	

(vi) Code P333 is replaced by the following:

‘P333	If skin irritation or rash occurs:	Skin sensitisation (section 3.4)	1, 1A, 1B’	

(vii) Code P341 is replaced by the following:

‘P341	If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.	Respiratory sensitisation (section 3.4)	1, 1A, 1B’	

(viii) Code P342 is replaced by the following:

‘P342	If experiencing respiratory symptoms:	Respiratory sensitisation (section 3.4)	1, 1A, 1B’	

(ix) Code P352 is replaced by the following:

‘P352	Wash with plenty of soap and water.	Acute toxicity — dermal (section 3.1)	3, 4	
		Skin irritation (section 3.2)	2	
		Skin sensitisation (section 3.4)	1, 1A, 1B’	

(x) Code P363 is replaced by the following:

‘P363	Wash contaminated clothing before reuse.	Acute toxicity — dermal (section 3.1)	1, 2, 3, 4	
		Skin corrosion (section 3.2)	1A, 1B, 1C	
		Skin sensitisation (section 3.4)	1, 1A, 1B’	

(xi) Code P302 + P352 is replaced by the following:

‘P302 + P352	IF ON SKIN: Wash with plenty of soap and water.	Acute toxicity — dermal (section 3.1)	3, 4	
		Skin irritation (section 3.2)	2	
		Skin sensitisation (section 3.4)	1, 1A, 1B’	

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(xii) Code P304 + P341 is replaced by the following:

‘P304 + P341	IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.	Respiratory sensitisation (section 3.4)	1, 1A, 1B’	

(xiii) Code P333 + P313 is replaced by the following:

‘P333 + P313	If skin irritation or rash occurs: Get medical advice/ attention.	Skin sensitisation (section 3.4)	1, 1A, 1B’	

(xiv) Code P342 + P311 is replaced by the following:

‘P342 + P311	If experiencing respiratory symptoms: Call a POISON CENTRE or doctor/physician.	Respiratory sensitisation (section 3.4)	1, 1A, 1B’	

(xv) in Code P391, column 3, row 2, the words ‘chronic aquatic hazard (section 4.1)’ are replaced by ‘long-term aquatic hazard (section 4.1)’;

(c) Table 6.5 is replaced by the following:

‘Table 6.5

Precautionary statements — Disposal

Code (1)	Disposal precautionary statements (2)	Hazard class (3)	Hazard category (4)	Conditions for use (5)
P501	Dispose of contents/ container to …	Explosives (section 2.1)	Unstable explosives and Divisions 1.1, 1.2, 1.3, 1.4, 1.5	… in accordance with local/regional/ national/inter-national regulation (to be specified).
		Flammable liquids (section 2.6)	1, 2, 3	
		Self-reactive substances and mixtures (section 2.8)	Types A, B, C, D, E, F	
		Substances and mixtures which, in contact with water, emit flammable gases (section 2.12)	1, 2, 3	
		Oxidising liquids (section 2.13)	1, 2, 3	
		Oxidising solids (section 2.14)	1, 2, 3	
		Organic peroxides (section 2.15)	Types A, B, C, D, E, F	
		Acute toxicity — oral (section 3.1)	1, 2, 3, 4	

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Code (1)	Disposal precautionary statements (2)	Hazard class (3)	Hazard category (4)	Conditions for use (5)
		Acute toxicity — dermal (section 3.1)	1, 2, 3, 4	
		Acute toxicity — inhalation (section 3.1)	1, 2	
		Skin corrosion (section 3.2)	1A, 1B, 1C	
		Respiratory sensitisation (section 3.4)	1, 1A, 1B	
		Skin sensitisation (section 3.4)	1, 1A, 1B	
		Germ cell mutagenicity (section 3.5)	1A, 1B, 2	
		Carcinogenicity (section 3.6)	1A, 1B, 2	
		Reproductive toxicity (section 3.7)	1A, 1B, 2	
		Specific target organ toxicity — single exposure (section 3.8)	1, 2	
		Specific target organ toxicity — single exposure; respiratory tract irritation (section 3.8)	3	
		Specific target organ toxicity — single exposure; narcosis (section 3.8)	3	
		Specific target organ toxicity — repeated exposure (section 3.9)	1, 2	
		Aspiration hazard (section 3.10)	1	
		Hazardous to the aquatic environment — acute aquatic hazard(section 4.1)	1	
		Hazardous to the aquatic environment — long-term aquatic hazard (section 4.1)	1, 2, 3, 4	
P502	Refer to manufacturer/ supplier for information on recovery/recycling	Hazardous to the ozone layer (section 5.1)	1’	

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(2) in Part 2, Table 1.5, the following precautionary statement is added after Code P501:

‘P502	Language	
	BG	Обърнете се към производителя/доставчика за информация относно възстановяването/рециклирането
	ES	Pedir información al fabricante o proveedor sobre su recuperación o reciclado
	CS	Informujte se u výrobce nebo dodavatele o regeneraci nebo recyklaci
	DA	Indhent oplysninger om genvinding/genanvendelse hos producenten/leverandøren
	DE	Informationen zur Wiederverwendung/Wiederverwertung beim Hersteller/Lieferanten erfragen
	ET	Hankida valmistajalt/tarnijalt teavet kemikaali taaskasutamise/ringlussevõtu kohta
	EL	Απευθυνθείτε στον παραγωγό/προμηθευτή για την ανάκτηση/ανακύκλωση
	EN	Refer to manufacturer/supplier for information on recovery/recycling
	FR	Se reporter au fabricant/fournisseur pour des informations concernant la récupération/le recyclage
	GA	Féach an fhaisnéis ón monaróir/soláthróir maidir le haisghabháil/athchúrsáil
	IT	Chiedere informazioni al produttore o fornitore per il recupero/riciclaggio
	LV	Informācija par rekuperāciju/pārstrādi saņemama pie ražotāja/piegādātāja
	LT	Kreiptis į gamintoją (tiekėją) informacijai apie šių medžiagų ar preparatų panaudojimą arba perdirbimą gauti
	HU	A gyártó/szállító határozza meg a hasznosításra és újrafeldolgozásra vonatkozó információkat
	MT	Irreferi għall-manifattur/fornitur rigward informazzjoni dwar l-irkupru/riċiklaġġ
	NL	Raadpleeg fabrikant/leverancier voor informatie over terugwinning/recycling
	PL	Przestrzegać wskazówek producenta lub dostawcy dotyczących odzysku lub wtórnego wykorzystania
	PT	Solicitar ao fabricante/fornecedor informações relativas à recuperação/reciclagem
	RO	Adresați-vă producătorului pentru informații privind recuperarea/reciclarea
	SK	Informujte sa u výrobcu alebo dodávateľa o regenerácii alebo recyklácii
	SL	Za podatke glede obnovitve/reciklaže se obrnite na proizvajalca/dobavitelja
	FI	Hanki valmistajalta/toimittajalta tietoja uudelleenkäytöstä/kierrätyksestä
	SV	Rådfråga tillverkare/leverantör om återvinning/återanvändning’

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ANNEX V

Annex V to Regulation (EC) No 1272/2008 is amended as follows:

(1) the first sentence is replaced by the following:

‘The hazard pictograms for each hazard class, differentiation of a hazard class and hazard category shall satisfy the provisions of this Annex and Annex I, section 1.2 and conform in terms of symbols and general format, to the specimens shown.’;

(2) Part 2, section 2.3 is amended as follows:

(a) in column 1, the pictogram GHS07 is replaced by the following pictogram:

‘GHS07



’;

(b) in column 2, the words ‘Skin sensitisation, hazard category 1’ are replaced by ‘Skin sensitisation, hazard categories 1, 1A, 1B’;

(3) in Part 2, section 2.4, column 2, the words ‘Respiratory sensitisation, hazard category 1’ are replaced by ‘Respiratory sensitisation, hazard categories 1, 1A, 1B’;

(4) in Part 3, the pictogram GHS09 is replaced by the following pictogram:

‘GHS09



’;

(5) the following new Part 4 is added:

‘4. PART 4: ADDITIONAL HAZARDS

4.1. **Symbol: exclamation mark**

Pictogram (1)	Hazard class and hazard category (2)
GHS07 	Section 5.1 Hazardous to the ozone layer, hazard category 1’

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ANNEX VI

Annex VI to Regulation (EC) No 1272/2008 is amended as follows:

(1) Part 1 is amended as follows:

(a) Table 1.1 is amended as follows:

(i) in the Hazard Class Respiratory/skin sensitisation, the Category Code 'Resp. Sens. 1' is replaced by 'Resp. Sens. 1, 1A, 1B' and the Category Code 'Skin Sens. 1' is replaced by 'Skin. Sens. 1, 1A, 1B';

(ii) in the Hazard Class Hazardous for the ozone layer, the Category Code 'Ozone' is replaced by 'Ozone 1';

(b) in section 1.1.2.3, the last paragraph is replaced by the following:

'In case an M-factor has been harmonised for substances classified as hazardous to the aquatic environment in the categories Aquatic Acute 1 or Aquatic Chronic 1, this M-factor is given in Table 3.1 in the same column as the specific concentration limits. In case an M-factor for Aquatic Acute 1 and an M-factor for Aquatic Chronic 1 have been harmonised, each M-factor shall be listed in the same line as its corresponding differentiation. Where a single M-factor is given in Table 3.1 and the substance is classified as Aquatic Acute 1 and Aquatic Chronic 1, this M-factor shall be used by the manufacturer, importer or downstream user for the classification of a mixture containing this substance for acute and long-term aquatic hazards using the summation method. Where no M-factor is given in Table 3.1, M-factor(s) based on available data for the substance shall be set by the manufacturer, importer or downstream user. For the setting and use of M-factors, see section 4.1.3.5.5.5 of Annex I.';

(c) in section 1.1.3.1, 'Note H (Table 3.1)' and 'Note H (Table 3.2)' are deleted;

(d) section 1.1.4.4 is deleted;

(2) Part 3, is amended as follows:

(a) the first two paragraphs are replaced by the following:

'Table 3.1: List of harmonised classification and labelling of hazardous substances.

Table 3.2: The list of harmonised classification and labelling of hazardous substances from Annex I to Directive 67/548/EEC.';

(b) in Tables 3.1 and 3.2, last column, all the references to Note 'H' are deleted;

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(c) in Table 3.1, entries 602-002-00-2, 602-008-00-5, 602-013-00-2 and 602-084-00-X are replaced by the following:

'Index No	International chemical identification	EC No	CAS No	Classification		Labelling			Specific conc. limits, M-factors	Notes
				Hazard class and category code(s)	Hazard statement code(s)	Pictogram, signal word code(s)	Hazard statement code(s)	Supplementary hazard statement code(s)		
602-002-00-2	bromomethane; methylbromide	200-813-2	74-83-9	Press. Gas Muta. 2 Acute Tox. 3 * Acute Tox. 3 * STOT RE 2 * Eye Irrit. 2 STOT SE 3 Skin Irrit. 2 Aquatic Acute 1 Ozone 1	H341 H331 H301 H373 ** H319 H335 H315 H400 H420	GHS04 GHS06 GHS08 GHS09 Dgr	H341 H331 H301 H373 ** H319 H335 H315 H400 H420			U
602-008-00-5	carbon tetrachloride; tetrachloromethane	200-262-8	56-23-5	Carc. 2 Acute Tox. 3 * Acute Tox. 3 * Acute Tox. 3 * STOT RE 1 Aquatic Chronic 3 Ozone 1	H351 H331 H311 H301 H372 ** H412 H420	GHS06 GHS08 Dgr	H351 H331 H311 H301 H372 ** H412 H420		* STOT RE 1; H372: C ≥ 1 % STOT RE 2; H373: 0,2 % ≤ C < 1 %	
602-013-00-2	1,1,1-trichloroethane; methyl chloroform	200-756-3	71-55-6	Acute Tox. 4 * Ozone 1	H332 H420	GHS07 Wng	H332 H420			F'
602-084-00-X	1,1-dichloro-1-fluoro-ethane	404-080-1	1717-00-6	Aquatic Chronic 3 Ozone 1	H412 H420	►C1 GHS07 Wng ◄	H412 H420			

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ANNEX VII

Annex VII to Regulation (EC) No 1272/2008 is amended as follows:

in Table 1.1, last row, the hazard statement ‘EUH059’ is replaced by ‘H420’.