

## SCHEDULE 1

Regulations 2(1) and 4(4)

## CLASSIFICATION OF DANGEROUS SUBSTANCES AND DANGEROUS PREPARATIONS

## CATEGORIES OF DANGER

<i>Column 1</i> <i>Category of danger</i>	<i>Column 2</i> <i>Property (See Note 1)</i>	<i>Column 3</i> <i>Symbol-letter</i>
<b>PHYSICO-CHEMICAL PROPERTIES</b>		
Explosive	Solid, liquid, pasty or gelatinous substances and preparations which may react exothermically without atmospheric oxygen thereby quickly evolving gases, and which under defined test conditions detonate, quickly deflagrate or upon heating explode when partially confined.	E
Oxidising	Substances and preparations which give rise to a highly exothermic reaction in contact with other substances, particularly flammable substances.	O
Extremely flammable	Liquid substances and preparations having an extremely low flash point and a low boiling point and gaseous substances and preparations which are flammable in contact with air at ambient temperature and pressure.	F+
Highly flammable	The following substances and preparations, namely— (a) substances and preparations which may become hot and finally catch fire in contact with air at ambient temperature without any application of energy,	F
<i>Notes</i>		
1. As further described in the approved classification and labelling guide.		
2. The categories are specified in the approved classification and labelling guide.		
3. In certain cases specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation and in the approved classification and labelling guide substances and preparations classified as dangerous for the environment do not require to be labelled with the symbol and indication of danger.		

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<i>Column 1</i> <i>Category of danger</i>	<i>Column 2</i> <i>Property (See Note 1)</i>	<i>Column 3</i> <i>Symbol-letter</i>
	(b) solid substances and preparations which may readily catch fire after brief contact with a source of ignition and which continue to burn or to be consumed after removal of the source of ignition,	
	(c) liquid substances and preparations having a very low flash point, or	
	(d) substances and preparations which, in contact with water or damp air, evolve extremely flammable gases in dangerous quantities.	
Flammable	Liquid substances and preparations having a low flash point.	none
HEALTH EFFECTS		
Very toxic	Substances and preparations which in very low quantities cause death or acute or chronic damage to health when inhaled, swallowed or absorbed via the skin.	T+
Toxic	Substances and preparations which in low quantities cause death or acute or chronic damage to health when inhaled, swallowed or absorbed via the skin.	T
Harmful	Substances and preparations which may cause death or acute or chronic damage to health when inhaled, swallowed or absorbed via the skin.	Xn

*Notes*

1. As further described in the approved classification and labelling guide.
2. The categories are specified in the approved classification and labelling guide.
3. In certain cases specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation and in the approved classification and labelling guide substances and preparations classified as dangerous for the environment do not require to be labelled with the symbol and indication of danger.

<i>Column 1</i> <i>Category of danger</i>	<i>Column 2</i> <i>Property (See Note 1)</i>	<i>Column 3</i> <i>Symbol-letter</i>
Corrosive	Substances and preparations which may, on contact with living tissues, destroy them.	C
Irritant	Non-corrosive substances and preparations which, through immediate, prolonged or repeated contact with the skin or mucous membrane, may cause inflammation.	Xi
Sensitising	Substances and preparations which, if they are inhaled or if they penetrate the skin, are capable of eliciting a reaction by hypersensitization such that on further exposure to the substance or preparation, characteristic adverse effects are produced.	
Sensitising by inhalation		Xn
Sensitising by skin contact		Xi
Carcinogenic (See Note 2)	Substances and preparations which, if they are inhaled or ingested or if they penetrate the skin, may induce cancer or increase its incidence.	
Category 1		T
Category 2		T
Category 3		Xn
Mutagenic (See Note 2)	Substances and preparations which, if they are inhaled or ingested or if they penetrate the skin, may induce heritable genetic defects or increase their incidence.	
Category 1		T
Category 2		T
Category 3		Xn

*Notes*

- As further described in the approved classification and labelling guide.
- The categories are specified in the approved classification and labelling guide.
- In certain cases specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation and in the approved classification and labelling guide substances and preparations classified as dangerous for the environment do not require to be labelled with the symbol and indication of danger.


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<i>Column 1</i> <i>Category of danger</i>	<i>Column 2</i> <i>Property (See Note 1)</i>	<i>Column 3</i> <i>Symbol-letter</i>
Toxic for reproduction (see Note 2)	Substances and preparations which, if they are inhaled or ingested or if they penetrate the skin, may produce or increase the incidence of non-heritable adverse effects in the progeny and/or of male or female reproductive functions or capacity.	
Category 1		T
Category 2		T
Category 3		Xn
ENVIRONMENTAL EFFECTS		
Dangerous for the environment (See Note 3)	Substances and preparations which, were they to enter into the environment, would present or might present an immediate or delayed danger for one or more components of the environment.	N
<i>Notes</i>		
1. As further described in the approved classification and labelling guide.		
2. The categories are specified in the approved classification and labelling guide.		
3. In certain cases specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation and in the approved classification and labelling guide substances and preparations classified as dangerous for the environment do not require to be labelled with the symbol and indication of danger.		

SCHEDULE 2





Regulations 2(1), 8(2) and 10(6)

INDICATIONS OF DANGER AND SYMBOLS FOR DANGEROUS SUBSTANCES AND DANGEROUS PREPARATIONS

<i>Column 1</i> <i>Indication of danger</i>	<i>Column 2</i> <i>Symbol-letter</i>	<i>Column 3</i> <i>Symbol</i>
Explosive	E	
Oxidising	O	

<i>Column 1</i> <i>Indication of danger</i>	<i>Column 2</i> <i>Symbol-letter</i>	<i>Column 3</i> <i>Symbol</i>
Extremely flammable	F+	
Highly flammable	F	
Very toxic	T+	
Toxic	T	
Harmful	Xn	

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<i>Column 1</i> <i>Indication of danger</i>	<i>Column 2</i> <i>Symbol-letter</i>	<i>Column 3</i> <i>Symbol</i>
		
Corrosive	C	
Irritant	Xi	
Dangerous for the environment	N	

SCHEDULE 3

Regulation 4(7)

PROVISIONS FOR CLASSIFYING DANGEROUS PREPARATIONS

PART 1

GENERAL PROVISIONS

**Application**

1. The provisions of this Schedule shall apply for the classification of preparations.

## Interpretation and application

2.—(1) In this Schedule, for the purposes of classification—

“physico-chemical properties” means the properties to be applied for the classifications “explosive”, “oxidising”, “extremely flammable”, “highly flammable” or “flammable”;

“health effects” means the effects to be assessed for the classifications “very toxic”, “toxic”, “harmful”, “corrosive”, “irritant”, “sensitising”, “carcinogenic”, “mutagenic” or “toxic for reproduction”; and

“environmental hazards” means the hazards to be assessed for the classification “dangerous for the environment”.

(2) In its application to preparations that are gases, this Part shall be modified so that reference to concentrations expressed as percentage by weight are to concentrations expressed as the same percentage by volume.

## Classification of preparations by physico-chemical properties

3.—(1) The requisite physico-chemical properties for the classification of preparations shall be determined in accordance with the criteria set out in the approved classification and labelling guide.

(2) Subject to sub-paragraph (3), preparations shall be classified as explosive, oxidising, extremely flammable, highly flammable or flammable when they satisfy the criteria referred to in sub-paragraph (1) for the category of danger.

(3) The determination of explosive, oxidising, extremely flammable, highly flammable or flammable properties is not necessary provided that—

- (a) none of the constituents possess such properties and that, on the basis of information available to the manufacturer, the preparation is unlikely to present dangers of this kind;
- (b) in the event of a change in composition of a preparation of known composition, scientific evidence indicates that a reassessment of the hazards will not lead to a change in classification; and
- (c) in the case of a preparation supplied in the form of an aerosol, that preparation satisfies the provisions of article 8.1a of Council Directive [75/324/EEC](#)(1).

## Classification of preparations by health effects

4.—(1) The health effects of a preparation shall be assessed by one or more of the following methods—

- (a) by the conventional method described in paragraphs 7 to 15 using concentration limits; or
- (b) by the criteria set out in the approved classification and labelling guide in relation to the preparation for an appropriate classification and label.

(2) Any one or more of the health effects of the preparation which are not assessed by the method set out in sub-paragraph (1)(b) shall be assessed in accordance with the conventional method.

(3) Where the health effects have been established by both methods, the results of the method referred to in sub-paragraph (1)(b) shall be used for classifying the preparation except in the case of carcinogenic and mutagenic effects and toxic effects for reproduction, when the conventional method referred to in sub-paragraph (1)(a) shall always be used.

(4) Where it can be demonstrated—

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(1) OJ No. L147, 9.6.1975, p. 40. Article 8 is amended to add paragraph 1a by Commission Directive [2008/47/EC](#), OJ No. L96, 9.4.2008, p. 15.

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- (a) by epidemiological studies, by scientifically valid case studies as specified in the approved classification and labelling guide or by statistically backed experience (such as the assessment of data from poison information units or concerning occupational diseases) that toxicological effects on man differ from those suggested by the application of the methods set out in paragraph (1), then the preparation shall be classified according to its effects on man;
- (b) that owing to effects such as potentiation, a conventional assessment would underestimate the toxicological hazard, those effects shall be taken into account in classifying the preparation; or
- (c) that owing to effects such as antagonism, a conventional assessment would overestimate the toxicological hazard, those effects shall be taken into account in classifying the preparation.

(5) Subject to sub-paragraph (6), for preparations of a known composition, with the exception of plant protection products, classified in accordance with the method referred to in sub-paragraph (1) (b), a new health effect assessment shall be performed either by the method referred to in sub-paragraph (1)(a) or (1)(b) whenever—

- (a) changes of composition of the initial concentration, as a weight/weight or volume/volume percentage, of one or more of the dangerous constituents are introduced by the manufacturer which exceed the permitted variations set out in the following table—

<i>Initial concentration range of the constituent</i>	<i>Permitted variation in actual concentration of the constituent</i>
≤2.5%	±30%
>2.5	±20%
≤10%	±10%
>10	±5
≤25%	
>25	
≤100%	

or,

- (b) changes of composition involving the substitution or addition of one or more constituents, which may or may not be dangerous within the definitions in Schedule 1, are introduced by the manufacturer.

(6) The revised assessment required by sub-paragraph (5) shall not be required where there is a valid scientific justification for considering that a re-evaluation of the hazard will not result in a change of classification.

**Use of concentration limits in classification for health effects by the conventional method**

5.—(1) In accordance with paragraph 4(1)(a), the health effects shall be assessed by the conventional method described in paragraphs 7 to 15 using concentration limits.

(2) Where the substances concerned are dangerous substances and are listed as dangerous substances in Table 3.2 of part 3 of Annex VI of the CLP Regulation and are assigned concentration limits necessary for the application of the method of assessment described below, these concentration limits shall be used.

(3) Where the substances concerned are dangerous substances and do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation as dangerous substances or appear there without the concentration limits necessary for the application of the method of evaluation described below, the concentration limits shall be assigned in accordance with Part II of this Schedule.



**Lower limits of concentration**

6.—(1) For preparations to which this Schedule applies, account shall be taken of dangerous substances which are classified as dangerous on the basis of their health or environmental effects (whether they are present as additives or impurities) when their concentrations are equal to or greater than those defined in the following table unless lower limits are given in Table 3.2 of part 3 of Annex VI of the CLP Regulation or in Part II of this Schedule—

<i>Category of danger of the substance</i>	<i>Concentration to take into consideration for</i>	
	<i>gaseous preparations % vol/vol</i>	<i>other preparations % w/w</i>
Very toxic	≥0.02	≥0.1
Carcinogenic	≥0.02	≥0.1
Category 1 or 2		
Mutagenic	≥0.02	≥0.1
Category 1 or 2		
Toxic for reproduction	≥0.02	≥0.1
Category 1 or 2		
Harmful	≥0.2	≥1
Corrosive	≥0.02	≥1
Irritant	≥0.2	≥1
Sensitising	≥0.2	≥1
Carcinogenic	≥0.2	≥1
Category 3		
Mutagenic	≥0.2	≥1
Category 3		
Toxic for reproduction	≥0.2	≥1
Category 3		
Dangerous for the environment N		≥0.1
Dangerous for the environment	≥0.1	≥0.1
Ozone		
Dangerous for the environment		≥1

(2) Some substances may have more than one health effect and each of these properties shall be characterised by its specific concentration limit.

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### Classification by the conventional method as very toxic

7.—(1) The following preparations shall be classified as very toxic owing to their acute lethal effects and assigned the symbol “T+”, the indication of danger “very toxic” and the risk phrase R26, R27 or R28—

- (a) preparations containing one or more substances classified as very toxic that produce such effects, in individual concentrations equal to or exceeding—
  - (i) either the concentration specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation for the substance or substances under consideration, or
  - (ii) the concentration specified in paragraph 1 of Part II of this Schedule (Table I or Table IA) where the substance or substances do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation or appear in it without concentration limits;
- (b) preparations containing more than one substance classified as very toxic in lower individual concentrations than the limits specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation or in paragraph 1 of Part II of this Schedule (Table I or Table IA), if the sum of the quotients obtained by dividing the percentage weight of each very toxic substance in the preparation by the very toxic limit specified for that substance is 1 or more, i.e.—

$$\sum \left( \frac{P_{T+}}{L_{T+}} \right) \geq 1$$

where—

$P_{T+}$  is the percentage by weight of each very toxic substance in the preparation,

$L_{T+}$  is the very toxic limit specified for each very toxic substance expressed as a percentage by weight or by volume.

(2) The following preparations shall be classified as very toxic owing to their non-lethal irreversible effects after a single exposure and assigned the symbol “T+”, the indication of danger “very toxic” and the risk phrase R39/route of exposure—

Preparations containing one or more dangerous substances which produce such effects in individual concentrations equal to or exceeding—

- (i) either the concentration specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation for the substance or substances under consideration, or
- (ii) the concentration specified in paragraph 2 of Part II of this Schedule (Table II or Table IIA) where the substance or substances do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation or appear in it without concentration limits.

### Classification by the conventional method as toxic

8.—(1) The following preparations shall be classified as toxic owing to their acute lethal effects and assigned the symbol “T”, the indication of danger “toxic” and the risk phrase R23, R24, or R25—

- (a) preparations containing one or more substances classified as very toxic or toxic that produce such effects in individual concentrations equal to or exceeding—
  - (i) either the concentration specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation for the substance or substances under consideration, or

- (ii) the concentration specified in paragraph 1 of Part II of this Schedule (Table I or Table IA) where the substance or substances do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation or appear in it without concentration limits;
- (b) preparations containing more than one substance classified as very toxic or toxic in lower individual concentrations than the limits specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation or in paragraph 1 of Part II of this Schedule (Table I or Table IA) if the sum of the quotients obtained by dividing the percentage weight of each very toxic or toxic substance in the preparation by the toxic limit specified for that substance is 1 or more, i.e.—

$$\sum \left( \frac{P_{T+}}{L_T} + \frac{P_T}{L_T} \right) \geq 1.$$

where—

$P_{T+}$  is the percentage by weight or by volume of each very toxic substance in the preparation,

$P_T$  is the percentage by weight or by volume of each toxic substance in the preparation,

$L_T$  is the respective toxic limit specified for each very toxic or toxic substance expressed as a percentage by weight or by volume.

(2) The following preparations shall be classified as toxic owing to their non-lethal irreversible effects after a single exposure and assigned the symbol “T”, the indication of danger “toxic” and the risk phrase R39/route of exposure—

Preparations containing one or more dangerous substances classified as very toxic or toxic which produce such effects in individual concentrations equal to or exceeding—

- (i) either the concentration specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation for the substance or substances under consideration, or
- (ii) the concentration specified in paragraph 2 of Part II of this Schedule (Table II or Table IIA) where the substance or substances do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation or appear in it without concentration limits.

(3) The following preparations shall be classified as toxic owing to their long-term effects and assigned the symbol “T”, the indication of danger “toxic” and the risk phrase R48/route of exposure—

Preparations containing one or more dangerous substances which produce such effects in individual concentrations equal to or exceeding—

- (i) either the concentration specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation for the substance or substances under consideration, or
- (ii) the concentration specified in paragraph 3 of Part II of this Schedule (Table III or Table IIIA) where the substance or substances do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation or appear in it without concentration limits.

### **Classification by the conventional method as harmful**

9.—(1) The following preparations shall be classified as harmful owing to their acute lethal effects and assigned the symbol “Xn”, the indication of danger “harmful” and the risk phrase R20, R21 or R22—

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- (a) preparations containing one or more substances classified as very toxic, toxic or harmful and that produce such effects in individual concentrations equal to or exceeding—
- (i) either the concentration specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation for the substance or substances under consideration, or
  - (ii) the concentration specified in paragraph 1 of Part II of this Schedule (Table I or Table IA) where the substance or substances do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation or appear in it without concentration limits;
- (b) preparations containing more than one substance classified as very toxic, toxic or harmful in lower individual concentrations than the limits specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation or in paragraph 1 of Part II of this Schedule (Table I or Table IA) if the sum of the quotients obtained by dividing the percentage weight of each very toxic, toxic or harmful substance in the preparation by the harmful limit specified for that substance is 1 or more, i.e.—

$$\sum \left( \frac{P_{T+}}{L_{Xn}} + \frac{P_T}{L_{Xn}} + \frac{P_{Xn}}{L_{Xn}} \right) \geq 1$$

where—

$P_{T+}$  is the percentage by weight or by volume of each very toxic substance in the preparation,

$P_T$  is the percentage by weight or by volume of each toxic substance in the preparation,

$P_{Xn}$  is the percentage by weight or by volume of each harmful substance in the preparation,

$L_{Xn}$  is the respective harmful limit specified for each very toxic, toxic or harmful substance expressed as a percentage by weight or by volume.

(2) The following preparations shall be classified as harmful owing to their acute effects to the lungs if swallowed and assigned the symbol “Xn”, the indication of danger “harmful” and the risk phrase R65—Preparations classified as harmful according to the criteria specified in the approved classification and labelling guide.

In applying the conventional method according to sub-paragraph (1), no account shall be taken of the classification of a substance as R65.

(3) The following preparations shall be classified as harmful owing to their non-lethal irreversible effects after a single exposure and assigned the symbol “Xn”, the indication of danger “harmful” and the risk phrase R68/route of exposure—

Preparations containing one or more dangerous substances classified as very toxic, toxic or harmful which produce such effects in individual concentrations equal to or exceeding—

- (i) either the concentration specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation for the substance or substances under consideration, or
- (ii) the concentration specified in paragraph 2 of Part II of this Schedule (Table II or Table IIA) where the substance or substances do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation or appear in it without concentration limits.

(4) The following preparations shall be classified as harmful owing to their long-term effects and assigned the symbol “Xn”, the indication of danger “harmful” and the risk phrase R48/ route of exposure—

Preparations containing one or more dangerous substances classified as toxic or harmful that produce such effects in individual concentrations equal to or exceeding—

- (i) either the concentration specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation for the substance or substances under consideration, or
- (ii) the concentration specified in paragraph 3 of Part II of this Schedule (Table III or Table IIIA) where the substance or substances do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation or appear in it without concentration limits.

**Classification by the conventional method as corrosive**

**10.—**(1) The following preparations shall be classified as corrosive and assigned the symbol “C”, the indication of danger “corrosive” and the risk phrase R35—

- (a) preparations containing one or more substances classified as corrosive to which is assigned the risk phrase R35 in individual concentrations equal to or exceeding—
  - (i) either the concentration specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation for the substance or substances under consideration, or
  - (ii) the concentration specified in paragraph 4 of Part II of this Schedule (Table IV or Table IVA) where the substance or substances do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation or appear in it without concentration limits;
- (b) preparations containing more than one substance classified as corrosive to which is assigned the risk phrase R35 in lower individual concentrations than the limits specified either in Table 3.2 of part 3 of Annex VI of the CLP Regulation or in paragraph 4 of Part II of this Schedule (Table IV or Table IVA) if the sum of the quotients obtained by dividing the percentage weight of each corrosive substance in the preparation by the corrosive limit R35 specified for that substance is 1 or more, ie—

$$\sum \left( \frac{P_{C.R35}}{L_{C.R35}} \right) \geq 1$$

where—

$P_{C.R35}$  is the percentage by weight or by volume of each corrosive substance to which is assigned the risk phrase R35 in the preparation,

$L_{C.R35}$  is the corrosive limit R35 specified for each corrosive substance to which is assigned the risk phrase R35 expressed as a percentage by weight or by volume.

(2) The following preparations shall be classified as corrosive and assigned the symbol “C”, the indication of danger “corrosive” and the risk phrase R34—

- (a) preparations containing one or more substances classified as corrosive to which is assigned the risk phrase R35 or R34 in individual concentrations equal to or exceeding—
  - (i) either the concentration specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation for the substance or substances under consideration, or
  - (ii) the concentration specified in paragraph 4 of Part II of this Schedule (Table IV or Table IVA) where the substance or substances do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation or appear in it without concentration limits;

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- (b) preparations containing more than one substance classified as corrosive to which is assigned the risk phrase R35 or R34 in lower individual concentrations than the limits specified either in Table 3.2 of part 3 of Annex VI of the CLP Regulation or in paragraph 4 of Part II of this Schedule (Table IV or Table IVA) if the sum of the quotients obtained by dividing the percentage weight of each corrosive substance in the preparation by the corrosive limit R34 specified for that substance is 1 or more, ie—

$$\sum \left( \frac{P_{C.R35}}{L_{C.R34}} + \frac{P_{C.R34}}{L_{C.R34}} \right) \geq 1$$

where—

$P_{C.R35}$  is the percentage by weight or by volume of each corrosive substance to which is assigned the risk phrase R35 in the preparation,

$P_{C.R34}$  is the percentage by weight or by volume of each corrosive substance to which is assigned the risk phrase R34 in the preparation,

$L_{C.R34}$  is the respective corrosive limit R34 specified for each corrosive substance to which is assigned the risk phrase R35 or R34 expressed as a percentage by weight or by volume.

#### **Classification by the conventional method as irritant**

**11.—(1)** The following preparations shall be classified as irritants liable to cause serious eye damage and assigned the symbol “Xi”, the indication of danger “irritant” and risk phrase R41—

- (a) preparations containing one or more substances classified as irritant to which is assigned the risk phrase R41 in individual concentrations equal to or exceeding—
- (i) either the concentration specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation for the substance or substances under consideration, or
  - (ii) the concentration specified in paragraph 4 of Part II of this Schedule (Table IV or Table IVA) where the substance or substances do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation or appear in it without concentration limits;
- (b) preparations containing more than one substance classified as irritant to which is assigned the risk phrase R41, or classified as corrosive and to which is assigned the risk phrase R35 or R34, in lower individual concentrations than the limits specified either in Table 3.2 of part 3 of Annex VI of the CLP Regulation or in paragraph 4 of Part II of this Schedule (Table IV or Table IVA) if the sum of the quotients obtained by dividing the percentage weight of each irritant substance in the preparation by the irritant limit R41 specified for that substance is 1 or more, ie—

$$\sum \left( \frac{P_{C.R35}}{L_{Xi.R41}} + \frac{P_{C.R34}}{L_{Xi.R41}} + \frac{P_{Xi.R41}}{L_{Xi.R41}} \right) \geq 1$$

where—

$P_{C.R35}$  is the percentage by weight or by volume of each corrosive substance to which is assigned the risk phrase R35 in the preparation,

$P_{C, R34}$  is the percentage by weight or by volume of each corrosive substance to which is assigned the risk phrase R34 in the preparation,

$P_{Xi, R41}$  is the percentage by weight or by volume of each irritant substance to which is assigned the risk phrase R41 in the preparation,

$L_{Xi, R41}$  is the respective irritant limit R41 specified for each corrosive substance to which is assigned the risk phrase R35 or R34 or irritant substance to which is assigned the risk phrase R41, expressed as a percentage by weight or by volume.

(2) The following preparations shall be classified as irritant to eyes and assigned the symbol “Xi”, the indication of danger “irritant” and risk phrase R36—

(a) preparations containing one or more substances classified as corrosive to which is assigned the risk phrase R35 or R34 or as irritant to which is assigned the risk phrase R41 or R36 in individual concentrations equal to or exceeding—

(i) either the concentration specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation for the substance or substances under consideration, or

(ii) the concentration specified in paragraph 4 of Part II of this Schedule (Table IV or Table IVA) where the substance or substances do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation or appear in it without concentration limits;

(b) preparations containing more than one substance classified as irritant to which is assigned the risk phrase R41 or R36 or as corrosive and to which is assigned the risk phrase R35 or R34, in lower individual concentrations than the limits specified either in Table 3.2 of part 3 of Annex VI of the CLP Regulation or in paragraph 4 of Part II of this Schedule (Table IV or Table IVA) if the sum of the quotients obtained by dividing the percentage weight of each irritant substance in the preparation by the irritant limit R36 specified for that substance is 1 or more, ie—

$$\sum \left( \frac{P_{C, R35}}{L_{Xi, R36}} + \frac{P_{C, R34}}{L_{Xi, R36}} + \frac{P_{Xi, R41}}{L_{Xi, R36}} + \frac{P_{Xi, R36}}{L_{Xi, R36}} \right) \geq 1$$

where—

$P_{C, R35}$  is the percentage by weight or by volume of each corrosive substance to which is assigned the risk phrase R35 in the preparation,

$P_{C, R34}$  is the percentage by weight or by volume of each corrosive substance to which is assigned the risk phrase R34 in the preparation,

$P_{Xi, R41}$  is the percentage by weight or by volume of each irritant substance to which is assigned the risk phrase R41 in the preparation,

$P_{Xi, R36}$  is the percentage by weight or by volume of each irritant substance to which is assigned the risk phrase R36 in the preparation,

$L_{Xi, R36}$  is the respective irritant limit R36 specified for each corrosive substance to which is assigned the risk phrase R35 or R34 or irritant substance to which is assigned the risk phrase R41 or R36, expressed as a percentage by weight or by volume.

(3) The following preparations shall be classified as irritant to skin and assigned the symbol “Xi”, the indication of danger “irritant” and the risk phrase R38—

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- (a) preparations containing one or more substances classified as irritant and to which is assigned the risk phrase R38 or as corrosive and to which is assigned the risk phrase R35 or R34, in individual concentrations equal to or exceeding—
- (i) either the concentration specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation for the substance or substances under consideration, or
  - (ii) the concentration specified in paragraph 4 of Part II of this Schedule (Table IV or Table IVA) where the substance or substances do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation or appear in it without concentration limits;
- (b) preparations containing more than one substance classified as irritant to which is assigned the risk phrase R38, or as corrosive and to which is assigned the risk phrase R35 or R34 in lower individual concentrations than the limits specified either in Table 3.2 of part 3 of Annex VI of the CLP Regulation or in paragraph 4 of Part II of this Schedule (Table IV or Table IVA) if the sum of the quotients obtained by dividing the percentage weight of each substance in the preparation by the irritant limit R38 specified for that substance is 1 or more, ie—

$$\sum \left( \frac{P_{C, R35}}{L_{Xi, R38}} + \frac{P_{C, R34}}{L_{Xi, R38}} + \frac{P_{Xi, R38}}{L_{Xi, R38}} \right) \geq 1$$

where—

$P_{C, R35}$  is the percentage by weight or by volume of each corrosive substance to which is assigned the risk phrase R35 in the preparation,

$P_{C, R34}$  is the percentage by weight or by volume of each corrosive substance to which is assigned the risk phrase R34 in the preparation,

$P_{Xi, R38}$  is the percentage by weight or by volume of each irritant substance to which is assigned the risk phrase R38 in the preparation,

$L_{Xi, R38}$  is the respective irritant limit R38 specified for each corrosive substance to which is assigned the risk phrase R35 or R34 or irritant substance to which is assigned the risk phrase R38, expressed as a percentage by weight or by volume.

(4) The following preparations shall be classified as irritant to the respiratory system and assigned the symbol “Xi”, the indication of danger “irritant” and risk phrase R37—

- (a) preparations containing one or more substances classified as irritant to which is assigned the risk phrase R37 in individual concentrations equal to or exceeding—
- (i) either the concentration specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation for the substance or substances under consideration, or
  - (ii) the concentration specified in paragraph 4 of Part II of this Schedule (Table IV or Table IVA) where the substance or substances do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation or appear in it without concentration limits;
- (b) preparations containing more than one substance classified as irritant to which is assigned the risk phrase R37 in lower individual concentrations than the limits specified either in Table 3.2 of part 3 of Annex VI of the CLP Regulation or in paragraph 4 of Part II of this Schedule (Table IV or Table IVA) if the sum of the quotients obtained by dividing the percentage weight of each irritant substance in the preparation by the irritant limit R37 specified for that substance is 1 or more, ie—



$$\sum \left( \frac{P_{Xi, R37}}{L_{Xi, R37}} \right) \geq 1$$

where—

$P_{Xi, R37}$  is the percentage by weight or by volume of each irritant substance to which is assigned the risk phrase R37 in the preparation,

$L_{Xi, R37}$  is the irritant limit R37 specified for each irritant substance to which is assigned the risk phrase R37, expressed as a percentage by weight or by volume.

- (c) gaseous preparations containing more than one substance classified as irritant and to which is assigned the risk phrase R37 or as corrosive and to which is assigned the risk phrase R35 or R34 in lower individual concentrations than the limits specified either in Table 3.2 of part 3 of Annex VI of the CLP Regulation or in paragraph 4 of Part II of this Schedule (Table IV or Table IVA) if the sum of the quotients obtained by dividing the percentage volume of each substance in the preparation by the irritant limit R37 specified for that substance is 1 or more, ie—

$$\sum \left( \frac{P_{C, R35}}{L_{Xi, R37}} + \frac{P_{C, R34}}{L_{Xi, R37}} + \frac{P_{Xi, R37}}{L_{Xi, R37}} \right) \geq 1$$

where—

$P_{C, R35}$  is the percentage by volume of each corrosive substance to which is assigned the risk phrase R35 in the preparation,

$P_{C, R34}$  is the percentage by volume of each corrosive substance to which is assigned the risk phrase R34 in the preparation,

$P_{Xi, R37}$  is the percentage by volume of each irritant substance to which is assigned the risk phrase R37 in the preparation,

$L_{Xi, R37}$  is the respective irritant limit R37 specified for each gaseous corrosive substance to which is assigned the risk phrase R35 or R34 or gaseous irritant substance to which is assigned the risk phrase R37, expressed as a percentage by weight or by volume.

### **Classification by the conventional method as sensitising**

**12.—**(1) The following preparations shall be classified as sensitising by skin contact and assigned the symbol “Xi”, the indication of danger “irritant” and the risk phrase R43—

Preparations containing one or more substances classified as sensitising and to which is assigned the risk phrase R43 that produces such effects in individual concentrations equal to or exceeding—

- (i) either the concentration specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation for the substance or substances under consideration, or

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- (ii) the concentration specified in paragraph 5 of Part II of this Schedule (Table V or Table VA) where the substance or substances do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation or appear in it without concentration limits.
- (2) The following preparations shall be classified as sensitising by inhalation and assigned the symbol “Xn”, the indication of danger “harmful” and the risk phrase R42—
- Preparations containing one or more substances classified as sensitising and to which is assigned risk phrase R42 that produces such effects in individual concentrations equal to or exceeding—
- (i) either the concentration specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation for the substance or substances under consideration, or
  - (ii) the concentration specified in paragraph 5 of Part II of this Schedule (Table V or Table VA) where the substance or substances do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation or appear in it without concentration limits.

#### **Classification by the conventional method as carcinogenic**

**13.**—(1) Preparations shall be classified as carcinogenic category 1 or 2 and assigned the symbol “T” and the risk phrase R45 or R49 if they contain one or more substances producing such effects to which is assigned the risk phrase R45 or R49 which denotes carcinogenic substances in category 1 and category 2 in individual concentrations equal to or exceeding—

- (a) either the concentration specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation for the substance or substances under consideration, or
- (b) the concentration specified in paragraph 6 of Part II of this Schedule (Table V or Table VIA) where the substance or substances do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation or appear in it without concentration limits.

(2) Preparations shall be classified as carcinogenic category 3 and assigned the symbol “Xn” and risk phrase R40 if they contain one or more substances producing such effects to which is assigned the risk phrase R40 which denotes carcinogenic substances in category 3 in individual concentrations equal to or exceeding—

- (a) either the concentration specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation for the substance or substances under consideration, or
- (b) the concentration specified in paragraph 6 of Part II of this Schedule (Table VI or Table VIA) where the substance or substances do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation or appear in it without concentration limits.

#### **Classification by the conventional method as mutagenic**

**14.**—(1) Preparations shall be classified as mutagenic category 1 or 2 and assigned the symbol “T” and risk phrase R46 if they contain one or more substances producing such effects to which is assigned the risk phrase R46 which denotes mutagenic substances in category 1 and category 2 in individual concentrations equal to or exceeding—

- (a) either the concentration specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation for the substance or substances under consideration, or
- (b) the concentration specified in paragraph 6 of Part II of this Schedule (Table VI or Table VIA) where the substance or substances do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation or appear in it without concentration limits.

(2) Preparations shall be classified as mutagenic category 3 and assigned the symbol “Xn” and the risk phrase R68 if they contain one or more substances producing such effects to which is assigned

the risk phrase R68 which denotes mutagenic substances in category 2 in individual concentrations equal to or exceeding—

- (a) either the concentration specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation for the substance or substances under consideration, or
- (b) the concentration specified in paragraph 6 of Part II of this Schedule (Table VI or Table VIA) where the substance or substances do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation or appear in it without concentration limits.

### **Classification by the conventional method as toxic for reproduction**

**15.**—(1) Preparations shall be classified as toxic for reproduction category 1 or 2 and assigned the symbol “T” and risk phrase R60 (fertility) if they contain one or more substances producing such effects to which is assigned the risk phrase R60 which denotes substances toxic for reproduction of category 1 and category 2 in individual concentrations equal to or exceeding—

- (a) either the concentration specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation for the substance or substances under consideration, or
- (b) the concentration specified in paragraph 6 of Part II of this Schedule (Table VI or Table VIA) where the substance or substances do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation or appear in it without concentration limits.

(2) Preparations shall be classified as toxic for reproduction category 3 and assigned the symbol “Xn” and the risk phrase R62 (fertility) if they contain one or more substances producing such effects to which is assigned the risk phrase R62 which denotes substances toxic for reproduction in category 3 in individual concentrations equal to or exceeding—

- (a) either the concentration specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation for the substance or substances under consideration, or
- (b) the concentration specified in paragraph 6 of Part II of this Schedule (Table VI or Table VIA) where the substance or substances do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation or appear in it without concentration limits.

(3) Preparations shall be classified as toxic for reproduction category 1 or 2 and assigned the symbol “T” and risk phrase R61 (development) if they contain one or more substances producing such effects to which is assigned the risk phrase R61 which denotes substances toxic for reproduction of category 1 and category 2 in individual concentrations equal to or exceeding—

- (a) either the concentration specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation for the substance or substances under consideration, or
- (b) the concentration specified in paragraph 6 of Part II of this Schedule (Table VI or Table VIA) where the substance or substances do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation or appear in it without concentration limits.

(4) Preparations shall be classified as toxic for reproduction category 3 and assigned the symbol “Xn” and the risk phrase R63 (development) if they contain one or more substances producing such effects to which is assigned the risk phrase R63 which denotes substances toxic for reproduction in category 3 in individual concentrations equal to or exceeding—

- (a) either the concentration specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation for the substance or substances under consideration, or
- (b) the concentration specified in paragraph 6 of Part II of this Schedule (Table VI or Table VIA) where the substance or substances do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation or appear in it without concentration limits.

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**Classification of preparations for environmental hazards**

16.—(1) The environmental hazards of a preparation shall be assessed by one or more of the following methods—

- (a) by the conventional method described in paragraphs 18 and 19 using concentration limits; or
- (b) by the criteria referred to in the approved classification and labelling guide in relation to the preparation for an appropriate classification and label.

(2) Where the environmental hazards have been established by both methods, the results of the method referred to in sub-paragraph (1)(b) shall be used for classifying the preparation.

(3) Subject to sub-paragraph (4), for preparations of a known composition, with the exception of plant protection products, classified in accordance with the method set out in sub-paragraph (1) (b), a new assessment of the environmental hazards shall be performed either by the method set out in sub-paragraph (1)(a) or (1)(b) whenever—

- (a) changes of composition of the initial concentration, as a weight/weight or volume/volume percentage, of one or more of the dangerous constituents are introduced by the manufacturer which exceed the permitted variations set out in the following table—

<i>Initial concentration range of the constituent</i>	<i>Permitted variation in actual concentration of the constituent</i>	
	$\leq 2.5\%$	$\pm 30\%$
>2.5	$\leq 10\%$	$\pm 20\%$
>10	$\leq 25\%$	$\pm 10\%$
>25	$\leq 100\%$	$\pm 5\%$

- (b) changes of composition involving the substitution or addition of one or more constituents, which may or may not be dangerous within the definitions in Schedule 1, are introduced by the manufacturer.

(4) The revised assessment required by paragraph (3) shall not be required where there is a valid scientific justification for considering that a re-evaluation of the hazard will not result in a change of classification.

**Use of concentration limits in classification for environmental effects**

17.—(1) In accordance with paragraph 16(1)(a), the environmental hazards shall be assessed by the conventional method described in paragraphs 18 and 19 using concentration limits.

(2) Where the substances concerned are dangerous substances and are listed as dangerous substances in Table 3.2 of part 3 of Annex VI of the CLP Regulation and are assigned concentration limits necessary for the application of the method of assessment described below, these concentration limits shall be used.

(3) Where the substances concerned are dangerous substances and do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation as dangerous substances or appear there without the concentration limits necessary for the application of the method of evaluation described below, the concentration limits shall be assigned in accordance with Part III of this Schedule.

**Conventional method for the evaluation of hazards to the aquatic environment**

18.—(1) The following preparations shall be classified as dangerous for the environment and assigned the symbol “N”, the indication of danger “dangerous for the environment” and the risk phrases R50 and R53 (R50-53)—

- (a) preparations containing one or more substances classified as dangerous for the environment and to which is assigned risk phrases R50-53 in individual concentrations equal to or greater than—
  - (i) either the concentration specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation for the substance or substances under consideration, or
  - (ii) the concentration specified in Part III of this Schedule (Table 1) where the substance or substances do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation or appear in it without concentration limits;
- (b) preparations containing more than one substance classified as dangerous to the environment and to which is assigned risk phrases R50-53 in lower individual concentrations than the limits specified under paragraph (a) if—

$$\sum \left( \frac{P_{N.R50-53}}{L_{N.R50-53}} \right) \geq 1$$

where—

$P_{n.R50-53}$  is the percentage by weight of each substance dangerous for the environment to which is assigned risk phrases R50-53 in the preparation,

$L_{n.R50-53}$  is the limit R50-53 for each substance dangerous for the environment to which is assigned the risk phrases R50-53 expressed as a percentage by weight.

(2) The following preparations shall be classified as dangerous for the environment and assigned the symbol “N”, the indication of danger “dangerous for the environment” and risk phrases R51 and R53 (R51-53) unless the preparation is already classified according to sub-paragraph (1)—

- (a) preparations containing one or more substances classified as dangerous for the environment and to which is assigned risk phrases R50-53 or R51-53 in individual concentrations equal to or greater than—
  - (i) either the concentration specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation for the substance or substances under consideration, or
  - (ii) the concentration specified in Part III of this Schedule (Table 1) where the substance or substances do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation or appear in it without concentration limits;
- (b) preparations containing more than one substance classified as dangerous to the environment and to which is assigned risk phrases R50-53 or R51-53 in lower individual concentrations than the limits specified under paragraph (a) if—

$$\sum \left( \frac{P_{N.R50-53}}{L_{N.R51-53}} + \frac{P_{N.R51-53}}{L_{N.R51-53}} \right) \geq 1$$

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where—

$P_{n-R5053}$  is the percentage by weight of each substance dangerous for the environment to which is assigned risk phrases R50-53 in the preparation,

$P_{n-R5153}$  is the percentage by weight of each substance dangerous for the environment to which is assigned risk phrases R51-53 in the preparation,

$L_{n-R5153}$  is the respective limit R51-53 for each substance dangerous for the environment to which is assigned the risk phrases R50-53 or R51-53 expressed as a percentage by weight.

(3) The following preparations shall be classified as dangerous for the environment and assigned the risk phrases R52 and R53 (R52-53) unless the preparation is already classified according to sub-paragraph (1) or (2)—

- (a) preparations containing one or more substances classified as dangerous for the environment and to which is assigned risk phrases R50-53 or R51-53 or R52-53 in individual concentrations equal to or greater than—
  - (i) either the concentration specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation for the substance or substances under consideration, or
  - (ii) the concentration specified in Part III of this Schedule (Table 1) where the substance or substances do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation or appear in it without concentration limits;
- (b) preparations containing more than one substance classified as dangerous for the environment and to which is assigned risk phrases R50-53 or R51-53 or R52-53 in lower individual concentrations than the limits specified under paragraph (a) if—R

$$\sum \left( \frac{P_{N,R50-53}}{L_{R52-53}} + \frac{P_{N,R51-53}}{L_{R52-53}} + \frac{P_{R52-53}}{L_{R52-53}} \right) \geq 1$$

where—

$P_{n-R50-sub5;3}$  is the percentage by weight of each substance dangerous for the environment to which is assigned risk phrases R50-53 in the preparation,

$P_{n-Rsub5;1-sub5;3}$  is the percentage by weight of each substance dangerous for the environment to which is assigned risk phrases R51-53 in the preparation,

$P_{Rsub5;2-sub5;3}$  is the percentage by weight of each substance dangerous for the environment to which is assigned risk phrases R52-53 in the preparation,

$L_{Rsub5;2-sub5;3}$  is the respective limit R52-53 for each substance dangerous for the environment to which is assigned the risk phrases R50-53, R51-53 or R52-53 expressed as a percentage by weight.

(4) The following preparations shall be classified as dangerous for the environment and assigned the symbol “N”, the indication of danger “dangerous for the environment” and the risk phrase R50 unless the preparation is already classified according to sub-paragraph (1)—

- (a) preparations containing one or more substances classified as dangerous for the environment and to which is assigned risk phrase R50 individual concentrations equal to or greater than—
  - (i) either the concentration specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation for the substance or substances under consideration, or

- (ii) the concentration specified in Part III of this Schedule (Table 2) where the substance or substances do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation or appear in it without concentration limits;
- (b) preparations containing more than one substance classified as dangerous to the environment and to which is assigned risk phrase R50 in lower individual concentrations than the limits specified under paragraph (a) if—

$$\sum \left( \frac{P_{N.R50}}{L_{N.R50}} \right) \geq 1$$

where—

$P_{n.R50}$  is the percentage by weight of each substance dangerous for the environment to which is assigned risk phrase R50 in the preparation,

$L_{n.R50}$  is the limit R50 for each substance dangerous for the environment to which is assigned risk phrase R50 expressed as a percentage by weight.

- (c) preparations containing one or more substances classified as dangerous to the environment and to which is assigned risk phrase R50 not meeting the criteria under paragraph (a) or (b) and containing one or more substances classified as dangerous to the environment and to which is assigned risk phrases R50-53 if—

$$\sum \left( \frac{P_{N.R50}}{L_{N.R50}} + \frac{P_{N.R50-53}}{L_{N.R50}} \right) \geq 1$$

where—

$P_{n.R50}$  is the percentage by weight of each substance dangerous for the environment to which is assigned risk phrase R50 in the preparation,

$P_{n.R50-53}$  is the percentage by weight of each substance dangerous for the environment to which is assigned risk phrases R50-53 in the preparation,

$L_{n.R50}$  is the respective limit R50 for each substance dangerous for the environment to which is assigned risk phrases R50 or R50-53 expressed as a percentage by weight.

- (5) The following preparations shall be classified as dangerous for the environment and assigned the risk phrase R52 unless the preparation is already classified according to sub-paragraph (1), (2), (3) or (4)—

- (a) preparations containing one or more substances classified as dangerous for the environment and to which is assigned risk phrase R52 in individual concentrations equal to or greater than—
  - (i) either the concentration specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation for the substance or substances under consideration, or

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- (ii) the concentration specified in Part III of this Schedule (Table 3) where the substance or substances do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation or appear in it without concentration limits;
- (b) preparations containing more than one substance classified as dangerous to the environment and to which is assigned risk phrase R52 in lower individual concentrations than the limits specified under paragraph (a) if—

$$\sum \left( \frac{P_{R52}}{L_{R52}} \right) \geq 1$$

where—

$P_{R52}$  is the percentage by weight of each substance dangerous for the environment to which is assigned risk phrase R52 in the preparation,

$L_{R52}$  is the limit R52 for each substance dangerous for the environment to which is assigned risk phrase R52 expressed as a percentage by weight.

(6) The following preparations shall be classified as dangerous for the environment and assigned the risk phrase R53 unless the preparation is already classified according to sub-paragraph (1), (2) or (3)—

- (a) preparations containing one or more substances classified as dangerous for the environment and assigned risk phrase R53 in individual concentrations equal to or greater than—
  - (i) either the concentration specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation for the substance or substances under consideration, or
  - (ii) the concentration specified in Part III of this Schedule (Table 4) where the substance or substances do not appear in Annex Table 3.2 of part 3 of VI of the CLP Regulation or appear in it without concentration limits;
- (b) preparations containing more than one substance classified as dangerous to the environment and to which is assigned risk phrase R53 in lower individual concentrations than the limits specified under paragraph (a) if—

$$\sum \left( \frac{P_{R53}}{L_{R53}} \right) \geq 1$$

where—

$P_{R53}$  is the percentage by weight of each substance dangerous for the environment to which is assigned risk phrase R53 in the preparation,

$L_{R53}$  is the limit R53 for each substance dangerous for the environment to which is assigned risk phrase R53 expressed as a percentage by weight.

- (c) preparations containing one or more substances classified as dangerous to the environment and to which is assigned risk phrase R53 not meeting the criteria under paragraph (b) and



containing one or more substances classified as dangerous to the environment and to which is assigned risk phrases R50-53, R51-53 or R52-53 if

$$\sum \left( \frac{P_{R53}}{L_{R53}} + \frac{P_{N,R50-53}}{L_{R53}} + \frac{P_{N,R51-53}}{L_{R53}} + \frac{P_{R52-53}}{L_{R53}} \right) \geq 1$$

where—

$P_{53}$  is the percentage by weight of each substance dangerous for the environment to which is assigned risk phrase R53 in the preparation,

$P_{n-R5053}$  is the percentage by weight of each substance dangerous for the environment to which is assigned risk phrases R50-53 in the preparation,

$P_{n-R5153}$  is the percentage by weight of each substance dangerous for the environment to which is assigned risk phrases R51-53 in the preparation

$P_{R5253}$  is the percentage by weight of each substance dangerous for the environment to which is assigned risk phrases R52-53 in the preparation

$L_{R53}$  is the respective limit R53 for each substance dangerous for the environment to which is assigned risk phrases R53, R50-53, R51-53 or R52-53 expressed as a percentage by weight.

### Conventional method for the evaluation of hazards to the ozone layer

**19.** Preparations containing one or more substances classified as dangerous for the environment and to which is assigned the symbol “N” and the risk phrase R59 in individual concentrations equal to or greater than—

- (i) either the concentration specified in Table 3.2 of part 3 of Annex VI of the CLP Regulation for the substance or substances under consideration, or
- (ii) the concentration specified in Part III of this Schedule (Table 5) where the substance or substances do not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation or appear in it without concentration limits,

shall be classified as dangerous for the environment and assigned the symbol “N”, the indication of danger “dangerous for the environment” and the risk phrase R59.

## PART II

### CONCENTRATION LIMITS TO BE USED IN THE EVALUATION OF HEALTH HAZARDS

An assessment must be made of the health effects that the use of a substance or a preparation might entail. For that purpose the dangerous health effects have been subdivided into:

- 
- |    |  |
|----|--|
| 1. | acute lethal effects;                                    |
| 2. | non-lethal irreversible effects after a single exposure; |
| 3. | severe effects after repeated or prolonged exposure;     |

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4.	corrosive effects, irritant effects;
5.	sensitising effects;
6.	carcinogenic effects, mutagenic effects, toxic effects for reproduction.

The systematic assessment of the dangerous health effects is expressed by means of concentration limits, expressed as weight/weight percentage except for gaseous preparations (Tables A) where they are expressed as a volume/volume percentage and in conjunction with the classification of a substance.

The classification of the substance is expressed either by a symbol and one or more risk phrases or by categories (category 1, category 2 or category 3) also expressed by risk phrases when substances are shown to be carcinogenic, mutagenic or toxic for reproduction. Therefore it is important to consider, in addition to the symbol, all the phrases denoting specific risks which are assigned to each substance under consideration.

### Acute lethal effects

#### 1

#### *Other than gaseous preparations*

**1.1** The concentration limits fixed in Table 1 determine the classification of the preparation in relation to the individual concentration of the substance(s) present whose classification is also shown.

**Table I**

<i>Classification of the substance</i>	<i>Classification of the preparation</i>		
	<i>T+</i>	<i>T</i>	<i>Xn</i>
T+ with R26, R27, R28	concentration $\geq 7\%$	1% concentration < 7%	0.1% concentration < 1%
T with R23, R24, R25		Concentration $\geq 25\%$	3% $\leq$ concentration < 25%
Xn with R20, R21, R22			concentration $\geq 25\%$

The R phrases denoting risk shall be assigned to the preparation in accordance with the following criteria—

- (i) the label shall include one or more of the above mentioned R phrases according to the classification used,
- (ii) in general, the R phrases selected should be those applicable to the substance(s) present in the concentration which gives rise to the most severe classification.

#### *Gaseous preparations*

**1.2** The concentration limits expressed as a volume/volume percentage in Table IA determine the classification of the gaseous preparations in relation to the individual concentrations of the gas(es) present whose classification is also shown.

**Table IA**

<i>Classification of the substance (gas)</i>	<i>Classification of the preparation</i>		
	<i>T+</i>	<i>T</i>	<i>X<sub>n</sub></i>
T+ with R26, R27, R28	concentration $\geq$ 1%	0.2% $\leq$ concentration < 1%	0.02% $\leq$ concentration < 0.2%
T with R23, R24, R25		concentration $\geq$ 5%	0.5% $\leq$ concentration < 5%
X <sub>n</sub> with R20, R21, R22			concentration $\geq$ 5%

The R phrases denoting risk shall be assigned to the preparation in accordance with the following criteria—

- (i) the label shall include one or more of the above mentioned R phrases according to the classification used,
- (ii) in general, the R phrases selected should be those applicable to the substance(s) present in the concentration which gives rise to the most severe classification.

### Non-lethal irreversible effects after a single exposure

#### 2

#### *Other than gaseous preparations*

**2.1** For substances that produce non-lethal irreversible effects after a single exposure (R39/route of exposure, R68/route of exposure), the individual concentration limits specified in Table II determine, when appropriate, the classification of the preparation.

**Table II**

<i>Classification of the substance</i>	<i>Classification of the preparation</i>		
	<i>T+</i>	<i>T</i>	<i>X<sub>n</sub></i>
T+ with R39/route of exposure	concentration $\geq$ 10% R39 (*) obligatory	1% $\leq$ concentration < 10% R39(*) obligatory	0.1% $\leq$ concentration < 1% R68(*) (†) obligatory
T with R39/ route of exposure		concentration $\geq$ 10% R39(*) obligatory	1% $\leq$ concentration < 10% R68(*) (†) obligatory
X <sub>n</sub> with R68/route of exposure			concentration $\geq$ 10% R68(*) (†) obligatory

(\*) In order to indicate the route of administration/ exposure the combined R phrases listed in Annex III of Council Directive [67/548/EEC](#) shall be used.

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(†) R68 here refers to substances classified as harmful. Concentration limits for substances required to be labelled R68 but classified as mutagenic are given in Table VI.

#### *Gaseous preparations*

**2.2** For gases that produce non-lethal irreversible effects after a single exposure (R39/route of exposure, R68/route of exposure), the individual concentration limits specified in Table IIA, expressed as a volume/volume percentage, determine, when appropriate, the classification of the preparation.

**Table IIA**

<i>Classification of the substance (gas)</i>	<i>Classification of the preparation</i>		
	<i>T+</i>	<i>T</i>	<i>X<sub>n</sub></i>
T+ with R39/route of exposure	concentration $\geq 1\%$ R39(*) obligatory	0.2% $\leq$ concentration $< 1\%$ R39(*) obligatory	0.02% $\leq$ concentration $< 0.2\%$ R68(*) (†) obligatory
T with R39/route of exposure		concentration $\geq 5\%$ R39(*) obligatory	0.5% $\leq$ concentration $< 5\%$ R68(*) (†) obligatory
X <sub>n</sub> with R68/route of exposure			concentration $\geq 5\%$ R68 (*) (†) obligatory

(\*) In order to indicate the route of administration/exposure the combined R phrases listed in Annex III of Council Directive [67/548/EEC](#) shall be used.

(†) R68 here refers to substances classified as harmful. Concentration limits for substances required to be labelled R68 but classified as mutagenic are given in Table VI.

#### **Severe effects after repeated or prolonged exposure**

### **3**

#### *Other than gaseous preparations*

**3.1** For substances that produce severe effects after repeated exposure (R48/route of exposure), the individual concentration limits specified in Table III determine, when appropriate, the classification of the preparation.

**Table III**

<i>Classification of the substance</i>	<i>Classification of the preparation</i>	
	<i>T+</i>	<i>X<sub>n</sub></i>
T with R48/ route of exposure	concentration $\geq 10\%$ R48(*) obligatory	1% $\leq$ concentration $< 10\%$ R48(*) obligatory
X <sub>n</sub> with R48/route of exposure		concentration $\geq 10\%$

Classification of the substance	Classification of the preparation	
	T+	Xn
		R48(*) obligatory

(\*) In order to indicate the route of administration/exposure the combined R phrases listed in Annex III of Council Directive 67/548/EEC shall be used.

#### Gaseous preparations

**3.2** For gases that produce severe effects after repeated or prolonged exposure (R48/route of exposure), the individual concentration limits specified in Table IIIA, expressed as a volume/volume percentage, determine, when appropriate, the classification of the preparation.

**Table IIIA**

Classification of the substance (gas)	Classification of the preparation	
	T+	Xn
T with R48/route of exposure	concentration $\geq$ 5%	0.5% $\leq$ concentration < 5%
	R48(*) obligatory	R48(*) obligatory
Xn with R48/route of exposure		concentration $\geq$ 5%
		R48(*) obligatory

(\*) In order to indicate the route of administration/exposure the combined R phrases listed in Annex III of Council Directive 67/548/EEC shall be used.

#### Corrosive and irritant effects including serious damage to eye

##### 4

#### Other than gaseous preparations

**4.1** For substances that produce corrosive effects (R34, R35) or irritant effects (R36, R37, R38, R41), the individual concentration limits specified in Table IV determine, when appropriate, the classification of the preparation.

**Table IV**

Classification of the substance	Classification of the preparation			
	C with R35	C with R34	Xi with R41	Xi with R36, R37, R38
C with R35	concentration $\geq$ 10%	5% $\leq$ concentration < 10%	5%(*)	1% $\leq$ concentration < 5%
	R35 obligatory	R34 obligatory		R36/38 obligatory

**Status:** This is the original version (as it was originally made).

Classification of the substance	Classification of the preparation			
	C with R35	C with R34	Xi with R41	Xi with R36, R37, R38
C with R34		Concentration $\geq$ 10% R34 obligatory	10%(*)	5% $\leq$ concentration < 10% R36/38 obligatory
Xi with R41			concentration $\geq$ 10% R41 obligatory	5% $\leq$ concentration < 10% R36 obligatory
Xi with R36, R37, R38				concentration $\geq$ 20% R36, R37, R38 are obligatory in the light of the concentration present if they apply to the substances under consideration

(\*) According to the approved classification and labelling guide, when a substance or preparation is classified as corrosive and assigned the risk phrase R34 or R35, the risk of severe damage to the eyes is considered implicit and the risk phrase R41 is not included on the label. Consequently, if the preparation contains corrosive substances with R35 or R34 below the concentration limits for a classification of the preparation as corrosive, such substances can contribute to a classification of the preparation as irritant (R41) or irritant (R36).

#### Note

Simple application of the conventional method to preparations containing substances classified as corrosive or irritant may result in under-classification or over-classification of the hazard, if other relevant factors (eg pH of the preparation) are not taken into account. Therefore, in classifying for corrosivity consider the advice given in the approved classification and labelling guide regarding classification as corrosive and paragraph 4(4)(b) and (c) of Part I of this Schedule.

#### Gaseous preparations

**4.2** For gases that produce such effects (R34, R35 or R36, R37, R38, R41), the individual concentration limits specified in Table IVA, expressed as a volume/volume percentage determine, when appropriate the classification of the preparation.

**Table IVA**

<i>Classification of the substance (gas)</i>	<i>Classification of the preparation</i>			
	<i>C with R35</i>	<i>C with R34</i>	<i>Xi with R41</i>	<i>Xi with R36, R37, R38</i>
C with R35	Concentration $\geq$ 1% R35 obligatory	0.2% $\leq$ concentration < 1% R34 obligatory	0.2%(*)	0.02% $\leq$ concentration < 0.2% R36/37/38 obligatory
C with R34		Concentration $\geq$ 5% R34 obligatory	5%(*)	0.5% $\leq$ concentration < 5% R36/37/38 obligatory
Xi with R41			concentration $\geq$ 5% R41 obligatory	0.5% $\leq$ concentration < 5% R36 obligatory
Xi with R36, R37, R38				concentration $\geq$ 5% R36, R37, R38 obligatory as appropriate

(\*) According to the approved classification and labelling guide, when a substance or preparation is classified as corrosive and assigned the risk phrase R34 or R35, the risk of severe damage to the eyes is considered implicit and the risk phrase R41 is not included on the label. Consequently, if the preparation contains corrosive substances with R35 or R34 below the concentration limits for a classification of the preparation as corrosive, such substances can contribute to a classification of the preparation as irritant (R41) or irritant (R36).

**Note**

Simple application of the conventional method to preparations containing substances classified as corrosive or irritant may result in under-classification or over-classification of the hazard, if other relevant factors (eg pH of the preparation) are not taken into account. Therefore, in classifying for corrosivity, consider the advice given in the approved classification and labelling guide regarding classification as corrosive and paragraph 4(4)(b) and (c) of Part I of this Schedule.

**Sensitising effects**

**Status:** This is the original version (as it was originally made).

*Other than gaseous preparations*

**5.1** Preparations that produce such effects are classified as sensitising and assigned:

- the symbol Xn and phrase R42 if this effect can be produced by inhalation,
- the symbol Xi and phrase R43 if this effect can be produced through contact with the skin.

The individual concentration limits specified in Table V determine, when appropriate, the classification of the preparation.

**Table V**

<i>Classification of the substance</i>	<i>Classification of the preparation</i>	
	<i>Sensitising with R42</i>	<i>Sensitising with R43</i>
Sensitising with R42	concentration $\geq$ 1%	
	R42 obligatory	
Sensitising with R43		concentration $\geq$ 1%
		R43 obligatory

*Gaseous preparations*

**5.2** Gases that produce such effects are classified as sensitising and assigned:

- the symbol Xn and phrase R42 if this effect can be produced by inhalation,
- the symbol Xi and phrase R43 if this effect can be produced by inhalation and through contact with the skin.

The individual concentration limits specified in Table VA expressed as a volume/volume percentage, determine, when appropriate, the classification of the preparation.

**Table VA**

<i>Classification of the substance (gas)</i>	<i>Classification of the preparation</i>	
	<i>Sensitising with R42</i>	<i>Sensitising with R43</i>
Sensitising with R42	concentration $\geq$ 0.2%	
	R42 obligatory	
Sensitising with R43		concentration $\geq$ 0.2%
		R43 obligatory

**Carcinogenic/mutagenic/toxic effects for reproduction**

**6**



*Other than gaseous preparations*

**6.1** For substances which produce such effects and for which specific concentration limits do not yet appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation, concentration limits laid down in Table VI shall determine, where appropriate, the classification of the preparation.

The following symbol and risk phrases are assigned:

Carcinogenic categories 1 and 2:	T; R45 or R49
Carcinogenic category 3:	Xn; R40
Mutagenic categories 1 and 2:	T; R46
Mutagenic category 3:	Xn R68
Toxic for reproduction fertility categories 1 and 2:	T; R60
Toxic for reproduction development categories 1 and 2:	T; R61
Toxic for reproduction fertility category 3:	Xn; R62
Toxic for reproduction development category 3:	Xn; R63

**Table VI**

<i>Classification of the substance</i>	<i>Classification of the preparation</i>	
	<i>Categories 1 and 2</i>	<i>Category 3</i>
Carcinogenic substances of category 1 or 2 with R45 or R49	concentration $\geq$ 0.1% carcinogenic  R45, R49 obligatory as appropriate	
Carcinogenic substances of category 3 with R40		concentration $\geq$ 1% carcinogenic  R40 obligatory ( <i>unless already assigned R45(*)</i> )
Mutagenic substances of category 1 or 2 with R46	concentration $\geq$ 0.1% mutagenic  R46 obligatory	
Mutagenic substances of category 3 with R68(**)		concentration $\geq$ 1% mutagenic  R68(**) obligatory ( <i>unless already assigned R46</i> )
Substances “toxic for reproduction” of category 1 or 2 with R60 (fertility)	concentration $\geq$ 0.5% toxic for reproduction (fertility)  R60 obligatory	

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<i>Classification of the substance</i>	<i>Classification of the preparation</i>	
	<i>Categories 1 and 2</i>	<i>Category 3</i>
Substances “toxic for reproduction” of category 3 with R62 (fertility)		concentration $\geq$ 5%toxic for reproduction(fertility)  R62 obligatory ( <i>unless already assigned R60</i> )
Substances “toxic for reproduction” of category 1 or 2 with R61 (development)	concentration $\geq$ 0.5%toxic for reproduction (development)  R61 obligatory	
Substances “toxic for reproduction” of category 3 with R63 (development)		concentration $\geq$ 5%toxic for reproduction (development)  R63 obligatory ( <i>unless already assigned R61</i> )

(\*) In cases where the preparation is assigned R49 and R40, both R phrases shall be kept, because R40 does not distinguish between the exposure routes, whereas R49 is only assigned for the inhalation route.

(\*\*) R68 here refers to substances classified as mutagenic. Concentration limits for substances required to be labelled R68 but classified as harmful are given in Table II.

### *Gaseous preparations*

**6.2** For gases which produce such effects and for which specific concentration limits do not yet appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation, concentration limits laid down in Table VIA, expressed as a volume/volume percentage, shall determine, where appropriate, the classification of the preparation.

The following symbol and risk phrases are assigned:

Carcinogenic categories 1 and 2:	T; R45 or R49
Carcinogenic category 3:	Xn; R40
Mutagenic categories 1 and 2:	T; R46
Mutagenic category 3:	Xn; R68
Toxic for reproduction fertility categories 1 and 2:	T; R60
Toxic for reproduction development categories 1 and 2:	T; R61
Toxic for reproduction fertility category 3:	Xn; R62
Toxic for reproduction development category 3:	Xn; R63

**Table VIA**

<i>Classification of the substance (gas)</i>	<i>Classification of the preparation</i>	
	<i>Categories 1 and 2</i>	<i>Category 3</i>
Carcinogenic substances of category 1 or 2 with R45 or R49	concentration $\geq$ 0.1% carcinogenic R45, R49 obligatory as appropriate	
Carcinogenic substances of category 3 with R40		concentration $\geq$ 1% carcinogenic R40  obligatory ( <i>unless already assigned R45(*)</i> )
Mutagenic substances of category 1 or 2 with R46	concentration $\geq$ 0.1% mutagenic  R46 obligatory	
Mutagenic substances of category 3 with R68(**)		concentration $\geq$ 1% mutagenic  R68(**) obligatory ( <i>unless already assigned R46</i> )
Substances “toxic for reproduction” of category 1 or 2 with R60 (fertility)	concentration $\geq$ 0.2% toxic for reproduction (fertility)  R60 obligatory	
Substances “toxic for reproduction” of category 3 with R62 (fertility)		concentration $\geq$ 1% toxic for reproduction (fertility)  R62 obligatory ( <i>unless already assigned R60</i> )
Substances “toxic for reproduction” of category 1 or 2 with R61 (development)	concentration $\geq$ 0.2% toxic for reproduction (development)  R61 obligatory	
Substances “toxic for reproduction” of category 3 with R63 (development)		concentration $\geq$ 1% toxic for reproduction (development)  R63 obligatory ( <i>unless already assigned R61</i> )

(\*) In cases where the preparation is assigned R49 and R40, both R phrases shall be kept, because R40 does not distinguish between the exposure routes, whereas R49 is only assigned for the inhalation route.

(\*\*) R68 here refers to substances classified as mutagenic. Concentration limits for substances required to be labelled R68 but classified as harmful are given in Table IIA.

**Status:** This is the original version (as it was originally made).

## PART III

### *Concentration limits to be used for the evaluation of Environment Hazards*

#### **The aquatic environment**

1. The concentration limits fixed in the following tables, expressed as a weight/weight percentage, determine the classification of the preparation in relation to the individual concentration of the substances present whose classification is also shown.

**Table 1a**

#### *Acute aquatic toxicity and long-term adverse effects*

<i>Classification of the substance</i>	<i>Classification of the preparation</i>		
N, R50-53	N,R50-53	N, R51-53	R52-53
N, R51-53	see Table 1b	See Table 1b	see Table 1b
R52-53		$C_n \geq 25\%$	$2.5\% \leq C_n < 25\%$
			$C_n \geq 25\%$

For preparations containing a substance classified with N, R50-53, the concentration limits and the resulting classification given in Table 1b are applicable.

**Table 1b**

#### ACUTE AQUATIC TOXICITY AND LONG-TERM ADVERSE EFFECTS OF SUBSTANCE VERY TOXIC TO THE AQUATIC ENVIRONMENT

<i>LG50 or EC50 value ("L(E)C50") of substance classified as N, R50-53 (mg/l)</i>	<i>Classification of the preparation</i>		
	N, R50-53 N,	R51-53	R52-53
$0.1 < L(E)C_{50} \leq 1$	$C_n \geq 25\%$	$2.5\% \leq C_n < 25\%$	$0.25\% \leq C_n < 2.5\%$
$0.01 < L(E)C_{50} \leq 0.1$	$C_n \geq 2.5\%$	$0.25\% \leq C_n < 2.5\%$	$0.025\% \leq C_n < 0.25\%$
$0.001 < L(E)C_{50} \leq 0.01$	$C_n \geq 0.25\%$	$0.025\% \leq C_n < 0.25\%$	$0.0025\% \leq C_n < 0.025\%$
$0.0001 < L(E)C_{50} \leq 0.001$	$C_n \geq 0.025\%$	$0.0025\% \leq C_n < 0.025\%$	$0.00025\% \leq C_n < 0.0025\%$
$0.00001 < L(E)C_{50} \leq 0.0001$	$C_n \geq 0.0025\%$	$0.00025\% \leq C_n < 0.0025\%$	$0.000025\% \leq C_n < 0.00025\%$

For preparations containing substances with a lower LC50 or EC50 value than 0.00001 mg/l, the corresponding concentration limits are calculated accordingly (in factor 10 intervals).

**Table 2***Acute aquatic toxicity*

<i>LC50 or EC50 value (“L(E)C50”) of substance classified either as N, R50 or as N, R50-53 (mg/l)</i>	<i>Classification of the preparation N, R50</i>
0.1 L(E)C <sub>50</sub> ≤ 1	C <sub>n</sub> ≥ 25%
0.01 L(E)C <sub>50</sub> ≤ 0.1	C <sub>n</sub> ≥ 2.5%
0.001 L(E)C <sub>50</sub> ≤ 0.01	C <sub>n</sub> ≥ 0.25%
0.0001 L(E)C <sub>50</sub> ≤ 0.001	C <sub>n</sub> ≥ 0.025%
0.00001 L(E)C <sub>50</sub> ≤ 0.0001	C <sub>n</sub> ≥ 0.0025%

For preparations containing substances with a lower LC50 or EC50 value than 0.00001 mg/l, the corresponding concentration limits are calculated accordingly (in factor 10 intervals).

**Table 3***Aquatic toxicity*

<i>Classification of the substance</i>	<i>Classification of the preparation R52</i>
R52	C <sub>n</sub> ≥ 25%

**Table 4***Long-term adverse effects*

<i>Classification of the substance</i>	<i>Classification of the preparation R53</i>
R53	C <sub>n</sub> ≥ 25%
N, R50-53	C <sub>n</sub> ≥ 25%
N, R51-53	C <sub>n</sub> ≥ 25%
R52-53	C <sub>n</sub> ≥ 25%

**The non-aquatic environment**

2. The concentration limits fixed in the following table, expressed as a weight/weight percentage or, for gaseous preparations as a volume/volume percentage, determine the classification of the preparation in relation to the individual concentration of the substances present whose classification is also shown.

**Table 5***Dangerous for the ozone layer*

<i>Classification of the substance</i>	<i>Classification of preparation N, R59</i>
N with R59	C <sub>n</sub> ≥ 0.1%

## SCHEDULE 4

Regulations 7 and 9

LABELLING PARTICULARS FOR DANGEROUS SUBSTANCES,  
DANGEROUS PREPARATIONS AND FOR CERTAIN OTHER PREPARATIONS

## PART 1

## GENERAL PROVISIONS RELATING TO LABELS

**Labelling particulars for dangerous substances**

1.—(1) In the case of a dangerous substance which is listed in Table 3.2 of part 3 of Annex VI of the CLP Regulation, the particulars to be shown on the label in accordance with regulation 7(2)(c) shall be the particulars specified for that dangerous substance in the relevant entry in that table.

(2) Subject to paragraph 4, in the case of a dangerous substance which is not listed in Table 3.2 of part 3 Annex VI of the CLP Regulation, the particulars required to be shown on the label in accordance with regulation 7(2)(c) shall be determined from the classification of the substance in accordance with regulation 4 in conjunction with the approved classification and labelling guide.

**Labelling particulars for dangerous preparations**

2.—(1) Subject to paragraphs 3 and 4, the provisions of this paragraph shall have effect in relation to the labelling of dangerous preparations.

(2) Subject to sub-paragraph (3), the particulars relating to the chemical name required to be shown on the label in accordance with regulation 7(3)(c)(i) shall be shown according to the following rules—

- (a) in the case of a dangerous preparation classified as requiring the indication of danger T+, T or Xn, only substances requiring those indications of danger present in the dangerous preparation in concentrations equal to or greater than—
  - (i) the lowest limit (the Xn limit) for the substance laid down in Table 3.2 of part 3 of Annex VI of the CLP Regulation, or
  - (ii) where there is no such limit, the relevant limit laid down in Part II of Schedule 3, have to be taken into consideration;
- (b) in the case of a dangerous preparation classified as requiring the indication of danger C, only substances requiring that indication of danger present in the dangerous preparation in concentrations equal to or greater than—
  - (i) the lowest limit (the Xi limit) for the substance laid down in Table 3.2 of part 3 of Annex VI of the CLP Regulation, or
  - (ii) where there is no such limit, the relevant limit laid down in Part II of Schedule 3, have to be taken into consideration;
- (c) if the dangerous preparation is assigned one or more of the following danger categories:
  - carcinogen category 1, 2 or 3,
  - mutagen category 1, 2 or 3,
  - toxic for reproduction category 1, 2 or 3,
  - very toxic, toxic or harmful due to non-lethal effects after a single exposure,
  - toxic or harmful due to severe effects after repeated or prolonged exposure,

— sensitising,

the name of any substance causing the dangerous preparation to be so assigned shall be referred to;

(d) as a consequence of the provisions set out in paragraphs (a) to (c), the name of any substance which led to the classification of the dangerous preparation in the following danger categories:

— explosive,

— oxidising,

— extremely flammable,

— highly flammable,

— flammable,

— irritant,

— dangerous for the environment,

need not be referred to on the label unless so required by paragraph (a), (b) or (c).

(3) The chemical name referred to in sub-paragraph (2) shall be—

(a) in the case of a substance listed in Table 3.2 of part 3 of Annex VI of the CLP Regulation, the name or one of the names under which that substance is listed; or

(b) in the case of a substance not so listed, an internationally recognised name.

(4) For the purpose of labelling, no account shall be taken of a substance in the dangerous preparation where the concentration of that substance is less than the concentration referred to in paragraph 6 of Part 1 of Schedule 3.

(5) Subject to sub-paragraph (4), the particulars to be shown on the label in accordance with regulation 7(3)(c)(ii), (iii) and (iv) shall be determined from the classification of the dangerous preparation made in accordance with regulation 4 in conjunction with the approved classification and labelling guide.

(6) As a general rule, a maximum of four chemical names shall suffice to identify the substances primarily responsible for the major health hazards which have given rise to the classification and the choice of the corresponding risk phrases—although in some cases more than four chemical names may be necessary.

### **Confidentiality of chemical names**

3.—(1) Subject to sub-paragraph (2), where the supplier of a dangerous preparation is able to demonstrate to the Executive that the disclosure on the label or safety data sheet of the chemical identity of a substance which is exclusively classified as—

(a) irritant with the exception of those assigned R41 or irritant in combination with one or more of the other properties mentioned in paragraph (2)(2)(d); or

(b) harmful or harmful in combination with one or more of the properties mentioned in paragraph (2)(2)(d) presenting acute lethal effects alone,

will put at risk the confidential nature of the supplier's intellectual property, that supplier shall, in accordance with the provisions of Annex VI of Council Directive 1999/45/EC, be permitted to refer to that substance either by means of a name that identifies the most important functional chemical groups or by means of an alternative name.

(2) The derogation in sub-paragraph (1) shall not apply in respect of a substance which has been assigned a Community exposure limit.

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(3) Where a supplier wishes to take advantage of the derogation contained in sub-paragraph (1), the supplier shall make application to the Executive accordingly, enclosing the information specified in Annex VI to Council Directive [1999/45/EC](#).

(4) The Executive may require such further information from the supplier as is necessary to determine the validity of an application made under sub-paragraph (3).

#### **Indications of danger and symbols for dangerous substances and dangerous preparations**

4.—(1) Except in the case of a dangerous substance which is listed in Table 3.2 of part 3 of Annex VI of the CLP Regulation, where a dangerous substance or dangerous preparation is required to have more than one indication of danger in either of the following groups listed in decreasing order of severity, namely—

- (a) explosive, oxidising, extremely flammable and highly flammable; or
- (b) very toxic, toxic, corrosive, harmful and irritant,

only one of the indications of danger with its symbol from each group corresponding to the most severe indication of danger in that group need be shown.

(2) The risk phrases R12 (extremely flammable) and R11 (highly flammable) need not be used if they repeat the indication of danger shown on the label.

## **PART II**

### **PARTICULAR PROVISIONS CONCERNING CERTAIN PREPARATIONS**

#### **A**

#### **SPECIAL PROVISIONS APPLYING TO DANGEROUS PREPARATIONS**

##### **Dangerous preparations to be supplied to the general public**

1.—(1) The label on the packaging of dangerous preparations intended to be supplied to the general public must in addition to the relevant safety advice bear the relevant safety phrase S1, S2, S45 or S46 in accordance with the approved classification and labelling guide.

(2) When the dangerous preparations referred to in sub-paragraph (1) are classified as very toxic, toxic or corrosive and where it is physically impossible to give the information on the package itself, packages containing such preparations must be accompanied by precise and easily understandable instructions for use including, where appropriate, instructions for the destruction of the empty package.

##### **Dangerous preparations intended for use by spraying**

2. The label on the packaging containing dangerous preparations intended to be used for spraying shall bear the safety phrase S23 and safety phrase S38 or S51 assigned in accordance with the approved classification and labelling guide.

##### **Dangerous preparations containing a substance affected by the risk phrase R33 (danger of cumulative effects)**

3. When a dangerous preparation contains at least one substance required to show the risk phrase R33, that phrase must be shown on the label on the packaging of the dangerous preparation when the concentration of that substance is equal to or higher than 1% unless a different value is shown for that substance in Table 3.2 of part 3 of Annex VI of the CLP Regulation.



**Dangerous preparations containing a substance affected by the risk phrase R64 (may cause harm to breast-fed babies)**

4. When a dangerous preparation contains at least one substance required to show the risk phrase R64, that phrase must be shown on the label on the packaging of the dangerous preparation when the concentration of that substance is equal to or higher than 1% unless a different value is shown for that substance in Table 3.2 of part 3 of Annex VI of the CLP Regulation.

**B**

**SPECIAL PROVISIONS APPLYING TO ANY PREPARATION**

**Paints and varnishes containing lead**

1.—(1) The label on the packaging of paints and varnishes containing lead in quantities exceeding 0.15% (expressed as weight of lead out of the total weight of the preparation and determined in accordance with ISO Standard 6503/1984) shall bear the following inscription—

“Contains lead. Should not be used on surfaces that are liable to be chewed or sucked by children.”.

(2) In the case of packages containing less than 125 millilitres of the preparations referred to in sub-paragraph (1), the inscription on the label may be—

“Warning! Contains lead.”.

**Cyanoacrylate based adhesives**

2.—(1) The label on the immediate packaging of glues based on cyanoacrylates shall bear the following inscription—

“Cyanoacrylate.

Danger.

Bonds skin and eyes in seconds.

Keep out of the reach of children.”.

(2) Appropriate safety advice shall accompany the package.

**Preparations containing isocyanates**

3.—(1) The label on the packaging of preparations containing isocyanates (whether as monomers, oligomers, prepolymers etc. or as preparations thereof) shall bear the following inscriptions—

“Contains isocyanates.

See information supplied by the manufacturer.”.

**Certain preparations containing epoxy constituents**

4. The label on the packaging of preparations containing epoxy constituents with an average molecular weight  $\leq 700$  shall bear the following inscription—

“Contains epoxy constituents.

See information supplied by the manufacturer.”.

**Preparations intended to be sold to the general public that contain active chlorine**

5. The label on the packaging of preparations containing more than 1% of active chlorine which are intended to be sold to the general public shall bear the following inscription—

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“Warning! Do not use together with other products. May release dangerous gases (chlorine).”.

#### **Preparations containing cadmium (alloys) intended to be used for brazing or soldering**

6. The label on the packaging of preparations containing cadmium (alloys) intended to be used for brazing or soldering shall bear the following inscriptions—

“Warning! Contains cadmium.

Dangerous fumes are formed during use.

See information supplied by the manufacturer.

Comply with the safety instructions.”.

#### **Preparations not classified as sensitising but containing at least one sensitising substance**

7. The label on the packaging of preparations containing at least one substance classified as sensitising and being present in a concentration  $\geq 0.1\%$  or in a concentration greater than or equal to that specified under a specific note for the substance in Table 3.2 of part 3 of Annex VI of the CLP Regulation must bear the inscription—

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

#### **Liquid preparations containing halogenated hydrocarbons**

8. For liquid preparations which show no flashpoint or a flashpoint higher than  $55^{\circ}\text{C}$  and contain a halogenated hydrocarbon and more than 5% flammable or highly flammable substances, the label on the packaging must bear the following inscription as appropriate—

“Can become highly flammable in use. Or

Can become flammable in use.”.

#### **Preparations containing a substance assigned the risk phrase R67**

9. When a preparation contains one or more substances assigned the risk phrase R67, the label on the packaging of the preparation must bear the following inscription—

“Vapours may cause drowsiness and dizziness,

when the total concentration of such substances present in the preparation is  $\geq 15\%$ , unless:

— the preparation is already classified with phrases R20, R23, R26, R68/20, R39/23 or R39/26, or

— the preparation is in a package not exceeding 125 ml.”

#### **Cement and cement preparations**

10.—(1) The label on the packaging of any cement or cement preparation which would contain, when hydrated, more than 0.0002% soluble chromium (VI) of the total dry weight of the cement but for the use of reducing agents shall be marked with information on the packing date, and on the storage conditions and the storage period appropriate to maintaining the activity of the reducing agent and to preventing the content of soluble chromium (VI) from exceeding 0.0002% of the total dry weight of the cement, unless it is supplied or used for controlled, closed and totally automated processes in which cement and cement-containing preparations are handled solely by machines and in which there is no possibility of contact with the skin.

(2) The label on the packaging of any cement or cement preparation containing more than 0.0002% soluble chromium (VI) of the total dry weight of the cement must bear the inscription—

“Contains chromium (VI). May produce an allergic reaction.”

unless the preparation is already classified and labelled as a sensitiser with risk phrase R43.

## C

### SPECIAL PROVISIONS APPLYING TO CERTAIN OTHER PREPARATIONS

#### **Preparations not intended for the general public**

**11.** The label on the packaging of a preparation of the type specified in Article 31(3) of REACH must bear the following inscription—

“Safety data sheet available for professional user on request.”.

## SCHEDULE 5

Regulation 11

### BRITISH AND INTERNATIONAL STANDARDS RELATING TO CHILD RESISTANT FASTENINGS AND TACTILE WARNING DEVICES

The British Standards and International Standards referred to in regulation 11 are as follows—

“BS EN 28317” means the British Standard Specification for packagings resistant to opening by children, BS EN 28317: 1993 which was published by the British Standards Institution and came into effect on 15 February 1993;

“ISO 8317” means the International Standard ISO 8317 (1 July 1989 edition) relating to “Child-resistant packagings—Requirements for the testing of reclosable packages” adopted by the International Standards Organisation;

“BS 6652” means the British Standard Specification for packagings resistant to opening by children, BS 6652: 1989 which was published by the British Standards Institution and came into effect on 30 June 1989;

“EN 862” means the CEN standard EN 862 (March 1997 edition) relating to “Packaging—Child-resistant packaging—Requirements and testing procedures for non-reclosable packages for non-pharmaceutical products” adopted by the European Committee for Standardisation;

“EN ISO 11683” means the EN ISO Standard 11683 (1997 Edition) relating to “Packaging—Tactile warnings of danger—Requirements.”;

“BS 7501” means the British Standard on the general criteria for the operation of testing laboratories BS 7501: 1989 which was published by the British Standards Institution and came into effect on 31 October 1989;

“EN 45 000” means the European Standards Series 45 000 which sets out the general criteria which laboratories must adhere to in order to obtain accreditation for the certification of child resistant fastenings.

*Status: This is the original version (as it was originally made).*

## SCHEDULE 6

Regulation 17

## AMENDMENTS

<i>Regulations to be amended</i>	<i>Regulations and Schedules to be amended</i>	<i>Amendments to be made</i>
The Pipelines Safety Regulations 1996(2)	Paragraph 10 of Schedule 2	For “regulation 5 of the Chemicals (Hazard Information and Packaging for Supply) Regulations 1994;” substitute “regulation 4 of the Chemicals (Hazard Information and Packaging for Supply) Regulations 2009;”.
The Health and Safety (Enforcing Authority) Regulations 1998(3)	Regulation 2(1)	After the definition of ““construction work” and “contractor”” insert— ““dangerous preparation” has the meaning assigned to it by regulation 2(1) of the Chemicals (Hazard Information and Packaging for Supply) Regulations 2009;” ““dangerous substance” has the meaning assigned to it by regulation 2(1) of the Chemicals (Hazard Information and Packaging for Supply) Regulations 2009;. Omit the definition of “preparation dangerous for supply”. Omit the definition of “substance dangerous for supply”.
	Paragraph 1(b) of Schedule 1	For “substance or preparation dangerous for supply” substitute “dangerous substance or dangerous preparation”.
The Biocidal Products Regulations 2001(4)	Regulation 2(1)	For the definition of “the 2002 Regulations” substitute ““the 2009 Regulations” means the Chemicals (Hazard

(2) S.I. 1996/825, to which there are amendments not relevant to these Regulations.

(3) S.I. 1998/494, to which there are amendments not relevant to these Regulations.

(4) S.I. 2001/880, as amended by S.I. 2007/293. There are other amendments not relevant to these Regulations.

<i>Regulations to be amended</i>	<i>Regulations and Schedules to be amended</i>	<i>Amendments to be made</i>
		Information and Packaging for Supply) Regulations 2009;”.
		Omit the definition of “approved supply list”.
		In the definition of “classified” for “the 2002 Regulations” substitute “the 2009 Regulations”.
		After the definition of “classified” add the definition ““The CLP Regulation” means Regulation (EC) No 1272/2008 of the European Parliament and of the Council 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;”
	Regulation 2(7)(a)	For “Part I of the approved supply list” substitute “Table 3.2 of part 3 of Annex VI of the CLP Regulation;”.
	Regulation 2(7)(b)	For “Part I of the approved supply list” substitute “Table 3.2 of part 3 of Annex VI of the CLP Regulation;”.
	Regulation 2(7)(c)(i)	For “Part I of the approved supply list” substitute “Table 3.2 of part 3 of Annex VI of the CLP Regulation;”.
	Regulation 2(7)(d)(i)	For “Part I of the approved supply list” substitute “Table 3.2 of part 3 of Annex VI of the CLP Regulation;”.
	Paragraph 13 of Schedule 4	For “the 2002 Regulations,” substitute “the 2009 Regulations,” and for “regulation 6 of those Regulations.” substitute “Regulation (EC) No 1907/2006 of the European Parliament and of the Council

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<i>Regulations to be amended</i>	<i>Regulations and Schedules to be amended</i>	<i>Amendments to be made</i>
		concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals.”
	Paragraph 6(a) of Schedule 6	For “Part I of the approved supply list” substitute “Table 3.2 of part 3 of Annex VI of the CLP Regulation;”.
	Paragraph 6(b) of Schedule 6	For “the 2002 Regulations” substitute “the 2009 Regulations;”.
	Paragraph 4 of Schedule 7	For “the 2002 Regulations” substitute “the 2009 Regulations”.
The Control of Lead at Work Regulations 2002 <sup>(5)</sup>	Regulation 2(1)	In the definition of “safety data sheet” for “the Chemicals (Hazard Information and Packaging for Supply) Regulations 2002;” substitute “the Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals.”
The Control of Substances Hazardous to Health Regulations 2002 <sup>(6)</sup>	Regulation 2(1)	In the definition of “the CHIP Regulations” for “the Chemicals (Hazard Information and Packaging for Supply) Regulations 2002;” substitute “the Chemicals (Hazard Information and Packaging for Supply) Regulations 2009;”.
		Omit the definition of “the approved supply list”.
		After the definition of “the CHIP Regulations” add the definition ““The CLP Regulation” means Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances

(5) S.I. 2002/2676.

(6) S.I. 2002/2677.

<i>Regulations to be amended</i>	<i>Regulations and Schedules to be amended</i>	<i>Amendments to be made</i>
		and mixtures amending and repealing Directives <a href="#">67/548/EEC</a> and <a href="#">1999/45/EC</a> , and amending Regulation (EC) No <a href="#">1907/2006</a> .”
		In the definition of “safety data sheet” for “regulation 5 of the CHIP Regulations;” substitute “Regulation (EC) No <a href="#">1907/2006</a> of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals.”
		In the definition of “substances hazardous to health” for “Part I of the approved supply list as dangerous for supply within the meaning of the CHIP Regulations” substitute “Table 3.2 of part 3 of Annex VI of the CLP Regulation;”.
The Dangerous Substances and Explosive Atmospheres Regulations 2002(7)	Regulation 2	In the definition of “the CHIP Regulations” for “the Chemicals (Hazard Information and Packaging for Supply) Regulations 2002;” substitute “the Chemicals (Hazard Information and Packaging for Supply) Regulations 2009;”.
		In the definition of “safety data sheet” for “regulation 5 of the CHIP Regulations;” substitute “Regulation (EC) <a href="#">1907/2006</a> of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals.”
The Control of Asbestos Regulations 2006(8)	Schedule 2, paragraph 1(1)(a)	For “the Chemicals (Hazard Information and Packaging for Supply) Regulations 2002” substitute “the Chemicals (Hazard Information and

(7) [S.I. 2002/2776](#).(8) [S.I. 2006/2739](#).

*Status:* This is the original version (as it was originally made).

<i>Regulations to be amended</i>	<i>Regulations and Schedules to be amended</i>	<i>Amendments to be made</i>
The REACH Enforcement Regulations 2008 <sup>(9)</sup>	Part 1 of Schedule 3, paragraph 1, sub-paragraph (p)(i)	Packaging for Supply) Regulations 2009”. For “the Chemicals (Hazard Information and Packaging for Supply) Regulations 2002;” substitute “the Chemicals (Hazard Information and Packaging for Supply) Regulations 2009;”.

## SCHEDULE 7

Regulation 18

## REVOCATIONS

<i>Regulations revoked</i>	<i>References</i>	<i>Extent of Revocation</i>
The Chemicals (Hazard Information and Packaging for Supply) Regulations 2002	<a href="#">S.I. 2002/1689</a>	The whole Regulations.
The Control of Substances Hazardous to Health (Amendment) Regulations 2004	<a href="#">S.I. 2004/3386</a>	Regulation 3.
The Chemicals (Hazard Information and Packaging for Supply) (Amendment) Regulations 2005	<a href="#">S.I. 2005/2571</a>	The whole Regulations.
The Legislative Reform (Health and Safety Executive) Order 2008	<a href="#">S.I. 2008/960</a>	The reference to the Chemicals (Hazard Information and Packaging for Supply) Regulations 2002 in Schedule 3.
The Export and Import of Dangerous Chemicals Regulations 2008	<a href="#">S.I. 2008/2108</a>	Regulation 5 paragraphs (2) and (4).
The Chemicals (Hazard Information and Packaging for Supply) (Amendment) Regulations 2008	<a href="#">S.I. 2008/2337</a>	The whole Regulations.
The REACH Enforcement Regulations 2008	<a href="#">S.I. 2008/2852</a>	Paragraphs 1 to 4 of Part 3 of Schedule 10.

<sup>(9)</sup> [S.I. 2008/2852](#).



