

## SCHEDULE 3

Regulation 4(7)

### PROVISIONS FOR CLASSIFYING DANGEROUS PREPARATIONS

#### PART I

#### 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—

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

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- (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—
- (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>	
	$\leq 2.5\%$	$\pm 30\%$
> 2.5	$\leq 10\%$	$\pm 20\%$
> 10	$\leq 25\%$	$\pm 10\%$
> 25	$\leq 100\%$	$\pm 5\%$

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
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		

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Category of danger of the substance	Concentration to take into consideration for	
	<i>gaseous preparations</i> % vol/vol	<i>other preparations</i> % w/w
Dangerous for the environment N		≥ 0.1
Dangerous for the environment ozone	≥ 0.1	≥ 0.1
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.

#### **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; and
- (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—

$P_{P+}$  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.

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### 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—

- (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, i.e.—

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

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 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;
- (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

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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, i.e.—

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

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 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, i.e.—

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

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 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, i.e.—

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

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,

$L_{Xi,R41}$  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 risk phrase R38—

- (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 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, i.e.—

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

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 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, i.e.—

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

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, i.e.—

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

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 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 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.

(2) The following preparations shall be classified as sensitising by inhalation and assigned the symbol “Xn”, the indication of danger “harmful” and risk phrase R42—

Preparations containing one or more substances classified as sensitising and to which is assigned the 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 substance 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 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 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

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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 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.

**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>
$\leq 2.5\%$	$\pm 30\%$
$> 2.5$	$\pm 20\%$
$> 10$	$\pm 10\%$
$> 25$	$\pm 5\%$

- (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.

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(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-R53)—

- (a) preparations containing one or more substances classified as dangerous for the environment and to which is assigned risk phrases R50-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 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-R53 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-R53) 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-R53 or R51-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 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-R53 or R51-R53 in lower individual concentrations than the limits specified under paragraph (a) if—

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

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,

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

$L_{N,R51-53}$  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-R53) 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-R53 or R51-R53 or R52-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 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-R53 or R51-R53 or R52-R53 in lower individual concentrations than the limits specified under paragraph (a) if—

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

where—

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

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

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

$L_{R52-53}$  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)—

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- (a) preparations containing one or more substances classified as dangerous for the environment and 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 for 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 for 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 for the environment and to which is assigned risk phrases R50-R53 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
  - (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 for 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 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 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 for 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 for the environment and to which is assigned risk phrases R50-R53, R51-R53 or R52-R53 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—

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

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

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

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$L_{R\ 53}$  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 shall 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;
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 I 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 $\geq 7\%$	$1\% \leq \text{concentration} < 7\%$	$0.1\% \leq \text{concentration} < 1\%$
T with R23, R24, R25		concentration $\geq 25\%$	$3\% \leq \text{concentration} < 25\%$
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—

- the label shall include one or more of the above mentioned R phrases according to the classification used,
- 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</i>	<i>Classification of the preparation</i>		
	<i>T+</i>	<i>T</i>	<i>Xn</i>
T+ with R26, R27, R28	concentration $\geq 1\%$	$0.2\% \leq \text{concentration} < 1\%$	$0.02\% \leq \text{concentration} < 0.2\%$
T with R23, R24, R25		concentration $\geq 5\%$	$0.5\% \leq \text{concentration} < 5\%$
Xn with R20, R21, R22			concentration $\geq 5\%$

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

- the label shall include one or more of the above mentioned R phrases according to the classification used,
- 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**

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### 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**

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

(\*) In order to indicate the route of administration/exposure the combined R phrases listed in Annex III of the 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 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**

Classification of the substance (gas)	Classification of the preparation		
	T+	T	Xn
T+ with R39/ route of exposure	concentration $\geq$ 1% R39 <sup>(*)</sup> obligatory	0.2% $\leq$ concentration < 1% R39 <sup>(*)</sup> obligatory	0.02% $\leq$ concentration < 0.2% R68 <sup>(*)</sup> (†) obligatory
T with R39/ route of exposure		concentration $\geq$ 5% R39 <sup>(*)</sup> obligatory	0.5% $\leq$ concentration < 5% R68 <sup>(*)</sup> (†) obligatory
Xn with R68/ route of exposure			concentration $\geq$ 5% R68 <sup>(*)</sup> (†) 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 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>Xn</i>
T with R48/ route of exposure	concentration $\geq$ 10% R48 <sup>(*)</sup> obligatory	$1\% \leq$ concentration $<$ 10% R48 <sup>(*)</sup> obligatory
Xn with R48/ route of exposure		concentration $\geq$ 10% R48 <sup>(*)</sup> 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**

<i>Classification of the substance (gas)</i>	<i>Classification of the preparation</i>	
	<i>T</i>	<i>Xn</i>
T with R48/ route of exposure	concentration $\geq$ 5% R48 <sup>(*)</sup> obligatory	$0.5\% \leq$ concentration $<$ 5% R48 <sup>(*)</sup> obligatory
Xn with R48/ route of exposure		concentration $\geq$ 5% R48 <sup>(*)</sup> 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 effect (R36, R37, R38, R41), the individual concentration limits specified in Table IV determine, when appropriate, the classification of the preparation.

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**Table IV**

<i>Classification of the substance</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 $\geq 10\%$ R35 obligatory	$5\% \leq$ concentration $< 10\%$ R34 obligatory	$5\%^{(*)}$	$1\% \leq$ concentration $< 5\%$ R36/38 obligatory
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 (e.g. 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 are 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 (e.g. pH of the preparation) are not taken into account. Therefore, in classifying for corrosivity, consider the advice given in approved classification and labelling guide regarding classification as corrosive and paragraph 4(4) (b) and (c) of Part I of this Schedule.

**Sensitising effects**

5

*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.

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**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 gaseous 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 that 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 (unless already assigned R45)
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 (unless already assigned R46)
substances “toxic for reproduction” of category 1 or 2 with R60 (fertility)	concentration $\geq$ 0.5% toxic for reproduction (fertility) R60 obligatory	
substances “toxic for reproduction” of category 3 with R62 (fertility)		concentration $\geq$ 5% toxic for reproduction (fertility) R62 obligatory (unless already assigned R60)
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 (unless already assigned R61)
<b>a</b>	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.	
<b>b</b>	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:

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

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 gaseous 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)
<b>a</b>	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.	
<b>b</b>	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.	

<i>Classification of the substance (gas)</i>	<i>Classification of the gaseous preparation</i>	
	<i>Categories 1 and 2</i>	<i>Category 3</i>
		R63 obligatory ( <i>unless already assigned R61</i> )
<b>a</b>	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.	
<b>b</b>	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.	

### 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, R51-53	R52-53
N, R50-53	see Table 1b	see Table 1b	see Table 1b
N, R51-53		$C_n \geq 25\%$	$2.5\% \leq C_n < 25\%$
R52-53			$C_n \geq 25\%$

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 substances very toxic to the aquatic environment*

<i>LC<sub>50</sub> or EC<sub>50</sub> value ("L(E)C<sub>50</sub>") of substance classified as N, R50-53 (mg/l)</i>	<i>Classification of the preparation</i>		
	N, R50-53	N, R51-53	R52-53
$0.1 < L(E)C_{50} \leq 1$	$C_n \geq 25\%$	$2.5\% \leq C_n < 25\%$	$0.25\% \leq C_n < 2.5\%$
$0.01 < L(E)C_{50} \leq 0.1$	$C_n \geq 2.5\%$	$0.25\% \leq C_n < 2.5\%$	$0.025\% \leq C_n < 0.25\%$

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

LC <sub>50</sub> or EC <sub>50</sub> value ("L(E)C <sub>50</sub> ") of substance classified as N, R50-53 (mg/l)	Classification of the preparation		
	N, R50-53	N, R51-53	R52-53
0.001 < L(E)C <sub>50</sub> ≤ 0.01	C <sub>n</sub> ≥ 0.25%	0.025% ≤ C <sub>n</sub> < 0.25%	0.0025% ≤ C <sub>n</sub> < 0.025%
0.0001 < L(E)C <sub>50</sub> ≤ 0.001	C <sub>n</sub> ≥ 0.025%	0.0025% ≤ C <sub>n</sub> < 0.025%	0.00025% ≤ C <sub>n</sub> < 0.0025%
0.00001 < L(E)C <sub>50</sub> ≤ 0.0001	C <sub>n</sub> ≥ 0.0025%	0.00025% ≤ C <sub>n</sub> < 0.0025%	0.000025% ≤ C <sub>n</sub> < 0.00025%

For preparations containing substances with a lower LC<sub>50</sub> or EC<sub>50</sub> value than 0.00001 mg/l, the corresponding concentration limits are calculated accordingly (in factor 10 intervals).

**Table 2**

*Acute aquatic toxicity*

LC <sub>50</sub> or EC <sub>50</sub> value ("L(E)C <sub>50</sub> ") of substance classified either as N, R50 or as N, R50-53 (mg/l)	Classification of the preparation N, R50
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 LC<sub>50</sub> or EC<sub>50</sub> value than 0.00001 mg/l, the corresponding concentration limits are calculated accordingly (in factor 10 intervals).

**Table 3**

*Aquatic toxicity*

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

**Table 4**

*Long-term adverse effects*

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

<i>Classification of the substance</i>	<i>Classification of the preparation R53</i>
N, R51-53	$C_n \geq 25\%$
R52-53	$C_n \geq 25\%$

### **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 the preparation N, R59</i>
N with R59	$C_n \geq 0.1\%$