

Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (repealed)

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ANNEX I

METHODS FOR THE EVALUATION OF PHYSICO-CHEMICAL PROPERTIES OF PREPARATIONS IN ACCORDANCE WITH ARTICLE 5

PART A

Exemptions to test methods of Annex V — Part A to Directive 67/548/EEC

See 2.2.5 of Annex VI to Directive 67/548/EEC.

PART B

Alternative calculation methods

- B.1. Non-gaseous preparations
 - 1. Method for the determination of oxidising properties of preparations containing organic peroxides.
See point 2.2.2.1 of Annex VI to Directive 67/548/EEC.
- B.2. Gaseous preparations
 - 1. Method for the determination of oxidising properties
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 - 2. Method for the determination of flammability properties
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ANNEX II

METHODS FOR THE EVALUATION OF HEALTH HAZARDS OF PREPARATIONS IN ACCORDANCE WITH ARTICLE 6

Introduction

An assessment must be made for all the health effects corresponding to the health effects of substances contained in a preparation. This conventional method described in Parts A and B of this Annex is a calculation method which is applicable to all preparations and which takes into consideration all the health hazards of substances contained in the preparation. 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 health effects of a preparation are to be assessed in accordance with Article 6(1)(a) by the conventional method described in parts A and B of this Annex using individual concentration limits.

- (a) where the dangerous substances listed in Annex I to Directive 67/548/EEC are assigned concentration limits necessary for the application of the method of assessment described in part A of this Annex, these concentration limits must be used;
- (b) where the dangerous substances do not appear in Annex I to Directive 67/548/EEC or appear there without the concentration limits necessary for the application of the method of evaluation described in part A of this Annex, the concentration limits must be assigned in accordance with the specifications in part B of this Annex.

The procedure for classification is set out in Part A of this Annex.

The classification of the substance(s) and the resulting classification of the preparation are expressed:

- either by a symbol and one or more risk phrases, or
- by categories (category 1, category 2 or category 3) also assigned risk phrases when substances and preparations 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.

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

Where they are not given in Annex I to Directive 67/548/EEC, the concentration limits to be taken into account for the application of this conventional method are those set out in Part B of this Annex.

PART A

Procedure for evaluation of health hazards

The evaluation proceeds stepwise as follows:

1. The following preparations are to be classified as very toxic:
 - 1.1. owing to their acute lethal effects and assigned the symbol 'T⁺', the indication of danger 'very toxic' and the risk phrases R26, R27 or R28;
 - 1.1.1. preparations containing one or more substances classified as very toxic that produce such effects, in individual concentrations equal to or greater than:
 - (a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or
 - (b) the concentration specified at point 1 in Part B of this Annex (Table I and I A) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

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- 1.1.2. preparations containing more than one substance classified as very toxic in lower individual concentrations than the limits specified under 1.1.1(a) or (b) if:

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

where:

P_{T+} = is the percentage by weight or by volume 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;

- 1.2. 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 at least one dangerous substance that produces such effects in individual concentrations equal to or greater than:

- (a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or
- (b) the concentration specified at point 2 in Part B of this Annex (Table II and II A) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits.

2. The following preparations shall be classified as toxic:

- 2.1. owing to their acute lethal effects and assigned the symbol 'T', the indication of danger 'toxic' and the risk phrases R23, R24 or R25;

2.1.1. preparations containing one or more substances classified as very toxic or toxic that produce such effects in individual concentrations equal to or greater than:

- (a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or
- (b) the concentration specified at point 1 in Part B of this Annex (Table I and I A) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

2.1.2. preparations containing more than one substance classified as very toxic or toxic in lower individual concentrations than the limits specified under 2.1.1(a) or (b) if:

$$\sum(P_{T+}L_{T+} + P_T L_T) \geq 1$$

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;

- 2.2. 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 at least one dangerous substance classified as very toxic or toxic that produce such effects in individual concentrations equal to or greater than:

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- (a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or
 - (b) the concentration specified at point 2 in Part B of this Annex (Table II and II A) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;
- 2.3. 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 at least one dangerous substance that produces such effects in individual concentrations equal to or greater than:

- (a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or
- (b) the concentration specified at point 3 in Part B of this Annex (Table III and III A) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits.

3. The following preparations shall be classified as harmful:

3.1. owing to their acute lethal effects and assigned the symbol 'X_n' and the indication of danger 'harmful' and the risk phrases R20, R21 or R22;

3.1.1. preparations containing one or more substances classified as very toxic, toxic or harmful and that produce such effects in individual concentrations equal to or greater than:

- (a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or
- (b) the concentration specified at point 1 in Part B of this Annex (Table I and I A) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits.

3.1.2. preparations containing more than one substance classified as very toxic, toxic or harmful in lower individual concentrations than the limits specified under 3.1.1(a) or (b) if:

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

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_{X_n} = is the percentage by weight or by volume of each harmful substance in the preparation,
- L_{X_n} = is the respective harmful limit specified for each very toxic, toxic or harmful substance, expressed as percentage by weight or by volume;

3.2. owing to their acute effects to the lungs if swallowed and assigned the symbol 'X_n', and the indication of danger 'harmful' and the risk phrase R65.

Preparations classified as harmful according to the criteria specified in paragraph 3.2.3 of Annex VI to Directive 67/548/EEC. In applying the conventional method according to the above paragraph 3.1 no account shall be taken of the classification of a substance as R65;

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- 3.3. owing to their non-lethal irreversible effects after a single exposure and assigned the symbol 'X_n', the indication of danger 'harmful' and the risk phrase [F1R68]/route of exposure.

Preparations containing at least one dangerous substance classified as very toxic, toxic or harmful that produces such effects in individual concentrations equal to or greater than:

- (a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or
- (b) the concentration specified at point 2 in Part B of this Annex (Table II and II A) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

Textual Amendments

F1 Substituted by [Commission Directive 2001/60/EC of 7 August 2001 adapting to technical progress Directive 1999/45/EC of the European Parliament and of the Council concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations \(Text with EEA relevance\).](#)

- 3.4. owing to their long-term effects and assigned the symbol 'X_n', the indication of danger 'harmful' and the risk phrase R48/route of exposure.

Preparations containing at least one dangerous substance classified as toxic or harmful that produces such effects in individual concentrations equal to or greater than:

- (a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or
- (b) the concentration specified at point 3 in Part B of this Annex (Table III and III A) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits.

4. The following preparations are to be classified as corrosive

- 4.1. and assigned the symbol 'C', the indication of danger 'corrosive' and the risk phrase R35;

4.1.1. preparations containing one or more substances classified as corrosive to which is assigned the phrase R35 in individual concentrations equal to or greater than:

- (a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or
- (b) the concentration specified at point 4 in Part B of this Annex (Table IV and IV A) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits.

4.1.2. preparations containing more than one substance classified as corrosive to which is assigned phrase R35 in lower individual concentrations than the limits specified under 4.1.1(a) or (b) if:

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

where:

- $P_{C, R35}$ = is the percentage by weight or by volume of each corrosive substance which is assigned phrase R35 in the preparation,
- $L_{C, R35}$ = is the corrosive limit R35 specified for each corrosive substance to which is assigned phrase R35, expressed as a percentage by weight or by volume;

4.2. and assigned the symbol 'C', the indication of danger 'corrosive' and the risk phrase R34;

4.2.1. preparations containing one or more substances classified as corrosive to which is assigned the phrase R35 or R34 in individual concentrations equal to or greater than:

- (a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or
- (b) the concentration specified at point 4 in Part B of this Annex (Table IV and IV A) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

4.2.2. preparations containing more than one of the substances classified as corrosive to which is assigned the phrase R35 or R34 in lower individual concentrations than the limits specified under 4.2.1(a) or (b) if:

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

where:

- $P_{C, R35}$ = is the percentage by weight or by volume of each corrosive substance to which is assigned phrase R35 in the preparation,
- $P_{C, R34}$ = is the percentage by weight or by volume of each corrosive substance to which is assigned phrase R34 in the preparation,
- $L_{C, R34}$ = is the respective corrosive limit R34 specified for each corrosive substance to which is assigned phrase R35 or R34, expressed as a percentage by weight or by volume.

5. The following preparations are to be classified as irritants:

5.1. liable to cause serious eye damage and assigned the symbol 'Xi', the indication of danger 'irritant' and the risk phrase R41;

5.1.1. preparations containing one or more substances classified as irritant to which is assigned phrase R41 in individual concentrations equal to or greater than:

- (a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or
- (b) the concentration specified at point 4 in Part B of this Annex (Table IV and IV A) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

5.1.2. preparations containing more than one of the substances classified as irritant and to which is assigned phrase R41, or classified as corrosive and to which is assigned phrase R35 or R34, in lower individual concentrations than the limits specified under 5.1.1(a) or (b) if:

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

where:

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- $P_{C, R35}$ = is the percentage by weight or by volume of each corrosive substance to which is assigned phrase R35 in the preparation,
- $P_{C, R34}$ = is the percentage by weight or by volume of each corrosive substance to which is assigned phrase R34 in the preparation,
- $P_{Xi, R41}$ = is the percentage by weight or by volume of each irritant substance to which is assigned phrase R41 in the preparation,
- $L_{Xi, R41}$ = is the respective irritant limit R41 specified for each corrosive substance to which is assigned phrase R35 or R34 or irritant substance to which is assigned phrase R41, expressed as percentage by weight or by volume;

5.2. irritant to eyes and assigned the symbol 'X₁', the indication of danger 'irritant' and the risk phrase R36;

5.2.1. preparations containing one or more substances classified as corrosive to which is assigned phrase R35 or R34 or as irritant and to which is assigned phrase R41 or R36 in individual concentrations equal to or greater than:

- (a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or
- (b) the concentration specified at point 4 in Part B of this Annex (Table IV and IV A) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

5.2.2. preparations containing more than one substance classified as irritant to which is assigned phrase R41 or R36, or as corrosive and to which is assigned phrase R35 or R34, in lower individual concentrations than the limits specified under 5.2.1(a) or (b) if:

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

where:

- $P_{C, R35}$ = is the percentage by weight or by volume of each corrosive substance to which is assigned phrase R35 in the preparation,
- $P_{C, R34}$ = is the percentage by weight or by volume of each corrosive substance to which is assigned phrase R34 in the preparation,
- $P_{Xi, R41}$ = is the percentage by weight or by volume of each irritant substance to which is assigned phrase R41 in the preparation,
- $P_{Xi, R36}$ = is the percentage by weight or by volume of each irritant substance to which is assigned phrase R36 in the preparation,
- $L_{Xi, R36}$ = is the respective irritant limit R36 specified for each corrosive substance to which is assigned phrase R35 or R34 or irritant substance to which is assigned phrase R41, or R36 expressed as percentage by weight or by volume;

5.3. irritant to skin and assigned the symbol 'X₂', the indication of danger 'irritant' and the risk phrase R38;

5.3.1. preparations containing one or more substances classified as irritant and to which is assigned phrase R38 or as corrosive and to which is assigned phrase R35 or R34 in individual concentrations equal to or greater than:

- (a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

- (b) the concentration specified at point 4 in Part B of this Annex (Table IV and IV A) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

- 5.3.2. preparations containing more than one of the substances classified as irritant and to which is assigned phrase R38, or as corrosive and to which is assigned phrase R35 or R34 in lower individual concentrations than the limits specified under 5.3.1(a) or (b) if:

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

where:

- $P_{C, R35}$ = is the percentage by weight or by volume of each corrosive substance to which is assigned phrase R35 in the preparation,
 $P_{C, R34}$ = is the percentage by weight or by volume of each corrosive substance to which is assigned phrase R34 in the preparation,
 $P_{Xi, R38}$ = is the percentage by weight or by volume of each irritant substance to which is assigned phrase R38 in the preparation,
 $L_{Xi, R38}$ = is the respective irritant limit R38 specified for each corrosive substance to which is assigned phrase R35 or R34 or irritant substance to which is assigned phrase R38, expressed as percentage by weight or by volume;

- 5.4. irritant to respiratory system and assigned the symbol 'X_i', the indication of danger 'irritant' and the risk phrase R37;

- 5.4.1. preparations containing one or more substances classified as irritant and to which is assigned phrase R37 in individual concentrations equal to or greater than:

- (a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or
 (b) the concentration specified at point 4 in Part B of this Annex (Table IV and IV A) where the substance or the substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

- 5.4.2. preparations containing more than one substance classified as irritant and to which is assigned phrase R37 in lower individual concentrations than the limits specified under 5.4.1(a) or (b) if:

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

where:

- $P_{Xi, R37}$ = is the percentage by weight or by volume of each irritant substance to which is assigned phrase R37 in the preparation,
 $L_{Xi, R37}$ = is the irritant limit R37 specified for each irritant substance to which is assigned phrase R37, expressed as percentage by weight or by volume;

- 5.4.3. gaseous preparations containing more than one of the substances classified as irritant to which is assigned phrase R37 or as corrosive and to which is assigned phrase R35 or R34 in lower individual concentrations than the limits specified under 5.4.1(a) or (b) if:

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

where:

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

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- P_{C, R34} = is the percentage by volume of each corrosive substance to which is assigned phrase R34 in the preparation,
- P_{Xi, R37} = is the percentage by volume of each irritant substance to which is assigned phrase R37 in the preparation,
- L_{Xi, R37} = is the respective irritant limit R37 specified for each gaseous corrosive substance to which is assigned phrase R35 or R34 or gaseous irritant substance to which is assigned phrase R37, expressed as percentage by weight or by volume.

6. The following preparations are to be classified as sensitising:

- 6.1. by skin contact and assigned the symbol 'X_i', the indication of danger 'irritant' and the risk phrase R43.

Preparations containing at least one substance classified as sensitising and to which is assigned phrase R43 that produces such effects in individual concentrations equal to or greater than:

- (a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or
- (b) the concentration specified at point 5 in Part B of this Annex (Table V and V A) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

- 6.2. by inhalation and assigned the symbol 'X_n', the indication of danger 'harmful' and the risk phrase R42.

Preparations containing at least one substance classified as sensitising to which is assigned phrase R42 that produces such effects in individual concentrations equal to or greater than:

- (a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or
- (b) the concentration specified at point 5 in Part B of this Annex (Table V and V A) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits.

7. The following preparations are to be classified as carcinogenic:

- 7.1. those of category 1 or 2 which are assigned the symbol 'T' and the phrase R45 or R49.

Preparations containing at least one substance producing such effects, classified as carcinogenic and to which is assigned phrase R45 or R49 which denotes carcinogenic substances in category 1 and category 2, in individual concentrations equal to or greater than:

- (a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or
- (b) the concentration specified at point 6 in Part B of this Annex (Table VI and VI A) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

- 7.2. those of category 3 which are assigned the symbol 'X_n' and the phrase R40.

Preparations containing at least one substance producing such effects classified as carcinogenic and to which is assigned phrase R40 which denotes carcinogenic substances in category 3, in individual concentrations equal to or greater than:

- (a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or
- (b) the concentration specified at point 6 in Part B of this Annex (Table VI and VI A) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits.

8. The following preparations are to be classified as mutagenic:

- 8.1. those of category 1 or 2 which are assigned the symbol 'T' and the phrase R46.

Preparations containing at least one substance producing such effects, classified as mutagenic and to which is assigned phrase R46 which denotes mutagenic substances in category 1 and category 2, in individual concentrations equal to or greater than:

- (a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or
- (b) the concentration specified at point 6 in Part B of this Annex (Table VI and VI A) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

- 8.2. those of category 3 which are assigned the symbol 'X_n' and the phrase [F¹R68].

Preparations containing at least one substance, producing such effects, classified as mutagenic and to which is assigned phrase R68] which denotes mutagenic substances in category 3, in individual concentrations equal to or greater than:

- (a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or
- (b) the concentration specified at point 6 in Part B of this Annex (Table VI and VI A) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits.

9. The following preparations are to be classified as toxic for reproduction:

- 9.1. those of category 1 or 2 which are assigned the symbol 'T' and the phrase R60 (fertility).

Preparations containing at least one substance producing such effects, classified as toxic for reproduction and to which is assigned phrase R60 which denotes substances toxic for reproduction of category 1 and category 2, in individual concentrations equal to or greater than:

- (a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or
- (b) the concentration specified at point 6 in Part B of this Annex (Table VI and VI A) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

- 9.2. those of category 3 which are assigned the symbol 'X_n' and the phrase R62 (fertility).

Preparations containing at least one substance producing such effects, classified as toxic for reproduction and to which is assigned phrase R62 which denotes substances toxic for reproduction of category 3, in individual concentrations equal to or greater than:

- (a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

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- (b) the concentration specified at point 6 in Part B of this Annex (Table VI and VI A) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;
- 9.3. those of category 1 or 2 which are assigned the symbol 'T' and the phrase R61 (development).

Preparations containing at least one substance producing such effects, classified as toxic for reproduction and to which is assigned phrase R61 which denotes substances toxic for reproduction of category 1 and category 2, in individual concentrations equal to or greater than:

- (a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or
- (b) the concentration specified at point 6 in Part B of this Annex (Table VI and VI A) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;
- 9.4. those of category 3 which are assigned the symbol 'X_n' and the phrase R63 (development).

Preparations containing at least one substance producing such effects, classified as toxic for reproduction and to which is assigned phrase R63 which denotes substances toxic for reproduction of category 3, in individual concentrations equal to or greater than:

- (a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or
- (b) the concentration specified at point 6 in Part B of this Annex (Table VI and VI A) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits.

PART B

Concentration limits to be used in evaluation of health hazards

For each health effect, the first table (Tables I to VI) sets out the concentration limits (expressed as a weight/weight percentage) to be used for non-gaseous preparations and the second table (Tables I A to VI A) sets out the concentration limits (expressed as a volume/volume percentage) to be used for gaseous preparations. These concentration limits are used in the absence of specific concentration limits for the substance under consideration in Annex I to Directive 67/548/EEC.

1. Acute lethal effects
- 1.1. Non-gaseous preparations

The concentration limits fixed in Table I, expressed as a weight/weight percentage, determine the classification of the preparation in relation to the individual concentration of the substance(s) present whose classification is also shown.

Table I

Classification of the substance	Classification of the preparation		
	T ⁺	T	X _n

Table I

T ⁺ with R26, R27, R28	concentration $\geq 7\%$	$1\% \leq$ concentration $< 7\%$	$0,1\% \leq$ concentration $< 1\%$
T with R23, R24, R25		concentration $\geq 25\%$	$3\% \leq$ concentration $< 25\%$
X _n with R20, R21, R22			concentration $\geq 25\%$

The R phrases denoting risk are to be assigned to the preparation in accordance with the following criteria:

- the label shall include one or more of the abovementioned 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.

1.2. Gaseous preparations

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

Table I A

Classification of the substance(gas)	Classification of the gaseous preparation		
	T ⁺	T	X _n
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 _n 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 abovementioned 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.

2. Non-lethal irreversible effects after a single exposure

2.1. Non-gaseous preparations

For substances that produce non-lethal irreversible effects after a single exposure (R39/route of exposure, ^{F1}R68/route of exposure), the individual concentration limits specified in Table II, expressed as a weight/weight percentage, determine, when appropriate, the classification of the preparation.

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Table II

Classification of the substance	Classification of the preparation		
	T ⁺	T	X _n
T ⁺ with R39/route of exposure	concentration ≥ 10 % R39 ^a obligatory	1 % ≤ concentration < 10 % R39 ^a obligatory	0,1 % ≤ concentration < 1 % R68 ^a obligatory
T with R39/route of exposure		concentration ≥ 10 % R39 ^a obligatory	1 % ≤ concentration < 10 % R68 ^a obligatory
X _n with R68/route of exposure			concentration ≥ 10 % R68] ^a obligatory

a In order to indicate the route of administration/exposure (route of exposure) the combined R phrases listed under points 3.2.1, 3.2.2 and 3.2.3 of the labelling guide (Annex VI to Directive 67/548/EEC) are to be used.

2.2. Gaseous preparations

For gases that produce non-lethal irreversible effects after a single exposure (R39/route of exposure, [F¹R68/route of exposure), the individual concentration limits specified in Table II A, expressed as a volume/volume percentage, determine, when appropriate, the classification of the preparation.

Table II A

Classification of the substance (gas)	Classification of the gaseous preparation		
	T ⁺	T	X _n
T ⁺ with R39/route of exposure	concentration ≥ 1 % R39 ^a obligatory	0,2 % ≤ concentration < 1 % R39 ^a obligatory	0,02 % ≤ concentration < 0,2 % R68 ^a obligatory
T with R39/route of exposure		concentration ≥ 5 % R39 ^a obligatory	0,5 % ≤ concentration < 5 % R68 ^a obligatory
X _n with R68/route of exposure			concentration ≥ 5 % R68] ^a obligatory

a In order to indicate the route of administration/exposure (route of exposure) the combined R phrases listed under points 3.2.1, 3.2.2 and 3.2.3 of the labelling guide (Annex VI to Directive 67/548/EEC) are to be used.

3. Severe effects after repeated or prolonged exposure

3.1. Non-gaseous preparations

For substances that produce severe effects after repeated or prolonged exposure (R 48/route of exposure), the individual concentration limits specified in Table III, expressed as a weight/weight percentage, determine, when appropriate, the classification of the preparation.

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Table III

Classification of the substance	Classification of the preparation	
	T	X _n
T with R48/route of exposure	concentration ≥ 10 % R48 ^a obligatory	1 % ≤ concentration < 10 % R48 ^a obligatory
X _n with R48/route of exposure		concentration ≥ 10 % R48 ^a obligatory

a In order to indicate the route of administration/exposure (route of exposure) the combined R phrases listed under points 3.2.1, 3.2.2 and 3.2.3 of the labelling guide (Annex VI to Directive 67/548/EEC) are to be used.

3.2. Gaseous preparations

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

Table III A

Classification of the substance(gas)	Classification of the gaseous preparation	
	T	X _n
T with R48/route of exposure	concentration ≥ 5 % R48 ^a obligatory	0,5 % ≤ concentration < 5 % R48 ^a obligatory
X _n with R48/route of exposure		concentration ≥ 5 % R48 ^a obligatory

a In order to indicate the route of administration/exposure (route of exposure) the combined R phrases listed under points 3.2.1, 3.2.2 and 3.2.3 of the labelling guide (Annex VI to Directive 67/548/EEC) are to be used.

4. Corrosive and irritant effects including serious damage to the eye

4.1. Non-gaseous preparations

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

Table IV

Classification of the substance	Classification of the preparation			
	C with R35	C with R34	X _i with R41	X _i with R36, R37, R38
a	According to the labelling guide (Annex VI to Directive 67/548/EEC), corrosive substances assigned risk phrases R35 or R34 must also be considered as being assigned phrase R41. 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 with R41 or irritant with R36.			

[²NB:

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 paragraph 3.2.5 of Annex VI to Directive 67/548/EEC and in the second and third indents of Article 6(3), of this Directive.]

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Table IV

C with R35	concentration ≥ 10 % R35 obligatory	5 % ≤ concentration < 10 % R34 obligatory	5 % ^a	1 % ≤ concentration < 5 % R36/38 obligatory
C with R34		concentration ≥ 10 % R34 obligatory	10 % ^a	5 % ≤ concentration < 10 % R36/38 obligatory
X _i with R41			concentration ≥ 10 % R41 obligatory	5 % ≤ concentration < 10 % R36 obligatory
X _i with R36, R37, R38				concentration ≥ 20 % R36, R37, R38 are obligatory in the light of the concentration present if they apply to the substances under consideration

a According to the labelling guide (Annex VI to Directive 67/548/EEC), corrosive substances assigned risk phrases R35 or R34 must also be considered as being assigned phrase R41. 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 with R41 or irritant with R36.

[²NB:

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 paragraph 3.2.5 of Annex VI to Directive 67/548/EEC and in the second and third indents of Article 6(3), of this Directive.]

4.2. Gaseous preparations

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

Table IV A

Classification of the substance(gas)	Classification of the gaseous preparation			
	C with R35	C with R34	X _i with R41	X _i with R36, R37, R38
C with R35	concentration ≥ 1 % R35 obligatory	0,2 % ≤ concentration < 1 % R34 obligatory	0,2% ^a	0,02 % ≤ concentration < 0,2 % R36/37/38 obligatory
C with R34		concentration ≥ 5 % R34 obligatory	5 % ^a	0,5 % ≤ concentration < 5 % R36/37/38 obligatory
X _i with R41			concentration ≥ 5 % R41 obligatory	0,5 % ≤ concentration < 5 % R36 obligatory
X _i with R36, R37, R38				concentration ≥ 5 % R36, R37, R38 obligatory as appropriate

^a According to the labelling guide (Annex VI to Directive 67/548/EEC), corrosive substances assigned risk phrases R35 or R34 must also be considered as being assigned phrase R41. 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 with R41 or irritant with R36.

[²NB:

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 paragraph 3.2.5 of Annex VI to Directive 67/548/EEC and in the second and third indents of Article 6(3), of this Directive.]

5. Sensitising effects

5.1. Non-gaseous preparations

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

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

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

Table V

Classification of the substance	Classification of the preparation	
	Sensitising with R42	Sensitising with R43
Sensitising with R42	concentration ≥ 1 %	

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Table V

	R42 obligatory	
Sensitising with R43		concentration \geq 1 % R43 obligatory

5.2. Gaseous preparations

Gaseous preparations that produce such effects are classified as sensitising and assigned:

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

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

Table V A

Classification of the substance(gas)	Classification of the gaseous preparation	
	Sensitising with R42	Sensitising with R43
Sensitising with R42	concentration \geq 0,2 % R42 obligatory	
Sensitising with R43		concentration \geq 0,2 % R43 obligatory

6. Carcinogenic/mutagenic/toxic effects for reproduction

6.1. Non-gaseous preparations

For substances which produce such effects, the concentration limits laid down in Table VI, expressed as a weight/weight 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:	X_n ; R40
Mutagenic categories 1 and 2:	T; R46
Mutagenic category 3:	X_n ; [F ¹ 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:	X_n ; R62
Toxic for reproduction development category 3:	X_n ; R63

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[^{F3}TABLE VI

Classification of the substance	Classification of the preparation	
	Categories 1 and 2	Category 3
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^a</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	
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>)

a 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.]

Textual Amendments

F3 Substituted by [Commission Directive 2006/8/EC of 23 January 2006 amending, for the purposes of their adaptation to technical progress, Annexes II, III and V to Directive 1999/45/EC of the European Parliament and of the Council concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations \(Text with EEA relevance\).](#)

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6.2. Gaseous preparations

For gases which produce such effects, the concentration limits laid down in Table VI A, 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:	X _n ; R40
Mutagenic categories 1 and 2:	T; R46
Mutagenic category 3:	X _n ; [F ¹ 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:	X _n ; R62
Toxic for reproduction development category 3:	X _n ; R63

[^{F3}TABLE VI A

Classification of the substance	Classification of the preparation	
	Categories 1 and 2	Category 3
Carcinogenic substances of category 1 or 2 with R45 or R49	Concentration ≥ 0,1 % carcinogenic R45, R49 obligatory as appropriate	
Carcinogenic substances of category 3 with R40		Concentration ≥ 1 % carcinogenic R40 obligatory (<i>unless already assigned R45^a</i>)
Mutagenic substances of category 1 or 2 with R46	Concentration ≥ 0,1 % mutagenic R46 obligatory	
Mutagenic substances of category 3 with R68		Concentration ≥ 1 % mutagenic R68 obligatory (<i>unless already assigned R46</i>)
Substances 'toxic for reproduction' of category 1 or 2 with R60 (fertility)	Concentration ≥ 0,2 % toxic for reproduction (fertility) R60 obligatory	

a 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.]

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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>)
<p>a 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.]</p>		

ANNEX III

METHODS FOR THE EVALUATION OF THE ENVIRONMENTAL HAZARDS OF PREPARATIONS IN ACCORDANCE WITH ARTICLE 7

Introduction

The systematic assessment of all the dangerous properties for the environment is expressed by means of concentration limits, expressed as a weight/weight percentage except for gaseous preparations where they are expressed as a volume/volume percentage and in conjunction with the classification of a substance.

Part A gives the calculation procedure according to Article 7(1)(a) and gives the R phrases to be assigned to the classification of the preparation.

Part B gives the concentration limits to be used when applying the conventional method and relevant symbols and R phrases for classification.

In accordance with Article 7(1)(a) the environmental hazards of a preparation shall be assessed by the conventional method described in parts A and B of this Annex, using individual concentration limits.

- (a) Where the dangerous substances listed in Annex 1 to Directive 67/548/EEC are assigned concentration limits necessary for the application of the method of assessment described in Part A of this Annex, these concentration limits must be used.
- (b) Where the dangerous substances do not appear in Annex I to Directive 67/548/EEC or appear there without the concentration limits necessary for the application of the method of evaluation described in Part A of this Annex, the concentration limits shall be assigned in accordance with the specification in Part B of this Annex.

Part C gives the test methods for the evaluation of the hazards for the aquatic environment.

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PART A

Procedure for the evaluation of environmental hazards

(a) Aquatic environment

I. Conventional method for the evaluation of hazards to the aquatic environment

The conventional method for the evaluation of hazards to the aquatic environment [^{X1}takes into account all the hazards that a preparation may entail] for this medium according to the following specifications.

Editorial Information

X1 Substituted by [Corrigendum to Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations \(Official Journal of the European Communities L 200 of 30 July 1999\)](#).

The following preparations are to be classified as dangerous for the environment:

1. and assigned the symbol 'N', the indication of danger 'dangerous for the environment' and the risk phrases R50 and R53 (R50-53):
 - 1.1. preparations containing one or more substances classified as dangerous to the environment and to which is assigned phrases R50-53 in individual concentrations equal to or greater than:
 - (a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or
 - (b) the concentration specified in Part B of this Annex (Table 1) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;
 - 1.2. preparations containing more than one substance classified as dangerous for the environment and to which is assigned phrases R50-53 in lower individual concentrations than the limits specified under I.1.1(a) or (b) if:

$$\sum(P_{N, R50-53} L_{N, R50-53}) \geq 1$$

where:

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

2. and assigned the symbol 'N', the indication of danger 'dangerous for the environment' and the risk phrases R51 and R53 (R51-53) unless the preparation is already classified according to I.1 above;
 - 2.1. preparations containing one or more than one substance classified as dangerous to the environment and to which is assigned phrases R50-53 or R51-53 in individual concentrations equal to or greater than:

- (a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or
- (b) the concentration specified in Part B of this Annex (Table 1) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;
- 2.2. preparations containing more than one of the substances classified as dangerous for the environment and to which is assigned phrases R50-53 or R51-53 in lower individual concentrations than the limits specified under I.2. (a) or (b) if:

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

where:

- $P_{N, R50-53}$ = is the percentage by weight of each substance dangerous for the environment to which is assigned 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 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 phrases R50-53 or R51-53, expressed as percentage by weight

3. and assigned the risk phrases R52 and R53 (R52-53) unless the preparation is already classified according to I.1 or I.2 above;

- 3.1. preparations containing one or more than one substance classified as dangerous to the environment and to which is assigned phrases R50-53 or R51-53 or R52-53 in individual concentrations equal to or greater than:

- (a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or
- (b) the concentration specified in Part B of this Annex (Table 1) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

- 3.2. preparations containing more than one of the substances classified as dangerous for the environment and to which is assigned phrases R51-53 or R50-53 or R52-53 in lower individual concentrations than the limits specified under I.3.1(a) or (b) if:

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

where:

- $P_{N, R50-53}$ = is the percentage by weight of each substance dangerous for the environment to which is assigned 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 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 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 phrases R50-53 or R51-53 or R52-53, expressed as percentage by weight;

4. 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 I.1 above;

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4.1. preparations containing one or more than one substance classified as dangerous to the environment and to which is assigned phrase R50 in individual concentrations equal to or greater than:

- (a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or
- (b) the concentration specified in Part B of this Annex (Table 2) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

4.2. preparations containing more than one substance classified as dangerous for the environment and to which is assigned phrase R50 in lower individual concentrations than the limits specified under I.4.1(a) or (b) if:

$$\sum(P_{N, R50} L_{N, R50}) \geq 1$$

where:

- $P_{N, R50}$ = is the percentage by weight of each substance dangerous for the environment to which is assigned phrase R50 in the preparation,
- $L_{N, R50}$ = is the limit R50 for each substance dangerous for the environment to which is assigned phrase R50, expressed as percentage by weight.

4.3. preparations containing one or more than one of the substances classified as dangerous for the environment and to which is assigned phrase R50 not meeting the criteria under I.4.1 or I.4.2 and containing one or more than one substance classified as dangerous for the environment and to which is assigned phrases R50-53 if:

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

where:

- $P_{N, R50}$ = is the percentage by weight of each substance dangerous for the environment to which is assigned 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 phrases R50-53 in the preparation,
- $L_{N, R50}$ = is the perspective limit R50 for each substance dangerous for the environment to which is assigned phrases R50 or R50-53, expressed as percentage by weight;

5. and assigned the risk phrase R52 unless the preparation is already classified according to I.1, I.2, I.3, or I.4 above:

5.1. preparations containing one or more than one substance classified as dangerous to the environment and to which is assigned phrase R52 in individual concentrations equal to or greater than:

- (a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or
- (b) the concentration specified in Part B of this Annex (Table 3) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

5.2. preparations containing more than one substance classified as dangerous for the environment and to which is assigned phrase R52 in lower individual concentrations than the limits specified under I.5.1 (a) or (b) if:

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

where:

P_{R52} = is the percentage by weight of each substance dangerous for the environment to which is assigned phrase R52 in the preparation,
 L_{R52} = is the limit R52 for each substance dangerous for the environment to which is assigned phrase R52, expressed as percentage by weight;

6. and assigned the risk phrase R53 unless the preparation is already classified according to I.1, I.2, or I.3 above:

6.1. preparations containing one or more than one substance classified as dangerous to the environment and to which is assigned phrase R53 in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

(b) the concentration specified in Part B of this Annex (Table 4) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

6.2. preparations containing more than one substance classified as dangerous for the environment and to which is assigned phrase R 53 in lower individual concentrations than the limits specified under I.6.1(a) or (b) if:

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

where:

P_{R53} = is the percentage by weight of each substance dangerous for the environment to which is assigned phrase R53 in the preparation,
 L_{R53} = is the limit R53 for each substance dangerous for the environment to which is assigned phrase R53, expressed as percentage by weight;

6.3. preparations containing one or more than one of the substances classified as dangerous for the environment and to which is assigned phrase R53 not meeting the criteria under I.6.2 and containing one or more than one substance classified as dangerous for the environment and to which is assigned phrases R50-53 or R51-53 or R52-53 if:

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

where:

P_{R53} = is the percentage by weight of each substance dangerous for the environment to which is assigned 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 phrase 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 phrase R51-53 in the preparation,
 P_{R52-53} = is the percentage by weight of each substance dangerous for the environment to which is assigned phrase R52-53 in the preparation,
 L_{R53} = is the respective limit R53 for each substance dangerous for the environment to which is assigned phrase R53 or R50-53 or R51-53 or R52-53, expressed as percentage by weight.

(b) Non-aquatic environment

(1) OZONE LAYER

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I. Conventional method for the evaluation of preparations dangerous for the ozone layer
The following preparations are to be classified as dangerous for the environment:

1. and assigned the symbol 'N', the indication of danger 'dangerous for the environment' and the risk phrase R59;
- 1.1. preparations containing one or more substances classified as dangerous to the environment and to which is assigned the symbol 'N' and the risk phrase R59 in individual concentrations equal to or greater than:
 - (a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or
 - (b) the concentration specified in Part B of this Annex (Table 5) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits^{F3}.]

F42.

Textual Amendments

- F4** Deleted by Commission Directive 2006/8/EC of 23 January 2006 amending, for the purposes of their adaptation to technical progress, Annexes II, III and V to Directive 1999/45/EC of the European Parliament and of the Council concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (Text with EEA relevance).

F42.1. preparations containing one or more substances classified as dangerous to the environment and to which is assigned R59 in individual concentrations equal to or greater than:

.....

(2) TERRESTRIAL ENVIRONMENT

I. Evaluation of preparations dangerous for the terrestrial environment

Classification of preparations using the risk phrases below will follow after the detailed criteria for use of the phrases have been incorporated in Annex VI to Directive 67/548/EEC.

R54	Toxic to flora
R55	Toxic to fauna
R56	Toxic to soil organisms
R57	Toxic to bees
R58	May cause long-term adverse effects in the environment.

PART B

Concentration limits to be used for the evaluation of environmental hazards

I. For the aquatic environment

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 substance(s) present whose classification is also shown.

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[^{F3}TABLE 1A

Acute aquatic toxicity and long-term adverse effects

Classification of the substance	Classification of the preparation		
	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			$C_n \geq 25 \%$

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

LC ₅₀ or EC ₅₀ value ('L(E)C ₅₀ ') of substance classified as N, R50-53 (mg/l)	Classification of the preparation		
	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.)

[^{F3}TABLE 2

Acute aquatic toxicity

LC ₅₀ or EC ₅₀ value ('L(E)C ₅₀ ') of substance classified either as N, R50 or as N, R50-53 (mg/l)	Classification of the preparation N, R50
$0,1 < L(E)C_{50} \leq 1$	$C_n \geq 25 \%$
$0,01 < L(E)C_{50} \leq 0,1$	$C_n \geq 2,5 \%$
$0,001 < L(E)C_{50} \leq 0,01$	$C_n \geq 0,25 \%$

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.)

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$0,0001 < L(E)C_{50} \leq 0,001$	$C_n \geq 0,025 \%$
$0,00001 < L(E)C_{50} \leq 0,0001$	$C_n \geq 0,0025 \%$

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

Classification of the substance	Classification of the preparation R52R52
R52	$C_n \geq 25 \%$

Table 4

Long-term adverse effects

Classification of the substance	Classification of the preparation R53R53
R53	$C_n \geq 25 \%$
N, R50—53	$C_n \geq 25 \%$
N, R51—53	$C_n \geq 25 \%$
R52—53	$C_n \geq 25 \%$

II. For the non-aquatic environment

The concentration limits fixed in the following tables, expressed as 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 substance(s) present whose classification is also shown.

[^{F3}TABLE 5

Dangerous for the ozone layer

Classification of the substance	Classification of the preparation N, R59
N with R59	$C_n \geq 0,1 \%$

PART C

Test methods for the evaluation of the hazards for the aquatic environment

Normally, the classification of a preparation is made on the basis of the conventional method. However, for the determination of the acute aquatic toxicity, there may be cases for which it is appropriate to carry out tests on the preparation.

The result of these tests on the preparation may only modify the classification concerning acute aquatic toxicity which would have been obtained by the application of the conventional method.

If such tests are chosen by the person responsible for the placing on the market, it must be ensured that the quality criteria of the test methods in Part C of Annex V to Directive 67/548/EEC have been complied with.

Furthermore, the tests are to be carried out on all three species in conformity with the criteria of Annex VI to Directive 67/548/EEC (algae, daphnia and fish), unless the highest hazard classification relating to acute aquatic toxicity has been assigned to the preparation after testing on one of the species or a test result was already available before this Directive entered into force.

ANNEX IV

SPECIAL PROVISIONS FOR CONTAINERS CONTAINING PREPARATIONS OFFERED OR SOLD TO THE GENERAL PUBLIC

PART A

Containers to be fitted with child-resistant fastenings

1. Containers of whatever capacity, containing preparations offered or sold to the general public and labelled as very toxic, toxic or corrosive in accordance with Article 10 and under the conditions laid down in Article 6 of this Directive, are to fitted with child-resistant fastenings.
2. Containers of whatever capacity containing preparations presenting an aspiration hazard (X_n, R65) and classified and labelled according to paragraph 3.2.3 of Annex VI to Directive 67/548/EEC with the exception of preparations placed on the market in the form of aerosols or in a container fitted with a sealed spray attachment.
3. Containers of whatever capacity, having at least one of the substances mentioned below present in a concentration equal to or greater than the maximum individual concentration specified,

No	Identification of the substance			Concentration limit
	CAS-Reg No	Name	Einecs No	
1	67-56-1	Methanol	2006596	≥ 3 %
2	75-09-2	Dichloromethane	2008389	≥ 1 %

which are offered or sold to the general public are to be fitted with child-resistant fastenings.

PART B

Containers to be fitted with a tactile warning of danger

Containers of whatever capacity, containing preparations offered or sold to the general public and labelled as very toxic, toxic, corrosive, harmful, extremely flammable or highly flammable in accordance with Article 10 and under the conditions laid down in Articles 5 and 6 of this Directive, are to carry a tactile warning of danger.

This provision does not apply to aerosols classified and labelled only as extremely flammable or highly flammable.

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[^{F3}ANNEX V

SPECIAL PROVISIONS CONCERNING THE LABELLING OF CERTAIN PREPARATIONS

A. For preparations classified as dangerous within the meaning of Articles 5, 6 and 7

1. Preparations sold to the general public
 - 1.1. The label on the packaging containing such preparations, in addition to the specific safety advice, must bear the relevant safety advice S1, S2, S45 or S46 in accordance with the criteria laid down in Annex VI to Directive 67/548/EEC.
 - 1.2. When such preparations are classified as very toxic (T+), toxic (T) or corrosive (C) and where it is physically impossible to give such 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.

2. Preparations intended for use by spraying

The label on the packaging containing such preparations must compulsorily bear the safety advice S23 accompanied by safety advice S38 or S51 assigned to it in accordance with the criteria laid down in Annex VI to Directive 67/548/EEC.

3. Preparations containing a substance assigned phrase R33: Danger of cumulative effects

When a preparation contains at least one substance assigned the phrase R33, the label on the packaging of the preparation must carry the wording of this phrase as set out in Annex III to Directive 67/548/EEC, when the concentration of this substance present in the preparation is equal to or higher than 1 %, unless different values are set in Annex I to Directive 67/548/EEC.

4. Preparations containing a substance assigned phrase R64: May cause harm to breastfed babies

When a preparation contains at least one substance assigned phrase R64, the label on the packaging of the preparation must carry the wording of this phrase as set out in Annex III to Directive 67/548/EEC, when the concentration of this substance present in the preparation is equal to or higher than 1 %, unless different values are set in Annex I to Directive 67/548/EEC.

B. For preparations irrespective of their classification within the meaning of Articles 5, 6 and 7

1. Preparations containing lead

1.1. Paint and varnishes

The label on the packaging of paints and varnishes containing lead in quantities exceeding 0,15 % (expressed as weight of metal) of the total weight of the preparation, as determined in accordance with ISO standard 6503/1984, must show the following particulars:

‘Contains lead. Should not be used on surfaces liable to be chewed or sucked by children’.

In the case of packages the contents of which are less than 125 millilitres, the particulars may be as follows:

‘Warning! Contains lead’.

2. Preparations containing cyanoacrylates

2.1. Adhesives

The label on the immediate packaging of adhesives based on cyanoacrylate must bear the following inscriptions:

Cyanoacrylate

Danger

Bonds skin and eyes in seconds

Keep out of the reach of children.

Appropriate advice on safety must accompany the package.

3. Preparations containing isocyanates

The label on the packaging of preparations containing isocyanates (as monomers, oligomers, prepolymers, etc., or as mixtures thereof) must bear the following inscriptions:

Contains isocyanates.

See information supplied by the manufacturer.

4. Preparations containing epoxy constituents with an average molecular weight ≤ 700

The label on the packaging of preparations containing epoxy constituents with an average molecular weight ≤ 700 must bear the following inscriptions:

Contains epoxy constituents.

See information supplied by the manufacturer.

5. Preparations sold to the general public which contain active chlorine

The label on the packaging of preparations containing more than 1 % of active chlorine must bear the following particular inscriptions:

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

6. Preparations containing cadmium (alloys) and intended to be used for brazing or soldering

The label on the packaging of the above mentioned preparations must bear the following inscription printed in clearly legible and indelible characters:

Warning! Contains cadmium.

Dangerous fumes are formed during use.

See information supplied by the manufacturer.

Comply with the safety instructions.

7. Preparations available as aerosols

Without prejudice to the provisions of this Directive, preparations available as aerosols are also subject to the labelling provisions in accordance with points 2.2 and 2.3 of the Annex to Directive 75/324/EEC as last amended by Directive 94/1/EC.

8. Preparations containing substances not yet tested completely

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Where a preparation contains at least one substance which, in accordance with Article 13.3 of Directive 67/548/EEC, bears the inscription ‘Caution — substance not yet tested completely’, the label on the packaging of the preparation must bear the inscription ‘Warning — this preparation contains a substance not yet tested completely’ if this substance is present in a concentration ≥ 1 %.

9. Preparations not classified as sensitising but containing at least one sensitising substance

The label on the packaging of preparations containing at least one substance classified as sensitising and being present in a concentration equal to or greater than 0,1 % or in a concentration equal to or greater than that specified under a specific note for the substance in Annex I to Directive 67/548/EEC must bear the inscription:

‘Contains (name of sensitising substance). May produce an allergic reaction’.

10. Liquid preparations containing halogenated hydrocarbons

For liquid preparations which show no flashpoint or a flashpoint higher than 55 °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’.

11. Preparations containing a substance assigned phrase R67: vapours may cause drowsiness and dizziness

When a preparation contains one or more substances assigned the phrase R67, the label on the packaging of the preparation must carry the wording of this phrase as set out in Annex III to Directive 67/548/EEC, when the total concentration of these substances present in the preparation is equal to or higher than 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.

12. Cements and cement preparations

The label on the packaging of cements and cement preparations 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 phrase R43.

C. For preparations not classified within the meaning of Articles 5, 6 and 7 but containing at least one dangerous substance

1. Preparations not intended for the general public

The label on the packaging of preparations referred to in Article 14.2.1(b) must bear the following inscription:

‘Safety data sheet available for professional user on request’.]

ANNEX VI

CONFIDENTIALITY FOR THE CHEMICAL IDENTITY OF A SUBSTANCE

PART A

Information to be communicated in the request for confidentiality

Introductory notes

- A. Article 15 indicates the conditions in which the person responsible for placing a preparation on the market may avail himself of the confidentiality.
- B. To avoid multiple requests for confidentiality relating to the same substance used in different preparations, a single request for confidentiality may suffice if a certain number of preparations have:
- the same dangerous constituents present in the same concentration range,
 - the same classification and labelling,
 - the same expected uses.

A single alternative denomination must be used to mask the chemical identity of the same substance in the preparations concerned. Furthermore, the request for confidentiality must contain all information indicated in the following request, without forgetting the name or the trade name of each preparation.

- C. The alternative designation used on the label must be the same as that given under heading 2 'Composition/information on ingredients' of the Annex to Directive 91/155/EEC as last amended by Directive 93/112/EEC.

This implies that the alternative designation used will contain enough information about the substance to ensure risk-free handling.

- D. In making the request to use an alternative designation the person responsible for placing on the market must take into account the need to provide enough information for necessary health and safety precautions to be taken in the workplace and to ensure that risks from handling the preparation can be minimised.

Request for confidentiality

In accordance with Article 15 the request for confidentiality must obligatorily contain the following information:

1. Name and full address (including telephone number) of the person established in the Community who is responsible for placing the preparation on the market (manufacturer, importer or distributor).
2. Precise identification of the substance(s) for which confidentiality is proposed and the alternative designation.

CAS No	Einecs No	Chemical name according to international nomenclature	Alternative designation

NB:

Where substances are classified provisionally, accompanying information (bibliographical references) should be provided as evidence that the provisional classification takes account of all existing pertinent information available on the properties of the substance.

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		and classification (Annex I to Council Directive 67/548/EEC or provisional classification)	
(a)			
(b)			
(c)			

NB:

Where substances are classified provisionally, accompanying information (bibliographical references) should be provided as evidence that the provisional classification takes account of all existing pertinent information available on the properties of the substance.

3. Justification for confidentiality (probability — plausibility).
4. Designation(s) or commercial name(s) of the preparation(s).
5. Is the designation or commercial name the same for all the Community?

YES #	NO #

If no, specify the designation(s) or commercial name(s) used in the different Member States:

[^{F5}Belgium:
Czech Republic:
Denmark:
Germany:
Estonia:
Greece:
Spain:
France:
Ireland:
Italy:
Cyprus:
Latvia:
Lithuania:
Luxembourg:
Hungary:
Malta:
Netherlands:
Austria:
Poland:
Portugal:
Slovenia:
Slovakia:

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Finland:
Sweden:
United Kingdom:]

6. Composition of the preparation(s) defined in point 2 of the Annex to Directive 91/155/EEC as last amended by Directive 93/112/EEC.
7. Classification of the preparation(s) according to Article 6 of this Directive.
8. Labelling of the preparation(s) according to Article 10 of this Directive.
9. Intended uses for the preparation(s).
10. Safety data sheet(s) conforming to Directive 91/155/EEC as last amended by Directive 93/112/EEC.

Textual Amendments

F5 Substituted by Council Directive 2004/66/EC of 26 April 2004 adapting Directives 1999/45/EC, 2002/83/EC, 2003/37/EC and 2003/59/EC of the European Parliament and of the Council and Council Directives 77/388/EEC, 91/414/EEC, 96/26/EC, 2003/48/EC and 2003/49/EC, in the fields of free movement of goods, freedom to provide services, agriculture, transport policy and taxation, by reason of the accession of the Czech Republic, Estonia, Cyprus, Latvia, Lithuania, Hungary, Malta, Poland, Slovenia and Slovakia.

PART B

Lexicon guide for establishing the alternative designations (generic names)

1. Introductory note

The lexicon guide is based on the procedure for the classification of dangerous substances (division of substances into families) which appears in Annex I to Directive 67/548/EEC.

Alternative designations to those based on this guide may be used. However, in all cases the names chosen must provide enough information to ensure the preparation can be handled without risk and that necessary health and safety precautions can be taken in the workplace.

The families are defined in the following manner:

- inorganic or organic substances whose properties are identified by having a common chemical element as their chief characteristic. The family name is derived from the name of the chemical element. These families are identified as in Annex I by the atomic number of the chemical element (001 to 103),
- organic substances whose properties are identified by having a common functional group as their chief characteristics.

The family name is derived from the functional group name.

These families are identified by the conventional number found in Annex I (601—650).

Sub-families bringing together substances with a common specific character have been added in certain cases.

2. Establishing the generic name

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General principles

For the purposes of establishing the generic name, the following general approach, involving two successive stages, is adopted:

- (i) identification of the functional groups and chemical elements present in the molecule;
- (ii) determination of the extent to which account should be taken of the most important functional groups and chemical elements.

The identified functional groups and elements taken into account are the names of the families and sub-families set out in point 3 in the form of a non-restrictive list.

3. Division of substances into families and sub-families

Family No Annex I to Directive 67/548/ EEC	Families Sub-families
001	Hydrogen compounds Hydrides
002	Helium compounds
003	Lithium compounds
004	Beryllium compounds
005	Boron compounds Boranes Borates
006	Carbon compounds Carbamates Inorganic carbon compounds Salts of hydrogen cyanide Urea and derivatives
007	Nitrogen compounds Quaternary ammonium compounds Acid nitrogen compounds Nitrates Nitrites
008	Oxygen compounds
009	Fluorine compounds Inorganic fluorides
010	Neon compounds
011	Sodium compounds
012	Magnesium compounds Organometallic magnesium derivatives
013	Aluminium compounds Organometallic aluminium derivatives
a	Specify according to the family corresponding to halogen.
b	Quinones included.

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014	Silicon compounds Silicones Silicates
015	Phosphorus compounds Acid phosphorus compounds Phosphonium compounds Phosphoric esters Phosphates Phosphites Phosphoramides and derivatives
016	Sulphur compounds Acid sulphur compounds Mercaptans Sulphates Sulphites
017	Chlorine compounds Chlorates Perchlorates
018	Argon compounds
019	Potassium compounds
020	Calcium compounds
021	Scandium compounds
022	Titanium compounds
023	Vanadium compounds
024	Chromium compounds Chromium VI compounds
025	Manganese compounds
026	Iron compounds
027	Cobalt compounds
028	Nickel compounds
029	Copper compounds
030	Zinc compounds Organometallic zinc derivatives
031	Gallium compounds
032	Germanium compounds
033	Arsenic compounds
034	Selenium compounds
035	Bromine compounds

a Specify according to the family corresponding to halogen.

b Quinones included.

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036	Krypton compounds
037	Rubidium compounds
038	Strontium compounds
039	Yttrium compounds
040	Zirconium compounds
041	Niobium compounds
042	Molybdenum compounds
043	Technetium compounds
044	Ruthenium compounds
045	Rhodium compounds
046	Palladium compounds
047	Silver compounds
048	Cadmium compounds
049	Indium compounds
050	Tin compounds Organometallic tin derivatives
051	Antimony compounds
052	Tellurium compounds
053	Iodine compounds
054	Xenon compounds
055	Caesium compounds
056	Barium compounds
057	Lanthanum compounds
058	Cerium compounds
059	Praseodymium compounds
060	Neodymium compounds
061	Promethium compounds
062	Samarium compounds
063	Europium compounds
064	Gandolinium compounds
065	Terbium compounds
066	Dysprosium compounds
067	Holmium compounds

a Specify according to the family corresponding to halogen.

b Quinones included.

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068	Erbium compounds
069	Thulium compounds
070	Ytterbium compounds
071	Lutetium compounds
072	Hafnium compounds
073	Tantalum compounds
074	Tungsten compounds
075	Rhenium compounds
076	Osmium compounds
077	Iridium compounds
078	Platinum compounds
079	Gold compounds
080	Mercury compounds Organometallic mercury derivatives
081	Thallium compounds
082	Lead compounds Organometallic lead derivatives
083	Bismuth compounds
084	Polonium compounds
085	Astate compounds
086	Radon compounds
087	Francium compounds
088	Radium compounds
089	Actinium compounds
090	Thorium compounds
091	Protactinium compounds
092	Uranium compounds
093	Neptunium compounds
094	Plutonium compounds
095	Americium compounds
096	Curium compounds
097	Berkelium compounds
098	Californium compounds

a Specify according to the family corresponding to halogen.

b Quinones included.

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099	Einsteinium compounds
100	Fermium compounds
101	Mendelevium compounds
102	Nobelium compounds
103	Lawrencium compounds
601	Hydrocarbons Aliphatic hydrocarbons Aromatic hydrocarbons Alicyclic hydrocarbons Polycyclic aromatic hydrocarbons (PAH)
602	Halogenated hydrocarbons ^a Halogenated aliphatic hydrocarbons ^a Halogenated aromatic hydrocarbons ^a Halogenated alicyclic hydrocarbons ^a
603	Alcohols and derivatives Aliphatic alcohols Aromatic alcohols Alicyclic alcohols Alcanolamines Epoxy derivatives Ethers Glycolethers Glycols and polyols
604	Phenols and derivatives Halogenated phenol derivatives ^a
605	Aldehydes and derivatives Aliphatic aldehydes Aromatic aldehydes Alicyclic aldehydes Aliphatic acetals Aromatic acetals Alicyclic acetals
606	Ketones and derivatives Aliphatic ketones Aromatic ketones ^b Alicyclic ketones
607	Organic acids and derivatives Aliphatic acids Halogenated aliphatic acids ^a

a Specify according to the family corresponding to halogen.

b Quinones included.

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	<p>Aromatic acids Halogenated aromatic acids^a Alicyclic acids Halogenated alicyclic acids^a Aliphatic acid anhydrides Halogenated aliphatic acid anhydrides^a Aromatic acid anhydrides Halogenated aromatic acid anhydrides^a Alicyclic acid anhydrides Halogenated alicyclic acid anhydrides^a Salts of aliphatic acid Salts of halogenated aliphatic acid^a Salts of aromatic acid Salts of halogenated aromatic acid^a Salts of alicyclic acid Salts of halogenated alicyclic acid^a Esters of aliphatic acid Esters of halogenated alicyclic acid^a Esters of aromatic acid Esters of halogenated aromatic acid^a Esters of alicyclic acid Esters of halogenated alicyclic acid^a Esters of glycol ether Acrylates Methacrylates Lactones Acyl halogenides</p>
608	Nitriles and derivatives
609	Nitro compounds
610	Chlornitrated compounds
611	Azoxy and azo compounds
612	<p>Amine compounds Aliphatic amines and derivatives Alicyclic amines and derivatives Aromatic amines and derivatives Aniline and derivatives Benzidine and derivatives</p>
613	<p>Heterocyclic bases and derivatives Benzimidazole and derivatives Imidazol and derivatives Pyrethrinoids Quinoline and derivatives</p>

a Specify according to the family corresponding to halogen.

b Quinones included.

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	Triazine and derivatives Triazole and derivatives
614	Glycosides and alkaloids Alkaloid and derivatives Glycosides and derivatives
615	Cyanates and isocyanates Cyanates Isocyanates
616	Amides and derivatives Acetamide and derivatives Anilides
617	Organic peroxides
647	Enzymes
648	Complex coal derivatives Acid extract Alkaline extract Anthracene oil Anthracene oil extract residue Anthracene oil fraction Carbolic oil Carbolic oil extract residue Coal liquids, liquid solvent extraction Coal liquids, liquid solvent extraction solvents Coal oil Coal tar Coal tar extract Coal tar solids residue Coke (coal tar) low temperature, high temperature pitch Coke (coal tar), high temperature pitch Coke (coal tar), mixed coal high temperature pitch Crude benzole Crude phenols Crude tar bases Distillate bases Distillate phenols Distillates Distillates (coal), liquid solvent extraction, primary Distillates (coal), solvent extraction, hydrocracked

a Specify according to the family corresponding to halogen.

b Quinones included.

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Distillates (coal), solvent extraction, hydrocracked hydrogenated middle
 Distillates (coal), solvent extraction, hydrocracked middle
 Extract residues (coal), low temperature coal tar alkaline
 Fresh oil
 Fuels, diesel, coal solvent extraction, hydrocracked, hydrogenated
 Fuels, jet aircraft, coal solvent extraction, hydrocracked, hydrogenated
 Gasoline, coal solvent extraction, hydrocracked naphtha
 Heat treatment products
 Heavy anthracene oil
 Heavy anthracene oil redistillate
 Light oil
 Light oil extract residues, high boiling
 Light oil extract residues, intermediate boiling
 Light oil extract residues, low boiling
 Light oil redistillate, high boiling
 Light oil redistillate, intermediate boiling
 Light oil redistillate, low boiling
 Methylnaphthalene oil
 Methylnaphthalene oil extract residue
 Naphtha (coal), solvent extraction, hydrocracked
 Naphthalene oil
 Naphthalene oil extract residue
 Naphthalene oil redistillate
 Pitch
 Pitch redistillate
 Pitch residue
 Pitch residue, heat treated
 Pitch residue, oxidised
 Pyrolysis products
 Redistillates
 Residues (coal), liquid solvent extractions
 Tar brown coal
 Tar brown coal, low temperature
 Tar oil, high boiling

a Specify according to the family corresponding to halogen.

b Quinones included.

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	Tar oil, intermediate boiling Wash oil Wash oil extract residue Wash oil redistillate
649	Complex oil derivatives Crude oil Petroleum gas Low boiling point naphtha Low boiling point modified naphtha Low boiling point cat-cracked naphtha Low boiling point cat-reformed naphtha Low boiling point thermally cracked naphtha Low boiling point hydrogen treated naphtha Low boiling point naphtha — unspecified Straight-run kerosine Kerosine — unspecified Cracked gas oil Gas oil — unspecified Heavy fuel oil Grease Unrefined or mildly refined base oil Base oil — unspecified Distillate aromatic extract Distillate aromatic extract (treated) Fots oil Slack wax Petrolatum
650	Various substances Do not use this family. Instead, use the families or sub-families mentioned above.
a	Specify according to the family corresponding to halogen.
b	Quinones included.

4. Practical application:

After having conducted a search to see if the substance belongs to one or more families or sub-families on the list, the generic name can be established in the following way:

- 4.1. If the name of a family or sub-family is sufficient to characterise the chemical elements or important functional groups, this name will be chosen as the generic name.

Examples:

— 1,4 dihydroxybenzen

family : phenols and derivatives
604

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—	butanol	generic name	:	phenol derivatives
		family 603	:	alcohols and derivatives
		sub-family	:	aliphatic alcohols
		generic name	:	aliphatic alcohol
—	2-Isopropoxyethanol	family 603	:	alcohols and derivatives
		sub-family	:	glycoethers
		generic name	:	glycoether
—	methacrylate	family 607	:	organic acids and derivatives
		sub-family	:	acrylates
		generic name	:	acrylate

4.2. If the name of a family or sub-family is not sufficient to characterise the chemical elements of important functional groups, the generic name will be a combination of the corresponding different family or sub-family names:

Examples:

—	chlorobenzene	family 602	:	halogenated hydrocarbons
		sub-family	:	halogenated aromatic hydrocarbons
		family 017	:	chlorine compounds
		generic name	:	chlorinated aromatic hydrocarbon
—	2,3,6-trichlorophenylacetic acid	family 607	:	organic acids
		sub-family	:	halogenated aromatic acids
		family 017	:	chlorine compounds
		generic name	:	chlorinated aromatic acid
—	1-chloro-1-nitropropane			

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	family	:	chloronitrated derivatives
	610		
	family	:	hydrocarbons
	601		
	sub-family	:	aliphatic hydrocarbons
	family		
	generic name	:	chlorinated aliphatic hydrocarbon
—	tetrapropyl dithiopyrophosphate		
	family	:	phosphorus compounds
	015		
	sub-family	:	phosphoric esters
	family	:	sulphur compounds
	016		
	generic name	:	thiophosphoric ester

NB:

In the case of certain elements, notably metals, the name of the family or sub-family may be indicated by the words 'organic' or 'inorganic'.

Examples:

—	dimercury chloride		
	family	:	mercury compounds
	080		
	generic name	:	inorganic mercury compound
—	barium acetate		
	family	:	barium compounds
	056		
	generic name	:	organic barium compound
—	ethyl nitrite		
	family	:	nitrogen compounds
	007		
	sub-family	:	nitrites
	family		
	generic name	:	organic nitrite
—	sodium hydrosulphite		
	family	:	sulphur compounds
	016		
	generic name	:	inorganic sulphur compound

(The examples cited are substances taken from Annex I to Directive 67/548/EEC (19th adaptation) in respect of which requests for confidentiality may be submitted).

ANNEX VII

PREPARATIONS COVERED BY ARTICLE 12(2)

Preparations as specified by paragraph 9.3 of Annex VI to Directive 67/548/EEC.

ANNEX VIII

PART A

Directives repealed in accordance with Article 21

- Directive 78/631/EEC on the approximation of the laws of the Member States relating to the classification, packaging and labelling of dangerous preparations (pesticides)
- Directive 88/379/EEC on the approximation of the laws of the Member States relating to the classification, packaging and labelling of dangerous preparations and its following adaptations to technical progress:
 - Directive 89/178/EEC
 - Directive 90/492/EEC
 - Directive 93/18/EEC
 - Directive 96/65/EC
- Directive 90/35/EEC defining in accordance with Article 6 of Directive 88/379/EEC the category of preparations the packaging of which must be fitted with child-resistant fastenings and/or carry a tactile warning of danger
- Directive 91/442/EEC on dangerous preparations the packaging of which must be fitted with child-resistant fastenings

PART B

Deadlines for transposition and for application in accordance with Article 22

Directive	Deadline for transposition	Deadline for application
78/631/EEC (OJ L 206, 29.7.1978, p. 13)	1 January 1981	1 January 1981
88/379/EEC (OJ L 187, 16.7.1988, p. 14)	7 June 1991	7 June 1991
89/178/EEC (OJ L 64, 8.3.1989, p. 18)	1 December 1990	1 June 1991
90/492/EEC (OJ L 275, 5.10.1990, p. 35)	1 June 1991	8 June 1991
93/18/EEC (OJ L 104, 29.4.1993, p. 46)	1 July 1994	1 July 1994
90/35/EEC (OJ L 19, 24.1.1990, p. 14)	1 August 1992	1 November 1992

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91/442/EEC (OJ L 238, 27.8.1991, p. 25)	1 August 1992	1 November 1992
96/65/EC (OJ L 265, 18.10.1996, p. 15)	31 May 1998	31 May 1998

PART C

Special provisions for Austria, Finland and Sweden concerning the application of the following Directives in accordance with Article 21

1. Austria, Finland and Sweden do not transpose or apply Council Directive 78/631/EEC of 26 June 1978 on the approximation of the laws of the Member States relating to the classification, packaging and labelling of dangerous preparations (pesticides), as last amended by Council Directive 92/32/EEC of 30 April 1992.
2. Austria is to apply Council Directive 88/379/EEC of 7 June 1988 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous preparations, as last amended by Directive 96/65/EC of 11 October 1996 under the following conditions:

The following provisions of Directive 88/379/EEC will not apply to Austria

- (a) Article 13 in conjunction with Articles 3 and 7 with respect to preparations containing substances listed in Appendix 1;
 - (b) Article 13 in conjunction with Article 7 with respect to labelling respecting the Austrian provisions on:
 - safety advice for waste disposal,
 - pictogram for waste disposal until two years after the entry into force of this Directive,
 - safety advice for countermeasures in case of accidents;
 - (c) Article 13 in conjunction with Article 7(1)(c) concerning the chemical names of dangerous substances present in dangerous preparations, until two years after the entry into force of this Directive.
3. Sweden is to apply Council Directive 88/379/EEC of 7 June 1988 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous preparations, as last amended by Directive 96/65/EC of 11 October 1996 under the following conditions:

The following provisions of Directive 88/379/EEC will not apply to Sweden:

- (a) Article 13 in conjunction with Articles 3 and 7 with respect to preparations
 - containing substances listed in Appendix 2,
 - containing substances presenting neurotoxic effects and defatting effects on the skin not covered by criteria for classification of Annex VI to Directive 67/548/EEC, and by risk phrases of Annex III to Directive 67/548/EEC,
 - containing substances presenting acutely toxic effects not covered by criteria for classification of Annex VI to Directive 67/548/EEC, and by risk phrases of Annex III to Directive 67/548/EEC, until two years after the entry into force of this Directive,

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- which are not classified as dangerous according to the ‘måttligt skadliga’ (Swedish: ‘moderately harmful’) criteria of Directive 88/379/EEC.
- (b) Article 13 in conjunction with Articles 3 and 7 with respect to
- the criteria for classification and labelling of preparations containing carcinogenic substances classified on the basis of criteria in point 4.2.1 of Annex VI to Directive 67/548/EEC,
 - labelling of preparations classified as carcinogenic, category 3, with a special R-pharse instead of R-pharse 40.

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Appendix 1

SUBSTANCES REFERRED TO IN ANNEX VIII, PART C, PARAGRAPH 2 (AUSTRIA)

Name of the substance	Index number in Annex I to Directive 67/548/EEC
Linuron	006-021-00-1
Trichlorosilan	014-001-00-9
Phosphorus trichloride	015-007-00-4
Phosphorus pentachloride	015-008-00-X
Phosphorus oxychloride	015-009-00-5
Sodium polysulphides	016-010-00-3
Disulphur dichloride	016-012-00-4
Thionyl chloride	016-015-00-0
Calcium hypochlorite	017-012-00-7
Potassium hydroxide	019-002-00-8
2-Dimethylaminoethanol	603-047-00-0
2-Diethylaminoethanol	603-048-00-6
Diethanolamine	603-071-00-1
N-Methyl-2-ethanolamine	603-080-00-0
2-Ethylhexan-1,3-diol	603-087-00-9
Isophorone	606-012-00-8
6-Methyl-1,3-dithiolo(4,5-b)chinoxalin-2-one	606-036-00-9
Acetic anhydride	607-008-00-9
Methyl formate	607-014-00-1
Ethyl formate	607-015-00-7
Acrylic acid	607-061-00-8
Chloroacetyl chloride	607-080-00-1
Nitrofen	609-040-00-9
Quintozen; Pentachloronitrobenzol	609-043-00-5
Dichlofluanid	616-006-00-7
Cumene hydroperoxide	617-002-00-8
Monocrotophos	015-072-00-9
Edifenphos	015-121-00-4
Triazophos	015-140-00-8

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Methanol	603-001-00-X
Trifenmorph; 4-Tritylmorpholin	613-052-00-X
Diuron	006-015-00-9
Fenbutanin oxide	050-017-00-2
1-Butanol, 2-Butanol, iso-Butanol	603-004-00-6

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Appendix 2

SUBSTANCES REFERRED TO IN ANNEX VIII, PART C, PARAGRAPH 3 (SWEDEN)

Name of the substance	Index number in Annex I to Directive 67/548/EEC
Acetone	606-001-00-8
Butanone	606-002-00-3
Amyl formate	607-018-00-3
Ethyl acetate	607-022-00-5
n-Butylacetate	607-025-00-1
sec-Butylacetate	607-026-00-7
tert-Butylacetate	607-026-00-7
iso-Butylacetate	607-026-00-7
Butylformate	607-017-00-8
Cyclohexane	601-017-00-1
1,4-Dimethylcyclohexane	601-019-00-2
Diethyl ether	603-022-00-4
Ethyl methyl ether	603-020-00-3
Amyl acetate	607-130-00-2
Ethyl lactate	607-129-00-7
Amyl propionate	607-131-00-8
2,4-Dimethylpentan-3-one	606-028-00-5
Di-n-propylether	603-045-00-X
Di-n-propyl ketone	606-027-00-X
Ethyl propionate	607-028-00-8
Heptane	601-008-00-2
Hexane (mixture of isomers) containing less than 5 % n-hexane	601-007-00-7
Isopropyl acetate	607-024-00-6
Isopropyl alcohol	603-003-00-0
4-Methoxy-4-methylpentane-2-one	606-023-00-8
Methyl acetate	607-021-00-X
Methyl cyclohexane	601-018-00-7
5-Methylhexane-2-one	606-026-00-4
Methyl lactate	607-092-00-7

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4-Methylpentan-2-one	606-004-00-4
Methyl propionate	607-027-00-2
Octane	601-009-00-8
Pentane	601-006-00-1
Pentan-3-one	606-006-00-5
Propan-1-ol	603-003-00-0
Propyl acetate	607-024-00-6
Propyl formate	607-016-00-2
Propyl propionate	607-030-00-9
Sodium bisulphite = polysulphite	016-010-00-3
Toluene-2,4-diisocyanate	615-006-00-4
Toluene-2,6-diisocyanate	615-006-00-4
Cadmiumfluoride	048-006-00-2
1,2-Epoxy-3(tolyloxy)-propane	603-056-00-X
Diphenylmethane-2,2'-diisocyanate	615-005-00-9
Diphenylmethane-2,4'-diisocyanate	615-005-00-9
Diphenylmethane-4,4'-diisocyanate	615-005-00-9
Hydroquinone	604-005-00-4
Hydroxypropyl acrylate	607-108-00-2
Turpentine	650-002-00-6
Butyl methyl ketone (2-Hexanone)	606-030-00-6
Hexane	601-007-00-7
Vanadium pentoxide	023-001-00-8
Sodium nitrate	
Zinc oxide	

ANNEX IX

CORRELATION TABLE

This Directive	88/379/EEC
Article 1	Article 1
1.1	1.1
1.2	1.2
1.3	

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1.4	
1.5	1.3
Article 2	Article 2
Article 3	Article 3.6
Article 4	Article 3.1
	Article 4
Article 5	Article 3.2
5.1	3.2
5.1, third indent	3.2, paragraph 3(b)
5.2—5.3	
5.4	
Article 6	Article 3.3
6.1	3.3, paragraphs (a) and (b)
6.2	
6.3	3.3, paragraphs 3 and 4
6.4	3.4
6.5	3.5, paragraphs 1 to 3
Article 7	
Article 8	Article 5
8.1	5.1
8.2	5.2
8.3	5.3
8.4	
Article 9	Article 6
9.1	6.1(a)
9.2	6.1(b)
9.3	6.2 and 6.3, second paragraph
Article 10	Article 7
10.1.1—1.2	
10.2	7.1
10.2.3.	7.1(c)
10.2.4.	7.1(d)
10.2.5.	7.4
Article 11	Article 8

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Article 12	Article 9
Article 13	
Article 14	Article 10
Article 15	Article 7
Article 16	Article 11
Article 17	Article 12
Article 18	Article 13
Article 19	Article 14
Article 20	Article 15
Article 21	
Article 22	Article 16
Article 23	Article 16(3)
Article 24	Article 17

CORRELATION TABLE

This Directive	88/379/EEC	90/35/EEC	91/442/EEC	93/18/EEC
Annex I.A	Article 3.2(2)			
Annex I.B				
Annex II.A. introduction (1— 3)				Annex I introduction
Annex II.A. introduction (4)				
Annex II.A.1	Article 3.5(a)			
Annex II.A.1.1.1	Article 3.5(a)(i)			
Annex II.A.1.1.2	Article 3.5(a)(ii)			
Annex II.A.1.2	Article 3.5(a)(iii)			
Annex II.A.2	Article 3.5(b)			
Annex II.A.2.1.1	Article 3.5(b)(i)			
Annex II.A.2.1.2	Article 3.5(b)(ii)			
Annex II.A.2.2	Article 3.5(b)(iii)			
Annex II.A.2.3	Article 3.5(b)(iv)			
Annex II.A.3	Article 3.5(c)			
Annex II.A.3.1.1	Article 3.5(c)(i)			
Annex II.A.3.1.2	Article 3.5(c)(ii)			

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Annex II.A.3.2	Article 3.5(c)(iii)			
Annex II.A.3.3	Article 3.5(c)(iv)			
Annex II.A.4	Article 3.5(d)			
Annex II.A.4.1.1	Article 3.5(d)(i)			
Annex II.A.4.1.2	Article 3.5(d)(ii)			
Annex II.A.4.2.1	Article 3.5(e)(i)			
Annex II.A.4.2.2	Article 3.5(e)(ii)			
Annex II.A.5	Article 3.5(f)			
Annex II.A.5.1.1	Article 3.5(f)(i)			
Annex II.A.5.1.2	Article 3.5(f)(ii)			
Annex II.A.5.2.1	Article 3.5(h)(i)			
Annex II.A.5.2.2	Article 3.5(h)(ii)			
Annex II.A.5.3.1	Article 3.5(g)(i)			
Annex II.A.5.3.2	Article 3.5(g)(ii)			
Annex II.A.5.4.1	Article 3.5(i)(i)			
Annex II.A.5.4.2	Article 3.5(i)(ii)			
Annex II.A.6				
Annex II.A.6.1	Article 3.5(g)(iii)			
Annex II.A.6.2	Article 3.5(c)(v)			
Annex II.A.7.1	Article 3.5(j)			Annex I.6
Annex II.A.7.2	Article 3.5(k)			
Annex II.A.8.1	Article 3.5(l), (m)			
Annex II.A.8.2	Article 3.5(n) Article 3.5(o), (p)			
Annex II.A.9.1 —9.4				
Annex II.B. introduction				Annex I. introduction
Annex II.B.1				Annex I.1
Annex II.B.1.1				Annex I.1.1
Annex II.B.1.2				Annex I.1.2
Annex II.B.2				Annex I.2
Annex II.B.2.1				Annex I.2.1
Annex II.B.2.2				Annex I.2.2

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Annex II.B.3				Annex I.3
Annex II.B.3.1				Annex I.3.1
Annex II.B.3.2				Annex I.3.2
Annex II.B.4				Annex I.4
Annex II.B.4.1				Annex I.4.1
Annex II.B.4.2				Annex I.4.2
Annex II.B.5				Annex I.5
Annex II.B.5.1				Annex I.5.1
Annex II.B.5.2				Annex I.5.2
Annex II.B.6				Annex I.6
Annex II.B.6.1				Annex I.6.1
Annex II.B.6.2				Annex I.6.2
Annex III.A				
Annex III.B				
Annex III.C				
Annex IV.B		Articles 1 and 2		
Annex IV.A.1		Article 1(1)		
Annex IV.A.2			Article 2; Annex (a)	
Annex IV.A.3			Article 1; Annex (b)	
Annex V.A.1				Annex II.A.1
Annex V.A.2				Annex II.A.2
Annex V.A.3				Annex II.A.3
Annex V.A.4				Annex II.A.4
Annex V.B.1				Annex II.B.1
Annex V.B.2				Annex II.B.2
Annex V.B.3				Annex II.B.3
Annex V.B.4				Annex II.B.4
Annex V.B.5				Annex II.B.5
Annex V.B.6				Annex II.B.6
Annex V.B.7	Article 3.2(3)(b)			
Annex V.B.8	Article 3.5(4)			
Annex V.C				
Annex VI				

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Annex VII				
Annex VIII				
Annex IX				