

## COUNCIL DIRECTIVE

of 7 June 1988

on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations

(88/379/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100A thereof,

Having regard to the proposal from the Commission <sup>(1)</sup>,

In cooperation with the European Parliament <sup>(2)</sup>,

Having regard to the opinion of the Economic and Social Committee <sup>(3)</sup>,

Whereas it is important to adopt measures with the aim of progressively establishing the internal market over a period expiring on 31 December 1992; whereas the internal market shall comprise an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured;

Whereas rules on dangerous substances have already been laid down in Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances <sup>(4)</sup>, as last amended by Directive 79/831/EEC <sup>(5)</sup>;

Whereas rules on certain dangerous preparations having very specific uses have already been laid down:

- in Council Directive 73/173/EEC of 4 June 1973 on the approximation of Member States' laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous preparations (solvents) <sup>(6)</sup>, as last amended by Directive 80/781/EEC <sup>(7)</sup>,
- in Council Directive 77/728/EEC of 7 November 1977 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of paints, varnishes, printing inks, adhesives and similar

products <sup>(8)</sup>, as last amended by Directive 83/265/EEC <sup>(9)</sup>,

Whereas, despite the abovementioned Community provisions, the rules, if any, applying to certain dangerous preparations in the Member States exhibit considerable differences as regards classification according to the degree of risk; whereas these differences constitute a not insignificant barrier to trade and directly affect the establishment and functioning of the common market;

Whereas it is therefore necessary to remove this barrier by approximating the relevant legislation existing in the Member States and incorporating in it the '*acquis communautaires*';

Whereas this Directive must, at the same time, ensure protection for the general public and, in particular, of persons who come into contact with dangerous preparations in the course of their work or in the pursuit of a hobby, of consumers, especially children and the visually handicapped, and also for the environment;

Whereas provisions on the classification, packaging and labelling of the preparations must be laid down at Community level; whereas the provisions concerning the information appearing on the label, the dimensions of the label and the assignment of the various danger symbols, standard phrases concerning risks and safety advice have also to be brought into line with Directive 67/548/EEC;

Whereas some preparations, although they contain constituents which are dangerous to health, are not necessarily dangerous in the form in which they are placed on the market; whereas there are exceptions, however, and whereas the latter must be the subject of special labelling, as appropriate, in accordance with the provisions of Directive 67/548/EEC as amended by Directive 79/831/EEC, or of Annex II to this Directive;

Whereas the assessment of the health hazards of a preparation may, under Article 3, be carried out by a calculation method, by determining the toxicological properties according to well-defined test methods or by a combination of the two; whereas Directive 86/609/EEC stipulates in Article 7 (2) that an experiment shall not be performed if another scientifically satisfactory method of obtaining the result sought, not entailing the

<sup>(1)</sup> OJ No C 317, 10. 12. 1986, p. 10 and OJ No C 353, 30. 12. 1987, p. 1.

<sup>(2)</sup> OJ No C 318, 30. 11. 1987, p. 73 and Decision of 13 April 1988 (not yet published in the Official Journal).

<sup>(3)</sup> OJ No C 189, 28. 7. 1986, p. 1.

<sup>(4)</sup> OJ No 196, 16. 8. 1967, p. 1.

<sup>(5)</sup> OJ No L 259, 15. 10. 1979, p. 10.

<sup>(6)</sup> OJ No L 189, 11. 7. 1973, p. 7.

<sup>(7)</sup> OJ No L 229, 30. 8. 1980, p. 57.

<sup>(8)</sup> OJ No L 303, 28. 11. 1977, p. 23.

<sup>(9)</sup> OJ No L 147, 6. 6. 1983, p. 11.

<sup>(10)</sup> OJ No L 358, 18. 12. 1986, p. 1.

use of an animal, is reasonably and practically available; whereas this Directive makes use of the results of assessments of toxicological properties only when these are already known and entails no obligation to conduct further experiments on animals;

Whereas the label constitutes a basic tool for users of the preparations by giving them the initial essential concise information; whereas it nevertheless needs to be supplemented by a two-fold system of more detailed information, one intended for professional users, and the second for the bodies appointed by the Member States and whose responsibility it is to give information reserved solely for medical purposes, both curative and preventive;

Whereas dangerous preparations may, although conforming to the provisions of this Directive, nevertheless constitute a danger to health or the environment; whereas it is therefore advisable to provide a procedure to reduce this danger;

Whereas the Commission will, on the basis of information to be supplied by the Member States be obliged to submit a report, within two years of application of this Directive, concerning any inadequacies or loopholes, as compared with the present Directive, in 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)<sup>(1)</sup>, as last amended by Directive 84/291/EEC<sup>(2)</sup>; whereas on the basis of this report, the Commission will, if appropriate, submit the necessary proposals,

HAS ADOPTED THIS DIRECTIVE:

#### Article 1

1. The purpose of this Directive is to approximate the laws, regulations and administrative provisions of the Member States on the:

- classification,
- packaging, and
- labelling

of preparations dangerous to man and the environment when they are placed on the market in the Member States.

2. This Directive shall apply to preparations which are placed on the market in the Member States and which:

- contain at least one substance classified as dangerous, within the meaning of Article 2, and
- are regarded as dangerous within the meaning of Article 3.

<sup>(1)</sup> OJ No L 206, 29. 7. 1978, p. 13.

<sup>(2)</sup> OJ No L 144, 30. 5. 1984, p. 1.

This Directive shall also apply to the preparations listed in Annex II.

3. This Directive shall not apply to:

- (a) medicinal or veterinary products as defined by Directive 65/65/EEC<sup>(3)</sup>, as last amended by Directive 87/21/EEC<sup>(4)</sup>;
- (b) cosmetic products as defined by Directive 76/768/EEC<sup>(5)</sup>, as last amended by Directive 86/199/EEC<sup>(6)</sup>;
- (c) mixtures of substances which, in the form of waste, are covered by Directive 75/442/EEC<sup>(7)</sup> and Directive 78/319/EEC<sup>(8)</sup>, as last amended by the Act of Accession of Spain and Portugal;
- (d) pesticides covered by Directive 78/631/EEC, as last amended by Directive 83/291/EEC;
- (e) munitions and explosives placed on the market with a view to obtaining a practical effect by explosion or a pyrotechnic effect.

In addition, this Directive shall not apply to:

- (f) foodstuffs in a finished stage intended for the final consumer;
- (g) animal feedingstuffs in a finished stage intended for the final consumer;
- (h) the carriage of dangerous substances by rail, road, inland waterway, sea or air;
- (i) preparations in transit which are under customs supervision provided they do not undergo any treatment or processing.

#### Article 2

The definitions appearing in Article 2 of Directive 67/548/EEC, with the exception of the definition in paragraph 1 (d) thereof, shall apply to this Directive.

#### Article 3

1. The general principles of the classification and labelling of preparations shall be applied according to the criteria in Annex VI to Directive 67/548/EEC, save where the alternative criteria referred to below are applied.

2. The requisite physico-chemical properties for the classification of preparations shall be determined by the methods specified in Annex V (A) to Directive 67/548/EEC.

<sup>(3)</sup> OJ No 22, 9. 2. 1965, p. 369/65.

<sup>(4)</sup> OJ No L 15, 17. 1. 1987, p. 36.

<sup>(5)</sup> OJ No L 262, 27. 9. 1976, p. 169.

<sup>(6)</sup> OJ No L 149, 3. 6. 1986, p. 38.

<sup>(7)</sup> OJ No L 194, 25. 7. 1975, p. 39.

<sup>(8)</sup> OJ No L 84, 31. 3. 1978, p. 43.

Preparations shall be regarded as explosive, oxidizing, extremely flammable, highly flammable or flammable when the results of the tests carried out by the methods mentioned above comply with the definitions in Article 2 of Directive 67/548/EEC and the specific evaluation criteria detailed in those methods.

By way of derogation from the preceding:

- (a) the determination of the explosive, oxidizing, extremely flammable, highly flammable or flammable properties is not necessary provided, however, that none of the constituents possesses such properties and that on the basis of the information available to the manufacturer the preparation is unlikely to present dangers of this kind;
- (b) the preparations placed on the market in the form of aerosols are subject to the flammability criteria specified in paragraphs 1.8 and 2.2 (c) of the Annex to Directive 75/324/EEC<sup>(1)</sup>, as last amended by the Act of Accession of Spain and Portugal.

3. The health hazards of a preparation shall be assessed by one or more of the following methods:

- (a) by the conventional method described below using concentration limits;
- (b) by determining by means of the methods specified in point B of Annex V to Directive 67/548/EEC, the toxicological properties of the preparation necessary for an appropriate classification and label in accordance with the criteria in Annex VI to that Directive.

Any one or more of the toxicological properties of the preparation which are not assessed by the method set out in (b) hereof shall be assessed in accordance with the conventional method.

Where a toxicological property has been established by both the methods above, the result of method (b) shall be used for classifying the preparation except in the case of carcinogenic, mutagenic and teratogenic effects.

Furthermore, where it can be demonstrated that:

- toxicological effects on man differ from those suggested by a toxicological determination or a conventional assessment, then the preparation shall be classified according to its effects on man,
- owing to effects such as potentiation a conventional assessment would underestimate the toxicological

hazard, these effects shall be taken into account in classifying the preparation,

- owing to effects such as antagonism, a conventional assessment would overestimate the toxicological hazard, these effects shall be taken into account in classifying the preparation.

4. For preparations of a known composition classified in accordance with method 3 (b) above a new health hazard assessment either by method 3 (a) or (b) shall be performed whenever:

- changes of composition of the initial concentration as a weight/weight percentage, of one or more of the dangerous constituents are introduced by the manufacturer, in accordance with the following table:

Initial concentration range of the constituent	Permitted variation in initial concentration of the constituent
$\leq 2,5$ %	$\pm 15$ %
$> 2,5 \leq 10$ %	$\pm 10$ %
$> 10 \leq 25$ %	$\pm 6$ %
$> 25 \leq 50$ %	$\pm 5$ %
$> 50 \leq 100$ %	$\pm 2,5$ %

- changes of composition involving the substitution or addition of one or more constituents, which may or may not be dangerous within the meaning of the definitions of this Directive, are introduced by the manufacturer.

5. In accordance with Article 3 (3) (a), the health hazards shall be assessed by the conventional method described below, using individual concentration limits.

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 below, these concentration limits must be used.

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 below, the concentration limits shall be assigned in accordance with the specifications in Annex I to this Directive.

When a preparation contains at least one substance which, in accordance with Article 8 (2) of Directive 67/548/EEC, bears the warning 'Caution — substance not yet fully tested', the label of the preparation must bear the warning 'Caution — this preparation contains a substance not yet fully tested' if the substance is present in a concentration equal to or in excess of 1 %.

<sup>(1)</sup> OJ No L 147, 9. 6. 1975, p. 40.

However, this substance must be treated on the same basis as the other substances present in the preparation when applying the method of evaluation by calculation, if the labelling gave at least an indication of the health hazard.

In that case,

(a) The following preparations shall be regarded as very toxic:

(i) owing to their acute lethal effects, preparations containing one or more substances classified or regarded as very toxic in individual concentrations exceeding:

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

— the concentration specified at point 1 of Annex I (Table I) to this Directive where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

(ii) owing to their acute lethal effects, preparations containing more than one substance classified or regarded as very toxic in individual concentrations not exceeding the limits specified either in Annex I to Directive 67/548/EEC or at point 1 of Annex I (Table I) to this Directive if the sum of the quotients obtained by dividing the percentage by weight of each very toxic substance in the preparation by the limit specified for that substance is 1 or more, i.e.

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

where:

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

$L_{T+}$  = is the limit specified for each very toxic substance expressed as a percentage;

(iii) owing to their non-lethal irreversible effects after one exposure, preparations containing one or more dangerous substances that produce such effects in individual concentrations exceeding:

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

— the concentration specified at point 2 of Annex I (Table II) to this Directive where the substance or substances under consideration do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits.

(b) The following preparations shall be regarded as toxic:

(i) owing to their acute lethal effects, preparations containing one or more substances classified or regarded as very toxic, toxic or in individual concentrations exceeding:

— either the concentrations specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

— the concentration specified at point 1 of Annex I (Table I) to this Directive where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

(ii) owing to their acute lethal effects, preparations containing more than one substance classified or regarded as very toxic or toxic in individual concentrations not exceeding the limits specified either in Annex I to Directive 67/548/EEC or at point 1 of Annex I (Table I) to this Directive if the sum of the quotients obtained by dividing the percentage by weight of each substance in the preparation by the toxic limit specified for that substance is 1 or more, i.e.

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

where:

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

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

$L_T$  is the limit specified for each very toxic or toxic substance expressed as a percentage;

(iii) owing to their non-lethal irreversible effects after one exposure, preparations containing one or more dangerous substances that produce such effects in individual concentrations exceeding:

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

— the concentration specified at point 2 of Annex I (Table II) to this Directive where the substance or substances under consideration do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

- (iv) owing to their long-term effects, preparations containing one or more dangerous substances that produce such effects in individual concentrations exceeding:
- either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or
  - the concentration specified at point 3 of Annex I (Table III) to this Directive where the substance or substances under consideration do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits.
- (c) The following preparations shall be regarded as harmful:
- (i) owing to their acute lethal effects, preparations containing one or more substances classified or regarded as very toxic, toxic or harmful in individual concentrations exceeding:
- either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or
  - the concentration specified at point 1 of Annex I (Table I) to this Directive where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;
- (ii) owing to their acute lethal effects, preparations containing more than one of the substances classified or regarded as very toxic or toxic or harmful in individual concentrations not exceeding the limits specified either in Annex I to Directive 67/548/EEC or at point 1 of Annex I (Table I) to this Directive if the sum of the quotients obtained by dividing the percentage by weight of each substance in the preparation by the harmful limit specified for that substance is 1 or more, i.e.

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

where:

- $P_{T+}$  is the percentage by weight of each very toxic substance in the preparation,
- $P_T$  is the percentage by weight of each toxic substance in the preparation,
- $P_{Xn}$  is the percentage by weight of each harmful substance in the preparation,
- $L_{Xn}$  is the limit specified for each very toxic, toxic or harmful substance expressed as a percentage;

- (iii) owing to their non-lethal irreversible effects after one exposure, preparations containing one or more dangerous substances that produce such effects in individual concentrations exceeding:
- either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or
  - the concentration specified at point 2 of Annex I (Table II) to this Directive where the substance or substances under consideration do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;
- (iv) owing to their long-term effects, preparations containing one or more dangerous substances that produce such effects in individual concentrations exceeding:
- either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or
  - the concentration specified at point 3 of Annex I (Table III) to this Directive where the substance or substances under consideration do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;
- (v) owing to their sensitizing effects by inhalation, preparations containing at least one dangerous substance to which is assigned phrase R 42 that produces such effects in individual concentrations exceeding:
- either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or
  - the concentration specified at point 5 of Annex I (Table V) to this Directive where the substance or substances under consideration do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits.

(d) The following preparations shall be regarded as very corrosive <sup>(1)</sup>:

- (i) preparations containing one or more substances classified or regarded as corrosive to which is assigned phrase R 35 in individual concentrations exceeding:
- either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or
  - the concentration specified at point 4 of Annex I (Table IV) to this Directive where the substance

<sup>(1)</sup> Within the meaning of this Directive 'very corrosive substance' means a substance to which is assigned the symbol C and the phrase denoting a risk R 35.

or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

- (ii) preparations containing more than one substance classified or regarded as corrosive to which is assigned phrase R 35 in individual concentrations not exceeding the limits specified either in Annex I to Directive 67/548/EEC or at point 4 of Annex I (Table IV) to this Directive if the sum of the quotients obtained by dividing the percentage by weight of each corrosive substance in the preparation by the corrosive limit specified for that substance is 1 or more, i.e.

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

where:

$P_{C,R35}$  is the percentage by weight of each corrosive substance in the preparation,

$L_{C,R35}$  is the corrosive limit specified for each corrosive substance to which is assigned phrase R 35 expressed as a percentage by weight.

- (e) The following preparations shall also be regarded as corrosive:

- (i) preparations containing one or more substances classified or regarded as corrosive to which is assigned phrase R 34 in individual concentrations exceeding:

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

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

- (ii) preparations containing more than one substance classified or regarded as corrosive to which is assigned phrase R 34 in individual concentrations not exceeding the limits specified either in Annex I to Directive 67/548/EEC or at point 4 of Annex I (Table IV) to this Directive if the sum of the quotients obtained by dividing the percentage by weight of each corrosive substance in the preparation by the corrosive limit specified for that substance is 1 or more, i.e.

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

where:

$P_{C,R35}$  is the percentage by weight of each corrosive substance to which is assigned phrase R 35 in the preparation,

$P_{C,R34}$  is the percentage by weight of each corrosive substance to which is assigned phrase R 34 in the preparation,

$L_{C,R34}$  is the corrosive limit specified for each corrosive substance to which is assigned phrase R 34 expressed as a percentage by weight.

- (f) The following preparations shall be regarded as liable to cause serious eye damage:

- (i) preparations containing one or more substances classified or regarded as irritant and to which is assigned phrase R 41 in individual concentrations exceeding:

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

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

- (ii) preparations containing more than one of the substances classified or regarded as corrosive or irritant to which is assigned phrase R 41 in individual concentrations not exceeding the limits specified either in Annex I to Directive 67/548/EEC or at point 4 of Annex I (Table IV) to this Directive if the sum of the quotients obtained by dividing the percentage by weight of each substance in the preparation by the irritant limit specified for that substance is 1 or more, i.e.

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

where:

$P_{Xi,R41}$  is the percentage by weight of each irritant substance to which is assigned phrase R 41 in the preparation,

$L_{Xi,R41}$  is the irritant limit specified for each irritant substance to which is assigned phrase R 41 expressed as a percentage by weight.

- (g) The following preparations shall be regarded as skin irritants:

- (i) preparations containing one or more substances classified or regarded as corrosive or irritant to

which is assigned phrase R 38 in individual concentrations exceeding:

- either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or
  - the concentration specified at point 4 of Annex I (Table IV) to this Directive where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;
- (ii) preparations containing more than one of the substances classified or regarded as corrosive or irritant to which is assigned phrase R 38 in individual concentrations not exceeding the limits specified either in Annex I to Directive 67/548/EEC or at point 4 of Annex I (Table IV) to this Directive if the sum of the quotients obtained by dividing the percentage by weight of each substance in the preparation by the irritant limit specified for that substance is 1 or more, i.e.

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

where:

$P_{C,R35}$  is the percentage by weight of each corrosive substance to which is assigned phrase R 35 in the preparation,

$P_{C,R34}$  is the percentage by weight of each corrosive substance to which is assigned phrase R 34 in the preparation,

$P_{Xi,R38}$  is the percentage by weight of each irritant substance to which is assigned phrase R 38 in the preparation,

$L_{Xi,R38}$  is the irritant limit specified for each corrosive or irritant substance to which is assigned phrase R 38 expressed as a percentage by weight;

- (iii) owing to their sensitizing effects by skin contact, preparations containing at least one dangerous substance to which is assigned phrase R 43 that produces such effects in individual concentrations exceeding:

- either the concentration specified in Annex I to Directive 67/548/EEC for the substance under consideration, or
- the concentration specified at point 5 of Annex I (Table V) to this Directive where the substance or

substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits.

- (h) The following preparations shall be regarded as eye irritants:

- (i) preparations containing one or more substances classified or regarded as irritant to which is assigned phrase R 41 or R 36 in individual concentrations exceeding:

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

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

- (ii) preparations containing more than one of the substances classified or regarded as irritant to which is assigned phrase R 41 or phrase R 36 in individual concentrations not exceeding the limits specified in Annex I to Directive 67/548/EEC or at point 4 of Annex I (Table IV) to this Directive if the sum of the quotients obtained by dividing the percentage by weight of each substance in the preparation by the irritant limit specified for that substance is 1 or more, i.e.

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

where:

$P_{Xi,R41}$  is the percentage by weight of each irritant substance which is assigned phrase R 41 in the preparation,

$P_{Xi,R36}$  is the percentage by weight of each irritant substance to which is assigned phrase R 36 in the preparation,

$L_{Xi,R36}$  is the irritant limit specified for each irritant substance to which is assigned phrase R 41 or phrase R 36 expressed as a percentage by weight.

- (i) The following preparations shall be regarded as irritants for the respiratory system:

- (i) preparations containing one or more substances classified or regarded as irritant to which is assigned phrase R 37 in individual concentrations exceeding:

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

- the concentration specified at point 4 of Annex I (Table IV) to this Directive where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;
- (ii) preparations containing more than one of the substances classified or regarded as irritant to which is assigned phrase R 37 in individual concentrations not exceeding the limits specified either in Annex I to Directive 67/548/EEC or at point 4 of Annex I (Table IV) to this Directive if the sum of the quotients obtained by dividing the percentage by weight of each substance in the preparation by the irritant limit specified for that substance is 1 or more, i.e.

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

where:

$P_{X_i, R37}$  is the percentage by weight of each irritant substance to which is assigned phrase R 37 in the preparation,

$L_{X_i, R37}$  is the irritant limit specified for each irritant substance to which is assigned phrase R 37 expressed as a percentage by weight.

- (j) Preparations shall be regarded as:

carcinogenic and assigned at least the symbol and indication of danger 'toxic', if they contain a substance producing such effects, to which is assigned the standard phrase R 45, which denotes carcinogenic substances in category 1 and category 2, in a concentration equal to or exceeding:

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

- (k) Preparations shall be regarded as:

suspect for humans owing to their possible carcinogenic effects and assigned at least the symbol and indication of danger 'harmful', if they contain a substance producing such effects to which is assigned the standard phrase R 40, which denotes carcinogenic substances in category 3, in a concentration equal to or exceeding:

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

- (l) Preparations shall be regarded as:

mutagenic and assigned at least the symbol and indication of danger 'toxic' if they contain a substance producing such effects, to which is assigned the standard phrase R 46 which denotes mutagenic substances in category 1, in a concentration equal to or exceeding:

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

- (m) Preparations shall be regarded as having to be treated as mutagenic and assigned at least the symbol and indication of danger 'harmful' if they contain a substance producing such effects to which is assigned the standard phrase R 46, which denotes mutagenic substances in category 2, in a concentration equal to or exceeding:

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

- (n) Preparations shall be regarded as:

suspect for humans because of their possible mutagenic effects and assigned at least the symbol and indication of danger 'harmful' if they contain a substance producing such effects to which is assigned the standard phrase R 40, which denotes mutagenic substances in category 3, in a concentration equal to or exceeding:

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

## (o) Preparations shall be regarded as:

teratogenic and assigned at least the symbol and indication of danger 'toxic' if they contain a substance producing such effects, which is assigned the standard phrase R 47, which denotes teratogenic substances in category 1, in a concentration equal to or exceeding:

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

## (p) Preparations shall be regarded as:

having to be treated as teratogenic and assigned at least the symbol and indication of danger 'harmful', if they contain a substance producing such effects to which is assigned the standard phrase R 47, which denotes teratogenic substances in category 2, in a concentration equal to or exceeding:

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

## (q) Preparations shall be regarded as:

having specific effects on health not further defined and assigned at least the symbol and indication of danger 'harmful' if they contain a substance which does not yet appear in Annex I to Directive 67/548/EEC but to which is provisionally assigned the standard phrase R 40 denoting such substances in a concentration exceeding that specified at point 6 of Annex I (Table VI) to this Directive.

## 6. For preparations covered by this Directive:

## (a) No account shall be taken of substances whether or not listed in Annex I to Directive 67/548/EEC, whether existing as impurities or as additives, if their concentration by weight is less than:

- 0,1% for substances classified as very toxic or toxic,
- 1% for substances classified as harmful, corrosive or irritant,

unless lower values have been specified in Annex I to Directive 67/548/EEC.

## (b) Dangerous substances not listed in Annex I to Directive 67/548/EEC but used as constituents of a preparation in a concentration by weight higher than that given at point (a) of this paragraph shall be given concentration limits characterizing the health hazards.

Some substances may have more than one property harmful to health, e.g. harmfulness/irritation, corrosiveness/harmfulness, corrosiveness/sensitization; each of these properties must therefore be characterized by its specific concentration limit.

These concentration limits shall be determined in accordance with Annex I to this Directive by the manufacturer or any other person who places such a preparation on the market.

*Article 4*

The classification of dangerous preparations according to the degree of hazard and the specific nature of the risks involved shall be based on the definitions laid down in Article 2. The preparations shall be classified according to the greatest degree of hazard in accordance with Article 7 (1) (d).

*Article 5*

1. Member States shall take all necessary measures to ensure that the preparations envisaged by this Directive cannot be placed on the market unless they comply therewith.

2. If there is any doubt with regard to the compliance referred to in paragraph 1, Member States may request information on the composition of the preparation and any other pertinent information.

3. To this end, the manufacturer, or those responsible for placing the preparation on the market, shall hold the data used for the classification and labelling of the preparation at the disposal of the authorities of the Member States.

*Article 6*

1. Member States shall take all the necessary measures to ensure that:

(a) dangerous preparations are not placed on the market unless their packaging meets the requirements of Article 15 (1) of Directive 67/548/EEC with respect to their strength, leak-tightness and fastening systems;

(b) containers which contain dangerous preparations offered or sold to the general public do not have:

- either a shape and/or graphic decoration likely to attract or arouse the active curiosity of children or to mislead consumers,

- or a presentation and/or a designation used for human and animal foodstuffs, medicinal or cosmetic products.
2. Member States shall take all the necessary measures to ensure that containers containing certain categories of dangerous preparations offered or sold to the general public and defined in accordance with the procedure referred to in paragraph 3:
- are fitted with child-resistant fastenings,
  - carry a tactile warning of danger.
3. The categories of dangerous preparations the packaging of which have to be fitted with the devices referred to in paragraph 2 shall be defined by the procedure referred to in Article 21 of Directive 67/548/EEC.

The technical specifications relating to such devices are given in parts A and B of Annex IX to Directive 67/548/EEC.

#### Article 7

1. The following information shall be clearly and indelibly marked on any package:

- (a) the trade name or designation of the preparation;
- (b) the name and full address including the telephone number of the person established in the Community who is responsible for placing the preparation on the market, whether it be the manufacturer, the importer or the distributor;
- (c) the chemical name of the substance or substances present in the preparation in accordance with the following detailed rules:
  - (i) — in the case of preparations classified as T<sup>+</sup>, T or X<sub>n</sub> in accordance with Article 3, only T<sup>+</sup>, T and X<sub>n</sub> substances present in concentrations equal to or in excess of the lowest limit (X<sub>n</sub> limit) for each of them laid down in Annex I to this Directive or to Directive 67/548/EEC must be taken into consideration,
    - in the case of preparations classified as C in accordance with Article 3, only C substances present in concentrations equal to or in excess of the lowest limit (X<sub>i</sub> limit) laid down in Annex I to this Directive or to Directive 67/548/EEC must be taken into consideration,
    - in the case of preparations to which are assigned phrases R 42, R 43, or R 42/43 in accordance with Article 3, only substances to which those phrases are assigned and which are present in concentrations equal to or in excess of the limit laid down in Annex I to this Directive or to Directive 67/548/EEC must be taken into consideration;
  - (ii) as a general rule a maximum of four chemical names shall suffice to identify the substances

primarily responsible for the major health hazards which have given rise to the classification and the choice of the corresponding phrases referring to the risk involved. In some cases, more than four chemical names may be necessary.

If the preparation is assigned in accordance with Article 3, one of the standard phrases R 39, R 40, R 42, R 43, R 42/43, R 45, R 46, R 47 and/or R 48, the name of the substance or substances must be mentioned.

The chemical name shall be one of the designations listed in Annex I to Directive 67/548/EEC or an internationally recognized designation if it is not yet listed therein.

Where a manufacturer can demonstrate that the disclosure of the chemical identity of a harmful substance not assigned one or more of the R phrases mentioned above on the label of a preparation will put at risk the confidential nature of his property, he shall be permitted to refer to that substance either by means of a name that identifies the most important functional chemical groups or by means of an alternative name.

Where this is the case, the manufacturer must inform the authorities of the Member State where the preparation is first placed on the market. These authorities shall inform the Commission and the other Member States.

Confidential information brought to the attention of the authorities of a Member State or of the Commission shall be treated in accordance with Article 11 (4) of Directive 67/548/EEC;

- (d) the symbols, where specified in this Directive, for and indications of the dangers involved in the use of the preparation, in accordance with Article 16 (2) (c) of Directive 67/548/EEC read in conjunction with Annex II thereto, and, in the case of aerosol preparations, in accordance with points 1.8 and 2.2 (c) of the Annex to Directive 75/324/EEC as far as flammability hazards are concerned.
- Where more than one danger symbol has to be assigned to a preparation:
- the obligation to apply the symbol T shall make the symbols C and X optional,
  - the obligation to apply the symbol C shall make the symbol X optional,
  - the obligation to apply the symbol E shall make the symbols F and O optional;
- (e) standard phrases indicating the special risks arising from such dangers (R phrases).

The indications concerning special risks (R phrases) shall conform to the wording in Annex III to Directive 67/548/EEC and shall be provided by the manufacturer or any other person placing the preparation on the market, in accordance with Annex I to this Directive and Annex VI, point II (D) to Directive 67/548/EEC.

As a general rule a maximum of four R phrases shall suffice to describe the risks; for this purpose the combined phrases listed in the aforementioned Annex III shall be regarded as single phrases. If the preparation falls within more than one danger category, however, these standard phrases must cover all the principal hazards associated with the preparation.

Thus, if a preparation is classified as both harmful and irritant, it shall be labelled 'harmful' and attention shall be drawn to its twin harmful and irritant characteristics by the appropriate R phrases.

The standard phrases 'extremely flammable' or 'highly flammable' need not appear if they repeat an indication of danger used pursuant to paragraph (d);

- (f) one or more standard phrases indicating the safety advice relating to the use of the preparation (S phrases).

The indications giving safety advice (S phrases) shall conform to the wording in Annex IV to Directive 67/548/EEC and shall be provided by the manufacturer or any other person placing the preparation on the market, in accordance with Annex II to this Directive and Annex VI, point II (D) to Directive 67/548/EEC.

As a general rule, a maximum of four S phrases shall suffice to formulate the most appropriate safety advice; for this purpose the combined phrases listed in the aforementioned Annex IV shall be regarded as single phrases.

The package shall be accompanied by safety advice on the use of the preparation where it is physically impossible to include the advice on the label or package itself.

In the case of highly flammable and flammable oxidizing preparations, there is no need to give a reminder of the special risks or the safety advice if the contents of the package do not exceed 125 ml. The same shall apply in the case of irritant preparations except where they contain substances that might cause sensitization.

- (g) the nominal quantity (nominal mass or nominal volume) of the contents in the case of preparations sold to the general public.

2. The special provisions applicable to certain preparations are set out in Annex II.

3. Article 3 (6) (a) shall apply *mutatis mutandis* to labelling.

4. Information such as 'non toxic', 'not harmful' or any other statement indicating that the preparation is not dangerous may not appear on the packaging or labelling of the preparations referred to in this Directive.

#### Article 8

1. Where the particulars required by Article 7 appear on a label, that label shall be firmly affixed to one or more surfaces of the packaging so that the said particulars can be read horizontally when the package is set down normally. The dimensions of the label shall be as follows:

<i>Capacity of the package</i>	<i>Dimensions (in millimetres)</i>
— not exceeding three litres:	if possible at least 52 × 74
— greater than three litres but not exceeding 50 litres:	at least 74 × 105
— greater than 50 litres but not exceeding 500 litres:	at least 105 × 148
— greater than 500 litres:	at least 148 × 210

Each symbol shall cover at least one-tenth of the surface area of the label but shall not be less than 1 cm<sup>2</sup>. The entire surface of the label shall adhere to the package immediately containing the preparation.

These dimensions are intended solely for provision of the information required by this Directive and if necessary of any supplementary health or safety information.

2. A label is not required when the particulars are clearly shown on the package itself, as specified in paragraph 1.

3. The colour and presentation of the label — or, in the case of paragraph 2, of the package — shall be such that the danger symbol and its background stand out clearly from it.

4. Member States may make the placing of dangerous preparations on the market in their territory subject to the use of their official language or languages for the purposes of labelling.

5. For the purpose of this Directive, labelling requirements shall be deemed to be satisfied:

- (a) in the case of an outer package containing one or more inner packages, if the outer package is labelled in

accordance with international rules on the transport of dangerous preparations and the inner package or packages are labelled in accordance with this Directive;

- (b) in the case of a single package, if such a package is labelled in accordance with international rules on the transport of dangerous preparations and with Article 7 (1) (a), (b), (c), (e) and (f), and (3).

For dangerous preparations that are not leaving the territory of a Member State, the labelling may be in accordance with national regulations instead of with the international rules on the transport of dangerous preparations.

#### Article 9

1. Member States may:

- (a) permit the labelling required by Article 7 to be applied in some other appropriate manner on packages which are either too small or otherwise unsuitable for labelling in accordance with Article 8 (1) and (2);
- (b) by way of derogation from Articles 6 and 7, permit the packaging of dangerous preparations which are neither explosive, very toxic nor toxic to be unlabelled or to be labelled in some other way if they contain such small quantities that there is no reason to fear any danger to persons handling such preparations or to other persons.

2. If a Member State makes use of the options provided for in paragraph 1, it shall forthwith inform the Commission thereof.

#### Article 10

Member States shall take the measures necessary to implement a system of specific information (in safety data-sheet form) relating to dangerous preparations.

The detailed arrangements for this system shall be laid down in accordance with the procedure provided for in Article 21 of Directive 67/548/EEC within a period of three years after the adoption of the Directive, taking into account the systems in force in the Member States.

This information is principally intended for use by industrial users and must enable them to take the necessary measures as regards the protection of health and safety at the place of work.

#### Article 11

This Directive shall not affect the right of Member States to specify, in due compliance with the Treaty, the requirements

they deem necessary to ensure that workers are protected when using the dangerous preparations in question, provided this does not mean that the classification, packaging, and labelling of dangerous preparations are modified in a way not provided for in this Directive.

#### Article 12

Member States shall appoint the body or bodies responsible for receiving information on dangerous preparations, including their chemical composition, placed on the market.

Member States shall take the necessary steps to ensure that the appointed bodies provide all the requisite guarantees for maintaining the confidentiality of the information received. Such information may only be used to meet any medical demand by formulating preventive and curative measures, in particular in emergencies.

Member States shall ensure that the information is not used for other purposes.

For preparations already on the market, Member States shall take measures to comply with this Directive within three years from the adoption thereof.

Member States shall ensure that the appointed bodies shall have at their disposal all the information required to carry out the tasks for which they are responsible from the manufacturers or persons responsible for marketing.

#### Article 13

Member States shall not prohibit, restrict or impede, on the grounds of classification, packaging or labelling as defined in this Directive, the placing on the market of dangerous preparations which satisfy this Directive and in particular Annex II thereto.

#### Article 14

1. Where a Member State has detailed evidence that a preparation, although satisfying the requirements of this Directive, constitutes a hazard by reason of its classification, packaging or labelling, it may provisionally prohibit the sale of that hazardous preparation or subject it to special conditions in its territory. It shall immediately inform the Commission and the other Member States of such action and give reasons for its decision.

2. In the case referred to in paragraph 1, the Commission shall consult the Member States concerned as soon as possible and then deliver its opinion without delay and take the appropriate measures.

If the Commission considers that technical adaptations to this Directive are necessary, such adaptations shall be adopted in accordance with the procedure laid down in Article 21 of Directive 67/548/EEC. In such a case, Member States which have adopted safeguard measures may maintain them until the adaptations enter into force.

*Article 15*

Amendments required to adapt the Annexes to technical progress shall be adopted in accordance with the procedure laid down in Article 21 of Directive 67/548/EEC.

*Article 16*

1. Member States shall bring into force not later than 36 months after the adoption of this Directive the laws, regulations and administrative provisions necessary to comply therewith. They shall forthwith inform the Commission thereof.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive not more than six months thereafter.

3. On the date this Directive enters into force, Directives 73/173/EEC and 77/728/EEC shall cease to apply. Nevertheless, preparations which are in conformity with the specifications of the abovementioned Directives may continue to be placed on the market until one year after the abovementioned date.

*Article 17*

This Directive is addressed to the Member States.

Done at Luxembourg, 7 June 1988.

*For the Council*  
*The President*  
M. BANGEMANN

## ANNEX I

## CONCENTRATION LIMITS TO BE USED IN APPLYING THE CONVENTIONAL METHOD OF ASSESSING HEALTH HAZARDS IN ACCORDANCE WITH ARTICLE 3 (5)

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

- acute lethal effects,
- non-lethal irreversible effects after a single exposure,
- severe effects after repeated or prolonged exposure;
  
- corrosive effects,
- irritant effects,
- sensitizing effects;
  
- carcinogenic effects,
- mutagenic effects,
- teratogenic effects.

The systematic assessment of all the dangerous health effects is expressed by means of concentration limits in conjunction with the classification of the substance, i.e. the symbol and phrases denoting the risk. Therefore given the symbol priority rule, it is important to consider, in addition to the symbol, all the phrases denoting specific risks which are assigned to each substance under consideration.

## 1. Acute lethal effects

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

TABLE I

Classification of the substance	Classification of the preparation		
	T <sup>+</sup>	T	X <sub>n</sub>
T <sup>+</sup> with R 26, R 27, R 28	concentration ≥ 7 %	1 % ≤ concentration < 7 %	0,1 % ≤ concentration < 1 %
T with R 23, R 24, R 25		concentration ≥ 25 %	3 % ≤ concentration < 25 %
X <sub>n</sub> with R 20, R 21, R 22			concentration ≥ 25 %

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

- the label shall include one or more of the 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

For substances that produce non-lethal irreversible effects after a single exposure (R 39, R 40), the individual concentration limits specified in Table II determine, when appropriate, the classification of the preparation and shall determine which particular standard R phrase is to be assigned to it.

TABLE II

Classification of the substance	Classification of the preparation		
	T <sup>+</sup>	T	X <sub>n</sub>
T <sup>+</sup> with R 39	concentration ≥ 10 % R 39 (*) obligatory	1 % ≤ concentration < 10 % R 39 (*) obligatory	0,1 % ≤ concentration < 1 % R 40 (*) obligatory
T with R 39		concentration ≥ 10 % R 39 (*) obligatory	1 % ≤ concentration < 10 % R 40 (*) obligatory
X <sub>n</sub> with R 40			concentration ≥ 10 % R 40 (*) obligatory

(\*) In accordance with the labelling guide of Annex VI, point II (D) of Directive 67/548/EEC and depending on the classification, the standard R phrases R 20 to R 28 are also to be assigned to indicate route of administration or means of exposure.

### 3. Severe effects after repeated or prolonged exposure

For substances that produce severe effects after repeated or prolonged exposure (R 48), the individual concentration limits specified in Table III determine, when appropriate, the classification of the preparation and shall determine which particular standard R phrase is to be assigned to it.

TABLE III

Classification of the substance	Classification of the preparation	
	T	X <sub>n</sub>
T with R 48	concentration ≥ 10 % R 48 (*) obligatory	1 % ≤ concentration < 10 % R 48 (*) obligatory
X <sub>n</sub> with R 48		concentration ≥ 10 % R 48 (*) obligatory

(\*) In accordance with the labelling guide of Annex VI, point II (D) of Directive 67/548/EEC and depending on the classification, the standard R phrases R 20 to R 28 are also to be assigned to indicate route of administration or means of exposure.

### 4. Corrosive and irritant effects

For substances that produce corrosive effects (R 34, R 35) or irritant effects (R 36, R 37, R 38, R 41) the individual concentration limits specified in Table IV determine, when appropriate, the classification of the preparation.

TABLE IV

Classification of the substance and/or relevant standard risk phrase	Classification of the preparation and standard risk phrase			
	at least C with R 35	at least C with R 34	at least X <sub>i</sub> with R 41	at least X <sub>i</sub> with R 36, R 37, R 38
at least C with R 35	concentration ≥ 10 % R 35; obligatory	5 % ≤ concentration < 10 % R 34; obligatory		1 % ≤ concentration < 5 % R 36, R 38; obligatory
at least C with R 34		concentration ≥ 10 % R 34; obligatory		5 % ≤ concentration < 10 % R 36, R 38; obligatory
at least X <sub>i</sub> with R 41			concentration ≥ 10 % R 41; obligatory	5 % ≤ concentration < 10 % R 36 obligatory
at least X <sub>i</sub> with R 36, R 37, R 38				concentration ≥ 20 % R 36, R 37 and R 38 are obligatory in the light of the concentration present if they apply to the substances under consideration

## 5. Sensitizing effects

Substances that produce such effects are classified:

- at least as harmful ( $X_n$ ) and assigned R 42 if this effect can be produced by inhalation,
- at least as irritant ( $X_i$ ) and assigned R 43 if this effect can be produced through contact with the skin,
- at least as harmful ( $X_n$ ) and assigned R 42/43 if this effect can be produced in both these ways.

The individual concentration limits specified in Table V determine, when appropriate, the classification of the preparation, and shall determine which particular R phrase is to be assigned to it.

TABLE V

Classification of the substance	Classification of the preparation and standard risk phrase	
	At least $X_n$ and R 42	At least $X_i$ and R 43
At least $X_n$ and R 42	concentration $\geq 1\%$ R 42 obligatory	
At least $X_i$ and R 43		concentration $\geq 1\%$ R 43 obligatory
At least $X_n$ and R 42/43	concentration $\geq 1\%$ R 42/43 obligatory	

## 6. Carcinogenic/mutagenic/teratogenic effects

For substances which produce such effects and for which specific concentration limits do not yet appear in Annex I to Directive 67/548/EEC and for those which, in accordance with point 3.1.1 of Annex III to Directive 83/467/EEC, are provisionally assigned the phrase R 40, the concentration limits laid down in Table VI shall determine, where appropriate, the classification of the preparation and the compulsory R phrase to be assigned to it.

TABLE VI

Substance	Classification of the preparation and standard risk phrase	
	At least T	At least $X_n$
At least T with R 45 for carcinogenic substances of category 1 or 2	$\geq 0,1\%$ R 45 obligatory	
At least $X_n$ with R 40 for carcinogenic substances of category 3		$\geq 1\%$ R 40 obligatory
At least T with R 46 for mutagenic substances of category 1	$\geq 0,1\%$ R 46 obligatory	
At least $X_n$ with R 46 for mutagenic substances of category 2		$\geq 0,1\%$ R 46 obligatory
At least $X_n$ with R 40 for mutagenic substances of category 3		$\geq 1\%$ R 40 obligatory
At least T with R 47 for teratogenic substances of category 1	$\geq 0,5\%$ R 47 obligatory	
At least $X_n$ with R 47 for teratogenic substances of category 2		$\geq 5\%$ R 47 obligatory
At least $X_n$ and R 40 provisionally in accordance with point 3.1.1 of Annex III to Directive 83/467/EEC		$\geq 1\%$ R 40 obligatory

## ANNEX II

## SPECIAL PROVISIONS ON THE LABELLING OF CERTAIN PREPARATIONS

## 1. PREPARATIONS CLASSIFIED AS VERY TOXIC, TOXIC OR CORROSIVE, SOLD TO THE GENERAL PUBLIC

- 1.1. The labels on packages containing such preparations must compulsorily bear the safety advice S<sub>1</sub>/S<sub>2</sub> and S<sub>46</sub> in addition to the specific safety advice.
- 1.2. 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 necessary, instructions for the destruction of the empty package.

## 2. PREPARATIONS CONTAINING LEAD

2.1. *Paints and varnishes*

Labels of packages of paints and varnishes containing lead in quantities exceeding 0,25 % 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.'

## 3. PREPARATIONS CONTAINING CYANOACRYLATES

3.1. *Glues*

The immediate packaging of glues 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.

## 4. PREPARATIONS CONTAINING ISOCYANATES

The package labels 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.'

5. PREPARATIONS CONTAINING EPOXY CONSTITUENTS WITH AN AVERAGE MOLECULAR WEIGHT  $\leq 700$ 

The package labels of preparations containing epoxy constituents with an average molecular weight  $\leq 700$  must bear the following inscriptions:

'Contains epoxy constituents.

See information supplied by the manufacturer.'

## 6. PREPARATIONS INTENDED FOR USE BY SPRAYING

The package label on preparations intended for use by spraying must bear the safety advice S 23 and S 38 or S 23 and S 51 depending on the application criteria specified in Directive 83/467/EEC.