

II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DIRECTIVE 93/18/EEC

of 5 April 1993

adapting for the third time to technical progress Council Directive 88/379/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 88/379/EEC 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⁽¹⁾, and in particular Article 15 thereof,

Whereas Council Directive 92/32/EEC⁽²⁾ amending Directive 67/548/EEC⁽³⁾ for the seventh time, replaces the definition 'teratogenic' by 'toxic for reproduction' and introduces this modification into Directive 88/379/EEC;

Whereas Annex VI to Directive 67/548/EEC, as last amended by Commission Directive 92/37/EEC⁽⁴⁾, provides for new criteria and new R type phrases for the category of danger 'toxic for reproduction', as well as new criteria for the use of certain R phrases concerning the nature of particular risks attributed to dangerous substances and preparations and in particular phrases R 33 and R 64;

Whereas the provisions set out in Annex I to Directive 88/379/EEC, as amended by Directive 90/492/EEC⁽⁵⁾, should therefore be revised and supplemented;

Whereas Annex II to Directive 88/379/EEC contains special labelling provisions applicable to certain prepara-

tions; whereas these special labelling provisions apply without distinction to all preparations under consideration whether or not considered dangerous within the meaning of the Directive;

Whereas it is necessary to make special provisions in addition to those relating to labelling in the case of preparations which although they contain at least one substance which is dangerous are not necessarily dangerous within the meaning of Directive 88/379/EEC;

Whereas the special provisions applicable to certain preparations set out in Annex II to Directive 88/379/EEC as amended by Directive 89/178/EEC⁽⁶⁾ should therefore be revised and supplemented;

Whereas the amendments to Annex II result in its restructuring featuring in particular a new presentation by chapter in order to maintain the clarity required in all legislation;

Whereas Article 8a of the Treaty established an area without internal barriers in which the free circulation of goods, of persons, of services and capital is assured;

Whereas, according to the scope and effects of the proposed action, the Community measures envisaged by this regulation are not only necessary but also indispensable for the attainment of the stated objectives and that these objectives cannot be achieved by Member States individually, and that furthermore their attainment at Community level is already provided for by Directive 88/379/EEC;

⁽¹⁾ OJ No L 187, 16. 7. 1988, p. 14.

⁽²⁾ OJ No L 154, 5. 6. 1992, p. 1.

⁽³⁾ OJ No L 196, 16. 8. 1967, p. 1.

⁽⁴⁾ OJ No L 154, 5. 6. 1992, p. 30.

⁽⁵⁾ OJ No L 275, 5. 10. 1990, p. 35.

⁽⁶⁾ OJ No L 64, 8. 3. 1989, p. 18.

Whereas the measures provided for in this Directive are in accordance with the opinion of the Committee for the Adaptation to Technical Progress of the Directives on the Removal of Technical Barriers to Trade in Dangerous Substances and Preparations,

HAS ADOPTED THIS DIRECTIVE :

Article 1

Annexes I and II to Directive 88/379/EEC are replaced by the Annex to this Directive.

Article 2

1. Member States shall adopt and publish the provisions necessary to comply with this Directive by 1 July 1994 at the latest and shall forthwith inform the Commission thereof.

2. These provisions shall take effect by 1 July 1994 at the latest.

3. When Member States adopt these provisions, these shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by Member States.

Article 3

This Directive is addressed to the Member States.

Done at Brussels, 5 April 1993.

For the Commission

Martin BANGEMANN

Member of the Commission

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 :

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. sensitizing effects ;
6. carcinogenic effects, mutagenic effects, toxic effects for reproduction.

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 (Tables A) where they are expressed as a volume/volume percentage and in conjunction with the classification of a substance.

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

1. Acute lethal effects

1.1. Other than gaseous preparations

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 ⁺ | T | X _n |
| T ⁺ 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 _n 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.

1.2. Gaseous preparations

The concentration limits expressed as a volume/volume percentage in Table 1 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 IA

| Classification of the substance (gas) | Classification of the gaseous preparation | | |
|---------------------------------------|---|-----------------------------|--------------------------------|
| | T ⁺ | T | X _n |
| T ⁺ with R 26, R 27, R 28 | concentration ≥ 1 % | 0,2 % ≤ concentration < 1 % | 0,02 % ≤ concentration < 0,2 % |
| T with R 23, R 24, R 25 | | concentration ≥ 5 % | 0,5 % ≤ concentration < 5 % |
| X _n with R 20, R 21, R 22 | | | concentration ≥ 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. Other than gaseous preparations

For substances that produce non-lethal irreversible effects after a single exposure (R 39/route of exposure, R 40/route of exposure), the individual concentration limits specified in Table II determine, when appropriate, the classification of the preparation.

TABLE II

| Classification of the substance | Classification of the preparation | | |
|--|---|---|--|
| | T ⁺ | T | X _n |
| T ⁺ with R 39/route of exposure | concentration ≥ 10 % R 39 (*) obligatory | 1 % ≤ concentration < 10 % R 39 (*) obligatory | 0,1 % ≤ concentration < 1 % R 40 (*) obligatory |
| T with R 39/route of exposure | | concentration ≥ 10 % R 39 (*) obligatory | 1 % ≤ concentration < 10 % R 40 (*) obligatory |
| X _n with R 40/route of exposure | | | concentration ≥ 10 % R 40 (*) obligatory |

(*) In order to indicate the route of administration/exposure (r of exp) 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) shall be used.

2.2. Gaseous preparations

For gases that produce non-lethal irreversible effects after a single exposure (R 39/route of exposure, R 40/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 R 39/route of exposure | concentration $\geq 1\%$ R 39 (*) obligatory | 0,2 % \leq concentration < 1 % R 39 (*) obligatory | 0,02 % \leq concentration < 0,2 % R 40 (*) obligatory |
| T with R 39/route of exposure | | concentration $\geq 5\%$ R 39 (*) obligatory | 0,5 % \leq concentration < 5 % R 40 (*) obligatory |
| X _n with R 40/route of exposure | | | concentration $\geq 5\%$ R 40 (*) obligatory |

(*) In order to indicate the route of administration/exposure (r of exp) 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) shall be used.

3. Severe effects after repeated or prolonged exposure

3.1. Other than gaseous preparations

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

TABLE III

| Classification of the substance | Classification of the preparation | |
|--|--|--|
| | T | X _n |
| T with R 48/route of exposure | concentration $\geq 10\%$ R 48 (*) obligatory | 1 % \leq concentration < 10 % R 48 (*) obligatory |
| X _n with R 48/route of exposure | | concentration $\geq 10\%$ R 48 (*) obligatory |

(*) In order to indicate the route of administration/exposure (r of exp) 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) shall be used.

3.2. Gaseous preparations

For gases that produce severe effects after repeated or prolonged exposure (R 48/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 R 48/route of exposure | concentration $\geq 5\%$ R 48 (*) obligatory | 0,5 % \leq concentration < 5 % R 48 (*) obligatory |
| X _n with R 48/route of exposure | | concentration $\geq 5\%$ R 48 (*) obligatory |

(*) In order to indicate the route of administration/exposure (r of exp) 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) shall be used.

4. Corrosive and irritant effects including serious damage to eye

4.1. Other than gaseous preparations

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 | Classification of the preparation | | | |
|--------------------------------------|--|--|--|--|
| | C with R 35 | C with R 34 | X _i with R 41 | X _i with R 36, R 37, R 38 |
| C with R 35 | concentration $\geq 10\%$ R 35 obligatory | $5\% \leq$ concentration $< 10\%$ R 34 obligatory | (¹) | $1\% \leq$ concentration $< 5\%$ R 36/38 obligatory |
| C with R 34 | | concentration $\geq 10\%$ R 34 obligatory | (¹) | $5\% \leq$ concentration $< 10\%$ R 36/38 obligatory |
| X _i with R 41 | | | concentration $\geq 10\%$ R 41 obligatory | $5\% \leq$ concentration $< 10\%$ R 36 obligatory |
| X _i with R 36, R 37, R 38 | | | | concentration $\geq 20\%$ R 36, R 37, R 38 are obligatory in the light of the concentration present if they apply to the substances under consideration |

(¹) According to the labelling guide (Annex VI to Directive 67/548/EEC), corrosive substances assigned risk phrases R 35 or R 34 must also be considered as assigned phrase R 41. Consequently, if the preparation contains corrosive substances with R 35 or R 34 below the concentration limits for a classification of the preparation as corrosive, such substances can contribute to a classification of the preparation as irritant (R 41) or irritant (R 36).

Therefore when the formulae of Article 3 (5) (f) (ii) and 3 (5) (h) (ii) of the present Directive are applied the following concentration limits must be used, unless different values are fixed in Annex I to Directive 67/548/EEC:

(a) when formula 5 (f) (ii) is applied the limit values for LX, R 41 are:

- 10 % for the substances X_i, R 41,
- 10 % for the substances C R 34,
- 5 % for the substances C R 35;

(b) when formula 5 (h) (ii) is applied the limit values for LX, R 36 are:

- 20 % for the substances X_i, R 36,
- 5 % for the substances X_i, R 41,
- 5 % for the substances C R 34,
- 1 % for the substances C R 35.

4.2. Gaseous preparations

For gases that produce such effects (R 34, R 35 or R 36, R 37, R 38, R 41), 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 R 35 | C with R 34 | X _i with R 41 | X _i with R 36, R 37, R 38 |
| C with R 35 | concentration $\geq 1\%$ R 35 obligatory | 0,2 % \leq concentration $< 1\%$ R 34 obligatory | (*) | 0,02 % \leq concentration $< 0,2\%$ R 37 obligatory |
| C with R 34 | | concentration $\geq 5\%$ R 34 obligatory | (*) | 0,5 % \leq concentration $< 5\%$ R 37 obligatory |
| X _i with R 41 | | | concentration $\geq 5\%$ R 41 obligatory | 0,5 % \leq concentration $< 5\%$ R 36 obligatory |
| X _i with R 36, R 37, R 38 | | | | concentration $\geq 5\%$ R 36, R 37, R 38 obligatory as appropriate |

(*) According to the labelling guide (Annex VI to Directive 67/548/EEC), corrosive substances assigned risk phrases R 35 or R 34 must also be considered as assigned phrase R 41. Consequently, if the preparation contains corrosive substances with R 35 or R 34 below the concentration limits for a classification of the preparation as corrosive, such substances can contribute to a classification of the preparation as irritant (R 41) or irritant (R 36).

Therefore when the formulae of Article 3 (5) (f) (ii) and 3 (5) (h) (ii) of the present Directive are applied the following concentration limits must be used, unless different values are fixed in Annex I to Directive 67/548/EEC:

(a) when formula 5 (f) (ii) is applied the limit values for LX, R 41 are:

- 5 % for the substances X_i R 41,
- 5 % for the substances C R 34,
- 0,2 % for the substances C R 35;

(b) when formula 5 (h) (ii) is applied the limit values for LX, R 36 are:

- 5 % for the substances X_i R 36,
- 0,5 % for the substances X_i R 41,
- 0,5 % for the substances C R 34,
- 0,02 % for the substances C R 35.

5. Sensitizing effects

5.1. Other than gaseous preparations

Substances that produce such effects are classified as sensitizing and assigned:

- the symbol X_n and phrase R 42 if this effect can be produced by inhalation,
- the symbol X_i and phrase R 43 if this effect can be produced through contact with the skin,
- the symbol X_n and phrase R 42/43 if this effect can be produced by inhalation and through contact with the skin.

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

TABLE V

| Classification of the substance | Classification of the preparation | |
|---------------------------------|--|---|
| | sensitizing with R 42 | sensitizing with R 43 |
| sensitizing with R 42 | concentration $\geq 1\%$ R 42 obligatory | |
| sensitizing with R 43 | | concentration $\geq 1\%$ R 43 obligatory |
| sensitizing with R 42/43 | concentration $\geq 1\%$ R 42/43 obligatory | |

5.2. Gaseous preparations

Gases that produce such effects are classified as sensitizing and assigned:

- the symbol X_n and phrase R 42 if this effect can be produced by inhalation,
- the symbol X_n and phrase R 42/43 if this effect can be produced by inhalation and 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 | |
|--|--|-----------------------|
| | sensitizing with R 42 | sensitizing with R 43 |
| sensitizing with R 42 | concentration $\geq 0,2\%$ R 42 obligatory | |
| sensitizing with R 42/43 | concentration $\geq 0,2\%$ R 42/43 obligatory | |

6. Carcinogenic/mutagenic/toxic effects for reproduction

6.1. Other than gaseous preparations

For substances which produce such effects and for which specific concentration limits do not yet appear in Annex I to Directive 67/548/EEC, concentration limits laid down in Table VI shall determine, where appropriate, the classification of the preparation.

TABLE VI

| Classification of the substance | Classification of the preparation | |
|--|---|---|
| | Categories 1 and 2 | Category 3 |
| carcinogenic substances of category 1 or 2 with R 45 or R 49 | $\geq 0,1\%$ carcinogenic R 45, R 49 obligatory as appropriate | |
| carcinogenic substances of category 3 with R 40 | | $\geq 1\%$ carcinogenic R 40 obligatory |
| mutagenic substances of category 1 or 2 with R 46 | $\geq 0,1\%$ mutagenic R 46 obligatory | |
| mutagenic substances of category 3 with R 40 | | $\geq 1\%$ mutagenic R 40 obligatory |
| substances 'toxic for reproduction' of category 1 or 2 with R 60 (fertility) | $\geq 0,5\%$ toxic for reproduction (fertility) R 60 obligatory | |
| substances 'toxic for reproduction' of category 3 with R 62 (fertility) | | $\geq 5\%$ toxic for reproduction (fertility) R 62 obligatory |
| substances 'toxic for reproduction' of category 1 or 2 with R 61 (development) | $\geq 0,5\%$ toxic for reproduction (development) R 61 obligatory | |
| substances 'toxic for reproduction' of category 3 with R 63 (development) | | $\geq 5\%$ toxic for reproduction (development) R 63 obligatory |

6.2. Gaseous preparations

For gases which produce such effects and for which specific concentration limits do not yet appear in Annex I to Directive 67/548/EEC, the concentration limits laid down in Table VI A, expressed as a volume/volume percentage, shall determine, where appropriate, the classification of the preparation.

TABLE VI A

| Classification of the substance (gas) | Classification of the preparation | |
|--|---|---|
| | Categories 1 and 2 | Category 3 |
| carcinogenic substances of category 1 or 2 with R 45 or R 49 | $\geq 0,1$ % carcinogenic R 45, R 49 obligatory as appropriate | |
| carcinogenic substances of category 3 with R 40 | | ≥ 1 % carcinogenic R 40 obligatory |
| mutagenic substances of category 1 or 2 with R 46 | $\geq 0,1$ % mutagenic R 46 obligatory | |
| mutagenic substances of category 3 with R 40 | | ≥ 1 % mutagenic R 40 obligatory |
| substances 'toxic for reproduction' of category 1 or 2 with R 60 (fertility) | $\geq 0,2$ % toxic for reproduction (fertility) R 60 obligatory | |
| substances 'toxic for reproduction' of category 3 with R 62 (fertility) | | ≥ 1 % toxic for reproduction (fertility) R 62 obligatory |
| substances 'toxic for reproduction' of category 1 or 2 with R 61 (development) | $\geq 0,2$ % toxic for reproduction (development) R 61 obligatory | |
| substances 'toxic for reproduction' of category 3 with R 63 (development) | | ≥ 1 % toxic for reproduction (development) R 63 obligatory |

ANNEX II

PARTICULAR PROVISIONS CONCERNING CERTAIN PREPARATIONS

CHAPTER I

Particular provisions relating to labelling

A. Special provisions for preparations classified dangerous within the meaning of Article 3

1. Preparations sold to the general public

1.1. The labels on packages containing such preparations, in addition to the specific safety advice, must bear the relevant safety advice S 1, S 2, S 45 or S 46 in accordance with the criteria fixed 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 package label containing such preparations must compulsorily bear the safety advice S 23 accompanied by one of the safety advice S 38 or S 51 assigned to it in accordance with the criteria fixed in Annex VI to Directive 67/548/EEC.

3. Preparations containing a substance affected by phrase R 33 : Danger of cumulative effects

When a preparation contains at least one substance affected by the phrase R 33, the label of the preparation must carry this phrase as it appears 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 fixed by Annex I to Directive 67/548/EEC.

4. Preparations containing a substance affected by phrase R 64 : May cause harm to breastfed babies

When a preparation contains at least one substance affected by the phrase R 64, the label of the preparation must carry this phrase as it appears 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 fixed by Annex I to Directive 67/548/EEC.

B. Special provisions for preparations irrespective of their classification within the meaning of Article 3

1. Preparations containing lead

1.1. Paints and varnishes

Labels of packages 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 cyanocrylates

2.1. Adhesives

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

'Cyanocrylate.

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 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.'

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

The package labels 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 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 packaging of the abovementioned 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.'
