

## COUNCIL DIRECTIVE

of 22 July 1980

amending Directive 73/173/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 (solvents)

(80/781/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament <sup>(1)</sup>,

Having regard to the opinion of the Economic and Social Committee <sup>(2)</sup>,

Whereas, for the better protection of the general public and, in particular, of persons who come into contact with dangerous solvent preparations in the course of their work or in the pursuit of a hobby, it is necessary to extend the scope of Council Directive 73/173/EEC of 4 June 1973 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (solvents) <sup>(3)</sup>;

Whereas the Directive will henceforth apply to not only mixtures of two or more dangerous solvents but also mixtures of solvents with other non-dangerous substances when they are intended to be used as solvents; whereas corrosive, irritant, highly flammable and flammable solvents are now likewise brought within the scope of the Directive;

Whereas it is desirable that the scope of this Directive be more clearly defined with respect to other Directives relating to products which likewise contain dangerous solvents;

Whereas the provisions concerning the information appearing on the label, the dimensions of the label and the assignment of the various danger symbols have also to be brought into line with Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions of

the Member States 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 the necessary amendment and amplification of the Annex to Directive 73/173/EEC will be carried out under the procedure provided for in Article 10 thereof,

HAS ADOPTED THIS DIRECTIVE:

*Article 1*

Articles 1 to 10 of Directive 73/173/EEC shall be replaced by the following:

*'Article 1*

1. This Directive shall concern:

- the classification
- the packaging
- the labelling

of the following preparations which are placed on the market in the Member States of the Community and are considered as dangerous within the meaning of Article 2:

- (a) preparations intended for use as solvents and containing only the substances listed in the Annex hereto, including those which contain impurities or additives as defined in Article 2 (5);
- (b) preparations intended for use as solvents and containing, in addition to the substances listed in the Annex hereto, liquid substances classified as extremely flammable, highly flammable or flammable as defined in Article 2 (2) of Directive 67/548/EEC of 27 June 1967 (hereinafter referred to as "the Directive of 27 June 1967") and/or substances not defined as dangerous in the same Article of that Directive.

<sup>(1)</sup> OJ No C 182, 31. 7. 1978, p. 62.

<sup>(2)</sup> OJ No C 269, 13. 11. 1978, p. 35.

<sup>(3)</sup> OJ No L 189, 11. 7. 1973, p. 7.

<sup>(4)</sup> OJ No 196, 16. 8. 1967, p. 1/67.

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

2. This Directive shall not apply to cosmetic preparations coming under Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products <sup>(1)</sup>.

3. Furthermore, this Directive shall not apply to the following:

- (a) medicines, narcotics, radioactive substances, foodstuffs and animal feed;
- (b) additives for foodstuffs and animal feed, fertilizers, pesticides and paints, varnishes, printing inks, adhesives and similar products where Community Directives on the classification, packaging and labelling of such preparations are in force, except where the Directives in question refer specifically to this Directive;
- (c) the carriage of dangerous preparations (solvents) by rail, road, inland waterway, sea or air;
- (d) munitions and explosives placed on the market with a view to producing a practical effect by explosion or a pyrotechnic effect;
- (e) dangerous preparations exported to third countries;
- (f) preparations in transit subject to customs supervision, provided that they do not undergo any treatment or processing;
- (g) substances which are in the form of waste and which are covered by Council Directive 75/442/EEC of 15 July 1975 relating to waste <sup>(2)</sup> and Council Directive 78/319/EEC of 20 March 1978 relating to toxic and dangerous waste <sup>(3)</sup>.

4. Articles 4 to 6 of this Directive shall not apply to containers for gaseous preparations which are compressed, liquefied or dissolved under pressure, with the exception of aerosols as defined in Article 2 of Council Directive 75/324/EEC of 20 May 1975 on the approximation of the laws of the Member States relating to aerosol dispensers <sup>(4)</sup>.

5. The definitions specified in Article 2 of the Directive of 27 June 1967 shall apply to this Directive, with the exception of those in (1) (c) and (d) and in (2) (k).

## Article 2

1. Dangerous substances as defined in the Directive of 27 June 1967 and used as solvents shall be divided into classes and sub-classes in accordance with the Annex hereto.

Very toxic and toxic substances are under class I, harmful substances under class II. Each sub-class shall be given a classification index  $I_1$  and an exemption index  $I_2$ , as in the table below:

Class of substance		Classification index $I_1$	Exemption index $I_2$
Very toxic and toxic	I/a	500	500
	I/b	100	100
	I/c	25	25
Harmful	II/a	5	20
	II/b	2	8
	II/c	1	4
	II/d	0.5	2

2. Preparations containing one or more of the substances listed in the Annex hereto shall be considered toxic if the sum of the products obtained by multiplying the weight percentage of each toxic or harmful substance in a preparation by its respective  $I_1$  index exceeds 500, that is:

$$\sum [P \times I_1] > 500;$$

where,

P is the weight percentage of each substance in the preparation,  $I_1$  is the index corresponding to the class of the substance.

3. Preparations containing one or more substances listed in the Annex hereto shall be considered harmful if:

- (a) the sum of the products specified in paragraph 2 is less than or equal to 500 that is:

$$\sum [P \times I_1] \leq 500$$

and

- (b) the sum of the products obtained by multiplying the weight percentage of each toxic or harmful

<sup>(1)</sup> OJ No L 262, 27. 9. 1976, p. 169.

<sup>(2)</sup> OJ No L 194, 25. 7. 1975, p. 39.

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

<sup>(4)</sup> OJ No L 147, 9. 6. 1975, p. 40.

substance in a preparation by its respective  $I_2$  index exceeds 100, that is:

$$\sum [P \times I_2] > 100;$$

where,

P is the weight percentage of each substance in the preparation,  $I_1$  and  $I_2$  are the indices corresponding to the class of the substance.

4. Preparations containing one or more of the substances listed in the Annex hereto shall not be classified as toxic or harmful if the sum of the products obtained by multiplying the weight percentage of each toxic or harmful substance in a preparation by its respective  $I_2$  index is less than or equal to 100, that is:

$$\sum [P \times I_2] \leq 100;$$

where,

P is the weight percentage of each substance in the preparation,  $I_2$  is the index corresponding to the class of the substance.

5. No account shall be taken of substances listed in the Annex hereto, whether existing as impurities or as additives in preparations covered by this Directive, if their concentration by weight is less than the following values:

- 0.2 % in the case of class I substances;
- 1 % in the case of class II substances or substances classified as corrosive;
- 2 % in the case of substances classified as irritant.

Impurities or additives which are not mentioned in the Annex to this Directive but which are given in Annex I to the Directive of 27 June 1967 shall be considered as follows:

- as belonging to class I/a, in the case of substances classified as very toxic or toxic;
- as belonging to class II/a, in the case of substances classified as harmful.

6. Preparations shall be considered

(a) corrosive:

if they contain one or more of the substances classified as corrosive in the Annex in an individual concentration which exceeds the limit

specified therein or in a total concentration which exceeds the limits also specified therein;

(b) irritant:

if they contain one or more of the substances classified as irritant or corrosive in the Annex in an individual concentration which exceeds the limit specified therein or in a total concentration which exceeds the limits also specified therein.

7. Preparations shall be considered extremely flammable:

if they are in liquid form and their flash point, as determined by one of the methods laid down in Annex V (A) to the Directive of 27 June 1967, is below 0 °C and their boiling point is less than 35 °C.

8. Preparations shall be considered highly flammable:

if they are in liquid form and their flash point, as determined by one of the methods laid down in Annex V (A) to the Directive of 27 June 1967, is below 21 °C.

9. Preparations shall be considered flammable:

if they are in liquid form and their flash point, as determined by one of the abovementioned methods, is equal to or greater than 21 °C and less than or equal to 55 °C.

10. Preparations in the form of aerosols shall be subject to the flammability criteria set out in paragraphs 1.8 and 2.2 (c) of the Annex to Directive 75/324/EEC.

### Article 3

Member States shall take all necessary measures to ensure that dangerous preparations (solvents) are not placed on the market unless they comply with the provisions of this Directive and the Annex thereto.

### Article 4

Member States shall take all necessary measures to ensure that dangerous preparations (solvents) are not placed on the market unless their packages and fastenings comply with the requirements of Article 15 of the Directive of 27 June 1967.

### Article 5

1. Member States shall take all necessary measures to ensure that preparations classified as dangerous

in accordance with Article 2 are not placed on the market unless the labelling on the package complies with the following requirements.

2. The following information shall be clearly and indelibly inscribed on the package of any preparation considered to be dangerous in accordance with Article 2:

- (a) the trade name or designation of the preparation;
- (b) — the chemical name(s) of the very toxic or toxic substance(s) of which more than 0.2 % is present and the percentage or percentage zone on the following scale:

conc. $\leq$ 1 %
1 < conc. $\leq$ 5 %
5 < conc. $\leq$ 20 %
20 < conc. $\leq$ 50 %
conc. > 50 %

Indication of the name of the substance(s) and of the percentage(s) shall not, however, be necessary if the preparation is neither toxic nor harmful;

— the chemical name(s) of the harmful substance(s) if the concentration thereof exceeds the following values:

- 3 % by weight in the case of class II/a substances
- 6 % by weight in the case of class II/b substances
- 10 % by weight in the case of class II/c substances
- 20 % by weight in the case of class II/d substances

Indication of the chemical name shall not, however, be necessary if the preparation is neither toxic nor harmful;

- the chemical name of the corrosive substance(s) if the concentration thereof exceeds the lowest values mentioned in the Annex;
- the chemical name of the irritant substances if they are accompanied by the risk indications R 42, R 43 or R 42/43 given in Annex I to the Directive of 27 June 1967 and if their concentration exceeds the limits laid down in the Annex;
- the words 'irritant solvents' if the preparation contains irritant substances other than those defined in the preceding

indent in a concentration exceeding the value laid down in the Annex; such indication shall not be necessary if the preparation is already classified as corrosive.

The chemical name shall be the designation listed in Annex I to the Directive of 27 June 1967.

The chemical name(s) of the substance(s) need not be stated if the preparation is classified as highly flammable or flammable only.

- (c) the name and address of the manufacturer or of any other person placing the preparation on the market;
- (d) symbols where specified in this Directive and indications of danger involved in the use of the preparation in accordance with Article 16 (2) (c) of the Directive of 27 June 1967, read in conjunction with Annex V thereto, and in the case of aerosol preparations, in accordance with paragraphs 1.8 and 2.2 (c) of the Annex to Directive 75/324/EEC where flammability hazards are concerned;
- (e) one or more standard phrases indicating the special risks involved in the use of the preparation;
- (f) one or more standard phrases indicating the safety advice relating to the use of the preparation.

3. The indications concerning special risks shall conform to the wording in Annex III to the Directive of 27 June 1967 and shall be selected by the manufacturer or any other person placing the preparation on the market.

No more than four standard indications need be shown. If the preparation falls within several danger categories, these standard indications shall cover all the principal hazards associated with the preparation.

4. The indications concerning safety advice shall conform to the wording in Annex IV to the Directive of 27 June 1967 and shall be selected by the manufacturer or any other person placing the preparation on the market. No more than four standard indications need be shown.

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

6. For irritant, highly flammable and flammable preparations, it is not necessary to indicate the special risks and safety advice if the package contains no more than 125 ml. This shall also apply in the case of harmful preparations of the same volume not retailed to the general public.

7. The provisions of Article 2 (5) of this Directive shall apply by analogy to labelling.

8. When more than one danger symbol is assigned to a preparation, the following shall apply:

- the obligation to indicate the symbol T makes the symbols X and C optional;
- the obligation to indicate the symbol C makes the symbol X optional;
- the obligation to indicate the symbol E makes the symbols F and O optional.

9. If a preparation is classified as both harmful and irritant, it shall be labelled harmful and attention shall be drawn to its harmful and irritant characteristics by appropriate warnings in accordance with Annex III to the Directive of 27 June 1967.

#### Article 6

1. Where the particulars required by Article 5 appear on a label, that label shall be firmly affixed to one or more surfaces of the packaging so that these particulars can be read horizontally when the package is set down normally. The dimensions of the label shall be as follows:

##### Capacity of the package

Dimensions (in millimetres) if possible

- not exceeding 3 litres  
at least  $52 \times 74$
- greater than 3 litres but not exceeding 50 litres  
at least  $74 \times 105$
- greater than 50 litres but not exceeding 500 litres  
at least  $105 \times 148$
- greater than 500 litres  
at least  $148 \times 210$ .

Each symbol shall cover at least one tenth of the surface area of the label but not be less than  $1 \text{ cm}^2$ . 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 indications.

2. A label is not required where 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 on the market of dangerous preparations in their territories subject to the use of the official language or languages in respect of the labelling thereof.

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 substances 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 substances and with Article 5 (2) (a), (b), (c), (e) and (f).

Where dangerous preparations do not leave the territory of a Member State, labelling may be permitted which complies with national rules instead of with international rules on the transport of dangerous substances.

#### Article 7

1. Member States may:

- (a) permit the labelling required by Article 5 to be applied in some other appropriate manner on packages which are either too small or otherwise unsuitable for labelling in accordance with Article 6 (1) and (2);

(b) by way of derogation from Articles 5 and 6, permit the packaging of dangerous preparations which are neither explosive 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 8*

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 the requirements of this Directive and the Annex thereto.

#### *Article 9*

1. Where a Member State establishes that a dangerous preparation, although satisfying the requirements of this Directive, presents a health or safety risk necessitating a classification or labelling other than those provided for by this Directive, it may, for a period not exceeding six months, prohibit the distribution, sale or use of that preparation in its territory. It shall immediately inform the other Member States and the Commission thereof and give reasons for its decision.

2. The Commission shall, within six weeks, consult with the Member States concerned, express its opinion without delay and take the appropriate steps. Where it deems an amendment referred to in

Article 10 to be necessary, the period provided for in paragraph 1 shall be extended until the procedure laid down in Article 21 of the Directive of 27 June 1967 has been completed.

#### *Article 10*

The amendments required for adapting the Annexes to technical progress shall be adopted in accordance with the procedure laid down in Article 21 of the Directive of 27 June 1967.

#### *Article 2*

1. Member States shall adopt and publish within 12 months of notification of the first Directive based on Article 10 of Directive 73/173/EEC the laws, regulations and administrative provisions needed to comply with this Directive. They shall apply these provisions within 18 months of notification of the first Directive based on Article 10 of Directive 73/173/EEC.

2. Member States shall communicate to the Commission the text of the provisions of national law which they adopt in the field covered by this Directive.

#### *Article 3*

This Directive is addressed to the Member States.

Done at Brussels, 22 July 1980.

*For the Council*

*The President*

G. THORN