

S.I. No. 272 of 1995.

EUROPEAN COMMUNITIES (CLASSIFICATION, PACKAGING AND LABELLING OF DANGEROUS PREPARATIONS) REGULATIONS, 1995.

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EUROPEAN COMMUNITIES (CLASSIFICATION, PACKAGING AND LABELLING OF DANGEROUS PREPARATIONS) REGULATIONS, 1995.

I, RICHARD BRUTON, Minister for Enterprise and Employment, in exercise of the powers conferred on me by section 3 of the European Communities Act, 1972 (No. 27 of 1972), and for the purpose of giving effect to Council Directive 88/379/EEC of 7 June, 1988(1), as amended by Council Directive 92/32/EEC of 30 April, 1992(2), and Commission Directives 89/178/EEC of 22 February, 1989(3), 90/35/EEC of 19 December, 1989(4), 90/492/EEC of 5 September, 1990(5), 91/155/EEC of 5 March, 1991(6), 91/442/EEC of 23 July, 1991(7), 93/18/EEC of 5 April, 1993(8), 93/21/EEC of 27 April, 1993(9) and 93/112/EC of 10 December, 1993(10) hereby make the following Regulations:—

Citation. 1. These Regulations may be cited as the European Communities (Classification, Packaging and Labelling of Dangerous Preparations) Regulations, 1995.

Commencement. 2. These Regulations shall come into operation on the 16th day of October, 1995.

Interpretation. 3. (1) In these Regulations, unless the context otherwise requires—

"aerosol dispensers" has the same meaning as in the European Communities (Aerosol Dispensers) Regulations, 1977 (S.I. No. 144 of 1977);

"Annex 1 to Council Directive 67/548/EEC" means Annex 1 (inserted by Commission Directive 76/907/EEC of 14 July, 1976) to Council Directive 67/548/EEC, as amended or replaced from time to time;

(1)O.J. No. L 187, 16.7.88, p. 14.

(2)O.J. No. L 154, 5.6.92, p.1.

(3)O.J. No. L 64, 8.3.89, p.18.

(4)O.J. No. L 19, 24.1.90, p.14.

(5)O.J. No. L 275, 5.10.90, p.35.

(6)O.J. No. L 76, 22.3.91, p.35.

(7)O.J. No. L 238, 27.8.91, p.25.

(8)O.J. No. L 104, 29.4.93, p.46.

(9)O.J. No. L 110, 4.5.93, p.20 and O.J. No. L 110A, 4.5.93, p.1.

(10)O.J. No. L314, 16.12.93, p.38.

"Annex II to Council Directive 67/548/EEC" (which is set out in Schedule 4 hereto) means Annex II (inserted by Commission Directive 83/467/EEC of 29 July, 1983) to Council Directive 67/548/EEC, as amended or replaced from time to time;

"Annex III to Council Directive 67/548/EEC" (which is set out in Schedule 5 hereto) means Annex III (inserted by Commission Directive 76/907/EEC of 14 July, 1976) to Council Directive 67/548/EEC, as amended or replaced from time to time;

"Annex IV to Council Directive 67/548/EEC" (which is set out in Schedule 6 hereto) means Annex IV (inserted by Commission Directive 76/907/EEC of 14 July, 1976) to Council Directive 67/548/EEC, as amended or replaced from time to time;

"Annex V to Council Directive 67/548/EEC" means Annex V (inserted by Commission Directive 84/449/EEC of 25 April, 1984) to Council Directive 67/548/EEC, as amended or replaced from time to time;

"Annex VI to Council Directive 67/548/EEC" means Annex VI (inserted by Council Directive 79/831/EEC of 18 September, 1979) to Council Directive 67/548/EEC, as amended or replaced from time to time;

"Annex IX to Council Directive 67/548/EEC" means Annex IX (inserted by Council Directive 79/831/EEC of 18 September, 1979) to Council Directive 67/548/EEC, as amended or replaced from time to time;

"Annex I to Council Directive 88/379/EEC" means Annex I to Council Directive 88/379/EEC of 7 June, 1988, as amended or replaced from time to time;

"Annex II to Council Directive 88/379/EEC" (which is set out in Schedule 10 hereto) means Annex II to Council Directive 88/379/EEC of 7 June, 1988, as amended or replaced from time to time;

"Article 2(1) of Council Directive 67/548/EEC" means Article 2(1) of Council Directive 67/548/EEC, as amended by Council Directive 92/32/EEC;

"Article 2(2) of Council Directive 67/548/EEC" means

Article 2(2) of Council Directive 67/548/EEC, as amended by Council Directive 92/32/EEC;

"Article 13(3) of Council Directive 67/548/EEC" means Article 13(3) of Council Directive 67/548/EEC, as amended by Council Directive 92/32/EEC;

"Authority" means the National Authority for Occupational Safety and Health;

"carcinogenic" has the same meaning as in Article 2(2) of Council Directive 67/548/EEC, as amended;

"child-resistant fastening" means a cap, lid, fastening or other means of fastening a package, which complies with the provisions of Part A of Annex IX to Council Directive 67/548/EEC;

"classified" shall be construed—

(a) in relation to a substance, as being classified as a dangerous substance in accordance with the provisions of Council Directive 67/548/EEC, or

(b) in relation to a preparation, as being classified as a dangerous preparation in accordance with the provisions of Regulation 5,

and "classification" shall be construed accordingly;

"Commission Directive 91/155/EEC" means Commission Directive 91/155/EEC of 5 March, 1991, as amended by Commission Directive 93/112/EEC of 10 December, 1993;

"corrosive" has the same meaning as in Article 2(2) of Council Directive 67/548/EEC, as amended;

"Council Directive 67/548/EEC" means Council Directive 67/548/EEC of 27 June, 1967, as amended or replaced from time to time;

"Council Directive 88/379/EEC" means Council Directive 88/379/EEC of 7 June, 1988, as amended by Council Directive 92/32/EEC of 30 April, 1992;

"Council Directive 92/32/EEC" means Council Directive 92/32/EEC of 30 April, 1992;

"dangerous for the environment" has the same meaning as in Article 2(2) of Council Directive 67/548/EEC, as amended;

"dangerous preparation" means a preparation classified in accordance with Regulation 5 and where appropriate Regulations 7 and 9;

"dangerous substance" shall have the same meaning as in Council Directive 67/548/EEC;

"EINECS" has the same meaning as in Article 2 (1) of Council Directive 67/548/EEC as amended;

"established in the State" means resident and having a place of business in the jurisdiction of the State and "this State" shall be construed accordingly;

"explosive" has the same meaning as in Article 2 (2) of Council Directive 67/548/EEC, as amended;

"extremely flammable" has the same meaning as in Article 2 (2) of Council Directive 67/548/EEC, as amended;

"flammable" has the same meaning as in Article 2 (2) of Council Directive 67/548/EEC, as amended;

"harmful" has the same meaning as in Article 2 (2) of Council Directive 67/548/EEC, as amended;

"highly flammable" has the same meaning as in Article 2 (2) of Council Directive 67/548/EEC, as amended;

"indication of danger" means the indication of danger specified in Column 3 of the Table to Schedule 4 and required to be contained on the label or marked on the package of a dangerous preparation in accordance with Regulation 17 (d);

"Inspector" has the same meaning as in the Safety, Health and Welfare at Work Act, 1989;

"irritant" has the same meaning as in Article 2 (2) of Council Directive 67/548/EEC, as amended;

"label" means the label required by Regulation 16 (1) (a) and containing the information required by Regulation 17;

"Minister" means the Minister for Enterprise and Employment;

"mutagenic" has the same meaning as in Article 2 (2) of Council Directive 67/548/EEC, as amended;

"other State" means a Member State of the European Communities other than this State;

"oxidizing" has the same meaning as in Article 2 (2) of Council Directive 67/548/EEC, as amended;

"package" means the packaging, receptacle or container containing a preparation and "packaging" shall be construed accordingly;

"person responsible for placing a preparation to which these Regulations apply, on the market" means a person (whether a manufacturer, supplier, distributor, wholesaler or retailer, established in the State) who places a preparation to which these Regulations apply on the market;

"placing on the market" means the making available to any person (within the meaning of Council Directive 67/548/EEC as amended by Council Directive 92/32/EEC) and importation into the European Communities customs territory shall be deemed to be placing on the market for the purpose of these Regulations;

"polymer" has the same meaning as in Article 2 (1) of Council Directive 67/548/EEC as amended;

"preparations" has the same meaning as in Article 2 (1) of Council Directive 67/548/EEC as amended;

"risk phrase" means a phrase listed in Schedule 5 being an indication of a particular nature of risk created by a substance or preparation labelled with that phrase;

"safety phrase" means a phrase listed in Schedule 6 being an indication of safety precautions required to be taken when handling or using a substance or preparation labelled with that phrase;

"sensitizing" has the same meaning as in Article 2 (2) of Council Directive 67/548/EEC, as amended;

"special labelling" means special information which, when required in accordance with the provisions of Annex II to Council Directive 88/379/EEC and Regulations 17(g) and 25 and Schedule 10, is contained on the label or marked on the package of a preparation;

"substances" has the same meaning as in Article 2 (1) of Council Directive 67/548/EEC as amended;

"symbol" means any symbol specified in Column 2 of the Table to Schedule 4 which, when required, is contained on the label or marked on the package in accordance with Regulation 17 (d);

"tactile warning of danger" means a method of warning a person, who has poor sight or no sight of the dangerous contents of a package to which the provisions of Regulation 15 (3) apply, and which complies with the provisions of Part B of Annex IX to Council Directive 67/548/EEC;

"toxic" has the same meanings as in Article 2 (2) of Council Directive 67/548/EEC, as amended;

"toxic for reproduction" has the same meaning as in Article 2 (2) of Council Directive 67/548/EEC, as amended;

"very toxic" has the same meaning as in Article 2 (2) of Council Directive 67/548/EEC, as amended;

(2) (a) In these Regulations reference to a Regulation or a Schedule is to a Regulation of, or to a Schedule to, these Regulations unless it is indicated that reference to some other enactment is intended.

(b) In these Regulations reference to a paragraph or a subparagraph is to the paragraph or subparagraph of the provision in which the reference occurs, unless it is indicated that reference to some other provision is intended.

(3) A word or expression that is used in these regulations and that is also used in Council Directive 88/379/EEC as amended and Council Directive 67/548/EEC as amended has, unless the contrary intention appears, the same meaning in these Regulations as in those Directives.

(4) References in these Regulations to Chapters 2, 3, 4 and 9 (and specified parts of these chapters) of Annex VI to Council Directive 67/548/EEC means those chapters or parts thereof in Annex VI to Council Directive 67/548/EEC as amended by Commission Directive 93/21/EEC of 27 April, 1993.

Construction and Application. 4. (1) The Safety, Health and Welfare at Work Act, 1989 (No. 7 of 1989), shall be construed and have effect as if these Regulations were an existing enactment within the meaning of section 2 (1) of that Act.

(2) These Regulations apply to dangerous preparations which are placed on the market, but do not apply to—

- (a) medical or veterinary products as defined by Council Directive 65/65/EEC;
- (b) cosmetic products as defined by Council Directive 76/768/EEC;
- (c) waste within the scope of Council Directive 75/442/EEC and Council Directive 78/319/EEC;
- (d) pesticides within the scope of Council Directive 78/631/EEC;
- (e) munitions and explosives to which Council Directive 88/379/EEC does not apply;
- (f) foodstuffs to which Council Directive 88/379/EEC does not apply;
- (g) animal feeding stuffs to which Council Directive 88/379/EEC does not apply;
- (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.

(3) Regulations 2 to 4, 14, 16 to 21 and 25 to 29 shall also apply to preparations, whether dangerous or not, which are contained in Annex II to Council Directive 88/379/EEC and Schedule 10 and which are placed on the market.

(4) These Regulations shall apply without prejudice to and not in substitution for any other enactments or any instruments made under any enactments.

Determination of Classification. 5. (1) For the purpose of these Regulations, a dangerous preparation shall be classified as one or more of the following classifications—

- (a) explosive,
- (b) oxidizing,
- (c) extremely flammable,
- (d) highly flammable,
- (e) flammable,
- (f) very toxic,
- (g) toxic,
- (h) harmful,
- (i) corrosive,
- (j) irritant,
- (k) dangerous for the environment ,

- (l) carcinogenic,
- (m) toxic for reproduction,
- (n) mutagenic,
- (o) sensitizing.

(2) Subject to paragraphs (5) and (6) of Regulation 6, the classifications mentioned in subparagraphs (a) to (e) of paragraph (1) shall be—

(a) within the meaning of the provisions of Council Directive 67/548/EEC and assigned the risk and safety phrases in accordance with those provisions, or

(b) as assessed in accordance with the provisions of Regulation 6 (2) in the case of gas preparations, provided that the provisions contained in Chapter 9.1.1.1 of Annex VI to Council Directive 67/548/EEC relating to quantities apply.

(3) The classifications mentioned in subparagraphs (f) to (j) and (o) of paragraph (1) shall be—

(a) within the meaning of the provisions of Council Directive 67/548/EEC and assigned the risk and safety phrases in accordance with those provisions, or

(b) as assessed in accordance with the provisions of—

(i) Regulation 7 (2), in case of preparations which are not gas preparations, and

(ii) Regulation 7 (3) in the case of gas preparations.

(4) The classification mentioned in subparagraph (1) (k) shall be within the meaning of the provisions of Council Directive 67/548/EEC and assigned the risk and safety phrases in accordance with these provisions.

(5) The classifications mentioned in subparagraphs (l), (m) and (n) of paragraph (1) shall be as assessed in accordance with the provisions of—

(a) Part VII of Schedule 2 in the case of preparations which are not gas preparations, and

(b) Part VII of Schedule 3 in the case of gas preparations.

(6) Notwithstanding any other provisions of this Regulation, the provisions of Chapter 9 of Annex VI to Council Directive 67/548/EEC shall apply to the classification or classifications of a preparation in appropriate cases.

Classifications. 6. (1) Subject to paragraphs (2) to (6), the physico-chemical properties for the determination of the classifications of preparations mentioned in Regulation 5 (2) (a) shall be determined according to the methods specified in Part A of Annex V to Council Directive 67/548/EEC.

(2) In the case of gas preparations manufactured in small quantities and for which it would not be reasonably practicable to comply with the provisions of paragraph (1), the determination of the extremely flammable classification may be assessed in accordance with the methods specified in Part I of Schedule 1.

(3) In a case where none of the substances in a preparation is classified as explosive, oxidizing, extremely flammable, highly flammable or flammable and where, on the basis of information available to the manufacturer of the preparation, such preparation is unlikely to be so classified, the provisions of paragraphs (1) and (2) need not be complied with and the preparation shall not be so classified.

(4) Notwithstanding the provisions of paragraph (1), the classification of a preparation, in the form of an aerosol, as extremely flammable shall be in accordance with the provisions contained in the European Communities (Aerosol Dispensers) Regulations, 1977.

(5) In the case of a gas preparation, the determination of the oxidizing classification shall be assessed in accordance with the method specified in Part II of Schedule 1.

(6) Notwithstanding the provisions of paragraph (1), the classification as oxidizing of a preparation containing at least one organic peroxide shall be assessed in accordance with Part III of Schedule 1.

Determination of Classification. 7. (1) Subject to paragraph (5) and Regulation 9, the properties for the determination of the classifications of a preparation mentioned in Regulation 5 (3) (a) shall be determined according to the methods specified in Part B of Annex V to Council Directive 67/548/EEC.

(2) Subject to paragraph (5) and Regulations 8 and 9 and notwithstanding the provisions of paragraph (1), the classifications of a preparation mentioned in Regulation 5 (3) (b) (i) shall be assessed in accordance with the provisions in Schedule 2 in the case of a preparation which is not a gas preparation.

(3) Subject to paragraph (5) and Regulations 8 and 9 and notwithstanding the provisions of paragraph (1), the classifications of a gas preparation mentioned in Regulation 5 (3) (b) (ii) shall be assessed in accordance with the provisions in Schedule 3.

(4) Where a property of a preparation has not been determined in accordance with the provisions of paragraph (1), the relevant classification of the preparation shall be assessed in accordance with the provisions of paragraph (2) or paragraph (3), as the case may be.

(5) Where a classification of a preparation has been determined in accordance with the provisions of paragraph (1) and has also been assessed in accordance with the provisions of paragraphs (2) or (3), the classification shall be that resulting from the provisions of paragraph (1).

Potential and Antagonism. 8. (1) Potential or a similar effect shall be taken into consideration in the classification of a preparation whose classification, assessed in accordance with the provisions of Regulations 5 (5), 7 (2), or 7 (3), would be underestimated because of such an effect.

(2) Antagonism or a similar effect shall be taken into consideration in the classification of a preparation whose classification, assessed in accordance with the provisions of Regulations 5 (5), 7 (2) or 7 (3), would be overestimated because of such an effect.

Variations in Effect. 9. Where there is adequate evidence to demonstrate that the effects on human persons differ from the determination or assessments arising out of Regulations 7 and 5 (5), the preparation shall be classified according to its effects on human persons.

Disregarding Impurities. 10. In the assessment and determination of the classifications of preparations in accordance with the provisions of Regulations 5 (5) and 7, no account shall be taken of substances present in the preparation, whether existing as impurities or as additives, if their concentration by weight in the preparation is less than—

(a) 0.1 per cent for substances classified as very toxic or toxic; or

(b) 1 per cent for substances classified as harmful, corrosive or irritant;

unless lower values have been specified in Annex 1 to Council Directive 67/548/EEC.

Changes in Concentration. 11. (1) Subject to paragraph (2) and Regulation 12, the classification or classifications of a dangerous preparation, whose composition is known and which has been classified in accordance with the provisions of Regulation 7 (1), shall be redetermined in accordance with the provisions of Regulation 5 (5) or Regulation 7 or both whenever there is a change in the concentration or concentrations of the dangerous substances in the preparation.

(2) The requirements of paragraph (1) shall not apply to a dangerous preparation where the change in the concentration of each dangerous substance is such that it is within the permitted variation specified in column 2 of the Table to this Regulation, corresponding to the initial concentration range specified opposite thereto in Column 1 of that Table.

Table

Initial concentration range of the dangerous substance Permitted variation in the initial concentration of the dangerous substance

2.5% 15%
>2.5% 10% 10%
> 10% 25% 6%
> 25% 50% 5%
> 50% 100% 2.5%

Changes in Composition. 12. The classification of a dangerous preparation whose composition is known and which has been classified in accordance with the provisions of Regulation 7 (1) shall, subject to Regulation 5 (5), be redetermined in accordance with the provisions of Regulation 5 (5) or Regulation 7 or both, whenever there is a change in the composition of the preparation involving the substitution or addition of one or more substances in the preparation, whether or not any such substance or substances is or are classified as dangerous.

Compliance with Regulations. 13. (1) A person shall not place on the market dangerous preparations to which these Regulations apply unless they comply with the provisions of these Regulations.

(2) Without prejudice to paragraph (1), preparations listed in Annex II to Council Directive 88/379/EEC shall comply with the provisions therein when placed on the market and, in addition in the case of preparations which are not dangerous, shall also comply with the Regulation mentioned in Regulations 14, 16 to 20 and 25 to 28.

Data on Preparation. 14. (1) The manufacturer of a preparation to which these Regulations apply, or, if he is not within the State, the person responsible for placing such a preparation on the market, shall have available for inspection by an Inspector all the information used in the classification and labelling of the preparation being information obtained from determining the properties of the preparation in accordance with the provisions of Regulations 5 and 7.

(2) The information to be kept available for the purpose of paragraph (1) of this Regulation shall be held by the manufacturer, or the person responsible for placing it on the market (if the manufacturer is not in this State) for at least 5 years after the last time the preparation has been placed on the market.

Packaging. 15. (1) A person shall not place on the market a dangerous preparation unless its packaging satisfies the following requirements:

(a) it is so designed and constructed that its contents cannot escape, except in a case where special safety devices are prescribed by law;

(b) the materials constituting the packaging and fastening are not susceptible to adverse attack by the contents or liable to form dangerous compounds with the contents;

(c) the packaging and fastenings are sufficiently strong and solid throughout to ensure that they will not loosen and will safely meet the normal stresses and strains of handling;

(d) containers fitted with replaceable fastening devices can be repeatedly fastened without the contents escaping;

(e) containers, containing dangerous preparations and which are offered or sold to the general public, do not have —

(i) a shape or graphic decoration or both likely to attract or arouse the active curiosity of children or to mislead consumers, or

(ii) a presentation or a designation or both used for human and animal foodstuffs, medical or cosmetic products.

(2) (a) (i) Containers containing dangerous preparations which are listed in Part I of Schedule 7 and which are intended to be offered or sold to the general public, shall not be placed on the market by any person unless they are fitted with child-resistant fastenings;

(ii) such child-resistant fastenings shall be the only fastenings fitted to such containers;

(b) the child-resistant fastenings required by subparagraph (a) shall comply with the specifications contained in Part A of Annex IX to Council Directive 67/548/EEC.

(3) (a) Containers containing dangerous preparations which are listed in Part II of Schedule 7 and which are intended to be offered or sold to the general public shall not be placed on the market by any person unless they carry a tactile warning of danger.

(a) The warning required by subparagraph (a) shall comply with the specifications contained in Part B of Annex IX to Directive 67/548/EEC.

Labels. 16. (1) Subject to Regulation 29, a person shall not place on the market a preparation to which these Regulations apply unless—

- (a) its packaging is provided with a label, or
- (i) the information, required to be contained on the label in accordance with the provisions of Regulation 17, is clearly marked on the package containing the preparation, such that it can be read horizontally when the package is set down normally; and
- (ii) the area of the surface of the package on which the information is marked in accordance with the provisions of this subparagraph complies with the provisions of subparagraph (3) in relation to the dimensions specified in Schedule 8,
- (b) the colour and presentation of the label or package containing such a preparation is such that any danger symbol or symbols required in accordance with the provisions of Regulations 17 (d) and 22 and its or their background stand out clearly from the label or package, and
- (c) the information, required to be contained on the label or marked on the package (as the case may be), shall be easily distinguishable from its background and the typeface in which the information is printed shall be of such a size and spacing so as to be easily read.

(2) Subject to Regulation 29—

- (a) the label shall be firmly affixed to one or more surfaces of the packaging and so affixed such that it can be read horizontally when the package is set down normally; and
 - (b) the entire surface of the label shall adhere to the package containing the preparation.
- (3) Subject to Regulations 27 and 29—

- (a) the presentation and dimensions of the label or the requirements of Regulation 16 (1) (a)
- (ii) (as the case may be) shall comply with the provisions of Schedule 8; and
- (b) the label or the area referred to in Regulation 16 (1) (a) (ii) (as the case may be) shall only be used to contain the information required by Regulation 17 and, if necessary, any supplementary health or safety information.

Information on Packages. 17. Subject to Regulations 27 and 29, a person shall not place on the market dangerous preparations to which these Regulations apply unless the following information is clearly and indelibly marked on packages containing those preparations or on the labels (as the case may be) in the Irish and English languages or in the English language;

- (a) the trade name of, or a description of, the preparation;
- (b) the name, full address and telephone number of the person, established in the European Community, responsible for placing the preparation on the market;
- (c) the name of the substance or substances present in the preparation in accordance with the provisions of Regulations 19, 20 and 21;
- (d) the symbol or symbols if required, together with any corresponding indication of danger in accordance with the provisions of Regulation 22;
- (e) one or more risk phrases, when appropriate, in accordance with the provisions of Regulation 23;
- (f) one or more safety phrases in accordance with the provisions of Regulation 24;

(g) special labelling, when appropriate, in accordance with Regulation 25;

(h) the quantity, either by volume or by mass, of the preparation in the package, in the case of preparations intended for sale to the general public; and

(i) the phrase "Caution — this preparation contains a substance not yet fully tested" in the case of a preparation containing at least one substance, in a concentration equal to or in excess of 1 per cent in the preparation, which bears the warning 'Caution — substance not yet fully tested' in accordance with Article 13 (3) of Council Directive 67/548/EEC.

Prohibition of Certain Phrases etc. 18. The phrase "non toxic", "not harmful" or any other statement that the preparation is not dangerous shall not be marked by any person on the package or contained on the label of a preparation to which these Regulations apply.

Named Substances. 19. (1) Subject to Regulations 20, 21 and 29 and to paragraphs (2) and (3), and in accordance with the requirements of Regulation 17 (c), the names of the following substances shall be marked on the package or set out on the label by any person who places the preparation on the market;—

(a) in the case of a preparation assigned one or more of the following risk phrases R39, R40, R42, R43, R42/43, R48, each substance to which is assigned one or more of these risk phrases and which is responsible, in accordance with the provisions of Regulation 5 (3), for the preparation being assigned that risk phrase or those risk phrases;

(b) in the case of a preparation assigned one or more of the following risk phrases R40, R45, R46, R49, R60, R61, R62 and/or R63, each substance to which is assigned one or more of these risk phrases and which is responsible, in accordance with the provisions of Regulation 5 (5), for the preparation being assigned that risk phrase or those risk phrases; and

(c) subject to paragraph (2) and Regulation 21—

(i) in the case of a preparation classified as very toxic, toxic or harmful, those substances, classified as very toxic, toxic or harmful, present in the preparation in a concentration in the preparation equal to or exceeding the lowest limit;

(ii) in the case of a preparation classified as corrosive, those substances, classified as corrosive, present in the preparation in a concentration equal to or exceeding the lowest limit.

(2) (a) Notwithstanding the provisions of subparagraph (1) (c) and subject to subparagraphs (1) (a), (1) (b) and (2) (b) a maximum of 4 names shall be sufficient to meet the requirements of paragraph (1) and Regulation 17 (c).

(b) Subject to Regulations 21 and 29, the names of the substances to be marked on the package or contained in the label in accordance with the provisions of paragraph (1) and Regulation 17 (c) shall identify the substances present in the preparation primarily responsible for the major health hazards which have given rise to the classification of the preparation and the choice of the corresponding phrases referring to the risk or risks involved.

(3) The requirements of Regulations 17 (c) shall apply to preparations to which the provisions of one or more of subparagraphs (a), (b) and (c), of paragraph (1) apply.

(4) (a) In paragraph (1), "lowest limit" means that concentration of a substance in a preparation which would, in accordance with the provisions of Schedule 2 or 3, (as the case may be) have the effect of the preparation being classified—

- (i) harmful in the case of subparagraph (1) (c) (i), or
- (ii) irritant in the case of subparagraph (1) (c) (ii).

(4) (b) In subparagraph (a) of paragraph (1), reference to a preparation assigned any of the risk phrases R39, R40 or R48 means a reference to that risk phrase incorporated in a combined risk phrase.

Chemical Names. 20. Subject to Regulations 21 and 29, the name of each substance to be marked on the package or contained on the label in accordance with the requirements of Regulations 17 (c) and 19 shall be one of the designations listed for that substance in Annex I to Council Directive 67/548/EEC if it is contained therein, or an internationally recognised designation if it is not so contained.

Exemption on Grounds of Confidentiality. 21. (1) Subject to the subsequent paragraphs of this Regulation and to Regulation 29 and notwithstanding their requirements, the provisions of Regulations 17 (c), 19 and 20 shall not apply, in the case of a dangerous substance present in a preparation where the name of that dangerous substance, marked on the package or contained on the label in accordance with the provisions of the said Regulations 17 (c), 19 and 20, would put at risk the manufacturer's property, provided that—

- (a) the substance is classified as harmful;
- (b) the substance is not assigned any of the risk phrases referred to in subparagraphs (1) (a) and (1) (b) of Regulation 19;
- (c) the manufacturer has demonstrated that the disclosure of the chemical identity of the substance would put at risk the confidential nature of his property; and
- (d) the manufacturer has marked on the package or on the label a name which identifies the most important functional groups, or an alternative name.

(2) Where a manufacturer has invoked the provisions of paragraph (1) he shall forthwith inform the Authority when the particular dangerous preparation is placed on the market for the first time in the State or elsewhere in the European Communities, and shall provide the Authority with the reasons or the alleged reasons for confidentiality, together with all information relevant to the classification and labelling of the dangerous preparation, including—

- (i) the name and full address (including telephone number) of the manufacturer and importer, if the preparation is manufactured outside the State,
- (ii) the designation or trade name of the preparation, including any different names used in the other States,
- (iii) the full composition of the preparation,
- (iv) the classification or classifications, in accordance with the provisions of Regulations 5 and 7. of the preparation,
- (v) the labelling, in accordance with the provisions of Regulations 17, 19, 20, 21. 22, 23, 24 and 25, of the preparation,
- (vi) the precise identification of each substance for which the provisions of this Regulation are invoked and the name identifying its most important functional groups, or an alternative name if one is used,
- (vii) the intended use of the preparation, and

(viii) the safety data sheet, in accordance with the provisions of Regulation 30 and Schedule 9, for the preparation.

(3) Where the Authority is of the opinion that the provisions of paragraph (1) do not apply in a particular case, it may serve a notice in writing to the manufacturer stating that it is of that opinion, and, thereupon, the provisions of paragraph (1) shall cease to apply in the case of that dangerous preparation.

(4) A person who is aggrieved by a notice under paragraph (3) may, within the period of fourteen days beginning on the day on which the notice is served on him, appeal to a Judge of the District Court, in the District Court District in which the notice was served, against the notice and in determining the appeal the Judge may, if he is satisfied that it is reasonable to do so, confirm, vary or cancel the notice.

(5) A person who appeals under paragraph (4) shall, at the same time, notify the Authority of the appeal and the grounds for the appeal and the Authority shall be entitled to appear, be heard and adduce evidence on the hearing of the appeal.

(6) Where an appeal under paragraph (4) is taken, and the notice is not cancelled, the notice shall take effect on the day next following the day on which the notice is confirmed on appeal or the appeal is withdrawn.

(7) The Authority may withdraw a notice under paragraph (3) at any time.

(8) For the purpose of the application of the provisions of paragraph (1), the Authority shall notify the Commission of the European Communities and the other States of the invocation of the provisions thereof and provide it with the information supplied to the Authority in accordance with the provisions of paragraph (2).

(9) Confidential information, brought to the attention of the Authority in the application of the provisions of paragraphs (1) and (2) shall be treated in accordance with the provisions of Article 19 (4) of Council Directive 67/548/EEC, as amended by Council Directive 92/32/EEC.

Danger Symbols etc. 22. (1) In accordance with the requirements of Regulation 17 (d) and subject to paragraph (2) and to Regulations 27 and 29, at least one danger symbol and its corresponding indication of danger shall be marked on the package of a dangerous preparation or contained in the label in accordance with the provisions of Schedule 4.

(2) Notwithstanding the requirements of paragraph (1), a danger symbol and indication of danger shall not be required to be marked on the package of a dangerous preparation or contained in the label in the case of a dangerous preparation classified only as flammable.

Risk Phrases. 23. (1) In accordance with the requirements of Regulations 17 (e) and subject to paragraphs (2) and (3), and to Regulation 29, the risk phrase or phrases, assigned to a dangerous preparation in accordance with the provisions of Regulations 5 to 7 and Schedules 1 to 3, shall be marked on the package of the dangerous preparation or contained in the label in accordance with the following provisions:

- (a) the risk phrase or phrases shall be selected from Schedule 5;
- (b) no more than four risk phrases shall be marked, but more may be added if considered appropriate;
- (c) when two or three of the risk phrases assigned can be included in a combined risk phrase in accordance with the provisions of Schedule 5, the combined risk phrase shall be used and, for the purpose of subparagraph (b), can be counted as one risk phrase;
- (d) the risk phrase or phrases to be marked on the package of the dangerous preparation or contained in the label shall be selected in accordance with the principles contained in Annex I to Council Directive 88/379/EEC and Annex VI to Council Directive 67/548/EEC;
- (e) the risk phrase or phrases to be marked on the package or contained in the label shall indicate the special risk or risks arising from the use of the dangerous preparation;
- (f) in the case of a dangerous preparation having more than one classification, the risk phrases to be marked on the package or contained in the label shall cover all the principal hazards associated with the dangerous preparation;
- (g) in the case of a dangerous preparation classified only both as harmful and as irritant, risk phrases drawing attention to both its harmful and its irritant characteristics shall be marked on the package or contained in the label.

(2) Notwithstanding the requirements of paragraph (1), the risk phrases R11 and R12 shall not be required to be marked on the package of a dangerous preparation or contained in the label if to do so would involve repeating the provisions of Regulations 17 (d) and 22 (1).

(3) Notwithstanding its provisions, the requirements of paragraph (1) shall not apply to a dangerous preparation classified only as one or more of the following, that is to say highly flammable, flammable, oxidizing and irritant, when the contents of the package of the preparation do not exceed 125 ml.

Safely Phrases. 24. (1) In accordance with the requirements of Regulation 17 (f) and subject to paragraphs (2) and (3) and to Regulations 26 and 29, the safety phrase or phrases shall be assigned to a dangerous preparation and marked on its package or contained in the label in accordance with the following provisions—

- (a) the safety phrase or phrases shall be selected from Schedule 6;
- (b) not more than four safety phrases shall be marked, but more may be added if considered appropriate;
- (c) when two or more safety phrases assigned to the dangerous preparation can be combined in a combined safety phrase in accordance with the provisions of Schedule 6, the combined safety phrase shall be used and, for the purposes of subparagraph (b), shall be counted as one safety phrase;
- (d) the safety phrase or phrases to be marked on the package or contained in the label shall be selected in accordance with the principles contained in Annex VI to Council Directive 67/548/EEC.

(2) The requirements of paragraph (1) shall not apply to a dangerous preparation, where it is physically impossible to mark the safety phrases on the package or contain them in the label; but in such a case the package shall be accompanied by a document containing such safety advice as would, but for the size of the package, have been marked on the package or contained in the label.

(3) Notwithstanding its provisions, the requirements of paragraph (1) shall not apply to a dangerous preparation classified only as one or more of the following, that is to say highly

flammable, flammable, oxidizing and irritant, when the contents of the package of the preparation do not exceed 125 ml.

Special Labelling Provisions. 25. In accordance with the requirements of Regulation 17 (g) and subject to Regulations 27 and 29, the safety phrases and the special Labelling phrases contained in Annex II to Council Directive 88/379/EEC and Schedule 10 shall be marked on the package of a preparation or contained in the label in accordance with the provisions contained in Annex II to Council Directive 88/379/EEC and contained in Schedule 10.

Outer Packages. 26. The requirements of these Regulations in relation to labelling shall be deemed to be satisfied if, in the case of an outer package containing one or more inner packages—

(a) the appropriate provisions and requirements of Regulations 16, 17, 18, 19, 20, 21, 22, 23, 24 and 25 are complied with in relation to the inner packages; and

(b) the outer package is labelled in accordance with—

(i) international rules on the transport of dangerous substances, or

(ii) the Dangerous Substances (Conveyance of Petroleum by Road) Regulations 1979 (S.I. No. 314 of 1979), or the Dangerous Substances (Conveyance of Scheduled Substances by Road) (Trade or Business) Regulations, 1980, (S.I. No. 235 of 1980).

Alternative Labelling. 27. Notwithstanding the provisions of Regulations 16 (3), 17 and 22, the requirements of these Regulations in relation to Labelling shall be deemed to be satisfied if—

(a) in the case of a single package, containing a preparation to which these Regulations apply, the package is labelled in accordance with—

(i) international rules on the transport of dangerous substances, or

(ii) the Dangerous Substances (Conveyance of Petroleum by Road) Regulations 1979 (S.I. No. 314 of 1979), or the Dangerous Substances (Conveyance of Scheduled Substances by Road) (Trade or Business) Regulations, 1980, (S.I. No. 235 of 1980), and

(b) the requirements of Regulation 17 (other than subparagraphs (d), (g), (h) and (i)) and Regulations 18, 19, 20, 21, 23 and 24 are complied with.

Definition for Purposes of Regulations 26 and 27. 28. For the purposes of Regulations 26 and 27, "international rules on the transport of dangerous substances" means—

(a) the European Agreement Concerning the International Carriage of Dangerous Goods by Road done at Geneva on 30 September, 1957;

(b) the International Regulations Concerning the Carriage of Dangerous Goods by Rail appended to the International Convention Concerning the Carriage of Goods by Rail, 1970;

(c) the International Maritime Dangerous Goods Code published by the International Maritime Organisation; or

(d) IATA Dangerous Goods Regulations published by the International Air Transport Association;

as amended.

Exemptions. 29. (1) Notwithstanding the provisions of Regulations 16 to 25 and paragraph (7), the Authority may grant at its discretion and subject to the provisions of Article 9 of Council Directive 88/379/EEC by certificate, subject to any conditions specified in the certificate, exemption from compliance with any or all of the requirements of those provisions where it is satisfied that compliance with these requirements is inappropriate or otherwise unsuitable in any case where the package containing a preparation to which these Regulations apply is too small or otherwise unsuitable for compliance with such a requirement.

(2) In the case of a preparation, to which these Regulations apply which has not been classified as explosive, very toxic, or toxic and notwithstanding the provisions of Regulations 16 to 25, the Authority may at its discretion and subject to the provisions of Article 9 of Council Directive 88/379/EEC by certificate grant, subject to any conditions specified in the certificate, exemption from any or all of the requirements of those provisions where it is satisfied that compliance with such a requirement is not necessary because of the small quantity contained in the package of the preparation, and because there is no reason to fear any danger to persons handling such a package of the preparation or to other persons from its handling.

(3) In any case of the application of paragraph (1) or (2) the Authority shall forthwith inform the Commission of the European Communities thereof.

(4) An exemption granted by the Authority under paragraph (1) or (2) may be revoked by the Authority at any time.

(5) Notwithstanding the provisions of Regulations 16 to 25 and paragraph (7), the provisions of Chapter 9 of Annex VI to Council Directive 67/548/EEC shall apply, in relation to any matter contained in any of those Regulations, to a preparation to which the provisions of that Chapter are appropriate.

(6) For the purposes of this Regulation, Article 9 of Council Directive 88/379/EEC shall mean Article 9 of Council Directive 88/379/EEC of 7 June, 1988.

(7) (a) The provisions of Regulations 16 (2) (a) and 16 (3) (a) shall not apply to a gas cylinder (containing a gas preparation) with a water capacity of less than or equal to 150 litres provided that

(i) it is provided with a label in accordance with ISO 7225:1994,

(ii) the label referred to in subparagraph (i) is placed on the cylinder in accordance with ISO 7225:1994,

(iii) the provisions of Regulations 16 (2) (b) and 16 (3) (b) apply in the case of the label referred to in subparagraph (i), and

(iv) where the provisions of Regulation 17 (c) are not contained in the label referred to in subparagraph (i), the name of the substance or substances are shown on the body of the gas cylinder in a clear and indelible way in accordance with Regulations 17 (c), 19, 20 and 21, in accordance with Chapter 9.1.3 of Annex VI to Council Directive 67/548/EEC.

(b) For the purposes of subparagraph (a), "ISO 7225:1994" means the International Standard ISO 7225:1994 of the International Organisation for Standardisation.

Material Safety Data Sheets. 30. (1) A person placing a dangerous preparation on the market shall have available, to provide when requested by any person, a safety data sheet giving information on the properties and hazards of the preparation and on safety advice on the handling, storage and use of the preparation.

(2) Without prejudice to the provisions of paragraph (1) and subject to paragraph (9), the person supplying the preparation shall provide the recipient with a safety data sheet referred to in paragraph (1) when that recipient is an industrial user of the preparation.

(3) Without prejudice to the provisions of paragraphs (1) and (2), the safety data sheet referred to in paragraph (1) shall, so far as is reasonably practicable, contain such information as will enable the industrial user to take the necessary measures to ensure, so far as is reasonably practicable, the protection of the health and safety of his employees at his place of work.

(4) Without prejudice to the provisions of paragraphs (1) and (3), a safety data sheet shall be in accordance with the provisions in Schedule 9.

(5) A safety data sheet referred to in paragraph (1) shall, in addition to the other requirements of this Regulation, have the name of the person responsible for providing it stated on it and shall contain the date on which it was published.

(6) The person responsible for providing a safety data sheet under paragraph (1) shall amend it when new information of a significant nature so requires, and the amended safety data sheet shall comply with the requirements of paragraph (5).

(7) Whenever a safety data sheet is amended, the amended safety data sheet shall be provided to all persons to whom the previous safety data sheet had been provided in accordance with the provisions of paragraph (2) and to whom the relevant preparations had been supplied within a year prior to the date on which the amended safety data sheet was published.

(8) For the purposes of this Regulation and Schedule 9, a safety data sheet shall be in writing and shall contain such information as is required by this Regulation.

(9) The provisions of paragraph (2) shall not apply in the case where the dangerous preparation is offered or sold to the general public provided—

(a) sufficient information to enable users to take the necessary measures as regards the protection of health and safety is furnished, and

(b) a "Safety Data Sheet" is available when requested, in accordance with the provisions of paragraph (1)

(10) (a) For the purpose of this Regulation and Schedule 9, "industrial user" means the person who (whether as an employer or self-employed person) uses the preparation in work carried on by way of trade or for the purposes of gain.

(b) For the purposes of this Regulation "employer" and "self-employed person" have the same meanings as in section 2 (1) of the Safety, Health and Welfare at Work Act, 1989.

Poison Information Centre. 31. (1) The Minister, after consultation with the Minister for Health, may appoint a body (hereinafter referred to as "the poison centre") for the purposes of this Regulation.

(2) The poison centre shall have power to require the person responsible for placing a dangerous preparation to which these Regulations apply on the market to provide it with information relating to the preparation.

(3) The information to be provided in accordance with the provisions of paragraph (2) shall be such as will enable the poison centre to carry out the functions assigned to it in accordance with the provisions of paragraph (4) and shall include the chemical composition of the preparation, including confidential information in accordance with the provisions of Regulation 21.

(4) The poison centre may use the information obtained in accordance with the provisions of paragraph (2) only to provide medical information in the case of exposure or likely exposure of persons to the preparation, especially in emergencies, and such medical information may be provided to formulate preventative and curative measures in relation to exposure of persons to the preparation.

(5) The poison centre shall not divulge to anyone other than the Authority any information deemed to be confidential in accordance with Regulation 21.

(6) The person responsible for placing a preparation to which these Regulations apply on the market shall, when requested to do so by the poison centre, provide the centre with information relating to the preparation in accordance with the provisions of paragraph (3).

Restriction on Sale. 32. (1) Where the Authority is of the opinion that a preparation, although satisfying the requirements of Council Directive 88/379/EEC, constitutes a hazard for man or the environment by reason of its classification, packaging or labelling, the Authority may, by notice in writing to the person who placed the preparation on the market, prohibit the sale of that preparation or subject its placing on the market to special conditions.

(2) A person who sells or offers for sale a preparation the sale of which is prohibited by the Authority by virtue of paragraph (1) shall be guilty of an offence.

(3) Where the Authority by virtue of paragraph (1) subjects the sale of any preparation to special conditions, a person who sells or offers for sale such a preparation shall be guilty of an offence unless such preparation satisfies such special conditions.

Taking and Detention of Preparations. 33. (1) An Inspector may, seize and retain, or seize, remove and retain any preparation which he believes is a preparation to which these Regulations apply and in relation to which he has reasonable grounds for suspecting that there is or has been a failure to comply with any provision of these Regulations.

(2) An Inspector may, by a notice in writing given to the owner or to the person in apparent charge or control of a preparation which has been seized under this Regulation—

(a) require things specified in the notice to be done in relation to the preparation before it is released by an Inspector,

(b) either—

(i) require the disposal of the preparation by the person to whom the notice is given, in a manner specified in the notice and at the expense of the owner, or

(ii) indicate the Inspector's intention of disposing of the preparation at the expense of the owner,

such disposal to be, in either case, such as will prevent the said preparation from being placed on the market or used,

and, where a notice given under this paragraph requires specified things to be done in relation to a preparation, the Inspector shall retain control of the preparation to which the notice relates until the requirements of the notice have been complied with.

(3) Where a notice is given under this Regulation, a person shall not, without the consent of the Inspector by whom the notice was given, sell, move, dispose of or otherwise interfere with the preparation in any way pending compliance with the requirements of the notice.

(4) Any person who is aggrieved by a notice given under paragraph (2) of this Regulation may, not later than the expiration of the period of seven days beginning on the date of the notice, appeal to the appropriate court against the notice.

(5) (a) Where an appeal is made to the appropriate court under paragraph (4) the court, if it is satisfied that—

(i) the preparation to which the relevant notice under this Regulation relates is one to which these Regulations apply, and

(ii) if such preparation were released, it might be placed on the market, and

(iii) there has been a failure to comply with the provisions of these Regulations—

shall order that the preparation be disposed of in the manner specified in the notice, or in such other manner as may be specified by the appropriate court which, in the opinion of the court, will prevent the preparation from being used or placed on the market.

(b) Where an order made by the appropriate court under this paragraph requires the preparation to which it relates to be disposed of by an Inspector, the cost of such disposal shall be recoverable by the Authority as a simple contract debt in any court of competent jurisdiction from the person who was the owner of the product at the time of its seizure under this Regulation.

(6) Subject to paragraph (5) a notice under this Regulation shall not come into force unless—

(a) where an appeal is taken against the notice, the appeal is withdrawn,

(b) in any other case, the period within which such an appeal may be taken has expired.

(7) In this Regulation "appropriate court" means in relation to an appeal made under this regulation against a notice given under paragraph (2):

(a) in case the estimated value of the preparation and cost of complying with the order to which the appeal relates does not exceed £5,000, the District Court for the district in which the goods were seized,

(b) in case the estimated amounts aforesaid does not exceed £30,000, the Judge of the Circuit Court for the circuit in which the goods were seized,

(c) in any other case, the High Court.

(8) (a) If, in relation to an appeal under this Regulation to the District Court, that court becomes of opinion during the hearing of the appeal that the estimated cost aforesaid will exceed £5,000, it may, if it so thinks fit, transfer the appeal to the Circuit or the High Court, whichever it considers appropriate having regard to the estimated cost aforesaid.

(b) If, in relation to an appeal under this Regulation to the Circuit Court, that court becomes of opinion during the hearing of the appeal that the estimated amounts aforesaid will exceed £30,000, it may, if it so thinks fit, by order transfer the appeal to the High Court.

Offences. 34. Any person who contravenes Regulation 13, 14, 15, 16, 17, 18, 19 (1), 20, 21 (2), 22, 23 (1), 24 (1), 25, 30 (1) to (8), 31 (6), or 33 (3) under these Regulations shall be guilty of an offence.

Revocations. 35. The European Communities (Classification, Packaging and Labelling of Dangerous Preparations) Regulations, 1992 (S.I. No. 393 of 1992), are hereby revoked.

Amendments to the Poisons Regulations, 1982. 36. (1) The provisions of paragraph (4) of Article 19 of the Poisons Regulations, 1982 (S.I. No. 188 of 1982), are hereby revoked.

(2) Subject to paragraph (3), the provisions of Articles 7, 10 (1), 11 and 12 (1) of the Poisons Regulations, 1982, shall not apply to any poison where—

(a) (i) it is a preparation to which these Regulations, as amended, apply; or
(ii) it is a substance to which the European Communities (Classification, Packaging, Labelling and Notification of Dangerous Substances) Regulations, 1994 (S.I. No. 77 of 1994) (as amended in cases where the amendments add or vary substances) apply; and

(b) its packaging and labelling are in accordance with the provisions of the appropriate Regulations referred to in subparagraph (a).

(3) Notwithstanding the provisions of paragraph (2), the provisions of Articles 7 (1) (d), 7 (5) and 7 (6) (c) of the Poisons Regulations, 1982, shall apply to a poison where the placing on the market of a substance or preparation, referred to in subparagraph (2) (a) and in compliance with the provisions of subparagraph (2) (b), is not prohibited, restricted or impeded on the grounds of classification, packaging or labelling within the meaning of the appropriate Regulations referred to in subparagraph (2) (a).

(4) In this Regulation:

(a) a reference to the Poisons Regulations, 1982 means a reference to the Poisons Regulations, 1982 (S.I. No. 188 of 1982), as amended; and

(b) a reference to a poison means a reference to a poison within the meaning of the Regulations referred to in subparagraph (a).

Proof of Document. 37. (1) In any proceedings under these Regulations prima facie evidence of the terms of any of the following, namely—

- (a) the European Agreement Concerning the International Carriage of Dangerous Goods by Road done at Geneva on 30 September, 1957,
 - (b) the International Regulations Concerning the Carriage of Dangerous Goods by Rail appended to the International Convention Concerning the Carriage of Goods by Rail, 1970,
 - (c) the International Maritime Dangerous Goods Code published by the International Maritime Organisation,
 - (d) IATA Dangerous Goods Regulations published by the International Air Transport Association,
 - (e) International Standard ISO 7225:1994,
 - (f) International Standard ISO 3219:1977,
 - (g) International Standard ISO 6503:1984,
 - (h) Chemical Abstracts Service of the American Chemical Society of the United States of America, or
 - (i) European Inventory of Existing Commercial Chemical Substances of the Commission of the European Communities,
- may be given by producing a document purporting to be a copy thereof.

(2) In any proceedings under these Regulations prima facie evidence of any amendments of the Agreement referred to in subparagraph (a) of paragraph (1) of this Regulation, or the Regulations referred to in subparagraph (b) of paragraph (1) of this Regulation, or the code referred to in subparagraph (c) of paragraph (1) of this Regulation, or the Regulations referred to in subparagraph (d) of paragraph (1) of this Regulation, or the International Standards referred to in subparagraphs (e), (f), or (g) of paragraph (1) of this Regulation, or the Chemical Abstracts Service referred to in subparagraph (h) of paragraph (1) of this Regulation may be given by the production of a document purporting to be a copy of such amendment.

Regulation 6.

SCHEDULE 1

Conventional Methods and Special Methods of Classification of Certain Preparations due to Physico-Chemical Properties

PART I

FLAMMABILITY

1. In the case of gas preparations produced to order in small amounts where it would not be reasonably practicable to comply with the provisions of Regulation 6 (1), the flammability may, in accordance with the provisions of Regulation 6 (2), be assessed in accordance with the provisions of this Schedule.

2. Subject to paragraph 1, a gas preparation shall be classified as extremely flammable and assigned the risk phrase R12 if it contains at least one gas substance, classified as extremely

flammable, and satisfies the provisions of subparagraph 9.1.1.1. of Chapter 9 of Annex VI to Council Directive 67/548/EEC.

PART II

OXIDIZING

1. A gas preparation shall be classified as oxidizing if it contains at least one gas substance, classified as oxidizing, in accordance with the provisions of subparagraph 9.1.1.2. of Chapter 9 of Annex VI to Council Directive 67/548/EEC.

2. A gas preparation, classified as oxidizing in accordance with the provisions of paragraph 1 shall be assigned the risk phrase R8 in accordance with the provisions of subparagraph 9.1.1.2. of Chapter 9 of Annex VI to Council Directive 67/548/EEC.

PART III

PREPARATIONS CONTAINING ORGANIC PEROXIDES

1. A preparation shall be classified as being oxidizing if it contains one or more organic peroxide substances classified as oxidizing and either—

(a) the sum of their concentrations in the preparation exceeds 5%; or

(b) (i) contains not more than a concentration of 5% hydrogen peroxide, and

(ii) the total available oxygen content from the organic peroxide substances (being the sum of that from each organic peroxide substance present in the preparation) exceeds a concentration of 0.5% as given by the following formula—

$$\text{AOC} = \frac{16 \times \sum (n_i \times c_i)}{m_i}$$

where

(A) AOC is the available oxygen content, expressed as a percentage, of each organic peroxide substance present in the preparation,

(B) n_i is the number of peroxide groups per molecule of each organic peroxide substance i in the preparation,

(C) c_i is the concentration, expressed as a percentage by mass, of each organic peroxide substance i in the preparation, and

(D) m_i is the molecular mass of each organic peroxide i in the preparation; in accordance with the provisions of Chapters 2.2.2.1. and 9.3. of Annex VI to Council Directive 67/548/EEC.

2. For the purposes of paragraph 1, the reference to concentration is a reference to a concentration expressed on a mass/mass basis.

Regulation 7.

SCHEDULE 2

Conventional Method of Assessment of Classification of Preparations, which are not gas preparations, due to Health effects.

PART I

GENERAL

1. The methods by which a preparation is classified in accordance with the provisions of Regulations 5 (3) (b) (i) and 7 (2) shall be in accordance with the provisions of this Schedule.

2. A preparation classified in accordance with this Schedule shall have the risk phrases assigned to it in accordance with the provisions of this Schedule.

3. For the purposes of this Schedule, a reference to a substance contained in a preparation shall include a reference to a preparation which is a constituent of the first-mentioned preparation.

4. For the purposes of this Schedule—

(a) carcinogenic categories 1, 2 and 3, mutagenic categories 1, 2 and 3 and toxic for reproduction categories 1, 2 and 3 shall have the same meanings as in Chapter 4 of Annex VI to Council Directive 67/548/EEC;

(b) a reference to a substance assigned a risk phrase shall mean—

(i) in the case of a substance which is a substance within the meaning of Regulation 3, the risk phrase assigned to it in accordance with the provisions of Council Directive 67/548/EEC;

(ii) in the case of a preparation (forming a constituent of another preparation), the risk phrase assigned to it in accordance with these Regulations.

(c) A reference to a preparation assigned a risk phrase, being a preparation which is being assessed in accordance with this Schedule, shall mean the risk phrase assigned to it in accordance with the provisions of this Schedule.

5. For the purpose of this Schedule—

(a) "appropriate limit" means the lowest concentration specified for a substance in Annex I to Council Directive 67/548/EEC which, if present in a preparation in a concentration equal to or exceeding this limit, would itself have the effect of that preparation being classified as

(i) very toxic in accordance with the provisions of paragraph 1 of Part II, or

(ii) very toxic in accordance with the provisions of paragraph 2 of Part II, or

(iii) toxic in accordance with the provisions of paragraph 1 of Part III, or

(iv) toxic in accordance with the provisions of paragraph 2 of Part III, or

(v) toxic in accordance with the provisions of paragraph 3 of Part III, or

(vi) harmful in accordance with the provisions of paragraph 1 of Part IV, or

(vii) harmful in accordance with the provisions of paragraph 2 of Part IV, or
(viii) harmful in accordance with the provisions of paragraph 3 of Part IV, or
(ix) corrosive in accordance with the provisions of paragraph 1 of Part V, or
(x) corrosive in accordance with the provisions of paragraph 2 of Part V, or
(xi) irritant in accordance with the provisions of paragraph 1 of Part VI, or
(xii) irritant in accordance with the provisions of paragraph 2 of Part VI, or
(xiii) irritant in accordance with the provisions of paragraph 3 of Part VI, or
(xiv) irritant in accordance with the provisions of paragraph 4 of Part VI, or
(xv) carcinogenic in accordance with the provisions of paragraph 1 of Part VII, or
(xvi) suspect for humans owing to its possible carcinogenic effects, in accordance with the provisions of paragraph 2 of Part VII, or
(xvii) mutagenic in accordance with the provisions of paragraph 4 of Part VII, or
(xviii) suspect for humans owing to its possible mutagenic effects, in accordance with the provisions of paragraph 5 of Part VII, or
(xix) toxic for reproduction in accordance with the provisions of paragraphs 7 or 8 of Part VII, or
(xx) having to be regarded as toxic for reproduction, in accordance with the provisions of paragraphs 9 or 10 of Part VII, or
(xxi) sensitising in accordance with the provisions of paragraphs 1, 2 or 3 of Part VIII; and
(b) "Appropriate limit range" means the range of concentrations, specified for a substance in Annex I to Council Directive 67/548/EEC, which is equal to or exceeding the appropriate limit for that substance for the relevant classification but less than that of the next more hazardous classification.

6. For the purposes of this Schedule, a reference to a Part is a reference to that Part of this Schedule unless it is indicated that reference to some other provision is intended.

7. For the purposes of this Schedule, a reference to a substance or a preparation assigned one or more of the risk phrases R20, R21, R22, R23, R24, R25, R26, R27, R28, R36, R37 or R38 shall include a reference to a combination risk phrase (other than a combination risk phrase incorporating R39, R40 or R48) which has two or more of those risk phrases incorporated into it.

8. For the purposes of this Schedule, a reference to a substance or preparation assigned any of the risk phrases R39, R40 (other than when assigned due to the substance's or preparation's possible carcinogenic or mutagenic effects) or R48 shall mean a reference to that risk phrase incorporated in a combined risk phrase.

9. For the purposes of this Schedule, a reference to concentration is a reference to a concentration expressed on a mass/mass basis.

PART II

VERY TOXIC CLASSIFICATION

1. (1) Subject to paragraph 3, a preparation shall be classified as being very toxic if—

(a) it contains at least one very toxic substance, assigned one or more of the risk phrases R26, R27 or R28, in a concentration equal to or exceeding—

(i) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, the appropriate limit specified therein for that substance, if it is so specified; or

(ii) in the case of a substance which is not contained in Annex I to Council Directive 67/548/EEC or is therein but does not have the limit specified, 7%

or

(b) it contains more than one very toxic substance (as mentioned in subparagraph (a)) the concentration in the preparation of each of which does not satisfy the provisions of subparagraph (a), and the sum of their quotients satisfies the following equation —

where

(i) S means the sum of,

(ii) PT⁺ is the concentration in the preparation of each very toxic substance, and

(iii) LT⁺ is—

(A) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, the appropriate limit specified therein for that substance, if it is so specified, or

(B) in the case of a substance which is not contained in Annex I to Council Directive 67/548/EEC or is therein but does not have the limit specified, 7%.

(2) (a) In the case of it being classified very toxic in accordance with the provisions of subparagraphs (a) or (b) of subparagraph (1), the preparation shall be assigned the risk phrase which shall be appropriate to the substance or substances most responsible for the very toxic classification of the preparation.

(b) For the purposes of subparagraph (a), the reference to the risk phrase shall include a combination risk phrase.

2. (1) A preparation shall be classified as being very toxic if it contains at least one very toxic substance assigned the risk phrase R39 in a concentration equal to or exceeding—

(a) in the case of a substance which is contained in Annex I to Council Directive 67/548/EEC, the appropriate limit specified therein for that substance, if it is so specified, or

(b) in the case of a substance which is not contained in Annex I to Council Directive 67/548/EEC or is therein but does not have the limit specified, 10%.

(2) In the case of it being classified very toxic in accordance with subparagraph (1), the preparation shall be assigned the risk phrase R39 in a combined risk phrase to indicate route of administration or exposure in accordance with Chapter 3.2.1 of Annex VI to Council Directive 67/548/EEC.

3. The provisions of paragraph I shall apply only in the case of a substance, assigned a risk phrase mentioned in paragraph I when that risk phrase does not form part of a combined risk phrase with risk phrase R39.

PART III

TOXIC CLASSIFICATION

1. (1) Subject to Part II and to paragraph 4, a preparation shall be classified as being toxic if—

(a) it contains at least one very toxic substance, assigned one or more of the risk phrases R26, R27 or R28, in a concentration—

(i) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, within the appropriate limit range specified therein for that substance, if it is so specified; or

(ii) in the case of a substance which is not contained in Annex I to Directive 67/548/EEC or is therein but does not have the limit range specified, equal to or exceeding 1% but less than 7%; or

(b) it contains at least one toxic substance, assigned one or more of the risk phrases R23, R24 or R25, in a concentration equal to or exceeding—

(i) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, the appropriate limit specified therein for that substance, if it is so specified; or

(ii) in the case of a substance which is not contained in Annex I to Directive 67/548/EEC or is therein but does not have the limit specified, 25%; or

(c) it contains more than one substance classified as very toxic or toxic (as mentioned in subparagraphs (a) and (b)), the concentration in the preparation of each of which does not satisfy the provisions of subparagraphs (a) or (b), and the sum of their quotients satisfies the following equation—

where

(a) S means the sum of,

(b) PT+ is the concentration in the preparation of each very toxic substance, and

(c) PT is the concentration in the preparation of each toxic substance, and

(d) LT is

(A) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, the appropriate limit specified therein for that substance, if it is so specified, or

(B) in the case of a very toxic substance which is not contained in Annex I to Council Directive 67/548/EEC or is therein but does not have the limit specified, 1%, or

(C) in the case of a toxic substance which is not contained in Annex I to Council Directive 67/548/EEC or is therein but does not have the limit specified, 25%.

(2) (a) In the case of it being classified toxic in accordance with the provisions of subparagraphs (a), (b) or (c) of subparagraph (1), the preparation shall, subject to subparagraph (3), be assigned the risk phrase which shall be appropriate to the substance or substances most responsible for the toxic classification of the preparation.

(b) For the purposes of subparagraph (a), the reference to the risk phrase shall include a combination risk phrase.

(3) In the case of a risk phrase, in accordance with the provisions of subparagraph (2), being assigned to a preparation due to the presence in it of a very toxic substance, that risk phrase shall be appropriate to that substance, but as if that substance were classified as a toxic substance.

2. (1) A preparation shall be classified as being toxic if it contains at least one substance classified as very toxic or toxic and assigned the risk phrase R39 in a concentration—

(a) in the case of a very toxic substance contained in Annex I to Council Directive 67/548/EEC, within the appropriate limit range specified therein for that substance, if it is so specified; or

(b) in the case of a toxic substance contained in Annex I to Council Directive 67/548/EEC, equal to or exceeding the appropriate limit specified therein for that substance, if it is so specified; or

(c) in the case of a very toxic substance which is not contained in Annex I to Council Directive 67/548/EEC or is therein but does not have the limit range specified, equal to or exceeding 1% but less than 10%; or

(d) in the case of a toxic substance which is not contained in Annex I to Council Directive 67/548/EEC or is therein but does not have the limit specified, equal to or exceeding 10%.

(2) In the case of its being classified toxic in accordance with subparagraph (1), the preparation shall be assigned the risk phrase R39 in a combined risk phrase to indicate route of administration or exposure in accordance with Chapter 3.2.2 of Annex VI to Council Directive 67/548/EEC.

(3) Notwithstanding the provisions of Part II and irrespective of any other provisions of these Regulations, the provisions of subparagraph (2) shall apply in the case of a very toxic preparation which would be classified as toxic in accordance with the provisions of subparagraph (1).

3. (1) A preparation shall be classified as being toxic if it contains at least one toxic substance assigned the risk phrase R48 in a concentration equal to or exceeding—

(a) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, the appropriate limit specified therein for that substance, if it is so specified, or

(b) in the case of a substance which is not contained in Annex I to Council Directive 67/548/EEC or is therein but does not have the limit specified, 10%.

(2) In the case of it being classified toxic in accordance with subparagraph (1), the preparation shall be assigned the risk phrase R48 in a combined risk phrase to indicate the route of administration or exposure in accordance with Chapter 3.2.2 of Annex VI to Council Directive 67/548/EEC.

(3) Notwithstanding the provisions of Part II and irrespective of any other provisions of these Regulations, the provisions of subparagraph (2) shall apply in the case of a very toxic preparation which would be classified as toxic in accordance with the provisions of subparagraph (1).

4. The provisions of paragraph 1 shall only apply in the case of a substance assigned a risk phrase mentioned in paragraph 1 where that risk phrase does not form part of a combined risk phrase with risk phrases R39 or R48.

PART IV

HARMFUL CLASSIFICATION

1. (1) Subject to Parts II and III and to paragraph 4 a preparation shall be classified as harmful if—

(a) it contains at least one very toxic substance, assigned one or more of the risk phrases R26, R27, R28 or at least one toxic substance, assigned one or more of the risk phrases R23, R24 or R25 in a concentration—

(i) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, within the appropriate limit range specified therein for that substance, if it is so specified; or

(ii) in the case of a substance which is not contained in Annex I to Council Directive 67/548/EEC or is contained therein but does not have the limit range specified—

(A) equal to or exceeding 0.1% but less than 1% in the case of a very toxic substance, or

(B) equal to or exceeding 3% but less than 25% in the case of a toxic substance; or

(b) it contains at least one harmful substance assigned one or more of the risk phrases R20, R21 or R22 in a concentration equal to or exceeding—

(i) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, the appropriate limit specified therein for that substance, if it is so specified, or

(ii) in the case of a substance which is not contained in Annex I to Council Directive 67/548/EEC or is therein but does not have the limit specified, 25%; or

(c) it contains more than one substance classified as very toxic, toxic or harmful (as mentioned in subparagraphs (a) and (b)), the concentration in the preparation of each of which does not satisfy the provisions of subparagraphs (a) or (b), and the sum of their quotients satisfies the following equation—

where

(i) S means the sum of;

(ii) PT+ is the concentration in the preparation of each very toxic substance;

(iii) PT is the concentration in the preparation of each toxic substance;

(iv) PXN is the concentration in the preparation of each harmful substance; and

(v) LXN is

(A) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, the appropriate limit specified therein for that substance if it is so specified, or

(B) in the case of a very toxic substance which is not contained in Annex I to Council Directive 67/548/EEC or is therein but does not have the limit specified, 0.1%, or

(C) in the case of a toxic substance which is not contained in Annex I to Council Directive 67/548/EEC or is therein but does not have the limit specified, 3%, or

(D) in the case of a harmful substance which is not contained in Annex I to Council Directive 67/548/EEC or is therein but does not have the limit specified, 25%.

(2) (a) In the case of its being classified harmful in accordance with the provisions of subparagraphs (a), (b) or (c) of subparagraph (1), the preparation shall, subject to paragraph (3), be assigned the risk phrase which shall be appropriate to the substance or substances most responsible for the harmful classification of the preparation.

(b) For the purposes of subparagraph (a), the reference to the risk phrase shall include a combination risk phrase.

(3) In the case of a risk phrase being, in accordance with the provisions of subparagraph (2), assigned to a preparation due to the presence in it of a very toxic or toxic substance, that risk phrase shall be that appropriate to that substance but as if that substance were classified as a harmful substance.

2. (1) A preparation shall be classified as harmful if it contains at least one substance, classified as very toxic or toxic and assigned the risk phrase R39 or harmful and assigned the risk phrase R40 (owing to non-lethal irreversible effects after a single dose but not including carcinogenic or mutagenic effects), in a concentration—

(a) in the case of a very toxic or toxic substance contained in Annex I to Council Directive 67/548/EEC, within the appropriate limit range specified therein for that substance, if it is so specified; or

(b) in the case of a harmful substance contained in Annex I to Council Directive 67/548/EEC, equal to or exceeding the appropriate limit specified therein for that substance, if it is so specified; or

(c) in the case of a very toxic substance which is not contained in Annex I to Council Directive 67/548/EEC or is therein but does not have the limit specified, equal to or exceeding 0.1% but less than 1%; or

(d) in the case of a toxic substance which is not contained in Annex I to Council Directive 67/548/EEC or is therein but does not have the limit specified, equal to or exceeding 1% but less than 10%; or

(e) in the case of a harmful substance which is not contained in Annex I to Council Directive 67/548/EEC or is therein but does not have the limit specified, equal to or exceeding 10%.

(2) In the case of its being classified harmful in accordance with subparagraph (1), the preparation shall be assigned the risk phrase R40 in a combined risk phrase to indicate route of administration or exposure in accordance with Chapter 3.2.3 of Annex VI to Council Directive 67/548/EEC.

(3) Notwithstanding the provisions of Parts II and III and irrespective of any other provisions of these Regulations, the provisions of subparagraphs (2) shall apply in the case of a very toxic or toxic preparation which would be classified as harmful in accordance with the provisions of subparagraph (1)'

3. (1) A preparation shall be classified as harmful if it contains at least one substance, classified as toxic or harmful and assigned the risk phrase R48, in a concentration—

(a) in the case of a toxic substance contained in Annex I to Council Directive 67/548/EEC, within the appropriate limit range specified therein for that substance, if it is so specified; or

(b) in the case of a harmful substance contained in Annex I to Council Directive 67/548/EEC, equal to or exceeding the appropriate limit specified therein for that substance, if it is so specified; or

(c) in the case of a toxic substance which is not contained in Annex I to Council Directive 67/548/EEC or is therein but does not have the limit specified, equal to or exceeding 1 % but less than 10%; or

(d) in the case of a harmful substance which is not contained in Annex I to Council Directive 67/548/EEC or is therein but does not have the limit specified, equal to or exceeding 10%.

(2) In the case of its being classified harmful in accordance with subparagraph (1), the preparation shall be assigned the risk phrase R48 in a combined risk phrase to indicate route of administration or exposure in accordance with Chapter 3.2.3 of Annex VI to Council Directive 67/548/EEC.

(3) Notwithstanding the provisions of Parts II and III and irrespective of any other provisions of these Regulations, the provisions of subparagraph (2) shall apply in the case of a preparation, classified as very toxic or toxic, which would be classified as harmful in accordance with the provisions of subparagraph (1).

4. The provisions of paragraph 1 shall only apply in the case of a substance assigned a risk phrase mentioned in paragraph 1 when that risk phrase does not form part of a combined risk phrase with risk phrases R39, R40 or R48.

PART V

CORROSIVE CLASSIFICATION

1. A preparation shall be classified as corrosive and shall be assigned the risk phrase R35 if—

(a) it contains at least one corrosive substance, assigned the risk phrase R35 in a concentration equal to or exceeding—

(i) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, the appropriate limit specified therein for that substance, if it is so specified; or

(ii) in the case of a substance which is not contained in Annex I to Council Directive 67/548/EEC or is contained therein but does not have the limit specified, 10%; or

(b) it contains more than one corrosive substance assigned the risk phrase R35, the concentration in the preparation of each of which does not satisfy the provisions of subparagraph (a), and the sum of their quotients satisfies the following equation—

where

(i) S means the sum of,

(ii) PC, R35 is the concentration in the preparation of each corrosive substance assigned the risk phrase R35, and —

(iii) LC, R35 is—

(A) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, the appropriate limit specified therein for that substance, if it is so specified, or

(B) in the case of a substance which is not contained in Annex I to Council Directive 67/548/EEC or is therein but does not have the limit specified, 10%.

2. Subject to paragraph 1 a preparation shall be classified as corrosive and assigned the risk phrase R34 if—

(a) it contains at least one corrosive substance assigned the risk phrase R35 or R34 in a concentration—

(i) in the case of a substance assigned the risk phrase R35 and contained in Annex I to Council Directive 67/548/EEC within the appropriate limit range specified therein for that substance, if it is so specified; or

(ii) in the case of a substance assigned the risk phrase R34 and contained in Annex I to Council Directive 67/548/EEC, equal to or exceeding the appropriate limit specified therein for that substance, if it is so specified; or

(iii) in the case of a substance assigned the risk phrase R35 and which is not contained in Annex I to Council Directive 67/548/EEC or is contained therein but does not have the limit range specified, equal to or exceeding 5% but less than 10%; or

(iv) in the case of a substance assigned the risk phrase R34 and which is not contained in Annex I to Council Directive 67/548/EEC or is contained therein but does not have the limit specified, equal to or exceeding 10%; or

(b) it contains more than one corrosive substance assigned the risk phrase R35 or R34, the concentration in the preparation of each of which does not satisfy the provisions of subparagraph (a), and the sum of their quotients satisfy the following equation—

where

(i) S means the sum of,

(ii) PC, R35 is the concentration in the preparation of each corrosive substance assigned the risk phrase R35,

(iii) PC, R34 is the concentration in the preparation of each corrosive substance assigned the risk phrase R34, and—

(iv) LC, R34 is—

(A) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, the appropriate limit specified therein for that substance, if it is so specified, or

(B) in the case of a substance assigned the risk phrase R35 and which is not contained in Annex I to Council Directive 67/548/EEC or is contained therein but does not have the limit specified, 5%, or

(C) in the case of a substance assigned the risk phrase R34 and which is not contained in Annex I to Council Directive 67/548/EEC or is contained therein but does not have the limit specified, 10%.

PART VI

IRRITANT CLASSIFICATION

1. Subject to Part V, a preparation shall be classified as irritant and assigned the risk phrase R38 if—

(a) it contains at least one corrosive substance, assigned the risk phrase R34 or R35 in a concentration—

(i) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, within the appropriate limit range specified therein for that substance, if it is so specified; or

(ii) in the case of a substance which is not contained in Annex I to Council Directive 67/548/EEC or is contained therein but does not have the limit range specified—

(A) in the case of a substance assigned the risk phrase R35, equal to or exceeding 1% but less than 5%, or

(B) in the case of a substance assigned the risk phrase R34, equal to or exceeding 5% but less than 10%; or

(b) it contains at least one irritant substance assigned the risk phrase R38, in a concentration equal to or exceeding—

(i) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, the appropriate limit specified therein for that substance, if it is so specified, or

(ii) in the case of a substance which is not contained in Annex I to Council Directive 67/548/EEC or is therein but does not have the limit specified, 20%; or

(c) it contains more than one substance classified as irritant (assigned the risk phrase R38) or corrosive, the concentration in the preparation of each of which does not satisfy the provisions of subparagraphs (a) or (b), and the sum of their quotients satisfies the following equation

where

(i) S means the sum of,

(ii) PC, R35 is the concentration in the preparation of each corrosive substance assigned the risk phrase R35,

(iii) PC, R34 is the concentration in the preparation of each corrosive substance assigned the risk phrase R34,

(iv) PX_i, R38 is the concentration in the preparation of each irritant substance assigned the risk phrase R38,

(v) LX_i, R38 is

(A) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, the appropriate limit specified therein for that substance, if it is so specified, or

(B) in the case of a corrosive substance, assigned the risk phrase R35, which is not contained in Annex I to Council Directive 67/548/EEC or is contained therein but does not have the limit specified, 1%, or

(C) in the case of a corrosive substance assigned the risk phrase R34, which is not contained in Annex I to Council Directive 67/548/EEC or is contained therein but does not have the limit specified, 5%, or

(D) in the case of an irritant substance, assigned the risk phrase R38, which is not contained in Annex I to Council Directive 67/548/EEC or is contained therein but does not have the limit specified, 20%.

2. Subject to Part V, a preparation shall be classified as irritant and shall be assigned the risk phrase R37 if—

(a) it contains at least one irritant substance assigned the risk phrase R37 in a concentration equal to or exceeding—

(i) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, the appropriate limit specified therein for that substance, if it is so specified; or

(ii) in the case of a substance which is not contained in Annex I to Council Directive 67/548/EEC, or is contained therein but does not have the limit value specified, 20%; or

(b) it contains more than one irritant substance assigned the risk phrase R37, the concentration in the preparation of each of which does not satisfy the provisions of subparagraph (a), and the sum of their quotients satisfies the following equation—

where

(i) S means the sum of,

(ii) PX_i , R37 is the concentration in the preparation of each irritant substance assigned the risk phrase R37, and—

(iii) LX_i , R37 is—

(A) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, the appropriate limit specified therein for that substance, if it so specified, or

(B) in the case of a substance which is not contained in Annex I to Council Directive 67/548/EEC or is contained therein but does not have the limit specified, 20%.

3. Subject to Part V and paragraph 4, a preparation shall be classified as irritant and shall be assigned the risk phrase R36 if—

(a) it contains at least one irritant substance assigned the risk phrase R36 in a concentration equal to or exceeding—

(i) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, the appropriate limit specified therein for that substance, if it is so specified; or

(ii) in the case of a substance which is not contained in Annex I to Council Directive 67/548/EEC, or is contained therein but does not have the limit specified, 20%; or

(b) it contains at least one substance assigned the risk phrase R41 in a concentration—

- (i) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, within the appropriate limit range specified therein for that substance, if it is so specified; or
- (ii) in the case of a substance which is not contained in Annex I to Council Directive 67/548/EEC, or is contained therein but does not have the limit range specified, equal to or exceeding 5% but less than 10%; or
- (c) it contains more than one substance classified as irritant and assigned the risk phrases R36 or R41, the concentration in the preparation of each of which does not satisfy the provisions of subparagraphs (a) or (b), or classified as corrosive and assigned the risk phrases R35 or R34 and the sum of their quotients satisfies the following equation—

where

(i) S means the sum of,

(ii) PC, R35 is the concentration in the preparation of each corrosive substance assigned the risk phrase R35,

(iii) PC, R34 is the concentration in the preparation of each corrosive substance assigned the risk phrase R34,

(iv) PXi, R41 is the concentration in the preparation of each irritant substance assigned the risk phrase R41,

(v) PXi, R36 is the concentration in the preparation of each irritant substance assigned the risk phrase R36, and

(vi) LXi, R36 is—

(A) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, the appropriate limit specified therein for that substance, if it so specified, or

(B) in the case of a corrosive substance assigned the risk phrase R35, which is not contained in Annex I to Council Directive 67/548/EEC or is contained therein but does not have the limit specified, 1%, or

(C) in the case of a corrosive substance assigned the risk phrase R34, which is not contained in Annex I to Council Directive 67/548/EEC or is contained therein but does not have the limit specified, 5%, or

(D) in the case of an irritant substance, assigned the risk phrase R41 which is not contained in Annex I to Council Directive 67/548/EEC or is contained therein but does not have the limit specified, 5%, or

(E) in the case of an irritant substance, assigned the risk phrase R36 which is not contained in Annex I to Council Directive 67/548/EEC or is contained therein but does not have the limit specified, 20%.

4. Subject to the provisions of Part V, a preparation shall be classified as irritant and assigned the risk phrase R41 if—

(a) it contains at least one irritant substance assigned the risk phrase R41 in a concentration equal to or exceeding—

- (i) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, the appropriate limit specified therein for that substance, if it is so specified; or
- (ii) in the case of a substance which is not contained in Annex I to Council Directive 67/548/EEC, or is contained therein but does not have the limit specified, 10%; or
- (b) it contains more than one substance classified as irritant and assigned the risk phrase R41, the concentration in the preparation of each of which does not satisfy the provisions of sub paragraph (a), or classified as corrosive and assigned the risk phrases R35 or R34 and the sum of their quotients satisfies the following equation—

where

(i) S means the sum of,

(ii) PC, R35 is the concentration in the preparation of each corrosive substance assigned the risk phrase R35,

(iii) PC, R34 is the concentration in the preparation of each corrosive substance assigned the risk phrase R34,

(iv) PXi, R41 is the concentration in the preparation of each irritant substance assigned the risk phrase R41, and

(v) LXi, R41 is—

(A) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, the appropriate limit specified therein for that substance, if it is so specified, or

(B) in the case of a corrosive substance assigned the risk phrase R35, which is not contained in Annex I to Council Directive 67/548/EEC or is contained therein but does not have the limit specified, 5%, or

(C) in the case of a corrosive substance assigned the risk phrase R34, which is not contained in Annex I to Council Directive 67/548/EEC or is contained therein but does not have the limit specified, 10%, or

(D) in the case of an irritant substance assigned the risk phrase R41, which is not contained in Annex I to Council Directive 67/548/EEC or is contained therein but does not have the limit specified, 10%.

PART VII

CARCINOGENIC/MUTAGENIC/TOXIC FOR REPRODUCTION

1. A preparation shall be classified as carcinogenic and assigned the risk phrase R45 or R49 (as appropriate) if it contains at least one substance assigned one of the risk phrases R45 or R49 in a concentration equal to or exceeding—

(a) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, the appropriate limit specified therein for that substance, if it is so specified; or

(b) in the case of a substance which is not contained in Annex I to Council Directive 67/548/EEC or is contained therein but does not have the limit specified, 0.1%.

2. A preparation shall be classified as suspect for humans owing to its possible carcinogenic effects and shall be assigned the risk phrase R40 if it contains at least one substance assigned the risk phrase R40 (due to the suspicion for humans owing to the possible carcinogenic effects of the substance), in a concentration equal to or exceeding—

(a) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, the appropriate limit specified therein for that substance, if it is so specified, or

(b) in the case of a substance which is not contained in Annex I to Council Directive 67/548/EEC or is therein but does not have the limit specified, 1%.

3. (1) A preparation classified as carcinogenic, in accordance with the provisions of paragraph 1 shall be assigned the 'toxic' symbol and 'toxic' indication of danger unless the preparation is otherwise classified as very toxic.

(2) A preparation classified as suspect for humans owing to its possible carcinogenic effects in accordance with provisions of paragraph 2 shall be assigned the "harmful" symbol and "harmful" indication of danger unless the preparation is otherwise classified as very toxic or toxic.

4. A preparation shall be classified as mutagenic and assigned the risk phrase R46 if it contains at least one substance, assigned the risk phrase R46, in a concentration equal to or exceeding—

(a) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, the appropriate limit specified therein for that substance, if it is so specified, or

(b) in the case of a substance which is not contained in Annex I to Council Directive 67/548/EEC or is therein but does not have the limit specified, 0.1%.

5. A preparation shall be classified as suspect for humans owing to its possible mutagenic effects and shall be assigned the risk phrase R40 if it contains at least one substance, classified as mutagenic category 3 and assigned the risk phrase R40 (due to the suspicion for humans owing to the possible mutagenic effects of the substance), in a concentration equal to or exceeding—

(a) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, the appropriate limit specified therein for that substance, if it is so specified, or

(b) in the case of a substance which is not contained in Annex I to Council Directive 67/548/EEC or is therein but does not have the limit specified, 1%.

6. (1) A preparation classified as mutagenic in accordance with the provisions of paragraph 4 shall be assigned the "toxic" symbol and "toxic" indication of danger unless the preparation is otherwise classified as very toxic.

(2) A preparation classified as suspect for humans owing to its possible mutagenic effects in accordance with the provisions of paragraph 5 shall be assigned the "harmful" symbol and "harmful" indication of danger unless the preparation is otherwise classified as very toxic or toxic.

7. A preparation shall be classified as toxic for reproduction and assigned the risk phrase R60 if it contains at least one substance assigned the risk phrase R60 in a concentration equal to or exceeding—

(a) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, the appropriate limit specified therein for that substance, if it is so specified, or

(b) in the case of a substance which is not contained in Annex I to Council Directive 67/548/EEC or is therein but does not have the limit specified, 0.5%.

8. A preparation shall be classified as toxic for reproduction and assigned the risk phrase R61 if it contains at least one substance assigned the risk phrase R61 in a concentration equal to or exceeding—

(a) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, the appropriate limit specified therein for that substance, if it is so specified, or

(b) in the case of a substance which is not contained in Annex I to Council Directive 67/548/EEC or is therein but does not have the limit specified, 0.5%.

9. A preparation shall be classified as having to be regarded as toxic for reproduction and assigned the risk phrase R62 if it contains at least one substance assigned the risk phrase R62 in a concentration equal to or exceeding—

(a) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, the appropriate limit specified therein for that substance, if it is so specified, or

(b) in the case of a substance which is not contained in Annex I to Council Directive 67/548/EEC or is therein but does not have the limit specified, 5%.

10. A preparation shall be classified as having to be regarded as toxic for reproduction and assigned the risk phrase R63 if it contains at least one substance assigned the risk phrase R63 in a concentration equal to or exceeding—

(a) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, the appropriate limit specified therein for that substance, if it is so specified, or

(b) in the case of a substance which is not specified in Annex I to Council Directive 67/548/EEC or is therein but does not have the limit specified, 5%.

11. (1) A preparation classified as toxic for reproduction in accordance with the provisions of paragraphs 7 and/or 8 shall be assigned the "toxic" symbol and "toxic" indication of danger unless the preparation is otherwise classified as very toxic.

(2) A preparation classified as having to be regarded as toxic for reproduction in accordance with the provisions of paragraphs 9 and/or 10 shall be assigned the "harmful" symbol and "harmful" indication of danger unless the preparation is otherwise classified as very toxic or toxic.

12. Notwithstanding the provisions of paragraphs 2, 5, 9 and 10 and Table VI of Annex I to Council Directive 88/379/EEC,

(a) the provisions of paragraph 2 shall not apply to a preparation to which the provisions of paragraph 1 apply,

(b) the provisions of paragraph 5 shall not apply to a preparation to which the provisions of paragraph 4 apply,

(c) the provisions of paragraph 9 shall not apply to a preparation to which the provisions of paragraph 7 apply, and

(d) the provisions of paragraph 10 shall not apply to a preparation to which the provisions of paragraph 8 apply.

PART VIII

SENSITIZING CLASSIFICATION

1. A preparation shall be classified as sensitizing and assigned the risk phrase R42 if it contains at least one substance, assigned the single risk phrase R42, in a concentration equal to or exceeding—

(a) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, the appropriate limit specified therein for that substance, if it is so specified; or

(b) in the case of a substance which is not contained in Annex I to Council Directive 67/548/EEC or is therein but does not have the limit specified, 1%.

2. A preparation shall be classified as sensitizing and assigned the combined risk phrase R42/43 if it contains at least one substance, assigned the combined risk phrase R42/43, in a concentration equal to or exceeding—

(a) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, the appropriate limit specified therein for that substance, if it is so specified; or

(b) in the case of a substance which is not contained in Annex I to Council Directive 67/548/EEC or is therein but does not have the limit specified, 1%.

3. A preparation shall be classified as sensitizing and assigned the risk phrase R43 if it contains at least one substance, assigned the single risk phrase R43, in a concentration equal to or exceeding—

(a) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, the appropriate limit specified therein for that substance, if it is so specified; or

(b) in the case of a substance which is not contained in Annex I to Council Directive 67/548/EEC or is therein but does not have the limit specified, 1%.

4. A preparation, which is assigned both the risk phrases R42 and R43 in accordance with both paragraphs 1 and 3, shall be assigned the combined risk phrase R42/43 instead of the two single risk phrases R42 and R43.

5. A preparation, classified as sensitizing and assigned the risk phrase R42 or R42/43 in accordance with paragraphs 1, 2 and/or 4, shall be assigned the "harmful" symbol and "harmful" indication of danger unless the preparation is otherwise classified as very toxic or toxic.

6. Subject to paragraphs 4 and 5, a preparation, classified as sensitizing and assigned the risk phrase R43 in accordance with paragraph 3, shall be assigned the "irritant" symbol and "irritant" indication of danger unless otherwise classified as corrosive.

Regulation 7.

SCHEDULE 3

Conventional Method of Assessment of Classification of Gas Preparations, due to Health effects.

PART I

GENERAL

1. The methods by which a preparation is classified in accordance with the provisions of Regulations 5 (3) (b) (ii) and 7 (3), shall be in accordance with the provisions of this Schedule.

2. A preparation classified in accordance with this Schedule shall have the risk phrases assigned to it in accordance with the provisions of this Schedule.

3. For the purposes of this Schedule, a reference to a substance contained in a preparation shall include a reference to a preparation which is a constituent of the first-mentioned preparation.

4. For the purposes of this Schedule—

(a) carcinogenic categories 1, 2 and 3, mutagenic categories 1,2 and 3 and toxic for reproduction categories 1, 2 and 3 shall have the same meanings as in Chapter 4 of Annex VI to Council Directive 67/548/EEC;

(b) a reference to a substance assigned a risk phrase shall mean—

(i) in the case of a substance, which is a substance within the meaning of Regulation 3, the risk phrase assigned to it in accordance with the provisions of Council Directive 67/548/EEC;

(ii) in the case of a preparation (forming a constituent of another preparation), the risk phrase assigned to it in accordance with these Regulations.

(c) A reference to a preparation assigned a risk phrase, which preparation is being assessed in accordance with this Schedule, shall mean that risk phrase assigned to it in accordance with the provisions of this Schedule.

5. For the purpose of this Schedule—

(a) "appropriate limit" means the lowest concentration specified for a substance in Annex I to Council Directive 67/548/EEC which, if present in a preparation in a concentration equal to or exceeding this limit, would itself have the effect of that preparation being classified as—

- (i) very toxic in accordance with the provisions of paragraph 1 of Part II, or
- (ii) very toxic in accordance with the provisions of paragraph 2 of Part II, or
- (iii) toxic in accordance with the provisions of paragraph 1 of Part III, or
- (iv) toxic in accordance with the provisions of paragraph 2 of Part III, or
- (v) toxic in accordance with the provisions of paragraph 3 of Part III, or
- (vi) harmful in accordance with the provisions of paragraph 1 of Part IV, or
- (vii) harmful in accordance with the provisions of paragraph 2 of Part IV, or
- (viii) harmful in accordance with the provisions of paragraph 3 of Part IV, or
- (ix) corrosive in accordance with the provisions of paragraph 1 of Part V, or
- (x) corrosive in accordance with the provisions of paragraph 2 of Part V, or
- (xi) irritant in accordance with the provisions of paragraph 1 of Part VI, or
- (xii) irritant in accordance with the provisions of paragraph 2 of Part VI, or
- (xiii) irritant in accordance with the provisions of paragraph 3 of Part VI, or
- (xiv) irritant in accordance with the provisions of paragraph 4 of Part VI, or
- (xv) carcinogenic in accordance with the provisions of paragraph 1 of Part VII, or
- (xvi) suspect for humans owing to its possible carcinogenic effects in accordance with the provisions of paragraph 2 of Part VII, or
- (xvii) mutagenic in accordance with the provisions of paragraph 4 of Part VII, or
- (xviii) suspect for humans owing to its possible mutagenic effects in accordance with the provisions of paragraph 5 of Part VII, or
- (xix) toxic for reproduction in accordance with the provisions of paragraphs 7 or 8 of Part VII, or
- (xx) having to be regarded as toxic for reproduction in accordance with the provisions of paragraphs 9 or 10 of Part VII, or
- (xxi) sensitizing in accordance with the provisions of paragraphs 1 or 2 of Part VIII; and

(b) "appropriate limit range" means the range of concentrations, specified for a substance in Annex I to Council Directive 67/548/EEC, which is equal to or exceeding the appropriate limit for that substance for the relevant classification but less than that of the next more hazardous classification.

6. For the purposes of this Schedule, a reference to a Part is a reference to that Part of this Schedule, unless it is indicated that reference to some other provision is intended.

7. For the purposes of this Schedule, a reference to a substance or a preparation assigned one or more of the risk phrases R20, R21, R22, R23, R24, R25, R26, R27, R28, R36, R37 or R38 shall include a reference to a combination risk phrase which has two or more of the first-mentioned risk phrases incorporated into it.

8. For the purposes of this Schedule, a reference to a substance or a preparation assigned any of the risk phrases R39, R40 (other than when assigned due to the substance's or preparation's possible carcinogenic or mutagenic effects) or R48 shall mean a reference to that risk phrase incorporated in a combination risk phrase.

9. For the purposes of this Schedule, a reference to concentration is a reference to a concentration expressed on a volume/volume basis.

PART II

VERY TOXIC CLASSIFICATION

1. (1) Subject to paragraph 3, a preparation shall be classified as being very toxic if—

(a) it contains at least one very toxic substance, assigned one or more of the risk phrases R26, R27 or R28, in a concentration equal to or exceeding—

(i) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, the appropriate limit specified therein for that substance, if it is so specified; or

(ii) in the case of a substance which is not contained in Annex I to Council Directive 67/548/EEC or is therein but does not have the limit specified, 1%,

or

(b) it contains more than one very toxic substance (as mentioned in subparagraph (a)) the concentration in the preparation of each of which does not satisfy the provisions of subparagraph (a), and the sum of their quotients satisfies the following equation—

where

(i) S means the sum of,

(ii) PT_i is the concentration in the preparation of each very toxic substance, and

(iii) LT_i is—

(A) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, the appropriate limit specified therein for that substance, if it is so specified, or

(B) in the case of a substance which is not contained in Annex I to Council Directive 67/548/EEC or is therein but does not have the limit specified, 1%.

(2) (a) In the case of it being classified very toxic in accordance with the provisions of subparagraphs (a) or (b) of subparagraph (1), the preparation shall be assigned the risk phrase which shall be appropriate to the substance or substances most responsible for the very toxic classification of the preparation.

(b) For the purposes of subparagraph (a), the reference to the risk phrase shall include a combination risk phrase.

2. (1) A preparation shall be classified as being very toxic if it contains at least one very toxic substance assigned the risk phrase R39 in a concentration equal to or exceeding—

(a) in the case of a substance which is contained in Annex I to Council Directive 67/548/EEC, the appropriate limit specified therein for that substance, if it is so specified, or

(b) in the case of a substance which is not contained in Annex I to Council Directive 67/548/EEC or is therein but does not have the limit specified, 1%.

(2) In the case of its being classified very toxic in accordance with subparagraph (1), the preparation shall be assigned the risk phrase R39 in a combined risk phrase to indicate route

of administration or exposure in accordance with Chapter 3.2.1 of Annex VI to Council Directive 67/548/EEC.

3. The provisions of paragraph 1 shall apply only in the case of a substance, assigned a risk phrase mentioned in paragraph 1 when that risk phrase does not form part of a combined risk phrase with risk phrase R39.

PART III

TOXIC CLASSIFICATION

1. (1) Subject to Part II and to paragraph 4, a preparation shall be classified as being toxic if—

(a) it contains at least one very toxic substance, assigned one or more of the risk phrases R26, R27 or R28, in a concentration—

(i) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, within the appropriate limit range specified therein for that substance, if it is so specified; or

(ii) in the case of a substance which is not contained in Annex I to Council Directive 67/548/EEC or is therein but does not have the limit range specified, equal to or exceeding 0.2% but less than 1%; or

(b) it contains at least one toxic substance, assigned one or more of the risk phrases R23, R24 or R25, in a concentration equal to or exceeding—

(i) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, the appropriate limit specified therein for that substance, if it is so specified; or

(ii) in the case of a substance which is not contained in Annex I to Council Directive 67/548/EEC or is therein but does not have the limit specified, 5%; or

(c) it contains more than one substance classified as very toxic or toxic (as mentioned in subparagraphs (a) and (b)), the concentration in the preparation of each of which does not satisfy the provisions of subparagraphs (a) or (b), and the sum of their quotients satisfies the following equation—

where

(a) S means the sum of,

(b) PT+ is the concentration in the preparation of each very toxic substance, and

(c) PT is the concentration in the preparation of each toxic substance, and

(d) LT is—

(A) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, the appropriate limit specified therein for that substance, if it is so specified, or

(B) in the case of a very toxic substance which is not contained in Annex I to Council Directive 67/548/EEC or is therein but does not have the limit specified, 0.2%, or

(C) in the case of a toxic substance which is not contained in Annex I to Council Directive 67/548/EEC or is therein but does not have the limit specified, 5%.

(2) (a) In the case of its being classified toxic in accordance with the provisions of subparagraphs (a), (b) or (c) of subparagraph (1), the preparation shall, subject to subparagraph (3), be assigned the risk phrase which shall be appropriate to the substance or substances most responsible for the toxic classification of the preparation;

(b) For the purposes of subparagraph (a), the reference to the risk phrase shall include a combination risk phrase.

(3) In the case of a risk phrase being, in accordance with the provisions of subparagraph (2), assigned to a preparation due to the presence in it of a very toxic substance, that risk phrase shall be appropriate to that substance, but as if that substance were classified as a toxic substance.

2. (1) A preparation shall be classified as being toxic if it contains at least one substance classified as very toxic or toxic and assigned the risk phrase R39 in a concentration—

(a) in the case of a very toxic substance contained in Annex I to Council Directive 67/548/EEC, within the appropriate limit range specified therein for that substance, if it is so specified; or

(b) in the case of a toxic substance contained in Annex I to Council Directive 67/548/EEC, equal to or exceeding the appropriate limit specified therein for that substance, if it is so specified; or

(c) in the case of a very toxic substance which is not contained in Annex I to Council Directive 67/548/EEC or is therein but does not have the limit range specified, equal to or exceeding 0.2% but less than 1%; or

(d) in the case of a toxic substance which is not contained in Annex I to Council Directive 67/548/EEC or is therein but does not have the limit specified, equal to or exceeding 5%.

(2) In the case of its being classified toxic in accordance with subparagraph (1), the preparation shall be assigned the risk phrase R39 in a combined risk phrase to indicate route of administration or exposure in accordance with Chapter 3.2.2 of Annex VI to Council Directive 67/548/EEC.

(3) Notwithstanding the provisions of Part II and irrespective of any other provisions of these Regulations, the provisions of subparagraph (2) shall apply in the case of a very toxic preparation which would be classified as toxic in accordance with the provisions of subparagraph (1).

3. (1) A preparation shall be classified as being toxic if it contains at least one toxic substance assigned the risk phrase R48 in a concentration equal to or exceeding—

(a) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, the appropriate limit specified therein for that substance, if it is so specified, or

(b) in the case of a substance which is not contained in Annex I to Council Directive 67/548/EEC or is therein but does not have the limit specified, 5%.

(2) In the case of its being classified toxic in accordance with subparagraph (1), the preparation shall be assigned the risk phrase R48 in a combined risk phrase to indicate the route of administration or exposure in accordance with Chapter 3.2.2 of Annex VI to Council Directive 67/548/EEC.

(3) Notwithstanding the provisions of Part II and irrespective of any other provisions of these Regulations, the provisions of subparagraph (2) shall apply in the case of a very toxic preparation which would be classified as toxic in accordance with the provisions of subparagraph (1).

4. The provisions of paragraph 1 shall only apply in the case of a substance assigned a risk phrase mentioned in paragraph 1 where that risk phrase does not form part of a combined risk phrase with risk phrases R39 or R48.

PART IV

HARMFUL CLASSIFICATION

1. (1) Subject to Parts II and III and to paragraph 4 a preparation shall be classified as harmful if—

(a) it contains at least one very toxic substance, assigned one or more of the risk phrases R26, R27, R28 or at least one toxic substance, assigned one or more of the risk phrases R23, R24 or R25 in a concentration—

(i) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, within the appropriate limit range specified therein for that substance, if it is so specified; or

(ii) in the case of a substance which is not contained in Annex I to Council Directive 67/548/EEC or is contained therein but does not have the limit range specified, —

(A) equal to or exceeding 0.02% but less than 0.2% in the case of a very toxic substance, or

(B) equal to or exceeding 0.5% but less than 5% in the case of a toxic substance; or

(b) it contains at least one harmful substance assigned one or more of the risk phrases R20, R21 or R22 in a concentration equal to or exceeding—

(i) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, the appropriate limit specified therein for that substance, if it is so specified, or

(ii) in the case of a substance which is not contained in Annex I to Council Directive 67/548/EEC or is therein but does not have the limit specified, 5%; or

(c) it contains more than one substance classified as very toxic, toxic or harmful (as mentioned in subparagraphs (a) and (b)), the concentration in the preparation of each of which does not satisfy the provisions of subparagraphs (a) or (b), and the sum of their quotients satisfies the following equation—

where

(i) S means the sum of,

(ii) PT+ is the concentration in the preparation of each very toxic substance;

(iii) PT is the concentration in the preparation of each toxic substance;

(iv) PXN is the concentration in the preparation of each harmful substance; and

(v) LXN is—

(A) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, the appropriate limit specified therein for that substance if it is so specified, or

(B) in the case of a very toxic substance which is not contained in Annex I to Council Directive 67/548/EEC or is therein but does not have the limit specified, 0.02%, or

(C) in the case of a toxic substance which is not contained in Annex I to Council Directive 67/548/EEC or is therein but does not have the limit specified, 0.5%, or

(D) in the case of a harmful substance which is not contained in Annex I to Council Directive 67/548/EEC or is therein but does not have the limit specified, 5%.

(2) (a) In the case of its being classified harmful in accordance with the provisions of subparagraphs (a), (b) or (c) of subparagraph (1), the preparation shall, subject to paragraph (3), be assigned the risk phrase which shall be appropriate to the substance or substances most responsible for the harmful classification of the preparation;

(b) for the purposes of subparagraph (a), the reference to the risk phrase shall include a combination risk phrase.

(3) In the case of a risk phrase being, in accordance with the provisions of subparagraph (2), assigned to a preparation due to the presence in it of a very toxic or toxic substance, that risk phrase shall be that appropriate to that substance but as if that substance were classified as a harmful substance.

2. (1) A preparation shall be classified as harmful if it contains at least one substance, classified as very toxic or toxic and assigned the risk phrase R39 or harmful and assigned the risk phrase R40 (owing to non-lethal irreversible effects after a single dose but not including carcinogenic or mutagenic effects), in a concentration—

(a) in the case of a very toxic or toxic substance contained in Annex I to Council Directive 67/548/EEC, within the appropriate limit range specified therein for that substance, if it is so specified; or

(b) in the case of a harmful substance contained in Annex I to Council Directive 67/548/EEC, equal to or exceeding the appropriate limit specified therein for that substance, if it is so specified; or

(c) in the case of a very toxic substance which is not contained in Annex I to Council Directive 67/548/EEC or is therein but does not have the limit specified, equal to or exceeding 0.02% but less than 0.2%; or

(d) in the case of a toxic substance which is not contained in Annex I to Council Directive 67/548/EEC or is therein but does not have the limit specified, equal to or exceeding 0.5% but less than 5%; or

(e) in the case of a harmful substance which is not contained in Annex I to Council Directive 67/548/EEC or is therein but does not have the limit specified, equal to or exceeding 5%.

(2) In the case of its being classified harmful in accordance with subparagraph (1), the preparation shall be assigned the risk phrase R40 in a combined risk phrase to indicate route of administration or exposure in accordance with Chapter 3.2.3 of Annex VI to Council Directive 67/548/EEC.

(3) Notwithstanding the provisions of Parts II and III and irrespective of any other provisions of these Regulations, the provisions of subparagraph (2) shall apply in the case of a very toxic or toxic preparation which would be classified as harmful in accordance with the provisions of subparagraph (1).

3. (1) A preparation shall be classified as harmful if it contains at least one substance, classified as toxic or harmful and assigned the risk phrase R48, in a concentration—

(a) in the case of a toxic substance contained in Annex I to Council Directive 67/548/EEC, within the appropriate limit range specified therein for that substance, if it is so specified; or

(b) in the case of a harmful substance contained in Annex I to Council Directive 67/548/EEC, equal to or exceeding the appropriate limit specified therein for that substance, if it is so specified; or

(c) in the case of a toxic substance which is not contained in Annex I to Council Directive 67/548/EEC or is therein but does not have the limit specified, equal to or exceeding 0.5% but less than 5% ; or

(d) in the case of a harmful substance which is not contained in Annex I to Council Directive 67/548/EEC or is therein but does not have the limit specified, equal to or exceeding 5%.

(2) In the case of its being classified harmful in accordance with subparagraph (1), the preparation shall be assigned the risk phrase R48 in a combined risk phrase to indicate route of administration or exposure in accordance with Chapter 3.2.3 of Annex VI to Council Directive 67/548/EEC.

(3) Notwithstanding the provisions of Parts II and III and irrespective of any other provisions of these Regulations, the provisions of subparagraph (2) shall apply in the case of a preparation, classified as very toxic or toxic, which would be classified as harmful in accordance with the provisions of subparagraph (1).

4. The provisions of paragraph 1 shall only apply in the case of a substance assigned a risk phrase mentioned in paragraph 1 when that risk phrase does not form part of a combined risk phrase with risk phrases R39, R40 or R48.

PART V

CORROSIVE CLASSIFICATION

1. A preparation shall be classified as corrosive and shall be assigned the risk phrase R35 if—

(a) it contains at least one corrosive substance, assigned the risk phrase R35 in a concentration equal to or exceeding—

(i) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, the appropriate limit specified therein for that substance, if it is so specified; or

(ii) in the case of a substance which is not contained in Annex I to Council Directive 67/548/EEC or is contained therein but does not have the limit specified, 1%; or

(b) it contains more than one corrosive substance assigned the risk phrase R35, the concentration in the preparation of each of which does not satisfy the provisions of subparagraph (a), and the sum of their quotients satisfies the following equation—

where

(i) S means the sum of,

(ii) PC, R35 is the concentration in the preparation of each corrosive substance assigned the risk phrase R35, and—

(iii) LC, R35 is—

(A) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, the appropriate limit specified therein for that substance, if it is so specified, or

(B) in the case of a substance which is not contained in Annex I to Council Directive 67/548/EEC or is therein but does not have the limit specified, 1%.

2. Subject to paragraph 1 a preparation shall be classified as corrosive and assigned the risk phrase R34 if—

(a) it contains at least one corrosive substance assigned the risk phrase R35 or R34 in a concentration—

(i) in the case of a substance assigned the risk phrase R35 and contained in Annex I to Council Directive 67/548/EEC within the appropriate limit range specified therein for that substance, if it is so specified; or

(ii) in the case of a substance assigned the risk phrase R34 and contained in Annex I to Council Directive 67/548/EEC, equal to or exceeding the appropriate limit specified therein for that substance, if it is so specified; or

(iii) in the case of a substance assigned the risk phrase R35 and which is not contained in Annex I to Council Directive 67/548/EEC or is contained therein but does not have the limit range specified, equal to or exceeding 0.2% but less than 1%; or

(iv) in the case of a substance assigned the risk phrase R34 and which is not contained in Annex I to Council Directive 67/548/EEC or is contained therein but does not have the limit specified, equal to or exceeding 5%; or

(b) it contains more than one corrosive substance assigned the risk phrase R35 or R34, the concentration in the preparation of each of which does not satisfy the provisions of subparagraph (a), and the sum of their quotients satisfy the following equation—

where

(i) S means the sum of,

(ii) PC, R35 is the concentration in the preparation of each corrosive substance assigned the risk phrase R35,

(iii) PC, R34 is the concentration in the preparation of each corrosive substance assigned the risk phrase R34,

(iv) LC, R34 is—

(A) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, the appropriate limit specified therein for that substance, if it is so specified, or

(B) in the case of a substance assigned the risk phrase R35 and which is not contained in Annex I to Council Directive 67/548/EEC or is contained therein but does not have the limit specified, 0.2%, or

(C) in the case of a substance assigned the risk phrase R34 and which is not contained in Annex I to Council Directive 67/548/EEC or is contained therein but does not have the limit specified, 5%.

PART VI

IRRITANT CLASSIFICATION

1. Subject to Part V, a preparation shall be classified as irritant and assigned the risk phrase R38 if—

(a) it contains at least one corrosive substance, assigned the risk phrase R34 or R35 in a concentration—

(i) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, within the appropriate limit range specified therein for that substance, if it is so specified; or

(ii) in the case of a substance which is not contained in Annex I to Council Directive 67/548/EEC or is contained therein but does not have the limit specified—

(A) in the case of a substance assigned the risk phrase R35, equal to or exceeding 0.02% but less than 0.2%, or

(A) in the case of a substance assigned the risk phrase R34, equal to or exceeding 0.5% but less than 5%; or

(b) it contains at least one irritant substance assigned the risk phrase R38, in a concentration equal to or exceeding—

(i) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, the appropriate limit specified therein for that substance, if it is so specified, or

(ii) in the case of a substance which is not contained in Annex I to Council Directive 67/548/EEC or is therein but does not have the limit specified, 5%; or

(c) it contains more than one substance classified as irritant (assigned the risk phrase R38) or corrosive, the concentration in the preparation of each of which does not satisfy the provisions of subparagraphs (a) or (b), and the sum of their quotients satisfies the following equation—

where

(i) S means the sum of,

(ii) PC, R35 is the concentration in the preparation of each corrosive substance assigned the risk phrase R35,

(iii) PC, R34 is the concentration in the preparation of each corrosive substance assigned the risk phrase R34,

(iv) PXi, R38 is the concentration in the preparation of each irritant substance assigned the risk phrase R38,

(v) LXi, R38 is—

(A) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, the appropriate limit specified therein for that substance, if it is so specified, or

(B) in the case of a corrosive substance, assigned the risk phrase R35, which is not contained in Annex I to Council Directive 67/548/EEC or is contained therein but does not have the limit specified, 0.02%, or

(C) in the case of a corrosive substance assigned the risk phrase R34, which is not contained in Annex I to Council Directive 67/548/EEC or is contained therein but does not have the limit specified, 0.5%, or

(D) in the case of an irritant substance, assigned the risk phrase R38, which is not contained in Annex I to Council Directive 67/548/EEC or is contained therein but does not have the limit specified, 5%.

2. Subject to Part V, a preparation shall be classified as irritant and shall be assigned the risk phrase R37 if—

(a) it contains at least one irritant substance assigned the risk phrase R37 in a concentration equal to or exceeding—

(i) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, the appropriate limit specified therein for that substance, if it is so specified; or

(ii) in the case of a substance which is not contained in Annex I to Council Directive 67/548/EEC, or is contained therein but does not have the limit value specified, 5%; or

(b) it contains more than one irritant substance assigned the risk phrase R37, the concentration in the preparation of each of which does not satisfy the provisions of subparagraph (a), and the sum of their quotients satisfies the following equation—

where

(i) S means the sum of,

(ii) PX_i , R37 is the concentration in the preparation of each irritant substance assigned the risk phrase R37, and—

(iii) LX_i , R37 is—

(A) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, the appropriate limit specified therein for that substance, if it so specified, or

(B) in the case of a substance which is not contained in Annex I to Council Directive 67/548/EEC or is contained therein but does not have the limit specified, 5%.

3. Subject to Part V and to paragraph 4, a preparation shall be classified as irritant and shall be assigned the risk phrase R36 if—

(a) it contains at least one irritant substance assigned the risk phrase R36 in a concentration equal to or exceeding—

(i) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, the appropriate limit specified therein for that substance, if it is so specified; or

(ii) in the case of a substance which is not contained in Annex I to Council Directive 67/548/EEC, or is contained therein but does not have the limit specified, 5%; or

(b) it contains at least one substance assigned the risk phrase R41 in a concentration in the preparation—

(i) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, the appropriate limit range specified therein for that substance, if it is so specified; or

(ii) in the case of a substance which is not contained in Annex I to Council Directive 67/548/EEC, or is contained therein but does not have the limit specified, equal to or exceeding 0.5% but less than 5%; or

(c) it contains more than one substance classified as irritant and assigned the risk phrases R 36 or R41, the concentration in the preparation of each of which does not satisfy the provisions of subparagraph (a) or (b), or classified as corrosive and assigned the risk phrases R35 or R34 and the sum of their quotients satisfies the following equation—

where

(i) S means the sum of,

(ii) PC, R35 is the concentration in the preparation of each corrosive substance assigned the risk phrase R35,

(iii) PC, R34 is the concentration in the preparation of each corrosive substance assigned the risk phrase R34,

(iv) PXi, R41 is the concentration in the preparation of each irritant substance assigned the risk phrase R41,

(v) PXi, R36 is the concentration in the preparation of each irritant substance assigned the risk phrase R36, and

(vi) LXi, R36 is—

(A) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, the appropriate limit specified therein for that substance, if it so specified, or

(B) in the case of a corrosive substance assigned the risk phrase R35, which is not contained in Annex I to Council Directive 67/548/EEC or is contained therein but does not have the limit specified, 0.02%, or

(C) in the case of a corrosive substance assigned the risk phrase R34, which is not contained in Annex I to Council Directive 67/548/EEC or is contained therein but does not have the limit specified, 0.5%, or

(D) in the case of an irritant substance, assigned the risk phrase R41 which is not contained in Annex I to Council Directive 67/548/EEC or is contained therein but does not have the limit specified, 0.5%, or

(E) in the case of an irritant substance, assigned the risk phrase R36 which is not contained in Annex I to Council Directive 67/548/EEC or is contained therein but does not have the limit specified, 5%.

4. Subject to the provisions of Part V, a preparation shall be classified as irritant and assigned the risk phrase R41 if—

(a) it contains at least one irritant substance assigned the risk phrase R41 in a concentration equal to or exceeding—

(i) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, the appropriate limit specified therein for that substance, if it is so specified; or

(ii) in the case of a substance which is not contained in Annex I to Council Directive 67/548/EEC, or is contained therein but does not have the limit specified, 5%; or

(b) it contains more than one substance classified as irritant and assigned the risk phrase R41, the concentration in the preparation of each of which does not satisfy the provisions of subparagraph (a), or classified as corrosive and assigned the risk phrases R35 or R34 and the sum of their quotients satisfies the following equation—

where

(i) S means the sum of,

(ii) PC, R35 is the concentration in the preparation of each corrosive substance assigned the risk phrase R35,

(iii) PC, R34 is the concentration in the preparation of each corrosive substance assigned the risk phrase R34,

(iv) PXi, R41 is the concentration in the preparation of each irritant substance assigned the risk phrase R41, and

(v) PXi, R41 is—

(A) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, the appropriate limit specified therein for that substance, if it is so specified, or

(B) in the case of a corrosive substance assigned the risk phrase R35, which is not contained in Annex I to Council Directive 67/548/EEC or is contained therein but does not have the limit specified, 0.2%, or

(C) in the case of a corrosive substance assigned the risk phrase R34, which is not contained in Annex I to Council Directive 67/548/EEC or is contained therein but does not have the limit specified, 5%, or

(D) in the case of an irritant substance assigned the risk phrase R41, which is not contained in Annex I to Council Directive 67/548/EEC or is contained therein but does not have the limit specified, 5%.

PART VII

CARCINOGENIC/MUTAGENIC/TOXIC FOR REPRODUCTION

1. A preparation shall be classified as carcinogenic and assigned the risk phrase R45 or R49 (as appropriate) if it contains at least one substance assigned one of the risk phrases R45 or R49 in a concentration equal to or exceeding—

(a) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, the appropriate limit specified therein for that substance, if it is so specified; or

(b) in the case of a substance which is not contained in Annex I to Council Directive 67/548/EEC or is contained therein but does not have the limit specified, 0.1%.

2. A preparation shall be classified as suspect for humans owing to its possible carcinogenic effects and shall be assigned the risk phrase R40 if it contains at least one substance assigned

the risk phrase R40 (due to the suspicion for humans owing to the possible carcinogenic effects of the substance), in a concentration equal to or exceeding—

(a) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, the appropriate limit specified therein for that substance, if it is so specified, or

(b) in the case of a substance which is not contained in Annex I to Council Directive 67/548/EEC or is therein but does not have the limit specified, 1%.

3. (1) A preparation classified as carcinogenic, in accordance with the provisions of paragraph 1 shall be assigned the "toxic" symbol and "toxic" indication of danger unless the preparation is otherwise classified as very toxic.

(2) A preparation classified as suspect for humans owing to its possible carcinogenic effects in accordance with provisions of paragraph 2 shall be assigned the "harmful" symbol and "harmful" indication of danger unless the preparation is otherwise classified as very toxic or toxic.

4. A preparation shall be classified as mutagenic and assigned the risk phrase R46 if it contains at least one substance, assigned the risk phrase R46, in a concentration equal to or exceeding—

(a) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, the appropriate limit specified therein for that substance, if it is so specified, or

(b) in the case of a substance which is not contained in Annex I to Council Directive 67/548/EEC or is therein but does not have the limit specified, 0.1%.

5. A preparation shall be classified as suspect for humans owing to its possible mutagenic effects and shall be assigned the risk phrase R40 if it contains at least one substance, classified as mutagenic category 3 and assigned the risk phrase R40 (due to the suspicion for humans owing to the possible mutagenic effects of the substance), in a concentration equal to or exceeding—

(a) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, the appropriate limit specified therein for that substance, if it is so specified, or

(b) in the case of a substance which is not contained in Annex I to Council Directive 67/548/EEC or is therein but does not have the limit specified, 1%.

6. (1) A preparation classified as mutagenic in accordance with the provisions of paragraph 4 shall be assigned the "toxic" symbol and "toxic" indication of danger unless the preparation is otherwise classified as very toxic.

(2) A preparation classified as suspect for humans owing to its possible mutagenic effects in accordance with the provisions of paragraph 5 shall be assigned the "harmful" symbol and "harmful" indication of danger unless the preparation is otherwise classified as very toxic or toxic.

7. A preparation shall be classified as toxic for reproduction and assigned the risk phrase R60 if it contains at least one substance assigned the risk phrase R60 in a concentration equal to or exceeding—

(a) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, the appropriate limit specified therein for that substance, if it is so specified, or

(b) in the case of a substance which is not contained in Annex I to Council Directive 67/548/EEC or is therein but does not have the limit specified, 0.2%.

8. A preparation shall be classified as toxic for reproduction and assigned the risk phrase R61 if it contains at least one substance assigned the risk phrase R61 in a concentration equal to or exceeding—

(a) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, the appropriate limit specified therein for that substance, if it is so specified, or

(b) in the case of a substance which is not contained in Annex I to Council Directive 67/548/EEC or is therein but does not have the limit specified, 0.2%.

9. A preparation shall be classified as having to be regarded as toxic for reproduction and assigned the risk phrase R62 if it contains at least one substance assigned the risk phrase R62 in a concentration equal to or exceeding—

(a) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, the appropriate limit specified therein for that substance, if it is so specified, or

(b) in the case of a substance which is not contained in Annex I to Council Directive 67/548/EEC or is therein but does not have the limit specified, 1%.

10. A preparation shall be classified as having to be regarded as toxic for reproduction and assigned the risk phrase R63 if it contains at least one substance assigned the risk phrase R63 in a concentration equal to or exceeding—

(a) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, the appropriate limit specified therein for that substance, if it is so specified, or

(b) in the case of a substance which is not specified in Annex I to Council Directive 67/548/EEC or is therein but does not have the limit specified, 1%.

11. (1) A preparation classified as toxic for reproduction in accordance with the provisions of paragraphs 7 and/or 8 shall be assigned the "toxic" symbol and "toxic" indication of danger unless the preparation is otherwise classified as very toxic.

(2) A preparation classified as having to be regarded as toxic for reproduction in accordance with the provisions of paragraphs 9 and/or 10 shall be assigned the "harmful" symbol and "harmful" indication of danger unless the preparation is otherwise classified as very toxic or toxic.

12. Notwithstanding the provisions of paragraphs 2, 5, 9 and 10 and Table VIA of Annex I to Council Directive 88/379/EEC,

(a) the provisions of paragraph 2 shall not apply to a preparation to which the provisions of paragraph 1 apply,

(b) the provisions of paragraph 5 shall not apply to a preparation to which the provisions of paragraph 4 apply,

(c) the provisions of paragraph 9 shall not apply to a preparation to which the provisions of paragraph 7 apply, and

(d) the provisions of paragraph 10 shall not apply to a preparation to which the provisions of paragraph 8 apply.

PART VIII

SENSITIZING CLASSIFICATION

1. A preparation shall be classified as sensitizing and assigned the risk phrase R42 if it contains at least one substance, assigned the single risk phrase R42, in a concentration equal to or exceeding—

(a) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, the appropriate limit specified therein for that substance, if it is so specified; or

(b) in the case of a substance which is not contained in Annex I to Council Directive 67/548/EEC or is therein but does not have the limit specified, 0.2%.

2. A preparation shall be classified as sensitizing and assigned the combined risk phrase R42/43 if it contains at least one substance, assigned the combined risk phrase R42/43, in a concentration equal to or exceeding—

(a) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, the appropriate limit specified therein for that substance, if it is so specified; or

(b) in the case of a substance which is not contained in Annex I to Council Directive 67/548/EEC or is therein but does not have the limit specified, 0.2%.

3. A preparation, classified as sensitizing and assigned the risk phrase R42 or R42/43 in accordance with paragraphs 1 or 2 shall be assigned the "harmful" symbol and "harmful" indication of danger unless the preparation is otherwise classified as very toxic or toxic.

Regulation 22.

SCHEDULE 4

DANGER SYMBOLS AND INDICATIONS OF DANGER

1. Any danger symbol or symbols and indication or indications of danger to be marked on the package of a dangerous preparation or contained in the label in accordance with the provisions of Regulations 17 (d) and 22 shall, subject to paragraph 3, be those assigned to the dangerous preparation in accordance with the provisions of paragraph 2.

2. (a) Any danger symbol or symbols and indication or indications of danger assigned to a dangerous preparation shall be that or those specified in the Table below, according to the classification or classifications of the dangerous preparation, determined in accordance with the provisions of Regulations 5, 6 and 7;

(b) Each such danger symbol and indication of danger shall be that specified, in columns 2 and 3 respectively of the Table below, for each classification in column 1 of the Table below of the dangerous preparation.

3. (a) In the case where more than one danger symbol has been assigned to a dangerous preparation, in accordance with the provisions of paragraph 2 and Regulation 5 (5)—

(i) the obligation to apply the symbol T shall make the symbols C and X optional,

(ii) the obligation to apply the symbol C shall make the symbol X optional,

(iii) the obligation to apply the symbol E shall make the symbols F and O optional.

(b) For the purposes of this paragraph, the reference characters specified in column 4 are those respectively for the danger symbols in column 2 of the Table below.

4. The danger symbols shall conform to those contained in Annex II to Directive 67/548/EEC and shall be printed in black on an orange-yellow background.

TABLE

Classification of Danger	Danger Symbol	Indication of Danger	Characters	Reference
Explosive	E	Explosive	E	E

Oxidising	O	Oxidising	O	O
-----------	---	-----------	---	---

Extremely flammable	F+	Extremely flammable	F+	F+
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Highly flammable	F	Highly flammable	F	F
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Flammable	NONE	NONE	NONE	NONE
-----------	------	------	------	------

Very Toxic	T+	Very Toxic	T+	T+
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Note: The letters E, O, F, F+, T, T+, C, Xn, Xi, N do not form part of the Danger Symbol.

Classification of Danger Danger Symbol Indication of Danger Characters Reference
Toxic T Toxic T

Harmful Xn Harmful Xn

Corrosive C Corrosive C

Irritant Xi Irritant Xi

Dangerous for the Environment N Dangerous for the Environment N

Note: The letters E, O, F, F+, T, T+, C, Xn, Xi, N do not form part of the Danger Symbol.

Regulation 23.

SCHEDULE 5

RISK PHRASES

1. The risk phrase or phrases to be marked on the package of a dangerous preparation or contained in the label in accordance with the provisions of Regulations 17 (e) and 23 shall be selected from those assigned to the dangerous preparation in accordance with the provisions of Regulations 5, 6 and 7 and Schedules 1, 2 and 3.

2. The risk phrase or phrases required to be marked on the package of a dangerous preparation or contained in the label in accordance with the provisions of paragraph 1 shall conform to those contained in Annex III to Council Directive 67/548/EEC, as set out in the Table below.

3. In the case of a dangerous preparation assigned two or more single risk phrases contained in Part I of the Table below in accordance with the provisions of paragraph 1, and which can be combined in a combined risk phrase contained in Part II of the Table below, that combined risk phrase shall be assigned to the dangerous preparation in place of the single phrase assigned.

TABLE

PART I

SINGLE RISK PHRASES

Risk Phrase

Reference No.

Risk Phrase

R1 Explosive when dry
R2 Risk of explosion by shock, friction, fire or other sources of ignition
R3 Extreme risk of explosion by shock, friction, fire or other sources of ignition
R4 Forms very sensitive explosive metallic compounds
R5 Heating may cause an explosion
R6 Explosive with or without contact with air
R7 May cause fire
R8 Contact with combustible material may cause fire
R9 Explosive when mixed with combustible material
R10 Flammable
R11 Highly flammable
R12 Extremely flammable
R14 Reacts violently with water
R15 Contact with water liberates extremely flammable gases
R16 Explosive when mixed with oxidizing substances
R17 Spontaneously flammable in air
R18 In use, may form flammable/explosive vapour-air mixture
R19 May form explosive peroxides
R20 Harmful by inhalation
R21 Harmful in contact with skin
R22 Harmful if swallowed
R23 Toxic by inhalation
R24 Toxic in contact with skin
R25 Toxic if swallowed
R26 Very toxic by inhalation
R27 Very toxic in contact with skin
R28 Very toxic if swallowed
R29 Contact with water liberates toxic gas
R30 Can become highly flammable in use
R31 Contact with acids liberates toxic gas
R32 Contact with acids liberates very toxic gas
R33 Danger of cumulative effects
R34 Causes burns
R35 Causes severe burns
R36 Irritating to eyes
R37 Irritating to respiratory system
R38 Irritating to skin
R39 Danger of very serious irreversible effects
R40 Possible risks of irreversible effects
R41 Risk of serious damage to eyes
R42 May cause sensitisation by inhalation
R43 May cause sensitisation by skin contact
R44 Risk of explosion if heated under confinement
R45 May cause cancer
R46 May cause heritable genetic damage
R48 Danger of serious damage to health by prolonged exposure
R49 May cause cancer by inhalation
R50 Very toxic to aquatic organisms
R51 Toxic to aquatic organisms
R52 Harmful to aquatic organisms

R53 May cause long-term adverse effects in the aquatic environment
R54 Toxic to flora
R55 Toxic to fauna
R56 Toxic to soil organisms
R57 Toxic to bees
R58 May cause long-term adverse effects in the environment
R59 Dangerous for the ozone layer
R60 May impair fertility
R61 May cause harm to the unborn child
R62 Possible risk of impaired fertility
R63 Possible risk of harm to the unborn child
R64 May cause harm to breastfed babies

PART II

COMBINED RISK PHRASES

Risk Phrase

Reference No.

Risk Phrase

R14/15 Reacts violently with water, liberating extremely flammable gases
R15/29 Contact with water liberates toxic, extremely flammable gas
R20/21 Harmful by inhalation and in contact with skin
R20/2 $\frac{1}{2}$ /2 Harmful by inhalation, in contact with skin and if swallowed
R20/22 Harmful by inhalation and if swallowed
R2 $\frac{1}{2}$ /2 Harmful in contact with skin and if swallowed
R23/24 Toxic by inhalation and in contact with skin
R23/24/25 Toxic by inhalation, in contact with skin and if swallowed
R23/25 Toxic by inhalation and if swallowed
R24/25 Toxic in contact with skin and if swallowed
R26/27 Very toxic by inhalation and in contact with skin
R26/27/28 Very toxic by inhalation, in contact with skin and if swallowed
R26/28 Very toxic by inhalation and if swallowed
R27/28 Very toxic in contact with skin and if swallowed
R36/37 Irritating to eyes and respiratory system
R36/37/38 Irritating to eyes, respiratory system and skin
R36/38 Irritating to eyes and skin
R37/38 Irritating to respiratory system and skin
R39/23 Toxic: danger of very serious irreversible effects through inhalation
R39/23/24 Toxic: danger of very serious irreversible effects through inhalation and in contact with skin
R39/23/24/25 Toxic: danger of very serious irreversible effects through inhalation, in contact with skin and if swallowed
R39/23/25 Toxic: danger of very serious irreversible effects through inhalation and if swallowed
R39/24 Toxic: danger of very serious irreversible effects in contact with skin

R39/24/25 Toxic: danger of very serious irreversible effects in contact with skin and if swallowed

R39/25 Toxic: danger of very serious irreversible effects if swallowed

R39/26 Very toxic: danger of very serious irreversible effects through inhalation

R39/26/27 Very toxic: danger of very serious irreversible effects through inhalation and in contact with skin

R39/26/27/28 Very toxic: danger of very serious irreversible effects through inhalation, in contact with skin and if swallowed

R39/26/28 Very toxic: danger of very serious irreversible effects through inhalation and if swallowed

R39/27 Very toxic: danger of very serious irreversible effects in contact with skin

R39/27/28 Very toxic: danger of very serious irreversible effects in contact with skin and if swallowed

R39/28 Very toxic: danger of very serious irreversible effects if swallowed

R40/20 Harmful: possible risk of irreversible effects through inhalation

R40/20/21 Harmful: possible risk of irreversible effects through inhalation and in contact with skin

R40/20/2½2 Harmful: possible risk of irreversible effects through inhalation, in contact with skin and if swallowed

R40/20/22 Harmful: possible risk of irreversible effects through inhalation and if swallowed

R40/21 Harmful: possible risk of irreversible effects in contact with skin

R40/2½2 Harmful: possible risk of irreversible effects in contact with skin and if swallowed

R40/22 Harmful: possible risk of irreversible effects if swallowed

R42/43 May cause sensitization by inhalation and skin contact

R48/20 Harmful: danger of serious damage to health by prolonged exposure through inhalation

R48/20/21 Harmful: danger of serious damage to health by prolonged exposure through inhalation and in contact with skin

R48/20/2½2 Harmful: danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed

R48/20/22 Harmful: danger of serious damage to health by prolonged exposure through inhalation and if swallowed

R48/21 Harmful: danger of serious damage to health by prolonged exposure in contact with skin

R48/2½2 Harmful: danger of serious damage to health by prolonged exposure in contact with skin and if swallowed

R48/22 Harmful: danger of serious damage to health by prolonged exposure if swallowed

R48/23 Toxic: danger of serious damage to health by prolonged exposure through inhalation

R48/23/24 Toxic: danger of serious damage to health by prolonged exposure through inhalation and in contact with skin

R48/23/24/25 Toxic: danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed

R48/23/25 Toxic: danger of serious damage to health by prolonged exposure through inhalation and if swallowed

R48/24 Toxic: danger of serious damage to health by prolonged exposure in contact with skin

R48/24/25 Toxic: danger of serious damage to health by prolonged exposure in contact with skin and if swallowed

R48/25 Toxic: danger of serious damage to health by prolonged exposure if swallowed

R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment

R51/53 Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment

R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment

Regulation 24.

SCHEDULE 6

SAFETY PHRASES

1. The safety phrase or phrases to be marked on the package of a dangerous preparation or contained in the label shall be selected in accordance with the provisions of Annex VI to Directive 67/548/EEC.

2. The safety phrase or phrases, required to be marked on the package of a dangerous preparation or contained in the label in accordance with the provisions of paragraph 1 shall conform to those contained in Annex VI to Directive 67/548/EEC, as set out in the Table below.

3. Where two or more single safety phrases contained in Part I of the Table below are selected, in accordance with the provisions of paragraph 1, and which can be combined in a combined safety phrase contained in Part II of the Table below, that combined safety phrase shall be assigned to the dangerous preparation in place of the single ones selected.

TABLE

PART I

SINGLE SAFETY PHRASE

Safety Phrase

Reference No.

Safety Phrase

S1 Keep locked up

S2 Keep out of reach of children

S3 Keep in a cool place

S4 Keep away from living quarters

S5 Keep contents under (appropriate liquid to be specified by the manufacturer)

S6 Keep under ... (inert gas to be specified by the manufacturer)

S7 Keep container tightly closed

S8 Keep container dry

S9 Keep container in a well ventilated place

S12 Do not keep the container sealed

S13 Keep away from food, drink and animal feeding stuffs

S14 Keep away from ... (incompatible materials to be indicated by the manufacturer)

S15 Keep away from heat
S16 Keep away from sources of ignition — No Smoking
S17 Keep away from combustible material
S18 Handle and open container with care
S20 When using do not eat or drink
S21 When using do not smoke
S22 Do not breathe dust
S23 Do not breathe gas/fumes/vapour/spray (appropriate wording to be specified by the manufacturer)
S24 Avoid contact with skin
S25 Avoid contact with eyes
S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice
S27 Take off immediately all contaminated clothing
S28 After contact with skin, wash immediately with plenty of .. (to be specified by the manufacturer)
S29 Do not empty into drains
S30 Never add water to this product
S33 Take precautionary measures against static discharges
S35 This material and its container must be disposed of in a safe way
S36 Wear suitable protective clothing
S37 Wear suitable gloves
S38 In case of insufficient ventilation, wear suitable respiratory equipment
S39 Wear eye/face protection
S40 To clean the floor and all objects contaminated by this material, use ... (to be specified by the manufacturer)
S41 In case of fire and/or explosion do not breathe fumes
S42 During fumigation/spraying wear suitable respiratory equipment (Appropriate wording to be specified by the manufacturer)
S43 In case of fire, use (indicate in the space the precise type of fire-fighting equipment. If water increases risk, add — Never use water)
S45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible)
S46 If swallowed, seek medical advice immediately and show this container or label
S47 Keep at temperature not exceeding °C (to be specified by the manufacturer)
S48 Keep wetted with ... (appropriate material to be specified by the manufacturer)
S49 Keep only in the original container
S50 Do not mix with (to be specified by the manufacturer)
S51 Use only in well ventilated areas
S52 Not recommended for interior use on large surface areas
S53 Avoid exposure — obtain special instructions before use
S56 Dispose of this material and its container to hazardous or special waste collection point
S57 Use appropriate containment to avoid environmental contamination
S59 Refer to manufacture/supplier for information on recovery/recycling
S60 This material and its container must be disposed of as hazardous waste
S61 Avoid release to the environment. Refer to special instructions/safety data sheets
S62 If swallowed, do not induce vomiting: seek medical advice immediately and show this container or label

PART II

COMBINED SAFETY PHRASES

Safety Phrase

Reference No.

Safety Phrase

S½ Keep locked up and out of the reach of children

S3/7 Keep container tightly closed in a cool place

S3/9/14 Keep in a cool, well ventilated place away from ... (incompatible materials to be indicated by the manufacturer)

S3/9/14/49 Keep only in the original container in a cool, well ventilated place away from... (incompatible materials to be indicated by the manufacturer)

S3/9/49 Keep only in the original container in a cool, well ventilated place

S3/14 Keep in a cool place away from ... (incompatible materials to be indicated by the manufacturer)

S7/8 Keep container tightly closed and dry

S7/9 Keep container tightly closed and in a well ventilated place

S7/47 Keep container tightly closed and at a temperature not exceeding °C (to be specified by the manufacturer)

S20/21 When using do not eat, drink or smoke

S24/25 Avoid contact with skin and eyes

S29/56 Do not empty into drains, dispose of this material and its container to hazardous or special waste collection point

S36/37 Wear suitable protective clothing and gloves

S36/37/39 Wear suitable protective clothing, gloves and eye/face protection

S36/39 Wear suitable protective clothing and eye/face protection

S37/39 Wear suitable gloves and eye/face protection

S47/49 Keep only in the original container at temperature not exceeding °C (to be specified by the manufacturer)".

Regulation 15.

SCHEDULE 7

CHILD-RESISTANT FASTENINGS AND TACTILE WARNINGS OF DANGER

PART I

Categories requiring child-resistant fastenings to be fitted to containers

1. When offered or sold to the general public, the container of a dangerous preparation having a classification listed in paragraph 2 shall be fitted with a child-resistant fastening in accordance with the provisions of Regulation 15 (2).

2. (1) The provisions of paragraph 1 shall apply to a dangerous preparation—

(a) classified as very toxic, toxic and/or corrosive;

or

(b) being a liquid preparation having a kinematic viscosity, measured by rotative viscosity in accordance with ISO 3219: 1977, of less than 7×10^{-6} m² per second at a temperature of 40° celsius and containing aliphatic and/or aromatic hydrocarbons in a total concentration in the preparation equal to or exceeding 10%;

or

(c) containing—

(i) methanol (CAS Reg. No. 67-56-1, EINECS No. 2006596) in the preparation in a concentration equal to or exceeding 3%, or

(ii) Dichloromethane (CAS Reg. No. 75-09-2, EINECS No. 2008389) in the preparation in a concentration equal to or exceeding 1%.

(2) For the purposes of subparagraph (1)—

(a) "ISO 3219: 1977" means the International Standard ISO 3219: 1977 (edition of 15 December, 1977) of the International Organisation for Standardisation;

(b) "CAS Reg No." means the CAS Registration Number, for a substance, of the Chemical Abstracts Service of the American Chemical Society of the United States of America; and

(c) "EINECS No." means the number allotted to a substance in the European Inventory of Existing Commercial Chemical Substances of the Commission of the European Community.

3. The provisions of paragraph 1 shall apply to containers of all capacities.

PART II

Categories Required to Carry Tactile Warnings of Danger on the Containers

1. When offered or sold to the general public, the container of a dangerous preparation having a classification listed in paragraph 2 shall carry a tactile warning of danger in accordance with the provisions of Regulation 15 (3).

2. The provisions of paragraph 1 shall apply to dangerous preparations classified as very toxic, toxic, corrosive, harmful, extremely flammable and/or highly flammable.

3. The provisions of paragraph 1 shall apply to containers of all capacities.

PART III

Aerosols

1. Except for subparagraph (1) (b) of paragraph 2 of Part I, the provisions of Parts I and II shall apply to preparations offered or sold to the general public in aerosol dispensers.

Regulation 16.

SCHEDULE 8

DIMENSIONS OF LABELS

1. The label required by Regulation 16 (1) (a) or the area specified in Regulation 16 (1) (a) (ii) (as the case may be) shall conform with the dimensions specified for each capacity category of package (containing a preparation to which these Regulations apply), set out in the Table below.

2. Any danger symbol required to be marked on the package of a dangerous preparation or contained in the label in accordance with the provisions of Regulations 17 (d) and 22 shall cover at least one-tenth of the surface area, referred to in paragraph 1, of the label or specified in Regulation 16 (1) (a) (ii) (as the case may be) and shall not in any case be less than 1 square centimetre in area.

TABLE

Capacity Category of Package	Dimension (in millimetres)
Not exceeding 3 litres if possible	at least 52 x 74
Greater than 3 litres but not exceeding 50 litres	at least 74 x 105
Greater than 50 litres but not exceeding 500 litres	at least 105 x 148
Greater than 500 litres	at least 148 x 210

Regulation 30.

SCHEDULE 9

MATERIAL SAFETY DATA SHEETS

1. The safety data sheet required to be provided in accordance with the provisions of Regulation 30 shall comply with the provisions of this Schedule.

2. Every person who is responsible for placing a dangerous preparation on the market (whether that person is a manufacturer, importer, distributor, wholesaler or a retailer) shall provide an industrial user (including a distributor, wholesaler or retailer) with a safety data sheet.

3. (a) The safety data sheet, required to be provided in accordance with the provisions of paragraph 2 shall be provided free of charge and shall be provided at or before the time when the dangerous preparation is first supplied.

(b) For the purposes of this paragraph, the time specified in subparagraph (a) when the safety data sheet is to be provided shall be the period beginning at the commencement of these Regulations.

(c) Notwithstanding the provisions of subparagraph (b) but subject to the provisions of paragraph 7, any industrial user (including a distributor, wholesaler or retailer) who was supplied with a dangerous preparation within 12 months preceding the commencement of

these Regulations, shall be provided with the safety data sheet required to be provided in accordance with the provisions of paragraph 2.

4. (a) Whenever a safety data sheet required to be provided in accordance with the provisions of paragraph 2 is amended in accordance with the provisions of Regulation 30 (6), the amended safety data sheet shall be identified as such and shall bear, in a conspicuous place in it the term "Revision" together with the date of the publication of it.

(b) The amended safety data sheet referred to in subparagraph (a) shall be provided free of charge to all industrial users (including distributors, wholesalers and retailers) who were supplied with the particular dangerous preparation within 12 months preceding the publication date of the amended safety data sheet.

5. The safety data sheet required to be provided in accordance with the provisions of paragraph 2 shall be clearly written in the Irish and English languages or in the English language.

6. (a) The safety data sheet required to be provided in accordance with the provisions of paragraph 2 shall contain information on the dangerous preparation under the headings set out in the Table below and shall contain those headings.

(b) The information required to be contained in the safety data sheet in accordance with the provisions of subparagraph (a) shall be in accordance with the principles of the guidelines laid down in the Annex to Commission Directive 91/155/EEC of 5 March, 1991, as amended by Commission Directive 93/112/EC of 10 December, 1993..

7. (a) Notwithstanding their provisions but subject to subparagraph (b), the requirements of paragraphs 2 and 3 do not apply in the case of a dangerous preparation which is offered or sold to the general public', provided the user is furnished with sufficient information to enable him to take the necessary measures as regards the protection of health and safety.

(b) Notwithstanding the provisions of subparagraph (a), a safety data sheet, required to be provided in accordance with paragraph 2, shall, when requested, be provided to an industrial user.

TABLE

Obligatory Headings for Safety Data Sheets

1. identification of the substance/preparation and of the company/undertaking;
2. composition/information on ingredients;
3. hazards identification;
4. first-aid measures;
5. fire-fighting measures;
6. accidental release measures;
7. handling and storage;
8. exposure controls/personal protection;
9. physical and chemical properties;

10. stability and reactivity;
11. toxicological information;
12. ecological information;
13. disposal considerations;
14. transport information
15. regulatory information
16. other information

Regulation 25.

SCHEDULE 10

SPECIAL PROVISIONS ON THE LABELLING OF CERTAIN PREPARATIONS

PART I

Dangerous Preparations

Preparations on sale to general public.

1. (a) In accordance with the provisions of Regulation 17 (g) and 25 and subject to subparagraph (b), a dangerous preparation which is offered or sold to the general public shall have marked on the package or on the label (as the case may be)

(i) the safety phrases S1 and S2, and

(ii) one of the safety phrases S45 or S46

in accordance with the criteria fixed in Annex VI to Council Directive 67/548/EEC.

(b) Notwithstanding the provisions of subparagraph (a) and Regulation 24 (2), the requirements of subparagraph (a) shall not apply in the case of a preparation classified as very toxic, toxic or corrosive where it is physically impossible to mark the safety phrases (required by subparagraph (a)) on the package or on the label provided the dangerous preparation is accompanied by precise and easily understandable instructions for use including, where appropriate, instructions for the destruction of the empty package.

Preparations intended for spraying.

2. In accordance with the provisions of Regulations 17 (g) and 25, a dangerous preparation intended for use by spraying shall have marked on the package or on the label (as the case may be)

(i) the safety phrase S23, and

(ii) one of the safety phrases S38 or S51

in accordance with the criteria fixed in Annex VI to Council Directive 67/548/EEC.

Preparations with R33 substances.

3. In accordance with the provisions of Regulations 17 (g) and 25, the risk phrase R33 shall be marked on the package or on the label (as the case may be) of a dangerous preparation when it contains at least one substance, assigned the risk phrase R33, in a concentration equal to or exceeding

(i) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, the relevant limit specified therein for that substance, if it is so specified, or

(ii) in the case of a substance which is not contained in Annex I to Council Directive 67/548/EEC or is contained therein but does not have the limit specified, 1%.

Preparations with R64 substances.

4. In accordance with the provisions of Regulations 17 (g) and 25, the risk phrase R64 shall be marked on the package or on the label (as the case may be) of a dangerous preparation when it contains at least one substance, assigned the risk phrase R64, in a concentration equal to or exceeding

(i) in the case of a substance contained in Annex I to Council Directive 67/548/EEC, the relevant limit specified therein for that substance, if it is so specified, or

(ii) in the case of a substance which is not contained in Annex I to Council Directive 67/548/EEC or is contained therein but does not have the limit specified, 1%.

5. (a) Subject to the provisions of subparagraph (b), the provisions of paragraphs 1,2,3 and 4 of this Part are in addition to the other provisions of these Regulations.

(b) In any case where one or more of the risk or safety phrases required by paragraphs 1, 2, 3 and 4 of this Part are already marked on the package or on the label, they need not be repeated.

6. For the purposes of this Part a reference to concentration is a reference to a concentration expressed

(i) on a volume/volume basis in the case of gas preparations,
and

(ii) on a mass/mass basis in the case of preparations which are not gas preparations.

PART II

Preparations whether or not Dangerous

1. The provisions of this Part shall apply to all preparations, to which the other provisions of this Part apply, whether or not the preparations are dangerous within the meaning of these Regulations.

Preparations containing lead (paints and varnishes).

2. (a) In accordance with the provisions of Regulations 17 (g) and 25 and subject to subparagraph (c), the following phrases shall be marked on the package or on the label (as the case may be) of a preparation consisting of paint or varnish which contains lead in accordance with the provisions of subparagraph (b):

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

(b) The provisions of subparagraph (a) shall apply to a preparation, consisting of paint or varnish which contains lead in quantities exceeding 0.15%, expressed as weight of metal, of the total weight of the preparation as determined in accordance with ISO 6503:1984.

(c) Notwithstanding its provisions, the requirements of subparagraph (a) shall be deemed to be satisfied in the case of a preparation in a package of which the contents are less than 125 millilitres if the following phrases are marked on the package or on the label (as the case may be) of the preparation:

"Warning. Contains lead."

(d) For the purposes of subparagraph (b), "ISO 6503:1984" means the International Standard ISO 6503: 1984 of the International Organisation for Standardisation.

Preparations containing cyanoacrylates (adhesives).

3. (a) In accordance with the provisions of Regulations 17(g) and 25, the following phrases shall be marked on the package or on the label (as the case may be) of a preparation consisting of an adhesive based on cyanoacrylate:

"Cyanoacrylate.

Danger.

Bonds skin and eyes in seconds.

Keep out of the reach of children."

(b) Appropriate advice on safety shall accompany the package of a preparation to which the provisions of subparagraph (a) apply.

Preparations containing isocyanates.

4. (a) In accordance with the provisions of Regulations 17 (g) and 25, the following phrases shall be marked on the package or on the label (as the case may be) of a preparation containing isocyanates:—

"Contains isocyanates.

See information supplied by the manufacturer."

(b) For the purposes of subparagraph (a) isocyanates shall include isocyanates as monomers, oligomers, prepolymers, etc., and as mixtures thereof.

Preparations containing epoxy constituents.

5. In accordance with the provisions of Regulations 17 (g) and 25, the following phrases shall be marked on the package or on the label (as the case may be) of a preparation containing epoxy constituents, with an average molecular weight equal to or less than 700:

"Contains epoxy constituents.

See information supplied by the manufacturer."

Preparations containing active chlorine on sale to the general public.

6. (a) In accordance with the provisions of Regulations 17 (g) and 25, and subject to subparagraph (b), the following phrases shall be marked on the package or on the label (as the case may be) of a preparation containing more than 1% active chlorine:

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

(b) The provisions of subparagraph (a) shall apply to preparations offered or sold to the general public.

Preparations containing cadmium (alloys) intended for brazing or soldering.

7. (a) In accordance with the provisions of Regulations 17 (g) and 25 and subject to subparagraph (b), the following phrases shall be printed in clearly legible and indelible characters on the package or on the label (as the case may be) of a preparation containing cadmium (alloys):

"Warning! Contains cadmium.
Dangerous fumes are formed during use.

See information supplied by the manufacturer.

Comply with the safety instructions."

(b) The provisions of subparagraph (a) shall apply to preparations intended to be used for brazing or soldering.

8. (a) Subject to subparagraph (b), the provisions of paragraphs 2, 3, 4, 5, 6 and 7 of this Part are in addition to the other provisions of these Regulations.

(b) In any case where the safety phrase S2 is already marked on the package or on the label of the preparation, the phrase, "Keep out of the reach of children" (required by paragraph 3 of this Part) need not be repeated.

GIVEN under my Official Seal, this 9th day of October, 1995.

RICHARD BRUTON,

Minister for Enterprise and Employment.

EXPLANATORY NOTE

These Regulations implement Council Directive 88/379/EEC of 7th June, 1988 on the classification, packaging and labelling of dangerous preparations placed on the market of the E.U. They apply to all dangerous preparations with exceptions for certain categories of preparations such as pesticides, cosmetics etc. which are covered by other Council Directives. Certain preparations which would not be classified as dangerous by the Directive and these Regulations are nevertheless subject to specific labelling requirements if the particular preparations are listed in Annex II of the Directive.

These Regulations also implement Commission Directives which adapt to technical progress the Annexes to or which expand some of the provisions of Directive 88/379/EEC. These Directives are

— Commission Directives 89/178/EEC of 22 February, 1989, 90/492/EEC of 5 September, 1990 and 93/18/EEC of 5 April, 1993 which adapt to technical progress Annexes I and II,

— Commission Directives 90/35/EEC of 19 December, 1989 and 91/442/EEC of 23 July, 1991 which define the categories of preparations requiring child-resistant fastenings and tactile warnings of danger, and

— Commission Directive 91/155/EEC of 5 March, 1991 and 93/112/EEC of 10 December, 1993 which contain the format for safety data sheets.

They also give effect to those parts of Council Directive 92/32/EEC of 30 April, 1992 and Commission Directive 93/21/EEC of 27 April, 1993 which are relevant for Dangerous Preparations.

These Regulations revoke the European Communities (Classification, Packaging and Labelling of Dangerous Preparations) Regulations, 1992 (S.I. No. 393 of 1992).