STATUTORY INSTRUMENTS

S.I. No. 62 of 2004

European Communities (Classification, Packaging and Labelling of Dangerous Preparations) Regulations 2004

PUBLISHED BY THE STATIONERY OFFICE
DUBLIN
To be purchased directly from the
GOVERNMENT PUBLICATION SALE OFFICE,
SUN ALLIANCE HOUSE, MOLESWORTH STREET, DUBLIN2,
Or by mail order from
GOVERNMENT PUBLICATIONS, POSTAL TRADE SECTION,
51 ST. STEPHEN'S GREEN, DUBLIN 2,
(Tel: 01-6476834/35/37; Fax: 01 6476843)
or through any bookseller.

(Prn 2152)

Price: €11.43

ARRANGEMENT OF REGULATIONS

Regulations
1. Citation.
2. Interpretation.
3. Application.
4. Exemptions.
5. Dangerous substances and preparations.
6. Determination of dangerous properties of preparation.
7. General principles of classification and labelling.
8. Evaluation of the hazards deriving from physico-chemical properties.
9. Evaluation of the health hazards of a preparation.
10. Evaluation of the environmental hazards of a preparation.
11. Placing on market of a preparation.
12. Data and information on preparations.
13. Packaging.
14. Labelling.
15. Implementation of labelling requirements.
16. Exemptions from packaging and labelling requirements.
17. Distance selling.
18. Safety data sheets.
19. Confidentiality of chemical names.
20. Poison information centre.
21. Provisional restriction on placing a preparation on market.
22. Taking and detention of preparations.
23. Offences.
24. Revocations.

SCHEDULE 1
CONCENTRATIONS OF DANGEROUS SUBSTANCES TO BE TAKEN INTO ACCOUNT FOR CLASSIFICATION OF A PREPARATION

SCHEDULE 2
METHODS FOR THE EVALUATION OF PHYSICO-CHEMICALS PROPERTIES OF PREPARATIONS

SCHEDULE 3
CONVENTIONAL METHOD FOR THE EVALUATION OF HEALTH HAZARDS OF PREPARATIONS

SCHEDULE 4
CONVENTIONAL METHOD FOR THE EVALUATION OF ENVIRONMENTAL HAZARDS OF PREPARATIONS

SCHEDULE 5
SPECIAL PROVISIONS FOR CONTAINERS CONTAINING PREPARATIONS OFFERED OR SOLD TO THE PUBLIC

SCHEDULE 6
NAMING OF SUBSTANCES IN A PREPARATION

SCHEDULE 7
SPECIAL PROVISIONS CONCERNING THE LABELLING OF CERTAIN PREPARATIONS

SCHEDULE 8
SYMBOLS AND INDICATIONS OF DANGER

SCHEDULE 9
RISKS PHRASES

SCHEDULE 10
SAFETY PHRASES

SCHEDULE 11
SPECIAL LABELLING PROVISIONS FOR SINGLE PACKAGES

SCHEDULE 12
OBLIGATORY HEADINGS FOR SAFETY DATA SHEETS

SCHEDULE 13
LABELLING OF A PLANT PROTECTION PRODUCT

I, Mary Harney, Minister for Enterprise, Trade 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 Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999[1], as amended by Commission Directive 2001/60/EC of 7 August 2001[2], Commission Directive 91/155/EEC of 5 March 1991[3], as amended by Commission Directive 2001/58/EC of 27 July 2001[4], Commission Directive 93/21/EEC of 27 April 1993[5] and Commission Directive 93/112/EC of 10 December 1993[6], hereby make the following regulations:

Citation.

1. These Regulations may be cited as the European Communities (Classification, Packaging and Labelling of Dangerous Preparations) Regulations 2004.

Interpretation.

2. (1) In these Regulations, unless the context otherwise requires -

"Act of 1989" means the Safety, Health and Welfare at Work Act 1989 (No. 7 of 1989);

"Annex I" means Annex I (inserted by Directive 76/907/EEC) to Directive 67/548/EEC;

"Annex II" means Annex II (inserted by Commission Directive 83/467/EEC of 29 June 1983[7]) to Directive 67/548/EEC, and which, for convenience of reference, is set out in Schedule 8;

---

[1] O.J. No. L200, 30.7.1999, p.1
[2] O.J. No. L226, 22.8.2001, p.5
[3] O.J. No. L 76, 22.3.1991, p. 35
[4] O.J. No. L212, 7.8.2001, p. 24
[5] O.J. No. L110, 4.5.1993, p. 20 and O.J. No. L110A, 4.5.1993, p.1
[6] O.J. No. L314, 16.12.1993, p. 38
[7] O.J. No. L257, 16.9.1983, p.1

"Annex III" means Annex III (inserted by Directive 76/907/EEC) to Directive 67/548/EEC, and which, for convenience of reference, is set out in Schedule 9;

"Annex IV" means Annex IV (inserted by Directive 76/907/EEC) to Directive 67/548/EEC and which, for convenience of reference, is set out in Schedule 10;

"Annex V" means Annex V (inserted by Commission Directive 84/449/EEC of 25 April 1984[8]) to Directive 67/548/EEC;

"Annex VI" means Annex VI (inserted by Commission Directive 79/831/EEC of 18 September 1979[9]) to Directive 67/548/EEC;

"Annex IX" means Annex IX (inserted by Commission Directive 91/410/EEC of 22 July 1991[10], as amended by Commission Directive 2000/32/EC of 19 May 2000[11]) to Directive 67/548/EEC;

"Authority" has the meaning assigned to it under the Act of 1989;

"dangerous preparation" shall be construed in accordance with Regulation 3(2);

"Directive" means Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999[1], as amended by Commission Directive 2001/60/EC of 7 August 2001[2];

"Directive 67/548/EEC" means Council Directive 67/548/EEC of 27 June 1967 [12];

"Directive 76/907/EEC" means Commission Directive 76/907/EEC of 14 July 1976 [13];

"Directive 86/609/EEC" means Council Directive 86/609/EEC of 24 November 1986 [14];

---

[8] O.J. No. L251, 19.9.1984, p.1
[9] O.J. No. L259, 15.10.1979, p.10
[10] O.J. No. L228, 17.8.1991, p.67
[11] O.J. No. L136, 8.6.2000, p.1
[1] O.J. No. L200, 30.7.1999, p.1
[2] O.J. No. L226, 22.8.2001, p.5
[12] O.J. No. P196, 16.8.1967, p. 1
[13] O.J. No. L360, 30.12.1976, p.1
[14] O.J. No. L358, 18.12.1986, p.1

"Directive 87/18/EEC" means Council Directive 87/18/EEC of 18 December 1986 [15];

"Directive 91/155/EEC" means Commission Directive 91/155/EEC of 5 March 1991 [3] as amended by Directive 2001/58/EC;

"Directive 91/414/EEC" means Council Directive 91/414/EEC of 15 July 1991 [16];

"Directive 93/112/EC" means Commission Directive 93/112//EC of 10 December 1993 [6];

"Directive 2001/58/EC" means Commission Directive 2001/58/EC of 27 July 2001 [4];

"Elincs" means the European List of Notified Chemical Substances, published from time to time, containing the list of substances placed on the market in the European Communities after 18 September 1981 and which have been the subject of a notification;

"inspector" has the meaning assigned to it by the Act of 1989;

"label" means the label required under these Regulations and cognate words shall be construed accordingly;

"Member State" means a Member State of the European Communities;

"Minister" means the Minister for Enterprise, Trade and Employment;

"monomer unit" means the reacted form of a monomer in a polymer;

"package" means the packaging, receptacle or container containing a preparation to which these Regulations apply, and cognate words shall be construed accordingly;

---

[15] O.J. No. L 15, 17.1.1987, p.29
[3] O.J. No. L76, 22.3.1991, p. 35
[16] O.J. No. L230, 19.8.1991, p.1
[6] O.J. No. L314, 16.12.1993, p. 38
[4] O.J. No. L212, 7.8.2001, p. 24

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

"risk phrase" means any phrase which is listed in Schedule 9;

"safety phrase" means any phrase which is listed in Schedule 10;

"substances" means chemical elements and their compounds in the natural state or obtained by any production process, including any additive necessary to preserve the stability of the product and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;

"symbol" means any symbol specified in Schedule 8;

"tactile warning of danger" means a method of warning of the dangerous contents of a package for a person who has poor sight or no sight that is referred to in Regulation 13, and which complies with Schedule 5.

(2) In these Regulations -

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

(b) reference to a paragraph or 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) In these Regulations a reference to -

(a) R followed by a number or numbers means a reference to the relevant risk phrase or phrases listed in Schedule 9,

(b) S followed by a number or numbers means a reference to the relevant safety phrase or phrases listed in Schedule 10.

(4) A word or expression that is used in these Regulations and is also used in the Directive, Directive 67/548/EEC, Commission Directive 2001/60/EC, Directive 91/155/EEC, Directive 2001/58/EC, Directive 91/414/EEC, Commission Directive 93/21/EEC of 27 April 1993[5], Directive 93/112/EC, Directive 86/609/EEC and Directive 87/18/EEC has, unless the contrary intention appears, the same meaning in these Regulations as it has in the Directive concerned.

(5) The Act of 1989 is to be construed and have effect as if these Regulations were existing enactments within the meaning of that Act and for the time being in force and specified in Part II of the Second Schedule to that Act.

Application.

3. (1) These Regulations apply to -

(a) the classification, packaging and labelling of a preparation referred to in paragraph (2), and

(b) a preparation referred to in paragraph (3) that may present hazards, whether or not it is classified as dangerous in accordance with these Regulations,

when such preparation is placed on the market.

(2) These Regulations apply to a preparation -

(a) which contains one or more than one dangerous substance, and

[5] O.J. No. L110, 4.5.1993, p. 20 and O.J. No. L110A, 4.5.1993, p.1

(b) is considered dangerous within the meaning of and in accordance with Regulation 8, 9 or 10.

(3) Regulations 13, 14 and 18 and Schedules 5 and 7 apply to a preparation that is not considered dangerous within the meaning of Regulation 8, 9 or 10 but which may present a specific hazard.

(4) Without prejudice to Directive 91/414/EEC, as amended by Commission Directive 96/68/EC of 21 October 1996[17], the provisions of these Regulations concerning the classification, packaging, labelling and safety data sheets shall apply, from 30 July 2004, to plant protection products.

Exemptions.

4. (1) These Regulations do not apply to the following preparations in the finished state, intended for the final user -

(a) medicinal products for human or veterinary use, as defined in Council Directive 65/65/EEC of 26 January 1965[18] as lastly amended by Commission Directive 93/39/EEC of 14 June 1993[19],

(b) cosmetic products, as defined by Council Directive 76/768/EEC of 27 July 1976[20] as lastly amended by Commission Directive 98/62/EC of 3 September 1998[21],

(c) mixtures of substances which, in the form of waste, are the subject of Council Directive 75/442/EEC of 15 July 1975[22] as lastly amended by Commission Decision 96/350/EEC of 24 May 1996[23] and Council

[17] O.J. No. L 277, 30.10.1996, p. 25
[18] O.J. No. P 22, 9.2.1965, p. 369
[19] O.J. No. L214, 24.8.1993 p. 22
[20] O.J. L262, 27.9.1976, p. 169
[21] O.J. No. L253, 15.9.1998, p. 20
[22] O.J. No. L194, 25.7.1975, p. 39
[23] O.J. No. L135, 6.6.1996, p. 32

Directive 91/689/EEC of 12 December 1991[24] as lastly amended by Council Directive 94/31/EC of 27 June 1994[25],

(d) foodstuffs,

(e) animal feeding stuffs,

(f) radioactive substances, within the meaning of Council Directive 80/836/Euratom of 15 July 1980[26], and

(g) medical devices, which are invasive or used in direct physical contact with the human body, within the meaning of Council Directive 93/42/EEC of 14 June 1993[27].

(2) These Regulations do not apply to -

(a) the carriage of dangerous preparations by rail, road, inland waterway, sea or air, or

(b) preparations in transit which are under customs supervision, provided they do not undergo any treatment or processing.

Dangerous substances and preparations.

5. For the purposes of these Regulations the following are dangerous -

(a) explosive substances and preparations, namely, solid, liquid, pasty or gelatinous substances and preparations which may also react exothermically without atmospheric oxygen thereby quickly evolving gases, and which, under defined test conditions, detonate, quickly deflagrate or upon heating explode when partially confined,

[24] O.J. No. L377, 31.12.1991, p. 20
[25] O.J. No. L168, 2.7.1994, p. 28
[26] O.J. No. L246, 17.9.1980, p. 1
[27] O.J. No. L169, 12.7.1993, p. 1

(b) oxidising substances and preparations, namely, substances and preparations which give rise to a highly exothermic reaction in contact with other substances, particularly flammable substances,

(c) extremely flammable substances and preparations, namely, liquid substances and preparations having an extremely low flash-point and a low boiling point and gaseous substances and preparations which are flammable in contact with air at ambient temperature and pressure,

(d) highly flammable substances and preparations, namely -

(i) substances and preparations which may become hot and finally catch fire in contact with air at ambient temperature without any application of energy,

(ii) solid substances and preparations which may readily catch fire after brief contact with a source of ignition and which continue to burn or to be consumed after removal of the source of ignition,

(iii) liquid substances and preparations having a very low flash-point, or

(iv) substances and preparations which, in contact with water or damp air, evolve extremely flammable gases in dangerous quantities,

(e) flammable substances and preparations, namely, liquid substances and preparations having a low flash-point,

(f) very toxic substances and preparations, namely, substances and preparations which in very low quantities cause death or acute or

chronic damage to health when inhaled, swallowed or absorbed via the skin,

(g) toxic substances and preparation, namely, substances and preparations which in low quantities cause death or acute or chronic damage to health when inhaled, swallowed or absorbed via the skin,

(h) harmful substances and preparations, namely, substances and preparations which may cause death or acute or chronic damage to health when inhaled, swallowed or absorbed via the skin,

(i) corrosive substances and preparations, namely, substances and preparations which may, on contact with living tissues, destroy them,

(j) irritant substances and preparations, namely, non-corrosive substances and preparations which, through immediate, prolonged or repeated contact with the skin or mucous membrane, may cause inflammation,

(k) sensitising substances and preparations, namely, substances and preparations which, if they are inhaled or if they penetrate the skin, are capable of eliciting a reaction of hypersensitisation such that on further exposure to the substance or preparation, characteristic adverse effects are produced,

(l) carcinogenic substances and preparations, namely, substances or preparation which, if they are inhaled or ingested or if they penetrate the skin, may induce cancer or increase its incidence,

(m) mutagenic substances and preparations, namely, substances and preparations which, if they are inhaled or ingested or if they penetrate the skin, may induce heritable genetic defects or increase their incidence,

(n) substances and preparations which are toxic for reproduction, namely, substances and preparations which, if they are inhaled or ingested or if they penetrate the skin, may produce, or increase the incidence of, non-heritable adverse effects in progeny or an impairment of male or female reproductive functions or capacity, and

(o) substances and preparations which are dangerous for the environment, namely, substances and preparations which, were they to enter the environment, would present or may present an immediate or delayed danger for one or more components of the environment.

Determination of dangerous properties of preparation.

6. (1) The evaluation of the hazards of a preparation shall be based on the determination of -

(a) any physico-chemical properties of that preparation,

(b) properties of that preparation that affect health, and

(c) environmental properties of that preparation in accordance with the procedures laid down in Regulations 8, 9 and 10.

(2) Where laboratory tests are conducted to determine the dangerous properties of a preparation, they shall be carried out on the preparation in the form in which it is as placed on the market.

(3) Where the determination of the dangerous properties is carried out in accordance with the procedures laid down in Regulations 8, 9 and 10, all dangerous substances within the meaning of Regulation 5 and in particular all dangerous substances which -

(a) are specified in Annex I,

(b) are specified in Elincs in accordance with Article 21 of Directive 67/548/EEC,

(c) are classified and labelled provisionally by the person responsible for placing on the market such dangerous substances in accordance with Article 6 of Directive 67/548/EEC,

(d) are classified and labelled in accordance with Article 7 of Directive 67/548/EEC and are not yet included in Elincs,

(e) are provided for under Article 8 of Directive 67/548/EEC, and

(f) are classified and labelled in accordance with Article 13 of Directive 67/548/EEC,

shall be taken into consideration in accordance with the methods laid down in those Regulations.

(4) In respect of a preparation to which these Regulations apply, dangerous substances referred to in paragraph (3) which are classified as dangerous on the basis of their health and their environmental effects or either of them, whether they are impurities or additives, shall be taken into consideration when their concentrations are equal to or greater than the concentrations set out in Schedule 1 unless lower values for concentrations are given in -

(a) Annex I,

(b) Part B of Schedule 3, or

(c) Part B of Schedule 4,

unless otherwise specified in Schedule 7.

General principles of classification and labelling.

7. (1) For the purposes of these Regulations a dangerous preparation shall be classified as one or more of the following -

(a) explosive,

(b) oxidising,

(c) extremely flammable,

(d) highly flammable,

(e) flammable,

(f) very toxic,

(g) toxic,

(h) harmful,

(i) corrosive,

(j) irritant,

(k) sensitising,

(l) carcinogenic,

(m) mutagenic,

(n) toxic for reproduction,

(o) dangerous for the environment.

(2) The general principles of the classification and labelling of preparations shall be applied in accordance with Annex VI unless the alternative criteria referred to in Regulation 8, 9, 10 or 14, including the Schedules and Annexes referred to in those Regulations, are applied.

Evaluation of the hazards deriving from physico-chemical properties.

8. (1) The hazards of a preparation deriving from its physico-chemical properties shall, subject to paragraph (3), be assessed by determining, in accordance with the methods specified in Part A of Annex V, the physico-chemical properties of the preparation that are necessary for ensuring that the appropriate classification and labelling of the preparation concerned is made and such assessment shall be in accordance with the criteria specified in Annex VI.

(2) Notwithstanding paragraph (1), in an assessment of the hazards of a preparation referred to in paragraph (1) -

(a) it is not necessary to determine the explosive, oxidising, extremely flammable, highly flammable or flammable properties of a preparation if -

(i) none of the constituents of such preparation possess such properties and that, on the basis of the information available to the manufacturer, the preparation is unlikely to present hazards of this kind,

(ii) in the event of a change in the composition of a preparation of known composition, scientific evidence indicates that a reassessment of the hazards will not lead to a change in classification, or

(iii) where a preparation is placed on the market in the form of an aerosol, the preparation and aerosol complies with the European Communities (Aerosol Dispensers) Regulations 1977 (S.I. No. 144 of 1977) as amended by the European Communities (Aerosol Dispensers)(Amendment) Regulations 1995 (S.I. No. 127 of 1995),

(b) in certain cases for which the methods laid down in Part A of Annex V are not appropriate, alternative calculation methods are laid down in Part B of Schedule 2, and

(c) certain exemptions from the application of the methods laid down in Part A of Annex V are referred to in Part A of Schedule 2.

(3) The hazards deriving from the physico-chemical properties of a preparation to which Directive 91/414/EEC applies shall be -

(a) assessed by determining physico-chemical properties of that preparation that is necessary for appropriate classification in accordance with the criteria set out in Annex VI, and

(b) determined by means of the methods laid down in Part A of Annex V unless other internationally recognised test methods are acceptable in accordance with Annex II and Annex III to Directive 91/414/EEC.

Evaluation of the health hazards of a preparation.

9. (1) The health hazards of a preparation to which these Regulations apply shall be assessed according to one or more of the following procedures by -

(a) a conventional method provided for in Schedule 3, or

(b) determining the toxicological properties of the preparation that is necessary to ensure that the appropriate classification in accordance with the criteria specified in Annex VI is assigned to such preparation, and the toxicological properties concerned shall be determined by means of the methods laid down in Part B of Annex V unless, in the case of plant protection products, other internationally recognised methods are acceptable in accordance with Annexes II and III to Directive 91/414/EEC.

(2) Without prejudice to Directive 91/414/EEC, where in the assessment of a health hazard of a preparation the methods outlined in paragraph (1)(b) may be used if they are justified or specifically authorised under Article 12 of Directive 86/609/EEC and if it can be scientifically demonstrated by the person responsible for placing on the market a preparation to which these Regulations apply that the toxicological properties of that preparation cannot be correctly determined by the method referred to in paragraph (1)(a) or on the basis of existing test results on animals, the methods referred to in paragraph (1)(b) may be used if they are justified or specifically authorised under Article 12 of Directive 86/609/EEC.

(3) Where a toxicological property of a preparation is established by the method referred to in paragraph (1)(b) to obtain new data, the test shall be conducted in compliance with the principles of good laboratory practice provided for in Directive 87/18/EEC and Directive 86/609/EEC and having specific regard to Articles 7 and 12 of the latter Directive.

(4) Subject to paragraphs (6), (7) and (8), where a toxicological property has been established on the basis of both the methods referred to in paragraph (1)(a) and (b), the results from the methods referred to in paragraph (1)(b) shall be used for classifying the preparation, except in the case of carcinogenic, mutagenic or toxic effects for reproduction, for which only the method set out in paragraph (1)(a) shall be used.

(5) Any of the toxicological properties of the preparation which are not assessed by the methods referred to in paragraph (1)(b) shall be assessed in accordance with the methods referred to in paragraph (1)(a).

(6) Where, in respect of a preparation to which these Regulations apply, it can be demonstrated by epidemiological studies, by scientifically valid case studies as specified in Annex VI, or statistically backed experience, including the assessment of data from poison information centres or units of occupational disease, that the toxicological effects of such preparation on a person differ from those suggested by the application of the methods outlined in paragraph (1), then the preparation shall be classified according to the effects on a person.

(7) Where, in respect of a preparation to which these Regulations apply, it can be demonstrated that, owing to effects such as potentiation, a conventional assessment would underestimate the toxicological hazard, those effects shall be taken into account in classifying the preparation.

(8) Where, in respect of a preparation to which these Regulations apply, it can be demonstrated that, owing to effects such as antagonism, a conventional assessment would overestimate the toxicological hazard, those effects shall be taken into account in classifying the preparation.

(9) For a preparation of a known composition, other than those to which Directive 91/414/EEC applies that is classified in accordance with paragraph (1)(b), a new evaluation of health hazard by the methods referred to in paragraph (1)(a) or (b) shall be performed where there is a change in composition of the initial concentration, as a weight/weight or volume/volume percentage, of one or more of the dangerous constituents that are introduced by the manufacturer in a manner specified in the Table to this paragraph.

TABLE

Initial concentration range of the constituent (1)	*Permitted variation in actual concentration of the constituent* (2)
≤ 2.5%	± 30%
> 2.5 ≤ 10%	± 20%
> 10 ≤ 25%	± 10%
> 25% ≤ 100%	± 5%

(10) For preparations of a known composition, other than those to which Directive 91/414/EEC applies, that are classified in accordance paragraph (1)(b), a new evaluation of health hazard by the methods referred to in paragraph (1)(a) or (b) shall be performed where there are changes of composition, introduced by the manufacturer, involving the substitution or addition of one or more constituents, which may or may not be dangerous within the meaning of Regulation 5.

(11) The evaluation pursuant to and in accordance with paragraph (9) or (10) shall apply unless there is valid scientific justification for considering that a re-evaluation of the hazard will not result in a change of classification.

Evaluation of the environmental hazards of a preparation.

10. (1) The hazards of a preparation for the environment shall be assessed by one or more of the following procedures -

(a) a conventional method referred to in Schedule 4, or

(b) by determining the hazardous properties of the preparation for the environment that is necessary to ensure the allocation of the appropriate classification in accordance with the criteria set out in Annex VI and -

(i) these properties shall be determined by the methods laid down in Part C of Annex V unless, in the case of plant protection products, other internationally recognised methods are acceptable in accordance with Annexes II and III of Directive 91/414/EEC, and

(ii) without prejudice to the testing requirements set out in Directive 91/414/EEC, the conditions for application of the test methods are set out in Part C of Schedule 4.

(2) Where an ecotoxicological property is established by one of the methods referred to in paragraph (1)(b) to obtain new data, the test shall be conducted in compliance with the principles of good laboratory practice provided for in Directive 87/18/EEC and Directive 86/609/EEC.

(3) Where the environmental hazards of a preparation have been assessed as required and in accordance with paragraph (2), the results of the methods referred to in paragraph (1)(b) shall be used for classifying the preparation.

(4) For a preparation of a known composition, other than those to which Directive 91/414/EEC applies, that is classified in accordance with paragraph (1)(b), a new evaluation of environmental hazard, either by the method referred to in paragraph (1)(a) or (b) shall be performed if there is a change in composition of the initial concentration, as a weight/weight or volume/volume percentage, of one or more of the dangerous constituents that are introduced by the manufacturer in accordance with the Table to this paragraph.

TABLE

Initial concentration range of the constituent (1)	*Permitted variation in actual concentration of the constituent* (2)
$\leq 2.5\%$	$\pm 30\%$
$> 2.5 \leq 10\%$	$\pm 20\%$
$> 10 \leq 25\%$	$\pm 10\%$
$> 25\% \leq 100\%$	$\pm 5\%$

(5) For a preparation of a known composition, other than those to which Directive 91/414/EEC applies, that is classified in accordance with paragraph (1)(b), a new evaluation of environmental hazard, either by the method referred to in paragraph (1)(a) or (b), shall be performed if there are changes in composition involving the substitution or addition of one or more constituents that are introduced by the manufacturer, which may or may not be dangerous within the meaning of Regulation 5.

(6) The new evaluation made pursuant to and in accordance with paragraph (4) or (5) shall apply unless there is valid scientific justification for considering that a re-evaluation of the hazard will not result in a change of classification.

Placing on market of a preparation.

11. A person shall not place on the market a preparation to which these Regulations apply unless such preparation complies with these Regulations.

Data and information on preparations.

12. (1) An inspector may request in writing information concerning the composition of a preparation to which these Regulations apply from any person who places on the market such preparation.

(2) A person who places on the market a preparation to which these Regulations apply shall maintain and have available for inspection -

(a) information concerning the composition of the preparation concerned,

(b) any other information that relates to the composition of the preparation concerned,

(c) the data used for the classification and labelling of the preparation concerned,

(d) information relating to the packaging requirements under Regulation 13 and the test certificate issued in accordance with Schedule 5 for the preparation concerned, and

(e) the data used for establishing the safety data sheet in accordance with Regulation 18.

(3) The information referred to in paragraphs (1) and (2) shall be kept by the person who places on the market the preparation concerned for a period of not less than 5 years following the date on which that preparation was placed on the market.

(4) The person who places a preparation to which these Regulations apply on the market shall ensure that the information referred to in paragraphs (1) and (2) shall be kept in legible form and be available for inspection by an inspector.

Packaging.

13. (1) A person shall not place on the market a preparation referred to in Regulation 3(2) or a preparation referred to in Regulation 3(3) and to which Schedule 5 applies, unless -

(a) the packaging of that preparation is, subject to paragraph (3), designed and constructed in such a manner that the contents cannot escape such packaging,

(b) the materials constituting the packaging and fastening of that preparation shall not be susceptible to adverse attack by the contents or liable to form dangerous compounds with the contents,

(c) the packaging and fastenings of that preparation shall be of sufficient and appropriate strength and be 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 fastenings devices shall be designed so that the packaging can be repeatedly fastened without the contents escaping, and

(e) the container which contains such preparation and which is offered or sold to the general public does not have -

(i) a shape and graphic decoration, or either of them, that is likely to attract or arouse the active curiosity of children or to mislead consumers, or

(ii) a presentation and a designation, or either of them, that is used for foodstuffs or animal feeding stuffs, medical products or cosmetic products.

(2) A container which contains a preparation that is offered or sold to the general public and to which Schedule 5 applies shall -

(a) be fitted with child-resistant fastenings and shall comply with the technical specifications in Part A of Annex IX, and

(b) a container which contains a preparation that is specified in Part B of Schedule 5 and which is intended to be offered or sold to the general public shall carry a tactile warning of danger and such warning shall comply with Part B of Annex IX.

(3) Paragraph (1)(a) does not apply to such packaging if special safety devices are required to be attached to such packaging.

(4) Where the packaging of a preparation complies with the requirements for carriage of dangerous goods by rail, road, inland waterway, sea or air, such packaging shall be deemed to satisfy paragraph (1)(a), (b) or (c).

Labelling.

14. (1) A person shall not place on the market -

(a) a preparation referred to in Regulation 3(2) unless the labelling on the packaging of such preparation satisfies the requirements of these Regulations and Parts A and B of Schedule 7, or

(b) a preparation referred to in Regulation 3(3), as defined in Parts B and C of Schedule 7, unless the labelling on the packaging of such preparation satisfies the requirements of paragraphs (3)(a) and (3)(b) and Parts B and C of Schedule 7.

(2) In respect of any plant protection product to which Directive 91/414/EEC applies, and without prejudice to the requirements of Article 16 and Annex V of that Directive, a person who places on the market such products shall include the statement that is specified in Schedule 13 on the label of that plant protection product.

(3) A person shall not place on the market a preparation referred to in paragraph (1) unless the following information is clearly and indelibly marked on the package containing that preparation -

(a) the trade name or designation of that preparation,

(b) the name, full address and telephone number of the person responsible for placing on the market that preparation, who is established in the European Community,

(c) the chemical name of the substance or substances present in that preparation in accordance with Schedule 6,

(d) the danger symbol relating to the preparation and the indication of dangers involved in the use of that preparation and the evaluation of

the hazards carried out in accordance with and as required under paragraphs (4) and (5),

(e) the relevant risk phrase or phrases or the danger involved in the use of that preparation,

(f) the relevant safety phrase or phrases relating to the safe use of that preparation,

(g) the special labelling, where appropriate, that is required under paragraph (1)(b), and

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

(4) The danger symbol, or where appropriate, danger symbols relating to the preparation, and the wording of the indications of danger involved in the use of the preparation that are required to be specified on the label shall -

(a) comply with the wording set out in Annex VI and Schedule 8 and be applied in accordance with the evaluation of the hazards carried out in accordance with Schedules 2, 3, and 4, and

(b) be printed in black on an orange-yellow background.

(5) Where more than one danger symbol is required to be assigned to a preparation to which these Regulations apply -

(a) the obligation to apply the symbol T shall make the application of symbols X and C optional, unless otherwise specified in Annex I,

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

(c) the obligation to apply the symbol E shall make the symbols F and O optional, and

(d) the obligation to indicate the symbol X_n makes the symbol X_i optional.

(6) Subject to paragraph (15), indications concerning special risks (risk phrases) shall comply with the wording in Annex VI and Schedule 9 and shall be assigned in accordance with the results of the hazard evaluation carried out in accordance with Schedules 2, 3 and 4.

(7) Subject to paragraph (8), a maximum of 6 risk phrases shall suffice to describe the risks and for this purpose, the combined phrases listed in Annex III shall be regarded as single phrases.

(8) If a preparation falls within more than one danger category, the risk phrases shall cover each of the principal hazards associated with the preparation and in certain circumstances more than 6 risk phrases may be necessary to describe the risks for that preparation.

(9) The risk phrases R11, highly flammable, or R12, extremely flammable, need not be used on the package of a preparation to which these Regulations apply if they describe an indication of danger used in accordance with paragraph (4).

(10) Subject to paragraph (15) -

(a) indications giving safety advice on a label (safety phrases) shall comply with the wording of safety phrases referred to in Schedule 10 and Annex VI,

(b) indications giving safety advice on a label (safety phrases) shall be assigned in accordance with the results of the hazard evaluation carried out in accordance with Schedules 2, 3 and 4, and

(c) a maximum of 6 safety phrases shall suffice to formulate the most appropriate safety advice on a label and for this purpose the combined phrases specified in Annex IV shall be taken to be single phrases.

(11) Notwithstanding paragraph (10)(c), in certain circumstances more than 6 phrases may be necessary to formulate the most appropriate safety advice for a preparation.

(12) Where it is physically impossible to include the safety advice on the label or package itself, the package shall be accompanied by safety advice on the use of the preparation.

(13) Without prejudice to Article 16(4) of Directive 91/414/EEC, indications such as "non-toxic", "non-harmful", "non-polluting" "ecological" or any other statement indicating that the preparation is not dangerous or likely to lead to an underestimation of the dangers of the preparation concerned shall not appear on the packaging or labelling of any preparation to which these Regulations apply.

(14) The information referred to in paragraph (1) shall be shown on the labelling on the packaging in the English language or in both the English and Irish languages.

(15) If the contents of a package do not exceed 125 millilitres, it shall not be necessary for the person who places on the market a preparation classified as -

(a) highly flammable, oxidising, irritant, except a preparation so classified that is assigned R41, or dangerous for the environment and assigned the N symbol, to indicate the risk phrase or the safety phrase for such preparation,

(b) flammable or dangerous for the environment and not assigned the N symbol to indicate the safety phrase for such preparation, but that person shall indicate the risk phrase for the preparation concerned.

(16) A person shall not place on the market a preparation to which these Regulations apply unless the label on such preparation complies with this Regulation.

Implementation of labelling requirements.

15. (1) Where the particulars required under Regulation 14 appear on a label, that label shall be -

(a) firmly affixed to one or more surfaces of the packaging so that those particulars can be read horizontally when the package is set down normally, and

(b) intended solely for the provision of the information required by these Regulations and, if necessary, of any supplementary health or safety information.

(2) The dimensions of a label shall comply with the dimensions, as appropriate, that are specified in the Table to this paragraph.

TABLE

Capacity of the package	*Dimensions (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

(3) A label shall not be required where the particulars are clearly shown on the package itself in accordance with this Regulation.

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

(5) The information required on a label under Regulation 14 shall stand out clearly from its background and shall be of such size and spacing as to be easily read and shall comply with the specific provisions, where appropriate, regarding the presentation and format of this information laid down in Annex VI.

(6) The requirements of these Regulations in relation to labelling shall be deemed to be satisfied if -

(a) in the case of an outer package containing one or more inner packages, the outer package is labelled in accordance with the international rules on the transport of dangerous goods and the inner package is labelled in accordance with these Regulations,

(b) in the case of a single package -

(i) the package is labelled in accordance with international rules on the transport of dangerous goods, Regulation 14(3)(a) to (c) and Regulation 14(6) to (10), and if the package concerns a preparation classified in accordance with Regulation 10, Regulation 14(4) and (5) apply with respect to the property in question when it has not been so identified on the label, or

(ii) where appropriate, for particular types of packaging, such as mobile gas cylinders, if the specific requirements referred to in Schedule 11 are complied with.

(7) In this Regulation –

"international rules on the transport of dangerous goods" means the requirements arising under -

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

(b) the International Maritime Dangerous Goods Code published by the International Maritime Organisation.

(8) In this Regulation and in Regulation 14, "label" means a label referred to in paragraph (1).

(9) In any proceeding under these Regulations *prima facie* evidence of the terms of any of the international rules on the transport of dangerous goods may be given by producing a document that purports to be a copy of such rules.

Exemptions from packaging and labelling requirements.

16. (1) The packaging and labelling requirements of Regulations 13 to 15 do not apply to explosives placed on the market with a view to producing a practical effect by explosion or a pyrotechnic effect.

(2) The Authority may grant at its discretion, by a certificate in writing, subject to any conditions specified in the certificate, an exemption from Regulations 14 and 15 in respect of -

(a) the packaging, subject to paragraph (3), of a preparation referred to in Regulation 3(2) which may be unlabelled or may be labelled in such other way as may be approved by the Authority, if it contains such small quantities that there is no reason to fear any danger to persons handling such preparation or to other persons,

(b) the packaging, subject to paragraph (3), of a preparation referred to in Regulation 3(2) which is explosive, very toxic, toxic, or sensitising which may be labelled in such other way as may be approved by the Authority if it is too small for labelling in accordance with Regulations 14 and 15 and there is no reason to fear any danger to persons handling such preparation or to other persons,

(c) the labelling required on a package which is too small or otherwise unsuitable for labelling in accordance with Regulations 14 and 15, which labelling may be applied on packages in such other appropriate manner as may be approved by the Authority, and

(d) the packaging of a preparation that is classified as dangerous for the environment only, which may be labelled in such other way as may be approved by the Authority if it is too small for labelling in accordance with Regulations 14 and 15 and there is no reason to fear any danger to the environment.

(3) The Authority shall not grant a certificate under paragraph (2)(a) if the preparation concerned is explosive, very toxic or toxic.

(4) An exemption under paragraph (2) does not permit the use of symbols, indications of danger, risk phrases or safety phrases that are different from those required by these Regulations.

(5) An exemption, granted by the Authority under paragraph (2), may be revoked at any time.

(6) The Authority shall inform the Commission of the European Communities of a certificate granted by it under paragraph (2).

(7) Where a preparation referred to in Regulation 3(2) does not leave the State, labelling of that preparation which complies with the national rules on the transport of dangerous goods may be used in respect of that preparation.

(8) Notwithstanding Regulations 14 to 16, Chapter 9 of Annex VI shall apply, in relation to any matter under any of those Regulations, to a preparation to which that Chapter is appropriate.

(9) In this Regulation "national rules on the transport of dangerous goods" means-

(a) Carriage of Dangerous Goods by Road Regulations 2004 (S.I. No. 29 of 2004), and

(b) European Communities (Transport of Dangerous Goods by Rail) Regulations 2001 (S.I. No. 500 of 2001).

Distance selling.

17. Without prejudice to Directive 97/7/EC of the European Parliament and of the Council of 20 May 1997[28], any advertisement for a preparation to which these Regulations apply which enables a member of the general public to conclude a contract for purchase without first having sight of the label for that preparation shall state the type or types of hazards indicated on the label in respect of that preparation.

Safety data sheets.

18. (1) The person responsible for placing on the market a preparation referred to in Regulation 3(2) shall provide a safety data sheet for that preparation and shall specify in such safety data sheet -

(a) information that concerns that preparation for the purpose of enabling a professional user to take the necessary measures regarding the protection of health, safety and the environment at the place of work, and

(b) information that concerns that preparation for the purpose of enabling any person, including the professional user, to take the necessary measures regarding the protection of health, safety and the environment at the place of work.

(2) A person who places on the market a preparation referred to in Regulation 3(3) shall provide, when so requested by a professional user, a safety data sheet specifying information that is appropriate and proportionate for a preparation that is not classified as

[28] O.J. No. L144, 4.6.1997

dangerous under these Regulations but which contains in an individual concentration of greater than or equal to 1 per cent by weight for a non-gaseous preparation and greater than or equal to 0.2 per cent by volume for a gaseous preparation at least -

(a) one substance posing health or environmental hazard, or

(b) one substance for which there is Community workplace exposure limits.

(3) The safety data sheet shall be provided free of charge to the recipient and may be communicated on paper or electronically -

(a) not later than the time at which the preparation is supplied to the person concerned, and

(b) following a revision of the safety data sheet arising out of significant and new information regarding safety and protection of health and the environment.

(4) An amended safety data sheet referred to in paragraph (3) shall be provided forthwith free of charge to all industrial or professional users, distributors, wholesalers and retailers who were supplied with the particular dangerous substance within the 12 months preceding the publication date of the amended safety data sheet.

(5) The safety data sheet referred to in paragraph (1) shall contain such information necessary for the protection of any person and the environment as the manufacturer, importer or distributor may reasonably be expected to be aware of.

(6) A safety data sheet referred to in paragraph (1) shall be clearly written in the English language or in both the English and Irish languages.

(7) (a) A safety data sheet shall contain information relating to each of the matters specified in Schedule 12 and shall be compiled in accordance with the Annex to Directive 91/155/EEC.

(b) The information required to be contained in the safety data sheet in accordance with subparagraph (a) shall comply with the guidelines laid down in the Annex to Directive 91/155/EEC, as amended by Directive 93/112/EC and Directive 2001/58/EC.

(c) Without prejudice to subparagraphs (a) and (b), the safety data sheet shall specify the information concerning -

(i) the name of the person responsible for providing the safety data sheet,

(ii) the date of publication or the date of preparation of the safety data sheet, and

(iii) for an amended safety data sheet, a notice of revision together with the revision date.

(8) Paragraphs (1) to (7) do not apply where the dangerous preparation is offered or sold to the general public if -

(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 this Regulation.

Confidentiality of chemical names.

19. (1)(a) Where the person responsible for placing on the market a preparation to which these Regulations apply can demonstrate that the disclosure on the label or, where appropriate and in accordance with these Regulations, the package or safety data sheet of the chemical identity of a substance which is exclusively classified as -

(i) irritant except those assigned R41 or irritant in combination with one or more of the other properties mentioned in Regulation 14 and paragraph 3 of Schedule 6, or

(ii) harmful or harmful in combination with one or more of the properties mentioned in Regulation 14 and paragraph 3 of Schedule 6 presenting acute lethal effects,

will put at risk the confidential nature of the intellectual property concerned, that person may refer to that substance either by means of a name that identifies the most important chemical groups or by means of an alternative name in accordance with Annex VI.

(b) Subparagraph (a) shall not apply if the substance concerned has been assigned a Community exposure limit.

(c) Where the person responsible for placing on the market a preparation referred to in subparagraph (a) wishes to avail of the confidentiality provisions provided under this Regulation that person shall make a request -

(i) if the preparation is to be first placed on the market in the State, to the Authority in accordance with Annex VI, and shall give the information required in the form in Part A of Annex VI and any other information which the Authority may request, or

(ii) if the preparation is to be first placed on the market in another Member State, to the competent authorities of that other Member State.

(d) The Authority may consent in writing to an application under this Regulation subject to any conditions which, in the opinion of the Authority, are appropriate to such confidentiality.

(2) Where a request under paragraph (1) is made to the Authority it shall notify the person who made the request of its decision in writing.

(3) Where the Authority has consented to an application under this Regulation, the person responsible for placing on the market the preparation concerned shall provide notification of that consent of the Authority to the competent authority of each Member State in which such person intends to market the product.

(4) Where the Authority is of the opinion that paragraph (1) does not apply in a particular case, it may notify the person who made the application in writing that it is of that opinion.

(5) The Authority shall ensure that confidential information that is brought to the attention of the Authority in respect of an application under this Regulation is treated in accordance with Article 19(4) of Directive 67/548/EEC, as amended by Council Directive 92/32/EEC of 30 April 1992[29].

Poison information centre.

20. (1) The Minister, after consultation with the Minister for Health and Children, may appoint a body (the "poison centre") for the purposes of this Regulation.

(2) The poison centre shall have power to require the person responsible for placing on the market a preparation referred to in Regulation 3(2) to provide it with information relating to the preparation.

(3) The information to be provided in accordance with paragraph (2) shall be such as will enable the poison centre to carry out the functions assigned to it in accordance with

paragraph (4) and shall include the chemical composition of the preparation, including confidential information in accordance with Regulation 19.

(4) The poison centre may use the information obtained in accordance with

[29] O.J. No. L154, 5.6.1992, P.1

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 preventive 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 19.

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

Provisional restriction on placing a preparation on market.

21. (1) Where the Authority has detailed evidence that a preparation, although satisfying the requirements of these Regulations, constitutes a hazard for the health and safety of any person or the environment on grounds relating to the Directive, the Authority may by notice in writing provisionally prohibit the placing of that preparation on the market or subject the placing on the market of that preparation to special conditions.

(2) The Authority shall immediately inform the Commission of the European Communities and other Member States of the prohibition referred to in paragraph (1) and the reasons for it.

(3) A person shall not place on the market a preparation in respect of which a prohibition referred to in paragraph (1) exists.

(4) Where the Authority, in accordance with paragraph (1), subjects the placing on the market of any preparation to special conditions, a person shall not place on the market the preparation concerned unless it satisfies those special conditions.

Taking and detention of preparations.

22. (1) An inspector may seize and retain, or seize, remove and retain any preparation which in the opinion of the inspector is a preparation to which these Regulations apply and in

relation to which he or she has reasonable grounds for suspecting that there is or has been a failure to comply with 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 any thing 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 intention of the inspector 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 marked 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 notice has been complied with.

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

(4) Any person who is aggrieved by a notice given under paragraph (2) which either requires the preparation to which it relates to be disposed of or indicates an intention to dispose of such preparation may, not later than the expiration of the period of 7 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,

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

(iii) there has been a failure to comply with 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 in withdrawn, or

(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 €6,348.69, the District Court for the district in which the goods were seized, or

(b) in case the estimated amount aforesaid does not exceed €38,092.14, the judge of the Circuit Court for the circuit in which the goods were seized, and

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

(8) If, in relation to an appeal under this Regulation to -

(a) the District Court, that court becomes of opinion during the hearing of the appeal that the estimated cost aforesaid will exceed €6,348.69, 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) the Circuit Court, that court becomes of opinion during the hearing of the appeal that the estimated amounts aforesaid will exceed €38,092.14, it may, if it so thinks fit, by order transfer the appeal to the High Court.

Offences.

23. (1) Any person who contravenes Regulation 11, 12, 13, 14, 15, 17, 18, 19(3), 20(6), 21(3) or 21(4) is guilty of an offence.

(2) Where an offence under these Regulations is committed by a body corporate and is proved to have been so committed with the consent or connivance of or to be attributable to any neglect on the part of any person, being a director, manager, secretary or other officer of the body corporate, or a person who was purporting to act in any such capacity, that person, as well as the body corporate, is guilty of an offence and shall be liable

to be proceeded against and punished as if he or she were guilty of the first-mentioned offence.

(3) Proceedings for an offence under these Regulations may be brought and prosecuted by the Authority.

(4) A person guilty of an offence under Regulation 11 or 21(3) or (4) is liable on summary conviction to a fine not exceeding €3,000 or imprisonment for a term not exceeding 3 months or both.

(5) A person guilty of an offence under these Regulations (other than Regulations 11 or 21(3) or (4) is liable on summary conviction to a fine not exceeding €3,000.

Revocations.

24. The European Communities (Classification, Packaging and Labelling of Dangerous Preparations) Regulations 1995 (S.I. No. 272 of 1995) and the European Communities (Classification, Packaging and Labelling of Dangerous Preparations)(Amendment) Regulations 1998 (S.I. No. 354 of 1998) are revoked.

SCHEDULE 1

Regulation 6

CONCENTRATIONS OF DANGEROUS SUBSTANCES TO BE TAKEN INTO ACCOUNT FOR CLASSIFICATION OF A PREPARATION

Concentrations of dangerous substances to be taken into account for classification of a preparation in accordance with Regulation 6.

Category of danger Of the substance	Concentration to take into Consideration for	
	Gaseous preparations %vol/vol	Other preparations %w/w
Very toxic	≥0.02	≥0.1
Toxic	≥0.02	≥0.1
Carcinogenic Category 1 or 2	≥0.02	≥0.1
Mutagenic Category 1 or 2	≥0.02	≥0.1
Toxic for reproduction Category 1 or 2	≥0.02	≥0.1
Harmful	≥0.2	≥1
Corrosive	≥0.02	≥1
Irritant	≥0.2	≥1
Sensitising	≥0.2	≥1
Carcinogenic Category 3	≥0.2	≥1
Mutagenic Category 3	≥0.2	≥1
Toxic for reproduction Category 3	≥0.2	≥1
Dangerous for the environment N		≥0.1
Dangerous for the environment ozone	≥0.1	≥0.1
Dangerous for the environment		≥1

SCHEDULE 2

Regulation 8

METHODS FOR THE EVALUATION OF PHYSICO-CHEMICALS PROPERTIES OF PREPARATIONS

For the purposes of this Schedule any reference to a section refers to a section of Annex V

PART A

Exemptions to test methods of Annex V - Part A as per point 2.2.5 of Annex V

Flammable

Substances and preparations shall be classified as flammable in accordance with the results of the tests given in Annex V. The risk phrase shall be assigned in accordance with the criteria mentioned below.

- R10 Flammable

- Liquid substances and preparations having a flash point equal to or greater than 21 °C, and less than or equal to 55 °C.

However, in practice it has been shown that a preparation having a flash point equal to or greater than 21 °C and less than or equal to 55 °C need not be classified as flammable if the preparation could not in any way support combustion and only so long as there is no reason to fear risks to those handling these preparations or to other persons.

PART B

Alternative calculation methods

B.1. Non-gaseous preparations

Method for the determination of oxidising properties of preparations containing organic peroxides as per point 2.2.2.1 of Annex VI.

Remarks concerning peroxides

For the explosive properties, an organic peroxide or preparation thereof in the form in which it is placed on the market is classified according to the criteria in section 2.2.1 on the basis of tests carried out in accordance with the methods given in Annex V.

For the oxidising properties the existing methods in Annex V cannot be applied to organic peroxides.

For substances, organic peroxides not already classified as explosive are classified as dangerous on the basis of their structure (e.g. R-O-O-H; R_1-O-O-R_2).

Preparations not already classified as explosive shall be classified using the calculation method based on the percentage of active oxygen shown in Section 9.5.

Any organic peroxide or preparation thereof not already classified as explosive is classified as oxidising, if the peroxide or its formulation contains:

- more than 5 % of organic peroxides or,

- more than 0.5 % available oxygen from the organic peroxides, and more than 5 % hydrogen peroxide.

B.2. Gaseous preparations

(1) Method for the determination of oxidising properties as per point 9.1.1.2 of Annex VI.

Oxidizing properties

Given the fact that Annex V does not contain a method to determine the oxidizing properties of gaseous mixtures, the evaluation of these properties must be realised according to the following estimation method.

The principle of the method is comparison of the oxidizing potential of gases in a mixture with that of the oxidizing potential of oxygen in air. The concentrations of gases in the mixture are expressed in % vol.

It is considered that the gas mixture is as oxidant as or more oxidant than air, if the following condition is verified:

$\Sigma_i \, x_i C_i \geq 21$

where: x_i is the concentration of gas i in % vol,
Ci is the coefficient of oxygen equivalency.

In this case, the preparation is classified as oxidizing and the phrase R8 will be assigned.

Coefficients of equivalency between oxidizing gases and oxygen

The coefficients used in the calculation to determine the oxidizing capacity of certain gases in a mixture with respect to the oxidizing capacity of oxygen in air, listed under 5.2. in the ISO Standard ISO 10156 edition 15. 12. 1990, are the following.

O_2	1
N_2O	0,6

When no value for the Ci coefficient exists for a gas in the cited standard a value of 40 is attributed to this coefficient.

(2) Method for the determination of flammability properties as per point 9.1.1.1 of Annex VI.

Flammability

The flammable properties of these preparations are determined in accordance with Article 3(2) of Council Directive 88/379/EEC of 7 June 1988[30] according to the methods specified in Part A of Annex V.

These preparations will be classified according to the results of the tests carried out and with respect to the criteria of Annex V and to the criteria of the labelling guide.

However, by derogation, in the case where gaseous preparations are produced to order in small amounts, the flammability of these gaseous mixtures can be evaluated by the following calculation method:

the expression of the gaseous mixture

$$A_1F_1 + \ldots + A_iF_i + \ldots A_nF_n + B_1I_1 + \ldots + B_iI_i + \ldots B_pI_p$$

where: Ai and Bi are the molar fractions

F_i flammable gas
I_i inert gas
n number of flammable gases
p number of inert gases

can be transformed in a form where all the I_i (inert gases) are expressed by a nitrogen equivalent using a coefficient K_i and where the equivalent content of inflammable gas A'_i is expressed as follows:

$$A'_i = A_i \times (100 / (A_i+K_iB_i))$$

By using the value of the maximum content of flammable gas which, in a mixture with nitrogen, gives a composition which is not flammable in air (Tci), the following expression can be obtained:

$$\Sigma_i A'_i / Tci \leq 1$$

The gas mixture is flammable if the value of the above expression is greater than one. The preparation is classified extremely flammable and, the phrase R12 is assigned.

[30] O.J. No. L187, 16.7.1988, p.14

Coefficients of equivalency (K_i)

The values of the coefficients of equivalency K_i, between the inert gases and nitrogen and the values of the maximum contents of flammable gas (Tci) may be found in tables 1 and 2 of the ISO Standard ISO 10156 edition 15. 12. 1990

Maximum content of flammable gas (Tci)

The value of the maximum content of flammable gas (Tci) may be found in table 2 of the ISO Standard ISO 10156 edition 15. 12. 1990

When a Tci value for a flammable gas does not appear in the above standard, the corresponding lower explosivity limit (LEL) will be used. If no LEL value exists, the value of Tci will be set at 1 % by volume.

Remarks

- The expression above can be used to allow an appropriate labelling of gaseous preparations, however, it should not be regarded as a method for replacing experimentation for the determination of technical safety parameters.
- Furthermore, this expression gives no information as to whether a mixture containing oxidizing gases can be prepared safely. When estimating flammability these oxidizing gases are not taken into account.
- The expression above will give reliable results only if the flammable gases do not influence each other as far as their flammability is concerned. This has to be considered, e.g. with halogenated hydrocarbons.

SCHEDULE 3

Regulation 9

CONVENTIONAL METHOD FOR THE EVALUATION OF HEALTH HAZARDS OF PREPARATIONS

Introduction

An assessment must be made for all the health effects corresponding to the health effects of substances contained in a preparation. This conventional method described in Parts A and B of this Schedule is a calculation method which is applicable to all preparations and which takes into consideration all the health hazards of substances contained in the preparation. For that purpose the dangerous health effects have been subdivided into:

1. acute lethal effects;
2. non-lethal irreversible effects after a single exposure;
3. severe effects after repeated or prolonged exposure;
4. corrosive effects, irritant effects;
5. sensitising effects;
6. carcinogenic effects, mutagenic effects, toxic effects for reproduction.

The health effects of a preparation are to be assessed in accordance with Regulation 9 by the conventional method described in parts A and B of this Schedule using individual concentration limits:

(a) where the dangerous substances listed in Annex I are assigned concentration limits necessary for the application of the method of assessment described in part A of this Schedule, these concentration limits must be used;

(b) where the dangerous substances do not appear in Annex I or appear there without the concentration limits necessary for the application of the method of evaluation described in part A of this Schedule, the concentration limits must be assigned in accordance with the specifications in part B of this Schedule.

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

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

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

Note: In the case of combined risk phrases where the second phrase denotes route of exposure only, then only the risk phrase denoting special risks needs to be taken into account for classification purposes, i.e., the route of exposure does not contribute to the additivity.

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

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

PART A - PROCEDURE FOR EVALUATION OF HEALTH HAZARDS

The evaluation proceeds stepwise as follows:

1. Very Toxic due to Acute Lethal Effects

1.1. Preparations should be classified as very toxic, assigned the corresponding symbol ' T+' with the indication of danger ' very toxic' and the appropriate risk phrases (R26, R27 or R28) in accordance with the following criteria:

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

(a) either the concentration specified in Annex I for the substance or substances under consideration,

(b) the concentration specified at point 1 in Part B of this Schedule (Table I and I A) where the substance or substances do not appear in Annex I or appear in it without concentration limits;

1.1.2. preparations containing more than one substance classified as very toxic in lower individual concentrations than the limits specified under 1.1.1(a) or (b) if the sum of the fractions in the formula below is equal to or greater than 1:

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

where:

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

L_{T+} is the lower concentration limit defined for the substance for classifying the preparation as very toxic (as per Table 1= 7% by weight). For gaseous preparations the lower concentration limits in Table 1A shall apply.

1.2. Toxic due to non-lethal irreversible effects after a single exposure

Preparations should be classified as very toxic, assigned the symbol 'T+', the indication of danger 'very toxic' and the risk phrase R39/route of exposure when they contain at least one dangerous substance that produces such effects in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I for the substance or substances under consideration, or

(b) the concentration specified at point 2 in Part B of this Schedule (Table II and II A) where the substance or substances do not appear in Annex I or appear in it without concentration limits.

2. Toxic due to acute lethal effects

2.1. Preparations should be classified as toxic and assigned the symbol 'T' the indication of danger 'toxic' and the risk phrases R23, R24 or R25 in accordance with the following criteria:

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

(a) either the concentration specified in Annex I for the substance or substances under consideration, or

(b) the concentration specified at point 1 in Part B of this Schedule (Table I and I A) where the substance or substances do not appear in Annex I or appear in it without concentration limits;

2.1.2. preparations containing more than one substance classified as very toxic or toxic in lower individual concentrations than the limits specified under 2.1.1(a) or (b) if the sum of the fractions in the formula below is equal to or greater than 1:

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

where:

P_{T+} is the percentage by weight or by volume of each very toxic substance in the preparation,
P_T is the percentage by weight or by volume of each toxic substance in the preparation,
L_T and L_{T+} are the lower concentration limits defined for each substance for classifying the preparation as toxic (as per Table 1 = 1% by weight for T+ substances

and 25% by weight for T substances). For gaseous preparations the lower concentration limits in Table 1A shall apply.

2.2. Non- lethal irreversible effects

Preparations should be classified as toxic, assigned the symbol 'T' the indication of danger 'toxic' and the risk phrase R39/route of exposure if they contain at least one dangerous substance classified as very toxic or toxic that produce such effects in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I for the substance or substances under consideration, or

(b) the concentration specified at point 2 in Part B of this Schedule (Table II and II A) where the substance or substances do not appear in Annex 1 or appear in it without concentration limits.

2.3. Severe effects after repeated or prolonged exposure

Preparations should be classified as toxic, assigned the symbol 'T', the indication of danger 'toxic' and the risk phrase R48/route of exposure if they contain at least one dangerous substance that produces such effects in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I for the substance or substances under consideration, or

(b) the concentration specified at point 3 in Part B of this Schedule (Table III and III A) where the substance or substances do not appear in Annex I or appear in it without concentration limits.

3. Harmful due to acute lethal effects

3.1. Preparations should be classified as harmful, assigned the symbol 'X_n' and the indication of danger 'harmful' and the risk phrases R20, R21 or R22 in accordance with the following criteria;

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

(a) either the concentration specified in Annex I for the substance or substances under consideration, or

(b) the concentration specified at point 1 in Part B of this Schedule (Table I and I A) where the substance or substances do not appear in Annex I or appear in it without concentration limits.

3.1.2 preparations containing more than one substance classified as very toxic, toxic or harmful in lower individual concentrations than the limits specified under 3.1.1(a) or (b) if the sum of the fractions in the formula below is equal to or greater than 1:

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

where:

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

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

P_{Xn} is the percentage by weight or by volume of each harmful substance in the preparation,

L_{T+}, L_T and L_{Xn} are the lower concentration limits defined for each substance for classifying the preparation as harmful (as per Table 1 = 0.1% by weight for T+ substances, 3% by weight for T substances and 25% by weight for Xn substances). For gaseous preparations the lower concentration limits in Table 1A shall apply.

3.2 Acute effects to the lungs if swallowed

Preparations should be classified as harmful, assigned the symbol 'X_n', and the indication of danger 'harmful' and the risk phrase R65 in accordance with the criteria specified in paragraph 3.2.3 of Annex VI. In applying the conventional method according to the above paragraph 3.1 no account shall be taken of the classification of a substance as R65.

3.3 Non-lethal irreversible effects after a single exposure

Preparations should be classified as harmful, assigned the symbol 'Xn', the indication of danger 'harmful' and the risk phrase R68/route of exposure if they contain at least one dangerous substance classified as very toxic, toxic or harmful that produces such effects in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I for the substance or substances under consideration, or

(b) the concentration specified at point 2 in Part B of this Schedule (Table II and IIA) where the substance or substances do not appear in Annex 1 or appear in it without concentration limits.

3.4 Severe effects after repeated or prolonged exposure

Preparations should be classified as harmful, assigned the symbol 'X_n', the indication of danger 'harmful' and the risk phrase R48/route of exposure if they contain at least one

dangerous substance classified as toxic or harmful that produces such effects in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I for the substance or substances under consideration, or

(b) the concentration specified at point 3 in Part B of this Schedule (Table III and III A) where the substance or substances do not appear in Annex I or appear in it without concentration limits.

4 Corrosive

4.1 Preparations should be classified as corrosive, assigned the symbol 'C', the indication of danger 'corrosive' and the risk phrase R35 in accordance with the following criteria:

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

(a) either the concentration specified in Annex I for the substance or substances under consideration, or

(b) the concentration specified at point 4 in Part B of this Schedule (Table IV and IV A) where the substance or substances do not appear in Annex I or appear in it without concentration limits.

4.1.2 preparations containing more than one substance classified as corrosive to which is assigned phrase R35 in lower individual concentrations than the limits specified under 4.1.1(a) or (b) if the sum of the fractions in the formula below is equal to or greater than 1:

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

where:

$P_{C,\ R35}$ is the percentage by weight or by volume of each corrosive substance which is assigned phrase R35 in the reparation,

$L_{C,\ R35}$ is the lower concentration limit defined for the substance for classifying the preparation as corrosive with R35 (as per Table IV = 10% by weight). For gaseous preparations the lower concentration limits in Table IVA shall apply.

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

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

(a) either the concentration specified in Annex I for the substance or substances under consideration, or

(b) the concentration specified at point 4 in Part B of this Schedule (Table IV and IV A) where the substance or substances do not appear in Annex I or appear in it without concentration limits;

4.2.2. preparations containing more than one of the substances classified as corrosive to which is assigned the phrase R35 or R34 in lower individual concentrations than the limits specified under 4.2.1(a) or (b) if the sum of the fractions in the formula below is equal to or greater than 1:

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

where:
$P_{C, R35}$ is the percentage by weight or by volume of each corrosive substance to which is assigned phrase R35 in the preparation

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

$L_{C, R35}$ and $L_{C, R34}$ are the lower concentration limits defined for each substance for classifying the preparation as corrosive with R34 (as per Table IV = 5% and 10% by weight respectively). For gaseous preparations the lower concentration limits in Table IVA shall apply.

5 Irritants:

5.1 Risk of serious damage to eyes

Preparations should be classified as irritant, assigned the symbol 'X_i', the indication of danger 'irritant' and the risk phrase R41 in accordance with the following criteria:

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

(a) either the concentration specified in Annex 1 for the substance or substances under consideration, or

(b) the concentration specified at point 4 in Part B of this Schedule (Table IV and IV A) where the substance or substances do not appear in Annex I or appear in it without concentration limits;

5.1.2. preparations containing more than one of the substances classified as irritant and to which is assigned phrase R41, or classified as corrosive and to which is assigned phrase R35 or R34, in lower individual concentrations than the limits specified under 5.1.1(a) or (b) if the sum of the fractions in the formula below is equal to or greater than 1:

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

where:

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

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

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

$L_{C,\,R35}$, $L_{C,\,R34}$, and $L_{Xi,\,R41}$ are the lower concentration limits defined for each substance for classifying the preparation as Irritant with risk phrase R41 (as per Table IV = 5%, 10% and 10% by weight respectively). For gaseous preparations the lower concentration limits in Table IVA shall apply.

5.2 Irritating to eyes

Preparations should be classified as irritant, assigned the symbol 'X_i', the indication of danger 'irritant' and the risk phrase R36 in accordance with the following criteria:

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

(a) either the concentration specified in Annex I for the substance or substances under consideration, or

(b) the concentration specified at point 4 in Part B of this Schedule (Table IV and IV A) where the substance or substances do not appear in Annex I or appear in it without concentration limits;

5.2.2 preparations containing more than one substance classified as irritant to which is assigned phrase R41 or R36, or as corrosive and to which is assigned phrase R35 or R34, in lower individual concentrations than the limits specified under 5.2.1(a) or (b) if the sum of the fractions in the formula below is equal to or greater than 1:

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

where:

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

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

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

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

$L_{C,\ R35}$, $L_{C,\ R34}$, and $L_{Xi,\ R41}$, $L_{Xi,\ R36}$ are the lower concentration limits defined for each substance for classifying the preparation as Irritant with risk phrase R36 (as per Table IV = 1%, 5%, 5% and 20% by weight respectively). For gaseous preparations the lower concentration limits in Table IVA shall apply.

5.3 Irritating to skin

Preparations should be classified as irritant, assigned the symbol 'X_I', the indication of danger 'irritant' and the risk phrase R38 in accordance with the following criteria:

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

(a) either the concentration specified in Annex I for the substance or substances under consideration, or

(b) the concentration specified at point 4 in Part B of this Schedule (Table IV and IV A) where the substance or substances do not appear in Annex I or appear in it without concentration limits;

5.3.2 preparations containing more than one of the substances classified as irritant and to which is assigned phrase R38, or as corrosive and to which is assigned phrase R35 or R34 in lower individual concentrations than the limits specified under 5.3.1(a) or (b) if the sum of the fractions in the formula below is equal to or greater than 1:

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

where:

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

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

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

$L_{C,\ R35}$, $L_{C,\ R34}$, and $L_{Xi,\ R38}$ are the lower concentration limits defined for each substance for classifying the preparation as Irritant with risk phrase R38 (as per Table IV = 1%, 5% and 20% by weight respectively). For gaseous preparations the lower concentration limits in Table IVA shall apply.

5.4 Irritating to respiratory system

Preparations should be classified as irritant, assigned the symbol 'X_i', the indication of danger 'irritant' and the risk phrase R37 in accordance with the following criteria:

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

(a) either the concentration specified in Annex I for the substance or substances under consideration, or

(b) the concentration specified at point 4 in Part B of this Schedule (Table IV and IV A) where the substance or the substances do not appear in Annex I or appear in it without concentration limits;

5.4.2. preparations containing more than one substance classified as irritant and to which is assigned phrase R37 in lower individual concentrations than the limits specified under 5.4.1(a) or (b) if the sum of the fractions in the formula below is equal to or greater than 1:

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

where:

$P_{Xi,\ R37}$ is the percentage by weight or by volume of each irritant substance to which is assigned phrase R37 in the preparation,

$L_{Xi,\ R37}$ is the lower concentration limit defined for the substance for classifying the preparation as Corrosive with risk phrase R37 (as per Table IV = 20%). For gaseous preparations the lower concentration limits in Table IVA shall apply.

5.4.3 gaseous preparations containing more than one of the substances classified as irritant to which is assigned phrase R37 or as corrosive and to which is assigned phrase R35 or R34 in lower individual concentrations than the limits specified under 5.4.1(a) or (b) if the sum of the fractions in the formula below is equal to or greater than 1:

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

where:

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

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

$P_{Xi, R37}$ is the percentage by volume of each irritant substance to which is assigned phrase R37 in the preparation,

$L_{C, R35}$, $L_{C, R34}$, and $L_{Xi, R37}$ are the lower concentration limits defined for each gaseous corrosive substance for classifying the preparation as Irritant with risk phrase R37 (as per Table IVA = 0.02%, 0.5% and 5% by weight respectively).

6 Sensitisers:

Skin sensitisers

6.1 Preparations should be classified as irritant, assigned the symbol 'X_i', the indication of danger 'irritant' and the risk phrase R43 if they contain at least one substance classified as sensitising and to which is assigned phrase R43 that produces such effects in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I for the substance or substances under consideration, or

(b) the concentration specified at point 5 in Part B of this Schedule (Table V and V A) where the substance or substances do not appear in Annex I or appear in it without concentration limits.

Respiratory sensitisers

6.2 Preparations should be classified as harmful, assigned the symbol 'X_n', the indication of danger 'harmful' and the risk phrase R42 if they contain at least one substance classified as sensitising to which is assigned phrase R42 that produces such effects in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I for the substance or substances under consideration, or

(b) the concentration specified at point 5 in Part B of this Schedule (Table V and V A) where the substance or substances do not appear in Annex I or appear in it without concentration limits.

7 Carcinogens:

7.1 Preparations should be classified as carcinogens category 1 or 2, assigned the symbol 'T' and the phrase R45 or R49 if they contain at least one substance producing such effects, classified as carcinogenic and to which is assigned phrase R45 or R49 which

denotes carcinogenic substances in category 1 and category 2, in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I for the substance or substances under consideration, or

(b) the concentration specified at point 6 in Part B of this Schedule (Table VI and VI A) where the substance or substances do not appear in Annex I or appear in it without concentration limits;

7.2 Preparations should be classified as carcinogens category 3 which are assigned the symbol 'X_n' and the phrase R40 if they contain at least one substance producing such effects classified as carcinogenic and to which is assigned phrase R40 which denotes carcinogenic substances in category 3, in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I for the substance or substances under consideration, or

(b) the concentration specified at point 6 in Part B of this Schedule (Table VI and VI A) where the substance or substances do not appear in Annex I or appear in it without concentration limits.

8 Mutagens

8.1 Preparations should be classified as mutagens category 1 or 2 which are assigned the symbol 'T' and the phrase R46 if they contain at least one substance producing such effects, classified as mutagenic and to which is assigned phrase R46 which denotes mutagenic substances in category 1 and category 2, in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I for the substance or substances under consideration, or

(b) the concentration specified at point 6 in Part B of this Schedule (Table VI and VI A) where the substance or substances do not appear in Annex I or appear in it without concentration limits.

8.2. Preparations should be classified as mutagens category 3 which are assigned the symbol 'X_n' and the phrase R68 if they contain at least one substance, producing such effects, classified as mutagenic and to which is assigned phrase R68 which denotes mutagenic substances in category 3, in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I for the substance or substances under consideration, or

(b) the concentration specified at point 6 in Part B of this Schedule (Table VI and VI A) where the substance or substances do not appear in Annex I or appear in it without concentration limits.

9 Toxic for Reproduction

Fertility

9.1 Preparations should be classified as toxic for reproduction category 1 or 2 which are assigned the symbol 'T' and the phrase R60 (fertility) if they contain at least one substance producing such effects, classified as toxic for reproduction and to which is assigned phrase R60 which denotes substances toxic for reproduction of category 1 and category 2, in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I for the substance or substances under consideration, or

(b) the concentration specified at point 6 in Part B of this Schedule (Table VI and VI A) where the substance or substances do not appear in Annex I or appear in it without concentration limits.

9.2 Preparations should be classified as toxic for reproduction category 3 which are assigned the symbol 'X_n' and the phrase R62 (fertility) if they contain at least one substance producing such effects, classified as toxic for reproduction and to which is assigned phrase R62 which denotes substances toxic for reproduction of category 3, in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I for the substance or substances under consideration, or

(b) the concentration specified at point 6 in Part B of this Schedule (Table VI and VI A) where the substance or substances do not appear in Annex I or appear in it without concentration limits.

Development

9.3 Preparations should be classified as toxic for reproduction category 1 or 2 which are assigned the symbol 'T' and the phrase R61 (development) if they contain at least one substance producing such effects, classified as toxic for reproduction and to which is assigned phrase R61 which denotes substances toxic for reproduction of category 1 and category 2, in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I for the substance or substances under consideration, or

(b) the concentration specified at point 6 in Part B of this Schedule (Table VI and VI A) where the substance or substances do not appear in Annex I or appear in it without concentration limits.

9.4 Preparations should be classified as toxic for reproduction category 3 which are assigned the symbol 'Xn' and the phrase R63 (development) if they contain at least one substance producing such effects, classified as toxic for reproduction and to which is assigned phrase R63 which denotes substances toxic for reproduction of category 3, in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I for the substance or substances under consideration, or

(b) the concentration specified at point 6 in Part B of this Schedule (Table VI and VI A) where the substance or substances do not appear in Annex I or appear in it without concentration limits.

PART B - Concentration limits to be used in evaluation of health hazards

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

1. Acute lethal effects

1.1. Non-gaseous preparations

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

Table I

Classification of the substance	Classification of the preparation		
	T +	T	X_n
T^+ with R26, R27, R28	concentration >= 7%	1% =< concentration <7%	0.1% =< concentration <1%
T with R23, R24, R25		concentration >= 25%	3% =< concentration <25%
X_n with R20, R21, R22			concentration >= 25%

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

- the label shall include one or more of the above mentioned risk phrases according to the classification used,

- in general, the risk phrases selected should be those applicable to the substance(s) present in the concentration which gives rise to the most severe classification.

1.2. Gaseous preparations

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

Table I A

Classification of the substance (gas)	Classification of the preparation		
	T +	T	X_n
T^+ with R26, R27, R28	concentration >= 1%	0.2% =< concentration <1%	0.2% =< concentration < 0.2%
T with R23, R24, R25		concentration >= 5%	0.5% =< concentration <5 %
X_n with R20, R21, R22			concentration >= 5%

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

- the label shall include one or more of the above mentioned risk phrases according to the classification used,

- in general, the risk phrases selected should be those applicable to the substance(s) present in the concentration which gives rise to the most severe classification.

2. Non-lethal irreversible effects after a single exposure

2.1. Non-gaseous preparations

For substances that produce non-lethal irreversible effects after a single exposure (R39/route of exposure, R40/route of exposure), the individual concentration limits specified in Table II, expressed as a weight/weight percentage, determine, when appropriate, the classification of the preparation.

Table II

Classification of the substance (gas)	Classification of the preparation		
	T +	T	X_n
T+ with R39/ route of exposure	concentration >= 10% R39 (*) obligatory	1% =< concentration <10% R39 (*) obligatory	0.1% =< concentration <1% R68 (*) obligatory
T with R39/ route of exposure		concentration >= 10% R39 (*) obligatory	1% =< concentration <10% R68 (*) obligatory
X_n with R68/ route of exposure			concentration >= 10% R68 (*) obligatory

(*) To indicate the route of administration/exposure (route of exposure) the combined risk phrases listed under paragraphs 3.2.1, 3.2.2, and 3.2.3 of the labelling guide (Annex VI) are to be used.

2.2 Gaseous preparations

For gases that produce non-lethal irreversible effects after a single exposure (R39/route of exposure, R40/route of exposure), the individual concentration limits specified in Table II A, expressed as a volume/volume percentage, determine, when appropriate, the classification of the preparation.

Table II A

Classification of the substance (gas)	Classification of the preparation		
	T +	T	X_n
T+ with R39/ route of exposure	concentration >= 1% R39 (*) obligatory	0.2% =< concentration <1% R39 (*) obligatory	0.02% =< concentration <0.2% R68 (*) obligatory
T with R39/ route of exposure		concentration >= 5% R39 (*) obligatory	0.5% =< concentration <5% R68 (*) obligatory
X_n with R68/ route of exposure			concentration >= 5% R68 (*) obligatory

(*) To indicate the route of administration/exposure (route of exposure) the combined risk phrases listed under paragraphs 3.2.1, 3.2.2, and 3.2.3 of the labelling guide (Annex VI) are to be used.

3. Severe effects after repeated or prolonged exposure

3.1 Non-gaseous preparations

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

Table III

Classification of the substance	Classification of the preparation	
	T	X_n
T+ with R48/ route of exposure	concentration >= 10% R48 (*) obligatory	1% =< concentration <10% R48 (*) obligatory
X_n with R48/ route of exposure		concentration >= 10% R48 (*) obligatory

(*) To indicate the route of administration/exposure (route of exposure) the combined risk phrases listed under paragraphs 3.2.1, 3.2.2, and 3.2.3 of the labelling guide (Annex VI) are to be used.

3.2 Gaseous preparations

For gases that produce severe effects after repeated or prolonged exposure (R48/route of exposure), the individual concentration limits specified in Table III A below, expressed as a

volume/volume percentage, determine, when appropriate, the classification of the preparation.

Table III A

Classification of the substance (gas)	Classification of the preparation	
	T	X_n
T+ with R48/ route of exposure	concentration >= 5% R48 (*) obligatory	0.5% =< concentration <5% R48 (*) obligatory
X_n with R48/ route of exposure		concentration >= 5% R48 (*) obligatory

(*) To indicate the route of administration/exposure (route of exposure) the combined risk phrases listed under paragraphs 3.2.1, 3.2.2, and 3.2.3 of the labelling guide (Annex VI) are to be used.

4 Corrosive and irritant effects including serious damage to the eye

4.1 Non-gaseous preparations

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

Table IV

Classification of the substance	Classification of the preparation			
	C with R35	C with R34	X_i with R41	X_i with R36, R37, R38
C with R35	concentration >= 10% R35 obligatory	5% =< concentration <10% R34 obligatory	(5%*)	1% =< concentration <5% R36/38 obligatory
C with R34		concentration >= 10% R34 obligatory	(10%*)	5% =< concentration <10% R36/38 obligatory
X_i with R41			concentration >= 10% R41 obligatory	5% =< concentration <10% R36 obligatory
X_i with R36, R37, R38				concentration >=20% R36, R37, R38 are obligatory in the light of the concentration present if they apply to the substances under consideration

(*) According to the labelling guide (Annex VI), corrosive substances assigned risk phrases R35 or R34 must also be considered as being assigned phrase R41. Consequently, if the preparation contains corrosive substances with R35 or R34 below the concentration limits for

a classification of the preparation as corrosive, such substances can contribute to a classification of the preparation as irritant with R41 or irritant with R36.

Note
Simple application of the conventional method to preparations containing substances classified as corrosive or irritant may result in under-classification or over-classification of the hazard, if other relevant factors (e.g. pH of the preparation) are not taken into account. Therefore, in classifying for corrosivity, consider the advice given in paragraph 3.2.5 of Annex VI and Regulation 11(6).

4.2 Gaseous preparations

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

Table IV A

Classification of the substance (gas)	Classification of the preparation			
	C with R35	C with R35	X_i with R41	X_i with R36, R37, R38
C with R35	concentration >= 1% R35 obligatory	0.2% =< concentration <1% R34 obligatory	0.2% (*)	0.02% =< concentration <0.2% R37/37/38 obligatory
C with R34		concentration >= 5% R34 obligatory	5% (*)	0.5% =< concentration <5% R36/37/38 obligatory
X_i with R41			concentration >= 5% R41 obligatory	0.5% =< concentration <5% R36 obligatory
X_i with R36, R37, R38				concentration <5% R36, R37, R38 obligatory as appropriate

(*) According to the labelling guide (Annex VI), corrosive substances assigned risk phrases R35 or R34 must also be considered as being assigned phrase R41. Consequently, if the preparation contains corrosive substances with R35 or R34 below the concentration limits for a classification of the preparation as corrosive, such substances can contribute to a classification of the preparation as irritant with R41 or irritant with R36.

Note
Simple application of the conventional method to preparations containing substances classified as corrosive or irritant may result in under-classification or over-classification of the hazard, if other relevant factors (e.g. pH of the preparation) are not taken into account. Therefore, in classifying for corrosivity, consider the advice given in paragraph 3.2.5 of Annex VI and Regulation 9(6).

5 Sensitising effects

5.1 Non-gaseous preparations

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

- the symbol Xn and phrase R42 if this effect can be produced by inhalation,

- the symbol Xi and phrase R43 if this effect can be produced through contact with the skin.

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

Table V

Classification of the substance	Classification of the preparation	
	Sensitising with R42	Sensitising with R43
Sensitising with R42	concentration >= 1% R42 obligatory	
Sensitising with R43		concentration >= 1% R43 obligatory

5.2 Gaseous preparations

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

- the symbol Xn and phrase R42 if this effect can be produced by inhalation,

- the symbol Xi and phrase R43 if this effect can be produced through contact with the skin.

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

Table V A

Classification of the substance (gas)	Classification of the preparation	
	Sensitising with R42	Sensitising with R43
Sensitising with R42	concentration >= 0.2% R42 obligatory	
Sensitising with R43		concentration >= 0.2% R43 obligatory

6. Cacinogenic/mutagenic/toxic effects for reproduction

6.1. Non-gaseous preparations

For substances which produce such effects, the concentration limits laid down in Table VI, expressed as a weight/weight percentage, shall determine, where appropriate, the classification of the preparation. The following symbols and risk phrases are assigned:

Carcinogenic categories 1 and 2:	T; R45 or R49
Carcinogenic category 3:	Xn ; R40
Mutagenic categories 1 and 2:	T; R46
Mutagenic category 3:	Xn ; R68
Toxic for reproduction fertility categories 1 and 2:	T; R60
Toxic for reproduction development categories 1 and 2:	T; R61
Toxic for reproduction fertility category 3:	Xn ; R62
Toxic for reproduction development category 3:	Xn ; R63

Table VI

Classification of the substance	Classification of the preparation	
	Categories 1 and 2	Category 3
carcinogenic substances of category 1 or 2 with R45 or R49	concentration >= 0.1% carcinogenic R45, R49 obligatory as appropriate	
carcinogenic substances of category 3 with R40		concentration >= 1% carcinogenic R40 obligatory
mutagenic substances of category 1 or 2 with R46`	concentration >= 0.1% mutagenic R46 obligatory	
mutagenic substances of category 3 with R68		concentration >= 1% mutagenic R68 obligatory
substances "toxic for repr oduction" of category 1 or 2 with R60 (fertility)	concentration >= 0.5% toxic for reproduction (fertility) R60 obligatory	
substances "toxic for repr oduction" of category 3 with R62 (fertility)		concentration >= 5% toxic for reproduction (fertility) R62 obligatory
substances "toxic for repr oduction" of category 1 or 2 with R61 (development)	concentration >= 0.5% toxic for reproduction (development) R61 obligatory	
substances "toxic for repr oduction" of category 3 with R63 (development)		concentration >= 5% toxic for reproduction (development) R63 obligatory

Carcinogenic categories 1 and 2:	T; R45 or R49
Carcinogenic category 3:	X_n ; R40
Mutagenic categories 1 and 2:	T; R46
Mutagenic category 3:	X_n ; R68
Toxic for reproduction fertility categories 1 and 2:	T; R60
Toxic for reproduction development categories 1 and 2:	T; R61
Toxic for reproduction fertility category 3:	X_n ; R62
Toxic for reproduction development category 3:	X_n ; R63

6.2. Gaseous preparations

For gases which produce such effects, the concentration limits laid down in Table VI A, expressed as a volume/volume percentage, shall determine, where appropriate, the classification of the preparation. The following symbols and risk phrases are assigned:

Carcinogenic categories 1 and 2:	T; R45 or R49
Carcinogenic category 3:	X_n ; R40
Mutagenic categories 1 and 2:	T; R46
Mutagenic category 3:	X_n ; R68
Toxic for reproduction fertility categories 1 and 2:	T; R60
Toxic for reproduction development categories 1 and 2:	T; R61
Toxic for reproduction fertility category 3:	X_n ; R62
Toxic for reproduction development category 3:	X_n ; R63

Table VI A

Classification of the substance	Classification of the preparation	
	Categories 1 and 2	Category 3
carcinogenic substances of category 1 or 2 with R45 or R49	concentration >= 0.1% carcinogenic R45, R49 obligatory as appropriate	
carcinogenic substances of category 3 with R40		concentration >= 1% carcinogenic R40 obligatory
mutagenic substances of category 1 or 2 with R46	concentration >= 0.1% mutagenic R46 obligatory	
mutagenic substances of category 3 with R68		concentration >= 1% mutagenic R68 obligatory
substances "toxic for reproduction" of category 1 or 2 with R60 (fertility)	concentration >= 0.2% toxic for reproduction (fertility) R60 obligatory	
substances "toxic for reproduction" of category 3 with R62 (fertility)		concentration >= 1% toxic for reproduction (fertility) R62 obligatory
substances "toxic for reproduction" of category 1 or 2 with R61 (development)	concentration >= 0.2% toxic for reproduction (development) R61 obligatory	
substances "toxic for reproduction" of category 3 with R63 (development)		concentration >= 1% toxic for reproduction (development) R63 obligatory

SCHEDULE 4

Regulation 10

CONVENTIONAL METHOD FOR THE EVALUATION OF ENVIRONMENTAL HAZARDS OF PREPARATIONS

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

INTRODUCTION

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

Part A gives the calculation procedure according to Regulation 12 (1) and gives the risk phrases to be assigned to the classification of the preparation.

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

In accordance with Regulation 12 (1) the environmental hazards of a preparation shall be assessed by the conventional method described in parts A and B of this Schedule, using individual concentration limits.

(a) Where the dangerous substances listed in Annex 1 are assigned concentration limits necessary for the application of the method of assessment described in Part A of this Schedule, these concentration limits must be used.

(b) Where the dangerous substances do not appear in Annex I or appear there without the concentration limits necessary for the application of the method of evaluation described in Part A of this Schedule, the concentration limits shall be assigned in accordance with the specification in Part B of this Schedule.

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

PART A - Procedure for the evaluation of environmental hazards

(a) Aquatic environment

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

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

1. Preparations should be classified as dangerous for the environment, assigned the symbol 'N', the indication of danger 'dangerous for the environment' and the risk phrases R50 and R53 (R50-53) in accordance with the following criteria:

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

(a) either the concentration specified in Annex I for the substance or substances under consideration, or

(b) the concentration specified in Part B of this Schedule (Table 1) where the substance or substances do not appear in Annex I or appear in it without concentration limits;

1.2. preparations containing more than one substance classified as dangerous for the environment and to which is assigned phrases R50-53 in lower individual concentrations than the limits specified under 1.1(a) or (b) if the sum of the fractions in the formula below is equal to or greater than 1:

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

where:

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

$L_{N,\ R50-53}$ is the lower concentration limit defined for the substance for classifying the preparation as dangerous for the environment N, R50-53, (as per Table 1 = 25% by weight).

2. Preparations should be classified as dangerous for the environment, assigned the symbol 'N' the indication of danger 'dangerous for the environment' and the risk phrases R51 and R53 (R51-53), unless the preparation is already classified according to paragraph 1 above, in accordance with the following criteria:

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

(a) either the concentration specified in Annex I for the substance or substances under consideration, or

(b) the concentration specified in Part B of this Schedule (Table 1) where the substance or substances do not appear in Annex I or appear in it without concentration limits;

2.2. preparations containing more than one of the substances classified as dangerous for the environment and to which is assigned phrases R50-53 or R51-53 in lower individual concentrations than the limits specified under 2.1(a) or (b) if the sum of the fractions in the formula below is equal to or greater than 1:

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

where:

$P_{N,\ R50\text{-}53}$ is the percentage by weight of each substance dangerous for the environment to which is assigned phrases R50-53 in the preparation,

$P_{N,\ R51\text{-}53}$ is the percentage by weight of each substance dangerous for the environment to which is assigned phrases R51-53 in the preparation,

$L_{N,\ R50\text{-}53}$, $L_{N,\ R51\text{-}53}$ are the lower concentration limits defined for the substances for classifying the preparations as dangerous for the environment N, R51-53, (as per Table 1 = 2.5% and 25% by weight for N, R50-53 and N, R51-53 substances respectively).

3. Preparations should be classified as dangerous for the environment and assigned the risk phrases R52 and R53 (R52-53), unless the preparation is already classified according to paragraph 1 or 2 above, in accordance with the following criteria:

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

(a) either the concentration specified in Annex I for the substance or substances under consideration, or

(b) the concentration specified in Part B of this Schedule (Table 1) where the substance or substances do not appear in Annex I or appear in it without concentration limits;

3.2. preparations containing more than one of the substances classified as dangerous for the environment and to which is assigned phrases R51-53 or R50-53 or R52-53 in lower individual concentrations than the limits specified under 3.1(a) or (b) if the sum of the fractions in the formula below is equal to or greater than 1:

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

where:

$P_{N,\ R50\text{-}53}$ is the percentage by weight of each substance dangerous for the environment to which is assigned phrases R50-53 in the preparation,

$P_{N,\ R51\text{-}53}$ is the percentage by weight of each substance dangerous for the environment to which is assigned phrases R51-53 in the preparation,

$P_{R52\text{-}53}$ is the percentage by weight of each substance dangerous for the environment to which is assigned phrases R52-53 in the preparation,

$L_{N,\ R50\text{-}53}$, $L_{N,\ R51\text{-}53}$ and $L_{R52\text{-}53}$ are the lower concentration limits defined for the substances for classifying the preparations as dangerous for the environment N, R52-53, (as per Table 1 = 0.25%, 2.5% and 25% by weight for N, R50-53 and N, R51-53, and R52-53 substances respectively).

4. Preparations should be classified as dangerous for the environment, assigned the symbol 'N' the indication of danger 'dangerous for the environment' and the risk phrase R50 unless the preparation is already classified according to 1 above:

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

(a) either the concentration specified in Annex I for the substance or substances under consideration, or

(b) the concentration specified in Part B of this Schedule (Table 2) where the substance or substances do not appear in Annex I or appear in it without concentration limits;

4.2. preparations containing more than one substance classified as dangerous for the environment and to which is assigned phrase R50 in lower individual concentrations than the limits specified under 4.1(a) or (b) if the sum of the fractions in the formula below is equal to or greater than 1:

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

where:

$P_{N,\ R50}$ is the percentage by weight of each substance dangerous for the environment to which is assigned phrase R50 in the preparation,

$L_{N,\ R50}$ is the lower concentration limit defined for the substance for classifying the preparation as N, R50, (as per Table 2 = 25% by weight).

4.3. preparations containing one or more than one of the substances classified as dangerous for the environment and to which is assigned phrase R50 not meeting the criteria under 4.1 or 4.2 and containing one or more than one substance classified as dangerous for the environment and to which is assigned phrases R50-53 if the sum of the fractions in the formula below is equal to or greater than 1:

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

where:

$P_{N,\ R50}$ is the percentage by weight of each substance dangerous for the environment to which is assigned phrase R50 in the preparation,

$P_{N,\ R50\text{-}53}$ is the percentage by weight of each substance dangerous for the environment to which is assigned phrases R50-53 in the preparation,

$L_{N,\ R50}$, $L_{N,\ R50\text{-}53}$ are the lower concentration limit defined for the substance for classifying the preparation as dangerous for the environment, N, R50, (as per Table 2 = 25% by weight for both N, R50 and N, R50-53 substances).

5. Preparations should be classified as dangerous for the environment and assigned the risk phrase R52 unless the preparation is already classified according to paragraphs 1, 2, 3, or 4 according to the following criteria:

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

(a) either the concentration specified in Annex I for the substance or substances under consideration, or

(b) the concentration specified in Part B of this Schedule (Table 3) where the substance or substances do not appear in Annex I or appear in it without concentration limits;

5.2. preparations containing more than one substance classified as dangerous for the environment and to which is assigned phrase R52 in lower individual concentrations than the limits specified under 5.1 (a) or (b) if the sum of the fractions in the formula below is equal to or greater than 1:

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

where:

P_{R52} is the percentage by weight of each substance dangerous for the environment to which is assigned phrase R52 in the preparation,

L_{R52} is the limit defined for each substance for classifying the preparation dangerous for the environment R52, (as per Table 3 = 25% by weight).

6. Preparations should be classified as dangerous for the environment and assigned the risk phrase R53 unless the preparation is already classified according to paragraph 1, 2, or 3 above:

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

(a) either the concentration specified in Annex I for the substance or substances under consideration, or

(b) the concentration specified in Part B of this Schedule (Table 4) where the substance or substances do not appear in Annex I or appear in it without concentration limits;

6.2. preparations containing more than one substance classified as dangerous for the environment and to which is assigned phrase R 53 in lower individual concentrations than the limits specified under 6.1(a) or (b) if the sum of the fractions in the formula below is equal to or greater than 1:

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

where:

P_{R53} is the percentage by weight of each substance dangerous for the environment to which is assigned phrase R53 in the preparation,

L_{R53} is the limit defined for each substance for classifying the preparation dangerous for the environment R52, (as per Table 4 = 25% by weight).

6.3. preparations containing one or more than one of the substances classified as dangerous for the environment and to which is assigned phrase R53 not meeting the criteria under I.6.2 and containing one or more than one substance classified as dangerous for the environment and to which is assigned phrases R50-53 or R51-53 or R52-53 if the sum of the fractions in the formula below is equal to or greater than 1:

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

where:

P_{R53} is the percentage by weight of each substance dangerous for the environment to which is assigned phrase R53 in the preparation,

$P_{N, R50-53}$ is the percentage by weight of each substance dangerous for the environment to which is assigned phrase R50-53 in the preparation,

$P_{N, R51-53}$ is the percentage by weight of each substance dangerous for the environment to which is assigned phrase R51-53 in the preparation,

P_{R52-53} is the percentage by weight of each substance dangerous for the environment to which is assigned phrase R52-53 in the preparation,

L_{R53}, $L_{N, R50-53}$, $L_{N, R51-53}$ and L_{R52-53} = are the lower concentration limits defined for the substances for classifying the preparations as dangerous for the environment R53, (as per Table 4 = 25%, by weight for N, R53, N, R50-53 and N, R51-53, and R52-53 substances respectively).

(b) Non-aquatic environment

(1) OZONE LAYER

1. Conventional method for the evaluation of preparations dangerous for the ozone layer

1.1 Preparations should be classified as dangerous for the environment, assigned the symbol ' N' , the indication of danger 'dangerous for the environment' and the risk phrase R59 if they contain one or more substances classified as dangerous to the environment and to which is assigned the symbol 'N' and the risk phrase R59 in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I for the substance or substances under consideration, or

(b) the concentration specified in Part B of this Schedule (Table 5) where the substance or substances do not appear in Annex I or appear in it without concentration limits;

1.2 Preparations should be classified as dangerous for the environment and assigned the risk phrase R59 if they contain one or more substances classified as dangerous to the environment and to which is assigned R59 in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I for the substance or substances under consideration, or

(b) the concentration specified in Part B of this Schedule (Table 5) where the substance or substances do not appear in Annex I or appear in it without concentration limits;

(2) TERRESTRIAL ENVIRONMENT

1. Evaluation of preparations dangerous for the terrestrial environment

Classification of preparations using the risk phrases below will follow after the detailed criteria for use of the phrases have been incorporated in Annex VI.

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

PART B - Concentration limits to be used for the evaluation of environmental hazards

I. For the aquatic environment

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

Table 1

Acute aquatic toxicity and long-term adverse effects

Classification of the substance	Classification of the preparation		
	N, R50-53	N, R51-53	R52-53
N, R50-53	C_n >= 25%	2.5% =< C_n < 25%	0.25% =< C_n < 2.5%
N, R51-53		C_n >= 25%	2.5% =< C_n < 25%
R52-53			C_n >= 25%

Table 2

Acute aquatic toxicity

Classification of the substance	Classification of the preparation N, R50
N, R50	C_n >= 25%
N, R50-53	C_n >= 25%

Table 3

Aquatic toxicity

Classification of the substance	Classification of the preparation N, R52
R52	C_n >= 25%

Table 4

Long-term adverse effects

Classification of the substance	Classification of the preparation N, R53
R53	C_n >= 25%
N, R50-53	C_n >= 25%
N, R51-53	C_n >= 25%
R52-53	C_n >= 25%

II. For the non-aquatic environment

The concentration limits fixed in the following tables, expressed as weight/weight percentage or, for gaseous preparations as a volume/volume percentage, determine the classification of the preparation in relation to the individual concentration of the substance(s) present whose classification is also shown.

Table 5

Dangerous for the ozone layer

Classification of the substance	Classification of the preparation N, R59
N with R59	C_n >= 0.1%

Classification of the substance	Classification of the preparation N, R59
R59	C_n >= 0.1%

PART C - Test methods for the evaluation of the hazards for the aquatic environment

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

The result of these tests on the preparation may only modify the classification concerning acute aquatic toxicity which would have been obtained by the application of the conventional method, i.e. cannot be used to modify long term toxicity effects.

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

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

SCHEDULE 5

Regulations 3 and 13

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

PART A

Containers to be fitted with child-resistant fastenings

1. Containers of whatever capacity, containing preparations offered or sold to the general public and labelled as very toxic, toxic or corrosive in accordance with Regulation 14 and under the conditions laid down in Regulation 9, are to fitted with child-resistant fastenings.

2. Containers of whatever capacity containing preparations presenting an aspiration hazard (Xn, R65) and classified and labelled according to paragraph 3.2.3 of Annex VI with the exception of preparations placed on the market in the form of aerosols or in a container fitted with a sealed spray attachment.

3. Containers of whatever capacity, having at least one of the substances mentioned below present in a concentration equal to or greater than the maximum individual concentration specified,

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

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

PART B

Containers to be fitted with a tactile warning of danger

Containers of whatever capacity, containing preparations offered or sold to the general public and labelled as very toxic, toxic, corrosive, harmful, extremely flammable or highly flammable in accordance with Regulation 14 and under the conditions laid down in Regulations 8 and 9, are to carry a tactile warning of danger.

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

PART C

Provisions relating to child-proof fastenings

Reclosable packages

Child-proof fastenings used on reclosable packages shall comply with ISO standard 8317 (1 July 1989 edition) relating to ' Child-resistant packages - Requirements and methods of testing for reclosable packages' adopted by the International Standard Organisation (ISO).

Non-reclosable packages

Child-proof fastenings used on non-reclosable packages shall comply with CEN standard EN 862 (March 1997 edition) relating to ' Packaging - Child-resistant packaging - Requirements and testing procedures for non-reclosable packages for non-pharmaceutical products' adopted by the European Committee for Standardisation (CEN).

Notes

1 Evidence of conformity with the above standard may be certified only by laboratories which conform with European Standards Series EN 45 000.

2. Specific cases

If it seems obvious that packaging is sufficiently safe for children because they cannot get access to the contents without the help of a tool, the test does not need to be performed.

In all other cases and when there are sufficient grounds for doubting the security of the closure for a child, the competent authority may ask the person responsible for putting the product on the market to give him a certificate from a laboratory described in Note 1, stating that either:

- the type of closure is such that it is not necessary to test to the ISO and CEN standards referred to above, or

- the closure has been tested and has been found to conform with the standard referred to above.

PART D

Provisions relating to tactile warning devices

The technical specifications for tactile warning devices shall conform with EN ISO standard 11683 (1997 edition) relating to "Packaging – Tactile warnings of danger – Requirements".

SCHEDULE 6

Regulation 14

NAMING OF SUBSTANCES IN A PREPARATION

1. In accordance with Regulation 14(3)(c) and subject to Regulation 16, the chemical name of the substance or substances present in the preparation shall be clearly and indelibly marked on any package in accordance with the following rules-

   (a) in the case of a preparation classified as very toxic, (T^+), toxic, (T), or harmful (X_n) in accordance with Regulation 9 only those substances classified as very toxic, (T^+), toxic, (T]) or harmful (X_n) present in concentrations equal to or greater than the lowest limit (limit X_n) specified in Annex I or, if no such limit is specified, Part B of Schedule 3 have to be taken into consideration,

   (b) in the case of a preparation classified in accordance with Regulation 9 as corrosive, (C), only corrosive substances present in concentrations equal to or greater than the lowest limit (limit X_i) specified in Annex I or, if no such limit is specified, Part B of Schedule 3 have to be taken into account,

   (c) the name of the substances which have given rise to the classification in one or more of the following danger categories -

      (i) carcinogen category 1, 2 or 3,

      (ii) mutagen category 1, 2, or 3,

      (iii) toxic for reproduction category 1, 2 or 3,

      (iv) very toxic, toxic or harmful due to non-lethal effects after a single exposure,

      (v) toxic or harmful due to severe effects after repeated or prolonged exposure,

      (vi) sensitising,

   shall be mentioned on the label.

2. The chemical name shall be one of the designations given in Annex I or an internationally recognised chemical nomenclature if no corresponding designation is yet listed in that Annex.

3. As a consequence of paragraphs 1 and 2, the name of any substance which has resulted in the classification in the following danger categories -

      (i) explosive,

      (ii) oxidising,

(iii) extremely flammable,

(iv) highly flammable,

(v) flammable,

(vi) irritant,

(vii) dangerous for the environment,

need not be mentioned on the label unless the substance has to be mentioned pursuant to paragraph (1)(a), paragraph (1)(b) or paragraph (1)(c).

4. (a) Subject to subparagraph (b), a maximum of 4 chemical names shall be sufficient to identify the substances primarily responsible for the major health hazards which have given rise to the classification and the choice of the corresponding phrases referring to the risk involved.

(b) Notwithstanding subparagraph (a), in certain circumstances more than 4 chemical names may be necessary to identify such substance.

SCHEDULE 7

Regulations 3 and 14

SPECIAL PROVISIONS CONCERNING THE LABELLING OF CERTAIN PREPARATIONS

A. For preparations classified as dangerous as defined under Regulation 3(2)

1. Preparations sold to the general public

1.1 The labels on packages containing such preparations, in addition to the specific safety advice, must bear the relevant safety advice S1, S2, S45 or S46 in accordance with the criteria laid down in Annex VI.

1.2 When such preparations are classified as very toxic (T+), toxic (T) or corrosive (C) and where it is physically impossible to give such information on the package itself, packages containing such preparations must be accompanied by precise and easily understandable instructions for use including, where appropriate, instructions for the destruction of the empty package.

2. Preparations intended for use by spraying

The package label containing such preparations must compulsorily bear the safety advice S23 accompanied by safety advice S38 or S51 assigned to it in accordance with the criteria laid down in Annex VI.

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

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

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

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

B. For preparations irrespective of their classification as defined under Regulation 3(3)

1. Preparations containing lead

1.1. Paint and varnishes

Labels of packages of paints and varnishes containing lead in quantities exceeding 0.15 % (expressed as weight of metal) of the total weight of the preparation, as determined in accordance with ISO standard 6503/1984, must show the following particulars:

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

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

"Warning! Contains lead".

2. Preparations containing cyanoacrylates

2.1. Adhesives

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

"Cyanoacrylate
Danger
Bonds skin and eyes in seconds
Keep out of the reach of children."

Appropriate advice on safety must accompany the package.

3. Preparations containing isocyanates

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

"Contains isocyanates.
See information supplied by the manufacturer."

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

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

"Contains epoxy constituents.
See information supplied by the manufacturer."

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

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

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

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

The packaging of the abovementioned preparations must bear the following inscription printed in clearly legible and indelible characters:

"Warning! Contains cadmium.
Dangerous fumes are formed during use.
See information supplied by the manufacturer.
Comply with the safety instructions."

7. Preparations available as aerosols

Without prejudice to these Regulations, preparations available as aerosols are also subject to the labelling provisions in accordance with points 2.2 and 2.3 of the Annex to Council Directive 75/324/EEC of 20 May 1975[31] as last amended by Commission Directive 94/1/EC of 6 January 1994[32].

8. Preparations containing substances not yet tested completely

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

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

The packaging of preparations containing at least one substance classified as sensitising and being present in a concentration equal to or greater than 0.1 % or in a concentration equal to or greater than that specified under a specific note for the substance in Annex I must bear the inscription:

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

---

[31] O.J. No. L147, 9.6.1975, p.40
[32] O.J. No. L23, 28.1.1994, p.28

10. Liquid preparations containing halogenated hydrocarbons

For liquid preparations which show no flashpoint or a flashpoint higher than 55 °C and contain a halogenated hydrocarbon and more than 5 % flammable or highly flammable substances, the packaging must bear the following inscription as appropriate:

"Can become highly flammable in use" or "Can become flammable in use".

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

When a preparation contains one or more substances assigned the phrase R67, the label of the preparation must carry the wording of this phrase as set out in Annex III, when the total concentration of these substances present in the preparation is equal to or higher than 15%, unless:

– the preparation is already classified with phrases R20, R23, R26, R68/20, R39/23 or R39/26

– or the preparation is in a package not exceeding 125ml.

12. Cements and cement preparations

The packaging of cements and cement preparations containing more than 0.0002 % soluble chromium (VI) of the total dry weight of the cement must bear the inscription:

"Contains chromium (VI). May produce an allergic reaction"

unless the preparation is already classified and labelled as a sensitiser with phrase R43.

C. For preparations not classified within the meaning of Regulation 3(2), but containing at least one dangerous substance

1. Preparations not intended for the general public

The label on the packaging of the preparations referred to in Regulation 18(1)(b) must bear the following inscription:

"Safety data sheet available for professional user on request".

SCHEDULE 8

Regulations 2 and 14

SYMBOLS AND INDICATIONS OF DANGER

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

E

Explosive

O

Oxidizing

F

Highly flammable

F+

Extremely flammable

T

Toxic

T+

Very Toxic

C

Corrosive

Xn

Harmful

Xi

Irritant

N

Dangerous for the environment

SCHEDULE 9

Regulations 2 and 14

RISKS PHRASES

NATURE OF SPECIAL RISKS ATTRIBUTED TO DANGEROUS SUBSTANCES AND PREPARATIONS

PART I SINGLE R-PHRASES

R1
Explosive when dry

R2
Risk of explosion by shock, 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 materials

R10
Flammable

R11
Highly flammable

R12
Extremely flammable

R14
Reacts violently with water

R15
Contact with water liberates highly 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
Limited evidence of a carcinogenic effect

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

R65
Harmful: May cause lung damage if swallowed

R66
Repeated exposure may cause skin dryness or cracking

R67
Vapours may cause drowsiness and dizziness

R68
Possible risk of irreversible effects

PART II COMBINATION OF R-PHRASES

R14/15
Reacts violently with water, liberating highly flammable gases

R15/29
Contact with water liberates toxic, highly flammable gas

R20/21
Harmful by inhalation and in contact with skin

R20/22
Harmful by inhalation and if swallowed

R20/21/22
Harmful by inhalation, in contact with skin and if swallowed

R21/22
Harmful in contact with skin and if swallowed

R23/24
Toxic by inhalation and in contact with skin

R23/25
Toxic by inhalation and if swallowed

R23/24/25
Toxic by inhalation, in contact with skin and if swallowed

R24/25
Toxic in contact with skin and if swallowed

R26/27
Very toxic by inhalation and in contact with skin

R26/28
Very toxic by inhalation and if swallowed

R26/27/28
Very toxic by inhalation and in contact with skin and if swallowed

R27/28
Very toxic in contact with skin and if swallowed

R36/37
Irritating to eyes and respiratory system

R36/38
Irritating to eyes and skin

R36/37/38
Irritating to eyes, respiratory system and skin

R37/38
Irritating to respiratory system and skin

R39/23
Toxic: danger of very serious irreversible effects through inhalation

R39/24
Toxic: danger of very serious irreversible effects in contact with skin

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

R39/23/24
Toxic: danger of very serious irreversible effects through inhalation and in contact with skin

R39/23/25
Toxic: danger of very serious irreversible effects through inhalation and if swallowed

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

R39/23/24/25
Toxic: danger of very serious irreversible effects through inhalation, in contact with skin and if swallowed

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

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

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

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

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

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

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

R68/20
Harmful: possible risk of irreversible effects through inhalation

R68/21
Harmful: possible risk of irreversible effects in contact with skin

R68/22
Harmful: possible risk of irreversible effects if swallowed

R68/20/21
Harmful: possible risk of irreversible effects through inhalation and in contact with skin

R68/20/22
Harmful: possible risk of irreversible effects through inhalation and if swallowed

R68/21/22
Harmful: possible risk of irreversible effects in contact with skin and if swallowed

R68/20/21/22
Harmful: possible risk of irreversible effects through inhalation, in contact with skin and if swallowed

R42/43
May cause sensitisation by inhalation and skin contact

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

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

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

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

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

R48/21/22
Harmful: danger of serious damage to health by prolonged exposure in contact with skin and if swallowed

R48/20/21/22
Harmful: danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed

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

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

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

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

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

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

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

SCHEDULE 10

Regulations 2 and 14

SAFETY PHRASES

PART I SINGLE SAFETY PHRASES

S 1
Keep locked up.

S 2
Keep out of the reach of children.

S 3
Keep in a cool place.

S 4
Keep away from living quarters.

S 5
Keep contents under ….. (appropriate liquid to be specified by the manufacturer).

S 6
Keep under ….. (inert gas to be specified by the manufacturer).

S 7
Keep container tightly closed.

S 8
Keep container dry.

S 9
Keep container in a well-ventilated place.

S 12
Do not keep the container sealed.

S 13
Keep away from food, drink and animal feedingstuffs.

S 14
Keep away from ….. (incompatible materials to be indicated by the manufacturer).

S 15
Keep away from heat.

S 16
Keep away from sources of ignition - No smoking.

S 17
Keep away from combustible material.

S 18
Handle and open container with care.

S 20
When using do not eat or drink.

S 21
When using do not smoke.

S 22
Do not breathe dust.

S 23
Do not breathe gas/fumes/vapour/spray …. (appropriate wording to be specified by the manufacturer).

S 24
Avoid contact with skin.

S 25
Avoid contact with eyes.

S 26
In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S 27
Take off immediately all contaminated clothing.

S 28
After contact with skin, wash immediately with plenty of …. (to be specified by the manufacturer).

S 29
Do not empty into drains.

S 30
Never add water to this product.

S 33
Take precautionary measures against static discharges.

S 35
This material and its container must be disposed of in a safe way.

S 36
Wear suitable protective clothing.

S 37
Wear suitable gloves.

S 38
In case of insufficient ventilation, wear suitable respiratory equipment.

S 39
Wear eye/face protection.

S 40
To clean the floor and all objects contaminated by this material, use …. (to be specified by the manufacturer).

S 41
In case of fire and/or explosion do not breathe fumes.

S 42
During fumigation/spraying wear suitable respiratory equipment …. (appropriate wording to be specified by the manufacturer).

S 43
In case of fire, use …. (indicate in the space the precise type of fire-fighting equipment. If water increases risk, add - ' Never use water`).

S 45
In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

S 46
If swallowed, seek medical advice immediately and show this container or label.

S 47
Keep at temperature not exceeding …. °C (to be specified by the manufacturer).

S 48
Keep wetted with …. (appropriate material to be specified by the manufacturer).

S 49
Keep only in the original container.

S 50
Do not mix with …. (to be specified by the manufacturer).

S 51
Use only in well-ventilated areas.

S 52
Not recommended for interior use on large surface areas.

S 53
Avoid exposure - obtain special instructions before use.

S 56
Dispose of this material and its container at hazardous or special waste collection point.

S 57
Use appropriate containment to avoid environmental contamination.

S 59
Refer to manufacturer/supplier for information on recovery/recycling.

S 60
This material and its container must be disposed of as hazardous waste.

S 61
Avoid release to the environment. Refer to special instructions/Safety data sheets.

S 62
If swallowed, do not induce vomiting: seek medical advice immediately and show this container or label.

S 63
In case of accident by inhalation: remove casualty to fresh air and keep at rest.

S 64
If swallowed, rinse mouth with water (only if the person is conscious).

PART II COMBINATION SAFETY PHRASES

S 1/2

Keep locked up and out of reach of children.

S 3/7

Keep container tightly closed in a cool place.

S 3/9/14

Keep in a cool, well-ventilated place away from …. (incompatible materials to be indicated by the manufacturer).

S 3/9/14/49

Keep only in the original container in a cool, well-ventilated place away from …. (incompatible materials to be indicated by the manufacturer).

S 3/9/49

Keep only in the original container in a cool, well-ventilated place.

S 3/14

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

S 7/8

Keep container tightly closed and dry.

S 7/9

Keep container tightly closed and in a well-ventilated place.

S 7/47

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

S 20/21

When using do not eat, drink or smoke.

S 24/25

Avoid contact with skin and eyes.

S 27/28

After contact with skin, take off immediately all contaminated clothing and wash immediately with plenty of …. (to be specified by the manufacturer).

S 29/35

Do not empty into drains; dispose of this material and its container in a safe way.

S 29/56

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

S 36/37

Wear suitable protective clothing and gloves.

S 36/37/39

Wear suitable protective clothing, gloves and eye/face protection.

S 36/39

Wear suitable protective clothing and eye/face protection.

S 37/39

Wear suitable gloves and eye/face protection.

S 47/49

Keep only in the original container at a temperature not exceeding …. °C (to be specified by the manufacturer).

SCHEDULE 11

Regulation 15

SPECIAL LABELLING PROVISIONS FOR SINGLE PACKAGES

Labelling of Mobile Gas Cylinders

For mobile gas containers the requirements concerning labelling are considered to be satisfied when they are in agreement with Regulation 15 (7).

However, by way of derogation from Regulation 15 (1) to (4), for gas containers with a water capacity of less than or equal to 150 litres, the format and dimensions of the label can follow the prescriptions of the ISO Standard 7225 (1994 edition) relating to 'Gas cylinders – Precautionary labels'. In this case, the label can bear the generic name or industrial/commercial name of the preparation where the dangerous component substances of the preparation are shown on the body of the gas cylinder in a clear and indelible way.

The information specified in Regulation 14 may be provided on a durable information disc or label held captive on the containers.

Gas containers intended for preparations containing stenched propane, butane or liquefied petroleum gas (LPG)

Propane, butane and liquefied petroleum gas are classified in Annex I. Although preparations containing these substances are classified in accordance with Regulations 10 to 12, they do not present a danger to human health when they are placed on the market in closed refillable cylinders or non-refillable cartridges within the scope on EN 417 as fuel gases which are only released for combustion (EN 417, September 1992 edition, relating to 'Non-refillable metallic gas cartridges for liquefied petroleum gases, with or without a valve, for use with portable appliances; construction, inspection, testing and marking').

These cylinders and cartridges must be labelled with the appropriate symbol and the risk and safety phrases concerning flammability. No information concerning the effects on human health is required on the label. However, the information concerning effects on human health which should have appeared on the label shall be transmitted to the professional user by the person responsible for placing the substance on the market in the format foreseen in Regulation 18. For the consumer, sufficient information shall be transmitted to enable them to take all necessary measures for health and safety as foreseen in Article 1(3) of Directive 91/155/EEC.

Alloys, preparations containing polymers, preparations containing elastomers

These preparations shall be classified according to Regulations 10 to 12, and labelled according to Regulation 14.

However some of these preparations although classified in accordance with Regulations 11 and 12 do not present a danger to human health by inhalation, ingestion or contact with the skin or to the aquatic environment in the form in which they are placed on the market. Such preparations do not require a label according to Regulation 14 or according to Schedule 7, B.9. However, all the information which would have appeared on the label shall be

transmitted to the professional user by means of an information system in a format foreseen in Regulation 18.

Preparations classified with R65

Preparations classified as harmful on the basis of an aspiration hazard need not be labelled as harmful with R65 when placed on the market in aerosol containers or in containers fitted with a sealed spray attachment.

SCHEDULE 12

Regulation 18

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

SCHEDULE 13

Regulation 14(2)

Labelling of a plant protection product

The following wording shall be printed on the label of a plant protection product referred to in Regulation 14(2):

"To avoid risks to man and the environment, comply with the instructions for use."

GIVEN under my Official Seal,

19 February 2004

Mary Harney

Minister for Enterprise,
Trade and Employment

EXPLANATORY NOTE

(*This note is not part of the instrument and does not purport to be a legal interpretation*).

These Regulations transpose Directive 1999/45/EC of the European Parliament and of the Council of 31 May, 1999 on the classification, packaging and labelling of dangerous preparations placed on the market of the E.C. This Directive replaces Council Directive 88/379/EEC. The Regulations also transpose the first adaptation to technical progress (ATP) of Directive 1999/45/EC - Commission Directive 2001/60/EC of 7 August 2001.

The Regulations apply to all dangerous preparations with exceptions for certain categories of preparations such as medicines, cosmetics etc., which are covered by other Council Directives. The Regulations require persons placing a dangerous preparation on the market, to classify and label it according to the inherent hazards including, for the first time, the danger to the environment hazard category. Certain preparations that 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 the Annex V to Directive 1999/45/EC, as amended by Commission Directive 2001/60/EC. The classification, labelling and packaging requirements of these Regulations have also been extended to include plant protection products from 30 July 2004. (Biocides, within the meaning of Council Directive 98/8/EC are covered in the same way as dangerous preparations within the Regulations.)

The requirements for classification and provision of Safety Data Sheets have been extended to explosive and pyrotechnic preparations for the first time.

The Regulations also transpose Commission Directive 2001/58/EC of 27 July 2001, which amends Commission Directive 91/155/EEC of 5 March 1991 concerning the provision of specific information relating to dangerous preparations in the form of Safety Data Sheets, requiring the provision of safety data sheets on request to professional users of certain preparations not classified as dangerous.

The Regulations revoke and replace the European Communities (Classification, Packaging and Labelling of Dangerous Preparations) Regulations, 1995 (S.I. No. 272 of 1995) and the European Communities (Classification, Packaging and Labelling of Dangerous Preparations)(Amendment) Regulations, 1998 (S.I. No. 354 of 1998).