STATUTORY INSTRUMENTS

S.I. No. 116 of 2003

EUROPEAN COMMUNITIES (CLASSIFICATION, PACKAGING, LABELLING AND NOTIFICATION OF DANGEROUS SUBSTANCES) REGULATIONS 2003

(Prn8)

S.I. No. 116 of 2003

EUROPEAN COMMUNITIES (CLASSIFICATION, PACKAGING, LABELLING AND NOTIFICATION OF DANGEROUS SUBSTANCES) REGULATIONS 2003

ARRANGEMENT OF REGULATIONS

REGULATION.

1. Citation
2. Interpretation
3. Construction and Application
4. Exemptions
5. Competent Authority
6. Placing on the Market
7. Testing and assessment
8. Classification
9. Obligation to carry out investigations
10. Full Notification
11. Reduced Notification for substances placed on the market in quantities of less than one tonne per annum
12. Substances Notified at least 10 years previously
13. Notification of Polymers
14. Pre-marketing Notification Period
15. Exemptions from the notification requirements
16. Follow up Information
17. Re-notification of the same substance and avoidance of duplicate testing in vertebrate animals
18. Confidentiality of data
19. Packaging
20. Labelling
21. Implementation of labelling
22. Exemptions from labelling and packaging requirements
23. Advertising
24. Safety Data Sheet
25. Supply of Substances
26. Restriction on Sale
27. Fees Payable by Notifier
28. Taking and Detention of Substances
29. Offences
30. Revocations

Schedule 1
Foreword to Annex I

Schedule 2
Annex II: Symbols and Indications of Danger for dangerous substances and preparations

Schedule 3
Annex III: Nature of special risks attributed to dangerous substances and preparations

Schedule 4
Annex IV: Safety Advice concerning dangerous substances and preparations

Schedule 5
Annex VI: General Classification and Labelling Requirements for dangerous substances and preparations

Schedule 6
Annex VIIA, Annex VIIB, Annex VIIC, Annex VIID and Annex VIII: Information required for the Technical dossier

Schedule 7
Annex IX: Provisions relating to child-proof fastenings and tactile warning devices

Schedule 8
Obligatory Headings for Safety Data Sheets

Schedule 9
Fees Payable by Notifier

S.I. No. 116 of 2003

EUROPEAN COMMUNITIES (CLASSIFICATION, PACKAGING, LABELLING AND NOTIFICATION OF DANGEROUS SUBSTANCES) REGULATIONS 2003

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 Council Directives 92/32/EEC of 30 April 1992[1], Directive 96/56/EC of the European Parliament and the Council of 3 September 1996[2], Commission Directives 91/155/EEC of 5 March 1991[3], 92/69/EEC of 31 July 1992[4], 93/21/EEC of 27 April 1993[5], 93/67/EEC of 20 July 1993[6], 93/72/EEC of 1 September 1993[7], 93/101/EC of 11 November 1993[8], 93/105/EC of 25 November 1993[9], 93/112/EC of 10 December 1993[10], 94/69/EC of 19 December 1994[11], 96/54/EC of 30 July 1996[12], 97/69/EC of 5 December 1997[13], 98/73/EC of 18 September 1998[14], 98/98/EC of 15 December 1998 [15], 2000/32/EC of 19 May 2000[16], 2000/21/EC of 25 April 2000[17], 2000/33/EC of 25 April 2000 [18], 2001/58/EC of 27 July 2001[19] and 2001/59/EC of 6 August 2001[20] hereby make the following regulations:

1. Citation.

These Regulations may be cited as the European Communities (Classification, Packaging, Labelling and Notification of Dangerous Substances) Regulations 2003.

2. Interpretation.

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

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

---

1 O.J. L 154, 5.6.1992, p. 1 and O.J. L 154A, 5.6.1992, p. 1

2 O.J. L 236, 18.9.1996, p. 35

3 O. J.L 76, 22.3.1991, p.35

4 O.J. L 383, 29.12.1992, p. 113 and O.J. L 383A, 29.12.1992, p. 1

5 O.J. L 110, 4.5.1993, p. 20 and O.J. L 110A, 4.5.1993, p. 1

6 O.J. L 227, 8.9.1993, p. 9.

7 O.J. L 258, 16.10.1993 p. 29 and O.J. L 258A, 16.10.1993, p.1

8 O.J. L 13, 15.1.1994, p.1

9 O.J. L 294, 30.11.1993, p. 21

10 O.J. L 314, 16.12.1993, p.38

11 O.J. L 381, 31.12.1994, p.1

12 O.J. L 248, 30.9.1996, p.1

13 O.J. L 343, 13.12. 1997, p. 19

14 O.J. l 305, 16.11.1998, p.1 as corrected by Corrigendum to Commission Directive 98/73/EC of 18 September, 1998, O.J. L285, 8.11.1999, p.1

15 O.J. L355, 30.12.1998, p.1 as corrected by Corrigendum to Commission Directive 98/98/EC of 15 December, 1998, O.J. L293, 15.11.1999, p.1 and Commission Decision of 19 May 2000, correcting Commission Directive 98/98/EC of 15 December, 1998, O.J. L136, 8.6.2000, p108

16 O.J. L 136, 8.6.2000, p. 1

17 O.J. L 103, 28.4.2000, p. 70

18 O.J. L 136, 8.6.2000, p. 90

19 O.J. L212, 7.8.2001, p.24

20 O.J. L225, 21.8.2001, p. 1

"Annex I" means Annex I to Council Directive 67/548/EEC[21] as lastly amended by Commission Directive 2001/59/EC of 6 August 2001, and any reference in the said Annex to "EEC Number" shall be construed as a reference to "EC Number" and which for convenience of reference the Foreword to Annex I is set out in Schedule 1;

"Annex II" means Annex II to Council Directive 67/548/EEC as amended by Commission Directive 93/21/EEC of 27 April 1993 and which for convenience of reference is set out in Schedule 2;

"Annex III" means Annex III to Council Directive 67/548/EEC as lastly amended by Commission Directive 2001/59/EC of 6 August 2001 and which for convenience of reference is set out in Schedule 3;

"Annex IV" means Annex IV to Council Directive 67/548/EEC as lastly amended by Commission Directive 2000/32/EC of 19 May 2000 and which for convenience of reference is set out in Schedule 4;

"Annex V" means Annex V to Council Directive 67/548/EEC as lastly amended by Commission Directive 2001/59/EC of 6 August 2001;

"Annex VI" means Annex VI to Council Directive 67/548/EEC as lastly amended by Commission Directive 2001/59/EC of 6 August 2001 and which for convenience of reference is set out in Schedule 5;

"Annex VII.A " means Annex VII.A to Council Directive 67/548/EEC as lastly amended by Commission Directive 2001/59/EC of 6 August 2001 and which for convenience of reference is set out in Schedule 6;

"Annex VII.B" means Annex VII.B to Council Directive 67/548/EEC as lastly amended by Commission Directive 93/105/EC of 25 November, 1993 and which for convenience of reference is set out in Schedule 6;

"Annex VII.C" means Annex VII.C to Council Directive 67/548/EEC as lastly amended by Commission Directive 93/105/EC of 25 November 1993 and which for convenience of reference is set out in Schedule 6;

"Annex VII.D" means Annex VII.D to Council Directive 67/548/EEC as lastly amended by Commission Directive 93/105/EC of 25 November 1993 and which for convenience of reference is set out in Schedule 6;

"Annex VIII" means Annex VIII to Council Directive 67/548/EEC as lastly amended by Commission Directive 2001/59/EC of 6 August 2001 and which for convenience of reference is set out in Schedule 6;

"Annex IX" means Annex IX of Council Directive 67/548/EEC as lastly amended by Commission Directive 2000/32/EC of 19 May 2000 and which for convenience of reference is set out in Schedule 7.

"Authority" has the meaning assigned to it by Regulation 5;

"child-resistant fastening" means the cap, lid, fastening or other means of fastening a package, which complies with the provisions of Part A of Annex IX;

"competent authority" has the meaning assigned to it by Regulation 5;

21 O.J. 196, 16.8.1967, p. 1

"Directives" means Council Directive 92/32/EEC of 30 April 1992[22], Directive 96/56/EC of the European Parliament and the Council of 3 September 1996[23], Commission Directives 91/155/EEC of 5 March 1991[24], 92/69/EEC of 31 July 1992[25], 93/21/EEC of 27 April 1993[26], 93/67/EEC of 20 July 1993[27], 93/72/EEC of 1 September 1993[28], 93/101/EC of 11 November 1993[29], 93/105/EC of 25 November 1993[30], 93/112/EC of 10 December 1993[31,] 94/69/EC of 19 December 1994[32], 96/54/EC of 30 July 1996[33], 97/69/EC of 5 December 1997[34], 98/73/EC of 18 September 1998[35], 98/98/EC of 15 December 1998 [36], 2000/32/EC of 19 May 2000[37], 2000/21/EC of 25 April 2000[38], 2000/33/EC of 25 April 2000 [39], 2001/58/EC of 27 July 2001[40] and 2001/59/EC of 6 August 2001[41];

"dossier" means a "notification dossier";

"EINECS" means the European Inventory of Existing Commercial Substances[42] containing the definitive list of all substances deemed to be on the market in the European Communities on 18 September 1981;

"ELINCS" means the European List of Notified Chemical Substances[43], 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;

"indication of danger" means the indication of danger specified in Schedule 2 and required to be contained on the label or marked on the package of a dangerous substance in accordance with Regulation 20;

"inspector" has the same meaning as in the Act of 1989;

---

22 O.J. L 154, 5.6.1992, p. 1 and O.J. L 154A, 5.6.1992, p. 1

23 O.J. L 236, 18.9.1996, p. 35

24 O. J.L 76, 22.3.1991, p.35

25 O.J. L 383, 29.12.1992, p. 113 and O.J. L 383A, 29.12.1992, p. 1

26 O.J. L 110, 4.5.1993, p. 20 and O.J. L 110A, 4.5.1993, p. 1

27 O.J. L 227, 8.9.1993, p. 9.

28 O.J. L 258, 16.10.1993 p. 29 and O.J. L 258A, 16.10.1993, p.1

29 O.J. L 13, 15.1.1994, p.1

30 O.J. L 294, 30.11.1993, p. 21

31 O.J. L 314, 16.12.1993, p.38

32 O.J. L 381, 31.12.1994, p.1

33 O.J. L 248, 30.9.1996, p.1

34 O.J. L 343, 13.12. 1997, p. 19

35 O.J. l 305, 16.11.1998, p.1 as corrected by Corrigendum to Commission Directive 98/73/EC of 18 September, 1998, O.J. L285, 8.11.1999, p.1

36 O.J. L355, 30.12.1998, p.1 as corrected by Corrigendum to Commission Directive 98/98/EC of 15 December, 1998, O.J. L293, 15.11.1999, p.1 and Commission Decision of 19 May 2000, correcting Commission Directive 98/98/EC of 15 December, 1998, O.J. L136, 8.6.2000, p108

37 O.J. L 136, 8.6.2000, p. 1

38 O.J. L 103, 28.4.2000, p. 70

39 O.J. L 136, 8.6.2000, p. 90

40 O.J. L212, 7.8.2001, p.24

41 O.J. L225, 21.8.2001, p. 1

42 O.J. C 146A, 15.6.1990, p.1

43 O.J. C 361, 7.12.1994, p.1

“international rules on the transport of dangerous substances” means any of the following (including amendments made to any of them):

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

(b) the International Regulations Concerning the Carriage of Dangerous Goods by Rail appended to the International Convention Concerning the Carriage of Dangerous Goods by Rail, 1980, and

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

"label" means the label referred to in Regulations 20 and 21 and labelling shall be construed accordingly;

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

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

"notification" means the documents, with the requisite information, presented to the competent authority of a Member State;

"notifier" means the person submitting a notification;

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

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

"placing on the market" means the making available to third parties, and importation into the European Communities customs territory shall be deemed to be placing on the market for the purposes of these Regulations;

"polymer" means a substance consisting of molecules characterised by the sequence of one or more types of monomer units and comprising a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant, and consisting of less than a simple weight majority of molecules of the same molecular weight, such molecules being distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units;

"preparations" means mixtures or solutions composed of two or more substances;

"process-orientated research and development" means the further development of a substance in the course of which pilot plant or production trials are used to test the fields of application of the substance;

"risk phrase" means any phrase which is listed in Annex III;

"safety phrase" means any phrase which is listed in Annex IV;

"scientific research and development" means scientific experimentation, analysis or chemical research carried out under controlled conditions and includes the determination of intrinsic properties, performance and efficacy as well as scientific investigation related to product development;

"sole representative" means the person established in the European Communities who is so designated by the manufacturer of a substance manufactured outside the European Communities for the purposes of submitting a notification for that substance placed on the market, either on its own or in a preparation;

"substance" means a chemical element and its 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 Annex II;

"tactile warning of danger" means a method of warning a person who has poor sight or no sight of the dangerous contents of a package referred to in Regulation 19, and which complies with the provisions of Part B of Annex IX;

(2) 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 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;

(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 highly 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 preparations, 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 preparations 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 the 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.

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

(b) In these Regulations a 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.

(c) Any requirement in these Regulations in relation to a substance shall apply to a substance to which these Regulations apply, unless otherwise indicated.

(d) A word or expression that is used in these Regulations and is also used in the Directives has, unless the contrary intention appears, the same meaning in these Regulations as it has in the Directives.

3. Construction and application.

(1) The Act of 1989 shall 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 to the Second Schedule of that Act.

(2) These Regulations apply to all substances, which are intended to be placed on the market either on their own or in a preparation, unless exempted under Regulation 4, 15 or 22.

(3) The testing and notification requirements of these Regulations apply to substances not listed in the EINECS, which are intended to be placed on the market either on their own or in a preparation.

(4) The classification requirements of these Regulations apply to all dangerous substances which are intended to be placed on the market.

(5) The packaging, labelling and safety data sheet requirements of these Regulations apply to substances, classified as dangerous under these Regulations, which are placed on the market.

4. Exemptions

(1) These Regulations shall 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 Directive 65/65/EEC[44] as lastly amended by Commission Directive 93/39/EEC[45]

(b) cosmetic products, as defined by Directive 76/768/EEC[46] as lastly amended by Commission Directive 98/62/EC[47]

(c) mixtures of substances which, in the form of waste, are the subject of Directives 75/442/EEC[48] as lastly amended by Commission Decision 96/350/EEC[49] and 91/689/EEC[50] as lastly amended by Council Directive 94/31/EEC[51] ,

44 O.J. 22, 9.2.1965, p. 369
45 O.J. L214, 24.8.1993 p22
46 O.J. L 262, 27.9. 1976, p. 169
47 O.J. L253, 15.9.1998, p20
48 O.J. L 194, 15.7. 1975 p. 39
49 O.J. L135, 6.6.1996, p32
50 O.J. L377, 31.12.1991, p20
51 O.J. L168, 2.7.1994, p28

(d) foodstuffs,

(e) animal feeding stuffs,

(f) pesticides,

(g) radioactive substances, as defined by Directive 80/836/EEC[52] , and

(h) other substances or preparations for which European Communities notification or approval procedures exist and for which requirements relating to notification or approval are equivalent to those required by these Regulations.

(2) These Regulations shall not apply to -

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

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

5. Competent authority.

The competent authority shall be the National Authority for Occupational Safety and Health established by Part III of the Act of 1989.

6. Placing on the market.

(1) A person shall not place on the market a substance to which these Regulations apply either on its own or in a preparation unless it has been notified, packaged and labelled, and safety data sheets have been provided in accordance with these Regulations.

(2) The notification referred to in paragraph (1) shall, for substances manufactured in the State, be submitted to the competent authority by the manufacturer concerned.

(3) The notification referred to in paragraph (1) shall, for substances manufactured outside the European Communities, be submitted to the competent authority, by any person established in the State who is responsible for placing the substance either on its own or in a preparation on the market, or by the person established within the State who is, for the purposes of submitting a notification for a given substance placed on the market, either on its own or in a preparation, designated by the manufacturer as his sole representative.

52 O.J. L 246,17..9. 1980, p. 1

(3) Paragraph (1) shall not apply to a substance placed on the market in quantities of less than one tonne per annum for any manufacturer which was notified under the European Communities (Dangerous Substances) (Classification, Packaging, Labelling and Notification) Regulations, 1982 (S.I. No. 258 of 1982); provided that –

(a) the substance has been notified in the State prior to the commencement of these Regulations, and

(b) the substance concerned has been manufactured by the same manufacturer of the substance to which the notification referred to in subparagraph (a) relates.

7. Testing and assessment.

(1) For the purposes of these Regulations -

(a) tests on substances shall as a general principle be conducted according to the methods laid down in Annex V,

(b) the physico-chemical properties of substances shall be determined according to the methods specified in Annex V (A),

(c) the toxicity of substances shall be determined according to the methods specified in Annex V (B),

(d) the ecotoxicity of substances shall be determined according to the methods specified in Annex V (C),

(e) laboratory tests on substances shall be carried out in compliance with the principles of good laboratory practice provided for in Directive 86/609/EEC[53] and Directive 87/18/EEC[54], and

(f) for substances on the EINECS, the adequacy of the data for the purposes of classification and labelling and the need to conduct new tests shall be decided on a case-by-case basis taking into account the need to minimise testing on vertebrate animals.

53 O.J. L 358, 18.12. 1986, p. 1

54 O.J. L 15, 17.1. 1987, p. 29

(2) (a) Where more than one notification exists for a substance manufactured by the same manufacturer outside the European Communities, the obligation to carry out supplementary testing required under these Regulations will fall collectively on all notifiers placing that substance on the market;

(b) For substances referred to in subparagraph (a), if the quantities detailed in Regulation 10(3) are attained, the competent authority shall each notifier and inform him of the identity of the other notifiers and shall draw his attention to the provisions of subparagraph (a).

(3) Where it is necessary in the opinion of the competent authority for the purposes of carrying out the evaluation of the risks which may be caused by a substance in accordance with Directive 93/67/EEC, the competent authority may ask for further information, verification or confirmatory tests concerning the substances or their transformation products of which they have been notified or have received information under these Regulations and may also request information referred to in Annex VIII earlier than provided for in Regulation 10(3).

8. Classification.

(1) For the purposes of these Regulations a dangerous substance 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) Dangerous substances shall be classified and labelled in accordance with the criteria in Annex VI.

(3) In classifying a substance account shall be taken of the concentration of any impurity in as far as the latter exceeds the concentration limits specified in Annex I and Article 3(3) of Directive 1999/45/EC[55].

9. Obligation to carry out investigation

Manufacturers, distributors and importers of dangerous substances, which appear in the EINECS but which hsve not yet been introduced into Annex 1 shall carry out an investigation to make themselves aware of the relevant and accessible data existing concerning the properties of such substances, and on the basis of this information shall package and provisionally label these substances in accordance with Regulations 19 to 21 and the criteria specified in Annex VI.

10. Full Notification

(1) A notifier intending to place on the European Communities market a substance in quantities of greater than or equal to one tonne per annum per manufacturer shall submit to the competent authority, a notification including -

(a) a technical dossier supplying the information necessary for evaluating the foreseeable risks, whether immediate or delayed, which the substance may entail for man and the environment, and containing all available relevant data for this purpose,

(b) a declaration concerning the unfavourable effects of the substance in relation to the various foreseeable uses,

(c) the proposed classification and labelling of the substance in accordance with these Regulations,

(d) in the case of dangerous substances, a proposal for a safety data sheet in accordance with Regulation 24,

(e) in the case of a manufacturer located outside the European Communities, a statement if appropriate from the manufacturer to the effect that, for the purpose of submitting a notification for the substance in question, he is designated as the manufacturer's sole representative,

55 O.J. L200, 30.7.2000, p.1

(f) if so desired by the notifier, a statement requesting on reasoned grounds that as a first notifier of a substance the notification be exempted from the provisions of Regulation 17(2) for a maximum period which shall not in any case exceed one year following the date of notification,

(g) if so desired by the notifier, a preliminary assessment of the real or potential risk to man and the environment on the basis of the principles adopted in Directive 93/67/EEC.

(2) A dossier required by paragraph (1) (a) shall contain the information and results of the studies referred to in Annex VII.A, together with a detailed and full description of the studies conducted and of the methods used or a bibliographical reference to them.

(3) Notwithstanding anything in Regulation 16, a notifier of a substance already notified shall inform the competent authority -

(a) when the quantity of the substance placed on the market reaches 10 tonnes per year per manufacturer or when the total quantity placed on the market reaches 50 tonnes per manufacturer, and in such case the competent authority may require some or all of the additional tests and studies laid down in Annex VIII, level 1, to be carried out within such period as it determines;

(b) when the quantity of the substance placed on the market reaches 100 tonnes per year per manufacturer or when the total quantity placed on the market reaches 500 tonnes per manufacturer, and in such case the competent authority shall require the additional tests and studies laid down in Annex VIII, level 1, to be carried out within such period as it determines, unless the notifier can give good reason why a particular test or study is not appropriate or an alternative scientific test or study would be preferable;

(c) when the quantity of a substance placed on the market reaches 1,000 tonnes per year per manufacturer or when the total quantity placed on the market reaches 5,000 tonnes per manufacturer, and in such case the competent authority shall draw up a programme of tests and studies according to Annex VIII, level 2, to be carried out by the notifier within such period as the competent authority determines.

(4) When additional tests or studies are carried out either in accordance with the requirements of paragraph (3) or voluntarily, the notifier shall provide the competent authority with the results of such tests or studies.

(5) Where a notifier requests the competent authority to grant permission to apply a reduced test package (RTP) for intermediates in accordance with Annex VIIA, section 7, or Annex VIII, Level 1, then the notifier shall:

(a) at any time at the request of the competent authority provide verification by an independent competent person, chosen in agreement with the competent authority and paid for by the notifier, that the conditions for application of the RTP are being applied on the site, or sites, in question, and

(b) immediately upgrade the dossier to the appropriate level, as if the RTP criteria did not apply, if in the opinion of the competent authority such verification is not demonstrated within such period as the competent authority determines.

(6) Notwithstanding paragraph (5) where the competent authority finds that any of the conditions for application of the RTP are not being applied on the site, or sites, for which a dossier has been accepted it shall so inform the notifier who shall upgrade the dossier to the appropriate level, as if the RTP criteria did not apply.

11. Reduced Notification for substances placed on the market in quantities of less than one tonne per annum

(1) Subject to Regulation 15(2), a notifier intending to place on the European Communities market a substance in quantities of less than one tonne per annum per manufacturer shall submit to the competent authority a notification including the information referred to in Regulation 10(1).

(2) A dossier required by paragraph (1) shall contain the information and results of the studies referred to in Annex VII.B, together with a full and detailed description of the studies conducted and of the methods used or a bibliographical reference to them if the competent authority so requires.

(3) When the quantities to be placed on the market are below 100kg per year per manufacturer the notifier may, without prejudice to Regulation 7(3), restrict the information in the technical dossier referred to in paragraph (2) to that provided for in Annex VII.C.

(4) In the case of a notifier who has submitted a reduced notification dossier under paragraph (3), he shall, before the quantity of the substance placed on the market reaches 100 kg per year per manufacturer or before the total quantity placed on the market reaches 500 kg per manufacturer, provide the competent authority with the additional information necessary to complete the technical dossier to the level referred to in paragraph (2).

(5) In the case of a notifier who has submitted a reduced notification dossier under paragraph (1) he shall, before the quantity of the substance placed on the market reaches 1 tonne per year per manufacturer, or before the total quantity placed on the market reaches 5 tonnes per manufacturer, submit a full notification in accordance with Regulation 10.

(6) The substances notified under paragraphs (1) and (3) shall, in so far as the notifier may reasonably be expected to be aware of their dangerous properties, be packaged and provisionally labelled in accordance with Regulations 19 to 21.

(7) Where it is not possible to label substances in accordance with Regulation 20, because all the results of tests provided for in Annex VII.A are not available, the label shall bear, in addition to the label deriving from the tests already carried out, the warning "Caution - substance not yet fully tested".

12. Substances notified at least 10 years previously

Where the information specified in Annex VII.A, VII.B, VII.C or VII.D is required in accordance with these Regulations, a notifier need only supply items 1 and 2 of the relevant Annex in the case of a substance for which the information was originally submitted at least 10 years previously.

13. Notification of Polymers

In the case of polymers, the provisions concerning the technical dossiers contained in the notifications referred to in Regulations 10(2) and 11(2) shall be construed as if the reference to Annex VII.A and Annex VII.B respectively were a reference to Annex VII.D.

14. Pre-marketing Notification Period

(1) (a) Substances notified under Regulation 10 may, in the absence of any indication to the contrary from the competent authority, be placed on the market no sooner than 60 days after receipt by the competent authority of a dossier in conformity with the requirements of these Regulations.

(b) Where the competent authority considers that the dossier is not in conformity with these Regulations and advises the notifier accordingly, the substance may be placed on the market no sooner than 60 days after receipt by the competent authority of the information necessary to bring the notification into conformity with these Regulations.

(2) (a) Substances notified under Regulation 11(1) or 11(3) may, in the absence of any indication to the contrary from the competent authority, be placed on the market no sooner than 30 days after receipt by the competent authority of a dossier in conformity with the requirements of these Regulations.

(b) Where the competent authority considers that the dossier is not in conformity with these Regulations and advises the notifier accordingly, the substance may be placed on the market no sooner than 30 days after receipt by the competent authority of the information necessary to bring the notification into conformity with these Regulations.

(c) Notwithstanding subparagraph (a) where the notifier has received notice from the competent authority of the official number which has been allocated to his notification indicating acceptance of the dossier, the substance may be placed on the market no sooner than 15 days after receipt of the dossier by the competent authority.

15. Exemptions from the notification requirements

(1) The following substances shall be exempt from the notification requirements specified in these Regulations –

(a) substances which appear on the EINECS inventory,

(b) additives and substances for exclusive use in animal feeding stuffs and to which Directives 70/524/EEC[56] and 82/471/EEC[57] apply,

(c) substances used exclusively as additives in foodstuffs, to which Directive 89/107/EEC[58] applies, and substances used exclusively as flavourings in foodstuffs to which Directive 88/388/EEC[59] applies,

(d) active ingredients used exclusively in medicinal products for human or veterinary use, as defined in Directive 65/65/EEC as amended by Commission Directive 93/39/EEC,

(e) substances for exclusive use in other product sectors for which European Communities notification or approval procedures exist, as set out in the Annex to Commission Directive 2000/21/EC of 25 April 2000, and for which the requirements for data submission are equivalent to those laid down in these Regulations, and

(f) substances manufactured in the European Communities, which are not included in EINECS or ELINCS but are intended solely for export outside the European Communities, provided the manufacturer notifies such substances to the competent authority, and in relation to which such notification includes the following information -

56 O.J. L 270, 14.12. 1970, p. 1
57 O.J. L 213, 21.7. 1982, p. 8
58 O.J. L 40, 11.2. 1989, p. 27
59 O.J. L 184, 15.7. 1988, p. 61

(i) the identity of the substance in accordance with point 1 of Annex VII.C,

(ii) the quantity of the substance to be exported,

(iii) the country of destination of the substance,

(iv) information on the hazards of the substance, where available,

(v) the proposed labelling of the substance, and

the competent authority may communicate the contents of such notifications to the Commission and the competent authorities of other Member States.

(2) The following substances shall be considered as having been notified within the meaning of these Regulations-

(a) polymers, with the exception of those which contain in combined form 2% or more of any substance which is not on EINECS;

(b) substances placed on the market in quantities of less than 10 kg per year per manufacturer;

(c) substances placed on the market in quantities not exceeding 100 kg per manufacturer per year, and intended solely for purposes of scientific research and development carried out under controlled conditions, provided the manufacturer or importer maintains written records, containing the identity of the substance labelling data, quantities and a list of customers involved, which shall be made available upon request to the competent authorities of each Member State where the manufacture, importation or scientific research and development takes place; and

(d) without prejudice to the provisions of paragraph (3)(a), substances placed on the market for the purposes of process-orientated research and development with a limited number of registered customers in quantities which are limited to the purpose of process-orientated research and development.

3(a) Substances referred to in paragraph (2)(d) shall qualify for an exemption for a period of one year if the manufacturer or importer communicates their identity, labelling data, quantity, the justification for the quantity and a list of customers and the research and development programme to the competent authorities of each Member State where the manufacture, importation or process-orientated research and development takes place

and complies with any conditions imposed by these authorities or the Member States on such research and development**,** and the conditions imposed by the competent authorities or the Member States may include information not exceeding that provided for in Annex VII.C for quantities less than 500 kg, Annex VII.B for quantities between 500 kg and less than 1 tonne, and Annex VII.A for other quantities.

(b) The manufacturer or importer shall also give an assurance to the competent authority that the substance or the preparation in which it is incorporated will be handled only by customers' staff in controlled conditions and will not be made available to the general public at any time either on its own or in a preparation.

(c) Where the competent authority considers that there may exist an unacceptable risk for man and the environment, it may restrict any product, containing a new substance, which was produced during the process-orientated research and development.

(d) The one-year exemption period referred to in subparagraph (a) may be extended for a further year where the notifier can demonstrate, to the satisfaction of the competent authority that such an extension is justified.

(4) (a) A substance referred to in paragraph (2) shall, where the manufacturer may reasonably be expected to be aware of its dangerous properties, be packaged and provisionally labelled by the manufacturer or his representative in accordance with Regulations 19 to 21.

(b) Where it is not possible to label the substances completely and in accordance with Regulation 20, because the results of all tests provided for in Annex VII.A are not available, the label shall bear, in addition to the label deriving from the tests already carried out, the warning "Caution - substance not yet fully tested".

(c) Where a substance referred to in paragraph (2) is labelled as very toxic, toxic, carcinogenic, toxic for reproduction, or mutagenic in accordance with Regulation 20, the manufacturer or importer of such a substance shall submit to the competent authority any appropriate information specified in Annex VII.A, Sections 2.3, 2.4 and 2.5, including, where available, acute toxicity data.

(5) Where the information specified in Annex VII.A, VII.B, VII.C or VII.D, is required in accordance with these Regulations a notifier need only supply items 1 and 2 of the relevant Annex in the case of a substance for which the information was originally submitted at least 10 years previously.

16. Follow-up Information

(1) Any notifier of a substance already notified in conformity with Regulation 10(1) or Regulation 11(1) shall inform the competent authority in writing of any –

(a) change in the annual or total quantities placed on the market by him or, by him or others as the case may be where he is the sole representative for a substance manufactured outside the European Communities,

(b) new knowledge of the effects of the substance on man of which he may reasonably be expected to have become aware,

(c) new knowledge of the effects of the substance on the environment of which he may reasonably be expected to have become aware,

(d) new uses for which the substance is placed on the market of which he may reasonably be expected to have become aware,

(e) change in the composition of the substance as given in section 1.3 of each of Annexes VII.A, VII.B, VII.C and VII.D,

(f) change in his status as manufacturer or importer.

(2) An importer of a substance produced by a manufacturer established outside the European Communities who imports the substance under a notification previously submitted by a sole representative shall ensure that the sole representative is provided with up-to-date information concerning the quantities of the substance placed on the market by him.

(3) Where the sole representative ceases to act in that capacity the importer shall submit the information required under paragraph (2) to such other sole representative as may exist or, in his absence, to the competent authority.

17. Re-notification of the same substance and avoidance of duplicate testing on vertebrate animals

(1) In the case of a substance which has already been notified in accordance with Regulation 10(1) or 11(1), the competent authority may agree that the subsequent notifier of that substance may, for the purposes of sections 3, 4 and 5 of each of Annexes VII.A, VII.B and VII.D and sections 3 and 4 of Annex VII.C, refer to the results of the tests and studies forwarded by the first notifier, in so far as the subsequent notifier can provide evidence that the substance renotified is the same as the one previously notified, including the degree of purity and the nature of impurities, but the first

notifier shall give his agreement in writing to the references to the results of the tests and studies he has forwarded before such reference can be made.

(2) Before carrying out testing on vertebrate animals for the purpose of submitting a notification under Regulations 10(1) or 11(1) and notwithstanding paragraph (1), prospective notifiers shall enquire of the competent authority as to -

(a) whether or not the substance they intend to notify has already been notified;
(b) the name and address of the first notifier, and

this enquiry shall be supported by evidence that the prospective notifier intends to place the substance on the market and, specify the quantities involved.

(3) Where a substance has been previously notified and the competent authority is satisfied with the evidence provided under paragraph (2), it shall supply the prospective notifier with the name and address of the first notifier and shall inform the first notifier of the name and address of the prospective notifier except where the first notifier has requested and been granted a temporary exemption from the provisions of this paragraph.

(4) The first notifier and the prospective notifier shall take all reasonable steps to reach an agreement on the sharing of information so as to avoid the duplication of testing on vertebrate animals.

(5) Notifiers of the same substance who have agreed to share information relating to Annex VII.A, VII.B, VII.C or VII.D in accordance with paragraphs (1) and (4) shall take all necessary steps to reach an agreement on the sharing of information derived from testing on vertebrate animals submitted in conformity with Regulation 10(3).

(6) Where notifiers and prospective notifiers of the same substance cannot reach an agreement on the sharing of data, the competent authority may require notifiers and prospective notifiers to share the data with a view to avoiding duplicative testing on vertebrate animals and may determine the procedure for utilizing information.

18. Confidentiality of data

(1) A notifier may, in a submission made under Regulations 10, 11 or 17, indicate the information required by these Regulations which the notifier considers to be commercially sensitive and disclosure of which could cause industrial or commercial damage to that notifier, and in respect of which that notifier requires to be kept secret from all persons other than the competent authority and the Commission, and shall give full justification in such cases.

(2) Industrial and commercial secrecy shall not apply to -

(a) the trade name of the substance,

(b) the name of the manufacturer and the notifier,

(c) physico-chemical data concerning the substance in connection with section 3 of each of Annexes VII.A, VII.B, VII.C, and VII.D,

(d) the possible ways of rendering the substance harmless,

(e) the summary results of the toxicological and ecotoxicological tests,

(f) the degree of purity of the substance or the identity of impurities or additives which are known to be dangerous within the meaning of these Regulations, if essential to classification and labelling for the purpose of introducing the substance into Annex I,

(g) the recommended methods and precautions referred to in Annexes VII.A, VII.B, VII.C, and VII.D, section 2.3, and the emergency measures referred to in Annex VII.A, VII.B, VII.C and VII.D, sections 2.4 and 2.5,

(h) the information contained in the safety data sheet,

(i) in the case of substances in Annex I, analytical methods that make it possible to detect a dangerous substance when discharged into the environment as well as to determine the direct exposure of humans.

(3) Where the notifier, manufacturer or importer himself subsequently discloses previously confidential information, he shall inform the competent authority accordingly.

(4) The competent authority, on receipt of information under Regulation 10, 11 or 17 shall decide at its discretion which information is covered by industrial and commercial secrecy in accordance with paragraph (1).

(5) Confidential information brought to the attention of the competent authority shall be kept secret by it.

(6) In all cases such confidential information -

(a) may be brought to the attention only of the Commission and the competent authority of another Member State,

(b) may, when administrative or legal proceedings involving sanctions are undertaken for the purpose of controlling substances placed on the market, be divulged to persons directly involved in such proceedings,

(c) may be divulged to persons directly involved in providing medical information in the case of exposure or likely exposure of persons to the substance, especially in emergencies, and such information may only be used to formulate preventative and curative measures in relation to exposure of persons to the substance.

(7) For a substance appearing in ELINCS which is not classified as dangerous for the purpose of these Regulations, its name may be included in the form of its trade name when requested by the competent authority.

(8) Substances referred to in paragraph (7) may be included in ELINCS in the form of their trade name for a maximum of three years unless the competent authority considers that the publication of the chemical name in the International Union of Pure and Applied Chemistry (IUPAC) nomenclature itself could reveal information concerning commercial exploitation or manufacture, in which case the name of the substance may be recorded under its trade name alone for as long as the competent authority sees fit.

(9) Dangerous substances to which these Regulations apply may, at the request of the competent authority, be entered on ELINCS in the form of their trade names alone until such time as they are introduced into Annex I.

(10) "Industrial and commercial secrecy" shall be construed in accordance with paragraph (1).

19. Packaging

A dangerous substance to which these Regulations apply shall not be placed on the market unless its packaging satisfies the following requirements -

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

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

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

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

(e) containers, containing dangerous substances which are offered or sold to the general public, and which are labelled "very toxic", "toxic" or "corrosive" as defined in these Regulations must have a child resistant fastening and bear a tactile warning of danger,

(f) containers, containing dangerous substances which are offered or sold to the general public, and which are labelled "harmful", "extremely flammable" or "highly flammable" as defined in these Regulations must bear a tactile warning of danger.

20. Labelling

(1) A dangerous substance to which these Regulations apply shall not be placed on the market unless the labelling on its packaging shows clearly and indelibly the following -

(a) the name of the substance under one of the designations given in Annex I, or, if the substance is not yet listed in Annex I, a name using an internationally recognised designation for that substance,

(b) the name and full address, including the telephone number, of the person established in the European Communities who is responsible for placing the substance on the market,

(c) danger symbols, if required, and an indication of the danger involved in the use of the substance,

(d) standard phrases (risk phrases) indicating the special risks arising from the dangers involved in using the substance,

(e) standard phrases (safety phrases) relating to the safe use of the substance,

(f) the EC number, if allocated, and

(g) for substances listed in Annex I, the words "EC label".

(2) Subject to paragraphs (3) and (5) -

(a) the design of danger symbols and the wording of the indications of danger shall comply with those laid down in Annex II;

(b) the danger symbol shall be printed in black on an orange-yellow background; and

(c) the danger symbols and indications of danger to be used for each substance shall –

(i) for substances listed in Annex I, be those indicated in that Annex; and

(ii) for substances not listed in Annex I, be assigned according to the rules laid down in Annex VI.

(3) When more than one danger symbol is assigned to a substance, the following requirements apply-

(a) the obligation to indicate the symbol T makes the symbols X and C optional, unless Annex I provides otherwise;

(b) the obligation to indicate the symbol C makes the symbol X optional; and

(c) the obligation to indicate the symbol E makes the symbol F and O optional.

(4) Subject to paragraph (8) -

(a) the wording of risk phrases shall comply with that laid down in Annex III,

(b) the risk phrases to be used for each substance shall -

(i) be as indicated in Annex I, and

(ii) for dangerous substances not yet appearing in Annex I the risk phrases to be used shall be assigned according to the rules laid down in Annex VI.

(5) The requirement to label with the symbol “Xn”, the indication of danger “Harmful” and the risk phrase R65 "Harmful: may cause lung damage if swallowed" shall not apply to substances which are placed on the market in aerosol containers or in containers fitted with a sealed spray attachment.

(6) Subject to paragraph (8) -

(a) the wording of safety phrases shall comply with that laid down in Annex IV, and

(b) the safety phrases to be used for each dangerous substance shall –

(i) be as indicated in Annex I,

(ii) for dangerous substances not yet appearing in Annex I, the safety phrase to be used shall be as assigned according to the rules laid down in Annex VI.

(7) The EC number shall be obtained from the EINECS or from the ELINCS.

(8) An indication of risk phrases and safety phrases need not be given if the package contains 125 millilitres or less of -

(a) an irritant, highly flammable, flammable or oxidising substance, or

(b) a harmful substance that is not retailed to the general public.

(9) Indications such as "non-toxic", "non-harmful" or any other similar indications shall not appear on the label or packaging of substances to which these Regulations apply.

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

(11) Subject to Regulation 22(2)(b), gas cylinders placed on the market and intended for propane, butane or liquefied petroleum gas shall be labelled in accordance with the requirements of these Regulations.

(12) Information regarding effects on human health is not required on the label of gas containers intended for propane, butane or liquefied petroleum gas if –

(a) the propane, butane or liquefied petroleum gas is placed on the market in closed refillable cylinders or in non-refillable cartridges within the scope of ISEN 417 1993 as fuel gases which are only released for combustion,

(b) the information regarding effects on human health is transmitted, in the format required by Regulation 24, to professional or industrial users, distributors, wholesalers, retailers and consumers by the person placing the propane, butane or liquefied petroleum gas on the market, and

(c) sufficient information regarding effects on human health is transmitted to consumers to enable them to take all necessary measures for health and safety as indicated in Article 1 paragraph 3 of Commission Directive 91/155/EEC of 5 March, 1991, as modified by Commission Directive 93/112/EEC of 10 December, 1993 and Commission Directive 2001/58/EC of 27 July 2001.

(13) For the purpose of paragraph 12 (a), “ISEN 417 1993” means Irish Standard ISEN 417 1993 of the National Standards Authority of Ireland.

21. Implementation of labelling

(1) Where the particulars required by Regulation 20 appear on a label, that label shall be firmly affixed to one or more surfaces of the packaging so that these particulars can be read horizontally when the package is set down normally.

(2) The dimensions of such a label shall be as follows -

	Capacity of the package	*Dimensions (in millimetres)*
-	Not exceeding three litres:	if possible at least 52 x 74
-	Greater than three 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) Each symbol required by Regulation 20 shall cover at least one-tenth of the surface area of the label but not be less than one square centimetre (1 cm^2), and the entire surface of the label shall adhere to the package immediately containing the substance.

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

(5) 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.

(6) The information required on a label by Regulation 20 shall stand out clearly from its background and shall be of such size and spacing as to be easily read and shall be in accordance with the provisions of Annex VI.

22. Exemptions from labelling and packaging requirements

(1) The packaging and labelling requirements of Regulations 19 to 21 shall not apply to munitions and explosives placed on the market with a view to producing a practical effect by explosion or a pyrotechnic effect.

(2) For the purpose of these Regulations, labelling requirements shall be deemed to be satisfied -

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

substances and the inner package or packages are labelled in accordance with Regulations 20 and 21; and

(b) in the case of a single package if such a package is labelled in accordance with international rules on the transport of dangerous substances and with Regulations 20(1)(a), (b), (d), (e) and (f), and where appropriate, for particular types of packaging such as mobile gas cylinders, in accordance with the specific requirements referred to in Annex VI.

(3) The packaging of dangerous substances which are not explosive, very toxic or toxic may be unlabelled or may be labelled in such other way as may be approved by the competent authority if they contain such small quantities that there is no reason to fear any danger to persons handling such substances or to other persons.

(4) The packaging of dangerous substances which are explosive, very toxic or toxic may be labelled in such other way as may be approved by the competent authority if they are too small for labelling in accordance with Regulations 20 and 21 and there is no reason to fear any danger to persons handling such substances or to other persons.

(5) The labelling required on packages which are either too small or otherwise unsuitable for labelling in accordance with Regulations 20 and 21 may be applied on packages in such other appropriate manner as may be approved by the competent authority.

(6) A derogation under paragraph (3), (4), or (5) shall not permit the use of symbols, indications of danger, risk phrases or safety phrases different from those required by these Regulations.

(7) Where dangerous substances do not leave the State, the competent authority may permit labelling that complies with national rules relating to the transport of dangerous substances.

23. Advertising

A person shall not publish any advertisement for a substance which belongs to one or more of the categories referred to in Regulation 8(1)(a) to (o) unless mention is made in the advertisement of the category or categories concerned.

24. Safety Data Sheet

(1) A person placing a dangerous substance to which these Regulations apply on the market shall prepare a safety data sheet giving information on that substance.

(2) A safety data sheet shall be amended by the person who provides it when any new information of a significant nature so requires.

(3) At, or before the first delivery, following the commencement of these Regulations, the manufacturer, importer or distributor of a dangerous substance to which these Regulations apply shall communicate the safety data sheet to any recipient who is a professional or industrial user, distributor, wholesaler or retailer of the substance.

(4) The safety data sheet referred to in paragraph (3) shall be provided free of charge to the recipient and may be communicated on paper or electronically.

(5) An amended safety data sheet referred to in paragraph (2) 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.

(6) Without prejudice to paragraphs (3) and (4), recipients or users of a dangerous substance shall on request be provided with the safety data sheet by the supplier of the substance to them.

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

(8) 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.

(9) (a) A safety data sheet required to be provided in accordance with this Regulation shall contain information on the dangerous substance under the headings set out in Schedule 8 and shall contain those headings.

(b) The information required to be contained in the safety data sheet in accordance with subparagraph (a) shall be compiled in accordance with the guidelines laid down in the Annex to Directive 2001/58/EC.

(c) The information required under subparagraph (a) shall include -

(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.

25. Supply of Substances

A notifier shall supply to the competent authority on request such quantities of a notified substance as the competent authority deems necessary for the carrying out of verification tests.

26. Restriction on Sale

Where the competent authority is of opinion that a substance, although satisfying the requirements of these Regulations, constitutes a hazard for man or the environment by reason of its classification, packaging or labelling, the competent authority may, by notice in writing to the person who placed the substance on the market, prohibit the sale of that substance or subject its placing on the market to special conditions.

27. Fees Payable by Notifier

The fee specified in column 2 of Schedule 9 shall be payable in advance by a notifier to the competent authority in relation to any matter referred to in the corresponding entry in column 1 of that Schedule.

28. Taking and Detention of Substances

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

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

(a) require things specified in the notice to be done in relation to the substance before it is released by an inspector; and

(b) may -

(i) require the disposal of the substance 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) indictate the inspector's intention of disposing of the substance at the expense of the owner,

and such disposal to be, in either case, such as will prevent the substance from being again placed on the market, and, where a notice given under this paragraph requires specified things to be done in relation to a substance, the inspector shall retain control of the substance to which the notice relates until the requirements of the notice have been complied with.

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

(4) Any person who is aggrieved by a notice given under paragraph (2) of this Regulation which either requires the substance to which it relates to be disposed of or indicates an intention to dispose of such substances may, not later than the expiration of the period of seven days beginning on the date of the notice, appeal to the appropriate court against the notice.

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

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

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

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

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

(b) Where an order made by a court under this paragraph requires the substance to which it relates to be disposed of by an inspector, the cost of such disposal shall be recoverable by the competent 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) A notice under this Regulation shall not come into force unless -

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

(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 substance 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;

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

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

(8) (a) If, in relation to an appeal under this Regulation to the District Court, that court becomes of the opinion during the hearing of the appeal that the estimated amounts aforesaid will exceed €6,348.69, it may, if it so thinks fit, transfer the appeal to the Circuit Court or the High Court, whichever it considers appropriate having regard to the estimated amounts aforesaid.

(b) If, in relation to an appeal under this regulation to the Circuit Court, that court becomes of opinion during the hearing of the appeal that the estimated amounts aforesaid will exceed €38,092.14, it may, if it so thinks fit, by order transfer the appeal to the High Court.

29. Offences

(1) A person shall be guilty of an offence if the person –

(a) contravenes Regulation 6, 9, 10, 11, 16, 17 (2), 19, 20, 21, 23, 24, 25 or 28 (3),

(b) places on the market a substance to which these Regulations apply and which has not been tested and classified in accordance with these Regulations,

(c) places on the market a substance referred to in Regulation 14(1) or (2) before the expiry of the relevant period specified in that Regulation,

(d) fails to comply with a requirement imposed on that person under Regulation 17 (6), or

(e) contravenes a prohibition, or fails to comply with a condition, imposed on that person under Regulation 26.

(2) Where an offence under these Regulations has been 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 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, shall be 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) A person guilty of an offence under these regulations shall be liable on summary conviction to a fine not exceeding €1,904.61 or imprisonment for a term not exceeding 6 months or both.

30. Revocations

The-

(a) European Communities (Classification, Packaging, Labelling and Notification of Dangerous Substances) Regulations, 1994 (S.I. No. 77 of 1994),

(b) European Communities (Classification, Packaging, Labelling and Notification of Dangerous Substances) (Amendment) Regulations, 1998 (S.I. No. 317 of 1998),

(c) European Communities (Classification, Packaging, Labelling and Notification of Dangerous Substances) (Amendment) (No. 2) Regulations, 1998 (S.I. No. 513 of 1998),

(d) European Communities (Classification, Packaging, Labelling and Notification of Dangerous Substances) (Amendment) Regulations, 1999 (S.I. No. 363 of 1999), and

(e) European Communities (Classification, Packaging, Labelling and Notification of Dangerous Substances) Regulations, 2000 (S.I. No. 393 of 2000),

are revoked.

SCHEDULE 1

FOREWORD TO ANNEX I

Introduction

Annex I is an index of dangerous substances for which harmonised classification and labelling have been agreed at Community level in accordance with the procedure laid down in Article 4(3) of Directive 67/548/EEC.

Numbering of entries

Entries in Annex I are listed according to the atomic number of the element most characteristic of the substance's properties. A list of the chemical elements, arranged according to atomic number is shown in Table A. Organic substances, because of their variety, have been placed in the usual classes, as shown in Table B.

The Index number for each substance is in the form of a digit sequence of the type ABC-RST-VW-Y, where:

- ABC is either the atomic number of the most characteristic chemical element (preceded by one or two zeros to make up the sequence) or the usual class number for organic substances,

- RST is the consecutive number of the substance in the series ABC,

- VW denotes the form in which the substance is produced or placed on the market,

- Y is the check-digit calculated in accordance with the ISBN (International Standard Book Number) method.

As an example, the Index number for sodium chlorate is 017-005-00-9.

For dangerous substances in the European Inventory of Existing Commercial Chemical Substance (Einecs, OJ No. C 146A, 15.6.1990) the Einecs number is included. This number is a seven-digit system of the type XXX-XXX-X which starts at 200-001-8.

For dangerous substances notified under the provisions of this Directive, the number of the substance in the European List of Notified Substance (ELINCS) is included. This number is a seven-digit system of the type XXX-XXX-X which starts at 400-010-9.

For dangerous substances in the list of "No-longer-polymers" (Document, Office for Official Publications of the European Communities, 1997. ISBN 92-827-8995-0) the "No-longer-polymer" number is included. This number is a seven-digit system of the type XXX-XXX-X which starts at 500-001-0.

The Chemical Abstracts Service (CAS) number is also included to assist identification of the entry. It should be noted that the Einecs number includes both anhydrous and hydrated forms of a substance, and there are frequently different CAS numbers for anhydrous and hydrated forms. The CAS number included is for the anhydrous form only, and therefore the CAS number shown does not always describe the entry as accurately as the Einecs number.

Einecs, ELINCS, "No-longer-polymer" or CAS numbers are not usually included for entries which comprise more than four individual substances.

Nomenclature

Wherever possible, dangerous substances are designated by their Einecs, ELINCS or "No-longer-polymer" names. Other substances not listed in Einecs, ELINCS or the list of "No-longer-polymers" are designated using an internationally recognised chemical name (e.g. ISO, IUPAC). An additional common name is included in some cases.

Impurities, additives and minor components are normally not mentioned unless they contribute significantly to the classification of the substance.

Some substances are described as a mixture of A and B. These entries refer to one specific mixture. In some cases where it is necessary to characterise the substance put on the market, the proportions of the main substances in the mixture are specified.

Some substances are described with a specific percentage purity. Substances containing a higher content of active material (e.g. an organic peroxide) are not included in the Annex I entry and may have other hazardous properties (e.g. explosive). Where specific concentration limits are shown, these apply to the substance or substances shown in the entry. In particular, in the case of entries which are mixtures of substances or substances described with a specific percentage purity, the limits apply to the substance as described in Annex I and not the pure substance.

Article 23(2)(a) of Directive 67/548/EEC[60] requires that for substances appearing in Annex I, the name of the substance to be used on the label should be one of the designations given in the Annex. For certain substances, additional information has been added in square brackets in order to help identify the substance. This additional information need not be included on the label.

Certain entries contain a reference to impurities. An example is Index No. 607-190-00-X: methyl acrylamidomethoxyacetate (containing ≥ 0,1 % acrylamide). In these cases the reference in brackets forms part of the name, and must be included on the label.

Certain entries refer to groups of substances. An example is Index No. 006-007-00-5: "hydrogen cyanide (salts of ...) with exception of complex cyanides such as ferrocyanides, ferricyanides and mercuric oxycyanide". For individual substances covered by these entries, the Einecs name or another internationally recognised name must be used.

Format of entries

The following information is given for each substance in Annex I:

(a) *the classification:*

(i) the process of classification consists of placing a substance in one or more categories of danger (as defined in Article 2(2) of Directive 92/32/EEC[61]) and assigning the qualifying risk phrase or phrases. The classification has consequences not only for labelling but also for other legislation and regulatory measures on dangerous substances;

(ii) the classification for each category of danger is normally presented in the form of an abbreviation representing the category of danger together with the appropriate risk phrase or phrases. However, in some cases (i.e. substances classified as flammable, sensitising and some substances classified as dangerous for the environment) the risk phrase alone is used;

(iii) the abbreviation for each of the categories of danger is shown below:
- explosive: E
- oxidising: O
- extremely flammable: F+
- highly Flammable: F
- flammable: R10
- very toxic: T+
- toxic: T
- harmful: Xn
- corrosive: C
- irritant: Xi
- sensitising: R42 and/or R43

60 This article corresponds to Regulation 20.

61 This article corresponds to Regulation 2(2).

- carcinogenic: Carc. Cat.[62]
- mutagenic: Muta. Cat. [62]
- toxic for reproduction: Repr. Cat. [62]
- dangerous for the environment: N or/and R52, R53, R59;

(iv) Additional risk phrases which have been assigned to describe other properties (see sections 2.2.6 and 3.2.8 of the labelling guide) are shown although they are not formally part of the classification.

(b) *the label*, including:

(i) the letter assigned to the substance in accordance with Annex II (see Article 23(2)(c) of Directive 67/548/EEC). This acts as an abbreviation for the symbol and for the indication of danger (if these are assigned);

(ii) the risk phrases, denoted as a series of numbers preceded by the letter R indicating the nature of the special risks, in accordance with Annex III (see Article 23(2)(d) of Directive 67/548/EEC). The numbers are separated by either:

- a dash (-) to denote separate statements concerning special risks (R), or

- an oblique stroke (/) to denote a combined statement, in a single sentence, of the special risks as set out in Annex III;

(iii) the safety phrases denoted as a series of numbers preceded by the letter S indicating the recommended safety precautions, in accordance with Annex IV (see Article 23(2)(e) of Directive 67/548/EEC). Again the numbers are separated by either a dash or an oblique stroke; the significance of recommended safety precautions are set out in Annex IV. The safety phrases shown apply only to substances; for preparations, phrases are selected according to the usual rules.

Note that for certain dangerous substances and preparations sold to the general public certain S-phrases are mandatory.

S1, S2 and S45 are obligatory for all very toxic, toxic and corrosive substances and preparations sold to the general public.

S2 and S46 are obligatory for all other dangerous substances and preparations sold to the general public other than those that have only been classified as dangerous for the environment.

Safety phrases S1 and S2 are shown in brackets in Annex I and can only be omitted from the label when the substance or preparation is sold for industrial use only.

(c) *the concentration limits* and associated classifications necessary to classify dangerous preparations containing the substance in accordance with Directive 1999/45/EC.

Unless otherwise shown, the concentration limits are a percentage by weight of the substance calculated with reference to the total weight of the preparation.

Where no concentration limits are given, the concentration limits to be used when applying the conventional method of assessing health hazards are those in Annex II, and when applying the conventional method of assessing environmental hazards are those in Annex III of Directive 1999/45/EC.

General Explanatory Notes

Groups of substances

A number of group entries are included in Annex I. In these cases, the classification and labelling requirements will apply to all substances covered by the description if they are placed on the market, insofar as they are listed in Einecs or ELINCS. Where a substance that is covered by a group entry occurs as an impurity in another

62 The category of carcinogen, mutagen or toxic for reproduction (i.e. 1, 2 or 3) is shown as appropriate.

substance, the classification and labelling requirements described in the group entry shall be taken into account in the labelling of the substance.

In some cases, there are classification and labelling requirements for specific substances that would be covered by the group entry. In such cases a specific Annex I entry will be present for the substance and the group entry will be annotated with the phrase "except those specified elsewhere in this Annex".

In some cases, individual substances may be covered by more than one group entry. Lead oxalate (Einecs No 212-413-5) is for instance covered by the entry for lead compounds (Index No 082-001-00-6) as well as for salts of oxalic acid (607-007-00-3). In these cases, the labelling of the substance reflects the labelling for each of the two group entries. In cases where different classifications for the same hazard are given, the classification leading to the more severe classification is used for the label of the particular substance (see section on Note A below).

Entries in Annex I for salts (under any denomination) cover both anhydrous and hydrous forms unless specifically specified otherwise.

Substances with an ELINCS number

In Annex I, substances with an ELINCS number have been notified under the provisions of this Directive. A producer or importer who has not previously notified these substances must refer to the provisions of this Directive if he intends to place these substances on the market.

Explanation of the notes relating to the identification, classification and labelling of substances

Note A:

The name of the substance must appear on the label in the form of one of the designations given in Annex I (see Article 23(2)(a)).

In Annex I, use is sometimes made of a general description such as "... compounds" or "... salts". In this case, the manufacturer or any other person who markets such a substance is required to state on the label the correct name, due account being taken of the chapter entitled "Nomenclature" of the Foreword:

Example: for BeCl2 (Einecs No 232-116-4): beryllium chloride.

The Directive also requires that the symbols, indications of danger, R- and S-phrases to be used for each substance shall be those shown in Annex I (Article 23(2)(c), (d) and (e)).

For substances belonging to one particular group of substances included in Annex I, the symbols, indications of danger, R- and S-phrases to be used for each substance shall be those shown in the appropriate entry in Annex I.

For substances belonging to more than one group of substances included in Annex I, the symbols, indications of danger, R- and S-phrases to be used for each substance shall be those shown in both the appropriate entries given in Annex I. In cases where two different classifications are given in the two entries for the same hazard, the classification reflecting the more severe hazard classification is used.

Example:

for substance AB - no individual entry in Annex I:

Annex I group entry for compounds of A:
Repr. Cat. 1; R61 Repr. Cat. 3; R62 Xn; R20/22 R33 N; R50-53

Annex I group entry for compounds of B:
Carc. Cat.1; R45 T; R23/25 N; R51-53

Classification of substance AB thus becomes:
Carc. Cat. 1; R45 Repr. Cat. 1; R61 Repr. Cat. 3; R62 T; R23/25 R33 N; R50-53

Note B:

Some substances (acids, bases, etc.) are placed on the market in aqueous solutions at various concentrations and, therefore, these solutions require different labelling since the hazards vary at different concentrations.

In Annex I entries with Note B have a general designation of the following type: "nitric acid ...%".

In this case the manufacturer or any other person who markets such a substance in aqueous solution must state the percentage concentration of the solution on the label.

Example: nitric acid 45%.

Unless otherwise stated, it is assumed that the percentage concentration is calculated on a weight/weight basis.

The use of additional data (e.g. specific gravity, degrees Baumé) or descriptive phrases (e.g. fuming or glacial) is permissible.

Note C:

Some organic substances may be marketed either in a specific isomeric form or as a mixture of several isomers.

In Annex I, a general designation of the following type is sometimes used: "xylenol".

In this case the manufacturer or any other person who markets such a substance must state on the label whether the substance is a specific isomer (a) or a mixture of isomers (b).

Example: (a) 2,4-dimethylphenol
(b) xylenol (mixture of isomers).

Note D:

Certain substances which are susceptible to spontaneous polymerisation or decomposition are generally placed on the market in a stabilised form. It is in this form that they are listed in Annex I to Directive 67/548/EEC.

However, such substances are sometimes placed on the market in a non-stabilised form. In this case, the manufacturer or any person who places such a substance on the market must state on the label the name of the substance followed by the words "non-stabilised".

Example: methacrylic acid (non-stabilised).

Note E:

Substances with specific effects on human health (see Chapter 4 of Annex VI) that are classified as carcinogenic, mutagenic and/or toxic for reproduction in categories 1 or 2 are ascribed Note E if they are also classified as very toxic (T+), toxic (T) or harmful (Xn). For these substances, the risk phrases R20, R21, R22, R23, R24, R25, R26, R27, R28, R39, R68 (harmful), R48 and R65 and all combinations of these risk phrases shall be preceded by the word "Also".

Examples: R45-23 "May cause cancer. Also toxic by inhalation"

R46-27/28 "May cause heritable genetic damage. Also very toxic in contact with skin and if swallowed".

Note F:
This substance may contain a stabiliser. If the stabiliser changes the dangerous properties of the substance, as indicated by the label in Annex I, a label should be provided in accordance with the rules for the labelling of dangerous preparations.

Note G:
This substance may be marketed in an explosive form in which case it must be evaluated using the appropriate test methods and a label should be provided reflecting its explosive property.

Note H:
The classification and label shown for this substance applies to the dangerous property(ies) indicated by the risk phrase(s) in combination with the category(ies) of danger shown. The requirements of Article 6[63] of Directive 67/548/EEC on manufacturers, distributors and importers of this substance apply to all other aspects of classification and labelling. The final label shall follow the requirements of section 7 of Annex VI of this Directive.

This note applies to certain coal- and oil-derived substances and to certain entries for groups of substances in Annex I.

Note J:
The classification as a carcinogen need not apply if it can be shown that the substance contains less than 0.1 % w/w benzene (Einecs No 200-753-7). This note applies only to certain complex coal- and oil-derived substances in Annex I.

Note K:
The classification as a carcinogen need not apply if it can be shown that the substance contains less than 0.1 % w/w 1,3-butadiene (Einecs No 203-450-8). If the substance is not classified as a carcinogen, at least the S-phrases (2-)9-16 should apply. This note applies only to certain complex oil-derived substances in Annex I.

Note L:

The classification as a carcinogen need not apply if it can be shown that the substance contains less than 3 % DMSO extract as measured by IP 346. This note applies only to certain complex oil-derived substances in Annex I.

Note M:
The classification as a carcinogen need not apply if it can be shown that the substance contains less than 0.005 % w/w benzo[a]-pyrene (Einecs No 200-028-5). This note applies only to certain complex coal-derived substances in Annex I.

Note N:
The classification as a carcinogen need not apply if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen. This note applies only to certain complex oil-derived substances in Annex I.

Note P:
The classification as a carcinogen need not apply if it can be shown that the substance contains less than 0.1 % w/w benzene (Einecs No 200-753-7).

63 This article corresponds to Regulation 9.

When the substance is classified as a carcinogen, Note E shall also apply.

When the substance is not classified as a carcinogen at least the S-phrases (2-)23-24-62 shall apply.

This note applies only to certain complex oil-derived substances in Annex I.

Note Q:
The classification as a carcinogen need not apply if it can be shown that the substance fulfils one of the following conditions:

- a short term biopersistence test by inhalation has shown that the fibres longer than 20 µm have a weighted half-life less than 10 days, or

- a short term biopersistence test by intratracheal instillation has shown that the fibres longer than 20 µm have a weighted half-life less than 40 days, or

- an appropriate intra-peritoneal test has shown no evidence of excess carcinogenicity, or

- absence of relevant pathogenicity or neoplastic changes in a suitable long term inhalation test.

Note R:
The classification as a carcinogen need not apply to fibres with a length weighted geometric mean diameter less two standard geometric errors greater than 6µm.

Note S:
This substance may not require a label according to Article 23 (see Section 8 of Annex VI).

Explanation of the notes relating to the labelling of preparations

The significance of the notes that appear to the right of the concentration limits is as follows:

Note 1:
The concentration stated or, in the absence of such concentrations, the general concentrations of Directive 1999/45/EC are the percentages by weight of the metallic element calculated with reference to the total weight of the preparation.

Note 2:
The concentration of isocyanate stated is the percentage by weight of the free monomer calculated with reference to the total weight of the preparation.

Note 3:
The concentration stated is the percentage by weight of chromate ions dissolved in water calculated with reference to the total weight of the preparation.

Note 4:
Preparations containing these substances have to be classified as harmful with R65 if they meet the criteria in Section 3.2.3 in Annex VI.

Note 5:
The concentration limits for gaseous preparations are expressed as volume per volume percentage.

Note 6:
Preparations containing these substances have to be assigned R67 if they meet the criteria in Section 3.2.8 in Annex VI.

This Note will no longer apply from the date on which the criteria for the use of R67 provided for in Directive 1999/45/EC enter into force.

TABLE A

List of chemical elements listed according to their atomic number [Z]

Z	Symbol	Element	Z	Symbol	Element	Z	Symbol	Element
1	H	Hydrogen	**19**	K	Potassium	**37**	Rb	Rubidium
2	He	Helium	**20**	Ca	Calcium	**38**	Sr	Strontium
3	Li	Lithium	**21**	Sc	Scandium	**39**	Y	Yttrium
4	Be	Berllium	**22**	Ti	Titanium	**40**	Zr	Zirconium
5	B	Boron	**23**	V	Vanadium	**41**	Nb	Nicobium
6	C	Carbon	**24**	Cr	Chromium	**42**	Mo	Molybdenum
7	N	Nitrogen	**25**	Mn	Manganese	**43**	Tc	Technetium
8	O	Oxygen	**26**	Fe	Iron	**44**	Ru	Ruthenium
9	F	Fluoride	**27**	Co	Cobalt	**45**	Rh	Rhodium
10	Ne	Neon	**28**	Ni	Nickel	**46**	Pd	Palladium
11	Na	Sodium	**29**	Cu	Copper	**47**	Ag	Silver
12	Mg	Magnesium	**30**	Zn	Zinc	**48**	Cd	Cadmium
13	Al	Aluminium	**31**	Ga	Gallium	**49**	In	Indium
14	Si	Silicon	**32**	Ge	Germanium	**50**	Sn	Tin
15	P	Phosphorus	**33**	As	Arsenic	**51**	Sb	Antimony
16	S	Sulphur	**34**	Se	Selenium	**52**	Te	Tellurium
17	C1	Chlorine	**35**	Br	Bromine	**53**	I	Iodine
18	Ar	Argon	**36**	Kr	Krypton	**54**	Xe	Xenon

TABLE A [Contd.]

List of chemical elements listed according to their atomic number [Z]

Z	Symbol	Element	Z	Symbol	Element	Z	Symbol	Element
55	Cs	Caesium	**72**	Hf	Hafnium	**89**	Ac	Actinium
56	Ba	Barium	**73**	Ta	Tantalum	**90**	Th	Thorium
57	La	Lanthanum	**74**	W	Tungsten	**91**	Pa	Protactinium
58	Ce	Cerium	**75**	Re	Rhenium	**92**	U	Uranium
59	Pr	Praseodymium	**76**	Os	Osmium	**93**	Np	Neptunium
60	Nd	Neodymium	**77**	Ir	Iridium	**94**	Pu	Plutonium
61	Pm	Promethium	**78**	Pt	Platinum	**95**	Am	Americium
62	Sm	Samarium	**79**	Au	Gold	**96**	Cm	Curium
63	Eu	Europium	**80**	Hg	Mercury	**97**	Bk	Berkelium
64	Gd	Gadolinium	**81**	T1	Thallium	**98**	Cf	Californium
65	Tb	Terbium	**82**	Pb	Lead	**99**	Es	Einsteinium
66	Dy	Dysprosium	**83**	Bi	Bismuth	**100**	Fm	Fermium
67	Ho	Holmium	**84**	Po	Polonium	**101**	Md	Mendelevium
68	Er	Erbium	**85**	At	Astatine	**102**	No	Nobelium
69	Tm	Thulium	**86**	Rn	Radon	**103**	Lw	Lawrencium
70	Yb	Ytterbium	**87**	Fr	Francium			
71	Lu	Lutetium	**88**	Ra	Radium			

TABLE B

SPECIAL CLASSIFICATION FOR ORGANIC SUBSTANCES			
601	Hydrocarbons	**606**	Ketones and their derivatives
602	Halogenated hydrocarbons	**607**	Organic acids and their derivatives
603	Alcohols and their derivatives	**608**	Nitriles
604	Phenols and their derivatives	**609**	Nitro compounds
605	Aldehydes and their derivatives	**610**	Chloronitro compounds
611	Azoxy-and azo compounds	**616**	Amides and their derivatives
612	Amine compounds	**617**	Organic Peroxides
613	Heterocyclic bases and their derivatives	**647**	Enzymes
614	Glycosides and alkaloids	**648**	Complex substances derived from coal
615	Cyanates and isocyanates	**649**	Complex substances derived from petroleum
650	Miscellandous substances		

SCHEDULE 2

ANNEX II

SYMBOLS AND INDICATIONS OF DANGER FOR DANGEROUS SUBSTANCES AND PREPARATIONS

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

N

Irritant

Dangerous for the environment

SCHEDULE 3

ANNEX III

NATURE OF SPECIAL RISKS ATTRIBUTED TO DANGEROUS SUBSTANCES AND PREPARATIONS

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

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 4

ANNEX IV

SAFETY ADVICE CONCERNING DANGEROUS SUBSTANCES AND PREPARATIONS

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).

Combination of S-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 5
ANNEX VI

GENERAL CLASSIFICATION AND LABELLING REQUIREMENTS FOR DANGEROUS SUBSTANCES AND PREPARATIONS

CONTENTS

1. GENERAL INTRODUCTION

2. CLASSIFICATION ON THE BASIS OF PHYSICOCHEMICAL PROPERTIES

2.1. Introduction

2.2. Criteria for classification, choice of symbols, indication of danger, choice of risk phrases
2.2.1. Explosive
2.2.2. Oxidising
2.2.3. Extremely flammable
2.2.4. Highly flammable
2.2.5. Flammable
2.2.6. Other physicochemical properties

3. CLASSIFICATION ON THE BASIS OF TOXICOLOGICAL PROPERTIES

3.1. Introduction

3.2. Criteria for classification, choice of symbols, indication of danger, choice of risk phrases
3.2.1. Very toxic
3.2.2. Toxic
3.2.3. Harmful
3.2.4. Comments regarding the use of R48
3.2.5. Corrosive
3.2.6. Irritant
3.2.7. Sensitisation
3.2.8. Other toxicological properties

4. CLASSIFICATION ON THE BASIS OF SPECIFIC EFFECTS ON HUMAN HEALTH

4.1. Introduction

4.2. Criteria for classification, indication of danger, choice of risk phrases
4.2.1. Carcinogenic substances
4.2.2. Mutagenic substances
4.2.3. Substances toxic to reproduction
4.2.4. Procedure for the classification of preparations concerning specific effects on health

5. CLASSIFICATION ON THE BASIS OF ENVIRONMENTAL EFFECTS

5.1. Introduction

5.2. Criteria for classification, indication of danger, choice of risk phrases
5.2.1. Aquatic environment
5.2.2. Non-aquatic environment

6. CHOICE OF SAFETY ADVICE PHRASES

6.1. Introduction

6.2. Safety phrases for substances and preparations

7. LABELLING

8. SPECIAL CASES: Substances

8.1. Mobile gas cylinders

8.2. Gas containers intended for propane, butane or liquefied petroleum gas (LPG)

8.3. Metals in massive form

8.4. Substances classified with R65

9. SPECIAL CASES: Preparations

9.1. Gaseous preparations (gas mixtures)

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

9.3. Alloys, preparations containing polymers, preparations containing elastomers

9.4. Preparations classified with R65

9.5. Organic peroxides

9.6. Additional labelling requirements for certain preparations

COMMISSION STATEMENT

1. GENERAL INTRODUCTION

1.1. The object of classification is to identify all the physicochemical, toxicological and ecotoxicological properties of substances and preparations which may constitute a risk during normal handling or use. Having identified any hazardous properties the substance or preparation must then be labelled to indicate the hazard(s) in order to protect the user, the general public and the environment.

1.2. This Annex sets out the general principles governing the classification and labelling of substances and preparations referred to in Article 4[64] of Directive 67/548/EEC and in Article 4 of Directive 1999/45/EC and other relevant Directives on dangerous preparations.

It is addressed to all those concerned (manufacturers, importers, national authorities) with methods of classifying and labelling dangerous substances and preparations.

1.3. The requirements of Directive 67/548/EEC and of Directive 1999/45/EC are intended to provide a primary means by which the general public and persons at work are given essential information about dangerous substances and preparations. The label draws the attention of persons handling or using substances and preparations to the inherent danger of certain such materials.

The label may also serve to draw attention to more comprehensive product information on safety and use available in other forms.

1.4. The label takes account of all potential hazards which are likely to be faced in the normal handling and use of dangerous substances and preparations when in the form in which they are placed on the market, but not necessarily in any different form in which they may finally be used, e.g. diluted. The most severe hazards are highlighted by symbols, such hazards and those arising from other dangerous properties are specified in standard risk phrases, and safety phrases give advice on necessary precautions.

In the case of substances, the information is completed by the name of the substance under an internationally recognised chemical nomenclature, the preferred name being the one used in the European Inventory of Existing Commercial Chemical Substances (Einecs), or in the European List of Notified Chemical Substances (ELINCS), the EC number and the name, address and telephone number of the person established in the Community who is responsible for placing the substance on the market.

In the case of preparations, the information in accordance with Article 10.2. of Directive 1999/45/EC, is completed by:

- the trade name or the designation of the preparation;
- the chemical name of the substance or substances present in the preparation; and
- the name, full address and telephone number of the person established in the Community who is responsible for placing the preparation on the market.

1.5. Article 6[65] of Directive 67/548/EEC requires that manufacturers, distributors and importers of dangerous substances which appear in the Einecs but which have not yet been introduced into Annex I shall be obliged to carry out an investigation to make themselves aware of the relevant and accessible data which exist concerning the properties of such substances. On the basis of this information, they shall package and provisionally label these substances according to the rules laid down in Articles 22 to 25[66] and the criteria in this Annex.

---

64 This article corresponds to Regulation 8

65 This article corresponds to Regulation 9

66 These articles correspond to Regulations 19, 20 and 21

1.6. **Data required for classification and labelling**

1.6.1. For substances the data required for classification and labelling may be obtained:

(a) as regards substances for which the information specified in Annex VII[67], is required, most of the necessary data for classification and labelling appear in the 'base set'. This classification and labelling must be reviewed, if necessary, when further information is available (Annex VIII);

(b) as regards other substances (e.g. those referred to in section 1.5 above), the data required for classification and labelling may, if necessary, be obtained from a number of different sources, for example:

- the results of previous tests;
- information required by international rules on the transport of dangerous substances;
- information taken from reference works and the literature; or
- information derived from practical experience.

The results of validated structure-activity relationships and expert judgement may also be taken into account where appropriate.

1.6.2. For preparations, normally the data required for classification and labelling may be obtained:

(a) if it concerns physicochemical data, by the application of the methods specified in Annex V. This applies also to preparations covered by Directive 91/414/EEC unless other internationally recognised methods are acceptable in accordance with the provisions of Annexes II and III to Directive 91/414/EEC (Article 5. 5. of Directive 1999/45/EC). For gaseous preparations a calculation method may be used for flammable and oxidising properties (see 9.1.1.1 and 9.1.1.2). For non-gaseous preparations containing organic peroxides a calculation method may be used for oxidising properties (see 2.2.2.1).

(b) if it concerns data on health effects:

- by the application of the methods specified in Annex V, unless, in the case of plant protection products, other internationally recognised methods are acceptable in accordance with the provisions of Annexes II and III to Directive 91/414/EEC (Article 6. 1. (b) of Directive 1999/45/EC),

- and/or by the application of a conventional method referred to in Article 6 and Annex II, Parts A 1 - 6 and B 1 – 5 of Directive 1999/45/EC, or,

- in the case of R65, by the application of the rules under 3.2.3

- however, if it concerns the evaluation of the carcinogenic, mutagenic and reproductive toxicity properties, by the application of a conventional method referred to in Article 6 and Annex II, Parts A 7 - 9 and B 6 of Directive 1999/45/EC.

(c) if it concerns data on ecotoxicological properties

(i) for aquatic toxicity only:

- by the application of the methods specified in Annex V, subject to the conditions referred to in Annex III Part C of Directive 1999/45/EC, unless, in the case of plant protection products, other internationally recognised methods are acceptable in accordance with the provisions of Annexes II and III to Directive 91/414/EEC (Article 7. 1. (b) of Directive 1999/45/EC), or

67 This Annex corresponds to Schedule 6

- by application of a conventional method referred to in Article 7 and Annex III, Parts A and B, of Directive 1999/45/EC.

(ii) for the evaluation of the potential for (or actual) bioaccumulation through the determination of log Pow (or BCF), or the evaluation of degradability, by application of a conventional method referred to in Article 7 and Annex III, Parts A and B, of Directive 1999/45/EC.

(iii) for dangers of the ozone layer by application of a conventional method referred to in Article 7 and Annex III, Parts A and B, of Directive 1999/45/EC.

Note concerning the performance of animal tests:

The performance of animal tests to establish experimental data is subject to the provisions of Directive 86/609/EEC regarding the protection of animals used for experimental purposes.

Note concerning physicochemical properties:

For organic peroxides and organic peroxide preparations data may be derived from the calculation method set out in Chapter 9.5. For gaseous preparations a calculation method may be used for flammable and oxidising properties (see chapter 9).

1.7. **Application of the guide criteria**

Classification must cover the physicochemical, toxicological and ecotoxicological properties of substances and preparations.

Classification of substances and preparations is made according to Chapter 1.6, on the basis of the criteria in Chapters 2 to 5 (substances) and Chapters 2, 3, 4.2.4 and 5 of this Annex. All types of hazard must be considered. For instance, classification under 3.2.1 does not imply that the sections such as 3.2.2 or 3.2.4 can be ignored.

The choice of symbol(s) and risk phrase(s) is made on the basis of the classification in order to ensure that the specific nature of the potential dangers identified in classification is expressed on the label.

Notwithstanding the criteria given under 2.2.3, 2.2.4 and 2.2.5, substances and preparations in the form of aerosols shall be subject to the provisions of Directive 75/324/EEC as amended and adapted to technical progress.

1.7.1. Definitions

'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 production process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.

A substance may be chemically very well defined (e.g. acetone) or a complex mixture of constituents of variable composition (e.g. aromatic distillates). For certain complex substances, some individual constituents have been identified.

‘Preparations' means mixtures or solutions composed of two or more substances.

1.7.2. Application of the guide criteria for substances

The guidance criteria set out in this Annex are directly applicable when the data in question have been obtained from test methods comparable with those described in Annex V. In other

cases, the available data must be evaluated by comparing the test methods employed with those indicated in Annex V and the rules specified in this Annex for determining the appropriate classification and labelling.

In some cases there may be doubt over the application of the relevant criteria, especially where these require the use of expert judgement. In such cases the manufacturer, distributor or importer should provisionally classify and label the substance on the basis of an assessment of the evidence by a competent person.

Without prejudice to Article 6, where the above procedure has been followed and there is concern over possible inconsistencies then a proposal may be submitted for the entry of the provisional classification into Annex I. The proposal should be made to one of the Member States and should be accompanied by appropriate scientific data (see also section 4.1).

A similar procedure may be followed when information is identified which gives cause for concern over the accuracy of an existing entry in Annex I.

1.7.2.1. *Classification of substances containing impurities, additives or individual constituents*

Where impurities, additives or individual constituents of substances have been identified, they shall be taken into account if their concentration is greater than or equal to the limits specified

- 0,1 % for substances classified as very toxic, toxic, carcinogenic (category 1 or 2), mutagenic (category 1 or 2), toxic to reproduction (category 1 or 2), or dangerous for the environment (assigned the symbol 'N' for the aquatic environment, dangerous for the ozone layer)

-1% for substances classified as harmful, corrosive, irritant sensitising, carcinogenic (category 3), mutagenic (category 3), toxic to reproduction (category 3), or dangerous for the environment (not assigned the symbol 'N', i.e. harmful to aquatic organisms, may cause long-term adverse effects)

unless lower values have been specified in Annex I.

With the exception of substances listed specifically in Annex I, classification should be carried out according to the requirements of Articles 5, 6 and 7 of Council Directive 1999/45/EC.

In the case of asbestos (650-013-00-6) this general rule does not apply until a concentration limit has been fixed in Annex I. Substances in which asbestos is present must be classified and labelled according to the principles in Article 6.

1.7.3. Application of the guide criteria for preparations

The guidance criteria set out in this Annex are directly applicable when the data in question have been obtained from test methods comparable with those described in Annex V with the exception of the criteria of Chapter 4 for which only the conventional method is applicable. A conventional method is also applicable in relation to the criteria of Chapter 5, with the exception of aquatic toxicity, subject to the conditions referred to in Annex III Part C of Directive 1999/45/EC. For preparations covered by Directive 91/414/EEC data for classification and labelling are also acceptable from other internationally recognised methods (see special provisions in Section 1.6 of this Annex). In other cases, the available data must be evaluated by comparing the test methods employed with those indicated in Annex V and the rules specified in this Annex for determining the appropriate classification and labelling.

Where the health and environmental hazards are assessed by applying a conventional method referred to in Articles 6 and 7 and Annexes II and III of Directive 1999/45/EC the individual concentration limits to be used are those set out either:

- in Annex I to Directive 67/548/EEC, or

- in Annex II Part B and/or Annex III Part B of Directive 1999/45/EC where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits.

In the case of preparations containing mixtures of gases, classification with respect to the health and environmental effects will be established by the calculation method on the basis of the individual concentration limits from Annex I to Directive 67/548/EEC or when these limits are not in Annex I on the basis of the criteria of Annexes II and III of Directive 1999/45/EC.

1.7.3.1. *Preparations or substances described in Section 1.7.2.1 used as constituents of another preparation*

The labelling of such preparations must be in conformity with the provisions of Article 10 according to the principles set out in Articles 3 and 4 of Directive 1999/45/EC. However, in certain cases, the information on the label of the preparation or substance described in Section 1.7.2.1 is insufficient to enable other manufacturers who wish to use it as a constituent of their own preparation(s) to carry out the classification and labelling of their preparation(s) correctly.

In these cases, the person established within the Community responsible for placing the original preparation or substance described in Section 1.7.2.1 on the market, whether it be the manufacturer, the importer or the distributor shall supply upon justified request and as soon as possible all necessary data concerning the dangerous substances present to enable correct classification and labelling of the new preparation. This data is also necessary to enable the person responsible for placing the new preparation on the market to comply with other requirements of Directive 1999/45/EC.

2. CLASSIFICATION ON THE BASIS OF PHYSICOCHEMICAL PROPERTIES

2.1. Introduction

The test methods relating to explosive, oxidising and flammable properties included in Annex V serve to give specific meaning to the general definitions given in Article 2 (2) (a) to (e) of Directive 67/548/EEC[68]. Criteria follow directly from the test methods in Annex V as far as they are mentioned.

If adequate information is available to demonstrate in practice that the physicochemical properties of substances and preparations (apart from organic peroxides) are different from those revealed by the test methods given in Annex V, then such substances and preparations should be classified according to the hazard they present, if any, to those handling the substances and preparations or to other persons.

2.2. Criteria for classification, choice of symbols, indication of danger and choice of risk phrases

In the case of preparations, the criteria referred to in Article 5 of Directive 1999/45/EC need to be taken into consideration.

2.2.1. Explosive

Substances and preparations shall be classified as explosive and assigned the symbol ‘E’ and the indication of danger ‘explosive’ in accordance with the results of the tests given in Annex V and in so far as the substances and preparations are explosive as placed on the market. One risk phrase is obligatory, it is to be specified on the basis of the following:

68 This article corresponds to Regulation 2(2)

R2 Risk of explosion by shock, friction, fire or other sources of ignition

- substances and preparations except those set out below.

R3 Extreme risk of explosion by shock, friction, fire or other source of ignition

- substances and preparations which are particularly sensitive such as picric acid salts or PETN.

2.2.2. Oxidising

Substances and preparations shall be classified as oxidising and assigned the symbol 'O' and the indication of danger 'oxidising' in accordance with the results of the tests given in Annex V. One risk phrase is obligatory, it is to be specified on the basis of the test results but subject to the following:

R7 May cause fire

- organic peroxides which have flammable properties even when not in contact with other combustible material.

R8 Contact with combustible material may cause fire

- other oxidising substances and preparations, including inorganic peroxides, which may cause fire or enhance the risk of fire when in contact with combustible material.

R9 Explosive when mixed with combustible material

- other substances and preparations, including inorganic peroxides, which become explosive when mixed with combustible materials, e.g. certain chlorates.

2.2.2.1. *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.

2.2.3. Extremely flammable

Substances and preparations shall be classified as extremely flammable and assigned the symbol 'F+' and the indication of danger 'extremely flammable' in accordance with the results of the tests given in Annex V. The risk phrase shall be assigned in accordance with the following criteria:

R12 Extremely flammable

- Liquid substances and preparations which have a flash point lower than 0 °C and a boiling point (or in case of a boiling range the initial boiling point) lower than or equal to 35 °C.

- Gaseous substances and preparations which are flammable in contact with air at ambient temperature and pressure.

2.2.4. Highly flammable

Substances and preparations shall be classified as highly flammable and assigned the symbol 'F' and the indication of danger 'highly flammable' in accordance with the results of the tests given in Annex V. Risk phrases shall be assigned in accordance with the following criteria:

R11 Highly flammable

- 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.
- Liquid substances and preparations having a flash point below 21°C but which are not extremely flammable.

R15 Contact with water liberates extremely flammable gases

- Substances and preparations which, in contact with water or damp air, evolve extremely flammable gases in dangerous quantities, at a minimum rate of one litre per kilogram per hour.

R17 Spontaneously flammable in air

- Substances and preparations which may become hot and finally catch fire in contact with air at ambient temperature without any input of energy.

2.2.5. 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.

2.2.6. Other physicochemical properties

Additional risk phrases shall be assigned to substances and preparations which have been classified by virtue of Sections 2.2.1 to 2.2.5 above or by Chapter 3, 4 and 5 below, in accordance with the following criteria (based on experience obtained during compilation of Annex I):

R1 Explosive when dry

For explosive substances and preparations put on the market in solution or in a wetted form, e.g. nitrocellulose with more than 12.6 % nitrogen.

R4 Forms very sensitive explosive metallic compounds

For substances and preparations which may form sensitive explosive metallic derivatives, e.g. picric acid, styphnic acid.

R5 Heating may cause an explosion

For thermally unstable substances and preparations not classified as explosive, e.g. perchloric acid > 50 %.

R6 Explosive with or without contact with air

For substances and preparations which are unstable at ambient temperatures, e.g. acetylene.

R7 May cause fire

For reactive substances and preparations, e.g. fluorine, sodium hydrosulphite.

R14 Reacts violently with water

For substances and preparations which react violently with water, e.g. acetyl chloride, alkali metals, titanium tetrachloride.

R16 Explosive when mixed with oxidising substances

For substances and preparations which react explosively with an oxidising agent, e.g. red phosphorus.

R18 In use, may form flammable/explosive vapour-air mixture

For preparations not in themselves classified as flammable, which contain volatile components which are flammable in air.

R19 May form explosive peroxides

For substances and preparations which may form explosive peroxides during storage, e.g. diethyl ether, 1,4-dioxan.

R30 Can become highly flammable in use

For preparations not in themselves classified as flammable, which may become flammable due to the loss of non-flammable volatile components.

R44 Risk of explosion if heated under confinement

For substances and preparations not in themselves classified as explosive in accordance with Section 2.2.1 above but which may nevertheless display explosive properties in practice if heated under sufficient confinement. For example, certain substances which

would decompose explosively if heated in a steel drum do not show this effect if heated in less-strong containers.

For other additional risk phrases see Section 3.2.8.

3. CLASSIFICATION ON THE BASIS OF TOXICOLOGICAL PROPERTIES

3.1. Introduction

3.1.1. Classification is concerned with both the acute and long-term effects of substances and preparations, whether resulting from a single instance of exposure or repeated or prolonged exposure.

Where it can be demonstrated by epidemiological studies, by scientifically valid case studies as specified in this Annex or by statistically backed experience, such as the assessment of data from poison information units or concerning occupational diseases, that toxicological effects on man differ from those suggested by the application of the methods outlined in Section 1.6 of this Annex, then the substance or preparation shall be classified according to its effects on man. However, tests on man should be discouraged and should not normally be used to negate positive animal data.

Directive 86/609/EEC seeks to protect animals used for experimental and other scientific purposes. For several endpoints there are validated *in vitro* test methods in Annex V of Directive 67/548/EEC and these tests should be used where appropriate.

3.1.2. The classification of substances must be made on the basis of the experimental data available in accordance with the following criteria which take into account the magnitude of these effects:

(a) for acute toxicity (lethal and irreversible effects after a single exposure), the criteria under Sections 3.2.1 to 3.2.3 are to be used,

(b) for sub-acute, sub-chronic or chronic toxicity the criteria under Sections 3.2.2 to 3.2.4 are to be used,

(c) for corrosive and irritant effects the criteria under Sections 3.2.5 and 3.2.6 are to be used,

(d) for sensitising effects the criteria under Section 3.2.7 are to be used,

(e) for specific effects on health (carcinogenicity, mutagenicity and reproductive toxicity), the criteria in Chapter 4 are to be used.

3.1.3. For preparations, the classification relating to dangerous for health is carried out:

(a) on the basis of a conventional method referred to in Article 6 and Annex II of Directive 1999/45/EC in the absence of experimental data. In this case, the classification is based on the individual concentration limits:

- either taken from Annex I to Directive 67/548/EEC, or
- from Annex II, Part B of Directive 1999/45/EC where the substance or substances do not appear in Annex I of Directive 67/548/EEC or appear in it without concentration limits.

(b) or when experimental data are available, according to the criteria described under Sections 3.1.2 excluding the carcinogenic, mutagenic and toxic to reproduction properties referred to under 3.1.2 (e) which must be evaluated by a conventional method referred to in Article 6 and Annex II, Parts A 7 – 9 and B 6 of Directive 1999/45/EC.

Note: Without prejudice to requirements of Directive 91/414/EEC, only where it can be scientifically demonstrated by the person responsible for placing the preparation on the market that the toxicological properties of the preparation cannot correctly be determined by the method outlined in paragraph 3.1.3 (a), or on the basis of existing test results on animals, the methods outlined in paragraph 3.1.3 (b) may be used, provided they are justified or specifically authorised under Article 12 of Directive 86/609/EEC.

Whichever method is used for the evaluation of the danger of a preparation, all the dangerous effects on health as defined in Annex II, Part B of Directive 1999/45/EC must be taken into consideration.

3.1.4. When the classification is to be established from experimental results obtained in animal tests the results should have validity for man in that the tests reflect, in an appropriate way, the risks to man.

3.1.5. The acute oral toxicity of substances or preparations placed on the market may be established either by a method permitting assessment of the LD_{50} value, or by determining the discriminating dose (the fixed dose method), or by determining the range of exposure where lethality is expected (the acute toxic class method).

3.1.5.1. The discriminating dose is the dose which causes evident toxicity but not mortality and must be one of the four dosage levels specified in Annex V (5, 50, 500 or 2 000 mg per kg body weight).

The concept 'evident toxicity' is used to designate toxic effects, after exposure to the substance tested, which are so severe that exposure to the next highest fixed dose would probably lead to mortality.

The results of testing at a particular dose following the fixed dose method may be either:

- less than 100 % survival,
- 100 % survival, but evident toxicity,
- 100 % survival, but no evident toxicity.

In the criteria in sections 3.2.1, 3.2.2 and 3.2.3 only the final test result is shown. The 2 000 mg/kg dose should be used primarily to obtain information on the toxic effects of substances which are of low acute toxicity and which are not classified on the basis of acute toxicity.

The fixed dose method requires in some cases testing at higher or lower doses, if not already tested at the relevant dose level. Refer also to the evaluation table in test method B.1 *bis.*

3.1.5.2. The range of exposure where lethality is expected is derived from the observed absence or presence of substance related mortality following the acute toxic class method. For initial testing one of three fixed starting doses (25, 200 or 2 000 mg per kg body weight) is used.

The acute toxic class method requires in some cases testing at higher or lower doses, if not already tested at the relevant dose level. Refer also to the test procedure flow charts in test method B.1 *tris* of Annex V.

3.2. **Criteria for classification, choice of symbols, indication of danger, choice of risk phrases**

3.2.1. Very toxic

Substances and preparations shall be classified as very toxic, and assigned the symbol 'T+' and indication of danger 'very toxic' in accordance with the criteria specified below.

Risk phrases shall be assigned in accordance with the following criteria:

R28 Very toxic if swallowed

Acute toxicity results:

- LD_{50} oral, rat $\leq$ 25 mg/kg,
- less than 100 % survival at 5 mg/kg oral, rat by the fixed dose procedure, or
- high mortality at doses $\leq$ 25 mg/kg oral, rat, by the acute toxic class method (for test result interpretation see flow charts in Annex 2 of test method B.1 *tris* of Annex V).

R27 Very toxic in contact with skin

Acute toxicity results:

- LD_{50} dermal, rat or rabbit: $\leq$ 50 mg/kg.

R26 Very toxic by inhalation

Acute toxicity results:

- LC_{50} inhalation, rat, for aerosols or particulates: $\leq$ 0.25 mg/litre/4hr,
- LC_{50} inhalation, rat, for gases and vapours: $\leq$ 0.5 mg/litre/4hr.

R39 Danger of very serious irreversible effects

- Strong evidence that irreversible damage other than the effects referred to in Chapter 4 is likely to be caused by a single exposure by an appropriate route, generally in the above-mentioned dose range.

In order to indicate the route of administration/exposure one of the following combinations shall be used: R39/26, R39/27, R39/28, R39/26/27, R39/26/28, R39/27/28, R39/26/27/28.

3.2.2. Toxic

Substances and preparations shall be classified as toxic and assigned the symbol 'T' and the indication of danger 'toxic' in accordance with the criteria specified below. Risk phrases shall be assigned in accordance with the following criteria.

R25 Toxic if swallowed

Acute toxicity results:

- LD_{50} oral, rat: $25 < LD_{50} \leq 200$ mg/kg,
- Discriminating dose, oral, rat, 5 mg/kg: 100 % survival but evident toxicity, or
- high mortality in the dose range > 25 to $\leq$ 200 mg/kg oral, rat, by the acute toxic class method (for test result interpretation see flow charts in Annex 2 of test method B.1 tris of Annex V).

R24 Toxic in contact with skin

Acute toxicity results:

- LD_{50} dermal, rat or rabbit: $50 < LD_{50} \leq 400$ mg/kg.

R23 Toxic by inhalation

Acute toxicity results:

- LC_{50} inhalation, rat, for aerosols or particulates: $0.25 < LC_{50} \leq 1$ mg/litre/4hr,
- LC_{50} inhalation, rat, for gases and vapours: $0.5 < LC_{50} \leq 2$ mg/litre/4hr.

R39 Danger of very serious irreversible effects

- strong evidence that irreversible damage other than the effects referred to in Chapter 4 is likely to be caused by a single exposure by an appropriate route, generally in the above-mentioned dose range.

In order to indicate the route of administration/exposure one of the following combinations shall be used: R39/23, R39/24, R39/25, R39/23/24, R39/23/25, R39/24/25, R39/23/24/25.

R48 Danger of serious damage to health by prolonged exposure

- serious damage (clear functional disturbance or morphological change which have toxicological significance) is likely to be caused by repeated or prolonged exposure by an appropriate route.

Substances and preparations are classified at least as toxic when these effects are observed at levels of one order of magnitude lower (i.e. 10-fold) than those set out for R48 in Section 3.2.3.

In order to indicate the route of administration/exposure one of the following combinations shall be used: R48/23, R48/24, R48/25, R48/23/24, R48/23/25, R48/24/25, R48/23/24/25.

3.2.3. Harmful

Substances and preparations shall be classified as harmful and assigned the symbol 'Xn' and the indication of danger 'harmful' in accordance with the criteria specified below. Risk phrases shall be assigned in accordance with the following criteria:

R22 Harmful if swallowed

Acute toxicity results:

- LD_{50} per oral, rat: $200 < LD_{50} \leq 2000$ mg/kg,
- discriminating dose, oral, rat, 50 mg/kg: 100 % survival but evident toxicity,
- less than 100 % survival at 500 mg/kg, rat oral by the fixed dose procedure. Refer to the evaluation table in the test method B.1 *bis* of Annex V, or
- high mortality in the dose range > 200 to $\leq$ 2 000 mg/kg oral, rat, by the acute toxic class method (for test result interpretation see flow charts in Annex 2 of test method B.1 *tris* of Annex V).

R21 Harmful in contact with skin

Acute toxicity results:

- LD_{50} dermal, rat or rabbit: $400 < LD_{50} \leq 2\,000$ mg/kg.

R20 Harmful by inhalation

Acute toxicity results:

- LC_{50} inhalation, rat, for aerosols or particulates: $1 < LC_{50} \leq 5$ mg/litre/4hr,
- LC_{50} inhalation, rat, for gases or vapours: $2 < LC_{50} \leq 20$ mg/litre/4hr.

R65 Harmful: may cause lung damage if swallowed

Liquid substances and preparations presenting an aspiration hazard in humans because of their low viscosity:

(a) For substances and preparations containing aliphatic, alicyclic and aromatic hydrocarbons in a total concentration equal to or greater than 10 % and having either

- a flow time of less than 30 sec. in a 3 mm ISO cup according to ISO 2431 (April 1996 / July 1999 edition) relating to 'Paints and varnishes - Determination of flow time by use of flow cups',

- a kinematic viscosity measured by a calibrated glass capillary viscometer in accordance with ISO 3104/3105 of less than 7×10^{-6} m^2/sec at 40° C (ISO 3104, 1994 edition, relating to 'Petroleum products - Transparent and opaque liquids - Determination of kinematic viscosity and calculation of dynamic viscosity'; ISO

3105, 1994 edition, relating to 'Glass capillary kinematic viscometers - Specifications and operating instructions'), or

- a kinematic viscosity derived from measurements of rotational viscometry in accordance with ISO 3219 of less than 7 x 10^{-6} m^2/sec at 40° C (ISO 3219, 1993 edition, relating to 'Plastics – Polymers/resins in the liquid state or as emulsions or dispersions - Determination of viscosity using a rotational viscometer with defined shear rate').

Note that substances and preparations meeting these criteria need not be classified if they have a mean surface tension greater than 33mN/m at 25° C as measured by the du Nouy tensiometer or by the test methods shown in Annex V Part A.5.

(b) For substances and preparations, based on practical experience in humans.

R68 Possible risk of irreversible effects

- strong evidence that irreversible damage other than the effects referred to in Chapter 4 is likely to be caused by a single exposure by an appropriate route, generally in the above-mentioned dose range.

In order to indicate route of administration/exposure one of the following combinations shall be used: R68/20, R68/21, R68/22, R68/20/21, R68/20/22, R68/21/22, R68/20/21/22.

R48 Danger of serious damage to health by prolonged exposure

- serious damage (clear functional disturbance or morphological change which has toxicological significance) is likely to be caused by repeated or prolonged exposure by an appropriate route.

Substances and preparations are classified at least as harmful when these effects are observed at levels of the order of:

- oral, rat $\leq$ 50 mg/kg (bodyweight)/day,
- dermal, rat or rabbit $\leq$ 100 mg/kg (bodyweight)/day,
- inhalation, rat $\leq$ 0.25 mg/l, 6h/day.

These guide values can apply directly when severe lesions have been observed in a sub-chronic (90 days) toxicity test. When interpreting the results of a sub-acute (28 days) toxicity test these figures should be increased approximately three fold. If a chronic (two years) toxicity test is available it should be evaluated on a case-by-case basis. If results of studies of more than one duration are available, then those from the study of the longest duration should normally be used.

In order to indicate route of administration/exposure one of the following combinations shall be used: R48/20, R48/21, R48/22, R48/20/21, R48/20/22, R48/21/22, R48/20/21/22.

3.2.3.1. *Comments regarding volatile substances*

For certain substances with a high saturated vapour concentration evidence may be available to indicate effects that give cause for concern. Such substances may not be classified under the criteria for health effects in this guide (3.2.3) or not covered by Section 3.2.8. However, where there is appropriate evidence that such substances may present a risk in normal handling and use then classification on a case-by-case basis in Annex I may be necessary.

3.2.4. Comments regarding the use of R48

Use of this risk phrase refers to the specific range of biological effects within the terms described below. For application of this risk phrase serious damage to health is to be considered to include death, clear functional disturbance or morphological changes which are toxicologically significant. It is particularly important when these changes are irreversible. It is also important to consider not only specific severe changes in a single organ or biological system but also generalised changes of a less severe nature involving several organs, or severe changes in general health status.

When assessing whether there is evidence for these types of effects reference should be made to the following guidelines:

1. Evidence indicating that R48 should be applied:

   (a) substance-related deaths;

   (b) (i) major functional changes in the central or peripheral nervous systems, including sight, hearing and the sense of smell, assessed by clinical observations or other appropriate methods (e.g. electrophysiology);

   (ii) major functional changes in other organ systems (for example the lung);

   (c) any consistent changes in clinical biochemistry, haematology or urinalysis parameters which indicate severe organ dysfunction. Haematological disturbances are considered to be particularly important if the evidence suggests that they are due to decreased bone marrow production of blood cells;

   (d) severe organ damage noted on microscopic examination following autopsy:

   (i) widespread or severe necrosis, fibrosis or granuloma formation in vital organs with regenerative capacity (e.g. liver);

   (ii) severe morphological changes that are potentially reversible but are clear evidence of marked organ dysfunction (e.g. severe fatty change in the liver, severe acute tubular nephrosis in the kidney, ulcerative gastritis); or

   (iii) evidence of appreciable cell death in vital organs incapable of regeneration (e.g. fibrosis of the myocardium or dying back of a nerve) or in stem cell populations (e.g. aplasia or hypoplasia of the bone marrow).

The above evidence will most usually be obtained from animal experiments. When considering data derived from practical experience special attention should be given to exposure levels.

2. Evidence indicating that R48 should not be applied:

   The use of this risk phrase is restricted to 'serious damage to health by prolonged exposure'. A number of substance-related effects may be observed in both humans and animals that would not justify the use of R48. These effects are relevant when attempting to determine a no-effect level for a chemical substance. Examples of well documented changes which would not normally justify classification with R48, irrespective of their statistical significance, include:

   (a) clinical observations or changes in bodyweight gain, food consumption or water intake, which may have some toxicological importance but which do not, by themselves, indicate 'serious damage`;

   (b) small changes in clinical biochemistry, haematology or urinalysis parameters which are of doubtful or minimal toxicological importance;

(c) changes in organ weights with no evidence of organ dysfunction;

(d) adaptative responses (e.g. macrophage migration in the lung, liver hypertrophy and enzyme induction, hyperplastic responses to irritants). Local effects on the skin produced by repeated dermal application of a substance which are more appropriately classified with R38 'irritating to skin'; or

(e) where a species-specific mechanism of toxicity (e.g. specific metabolic pathways) has been demonstrated.

3.2.5. Corrosive

The substance or preparation shall be classified as corrosive and assigned the symbol 'C' and the indication of danger 'corrosive' in accordance with the following criteria:

- A substance or a preparation is considered to be corrosive if, when it is applied to healthy intact animal skin, it produces full thickness destruction of skin tissue on at least one animal during the test for skin irritation cited in Annex V or during an equivalent method.

- Classification can be based on the results of a validated *in vitro* test, such as that cited in Annex V (B.40. Skin corrosion: rat skin transcutaneous electrical resistance assay and human skin model assay.)

- A substance or a preparation should also be considered corrosive if the result can be predicted, for example from strongly acid or alkaline reactions indicated by a pH of 2 or less or 11.5 or greater. However, where extreme pH is the basis for classification, acid/alkali reserve[69] may also be taken into consideration. If consideration of alkali/acid reserve suggests the substance or preparation may not be corrosive then further testing should be carried out to confirm this, preferably by use of an appropriate validated *in vitro* test. Consideration of acid/alkali reserve should not be used alone to exonerate substances or preparations from classification as corrosive.

Risk phrases shall be assigned in accordance with the following criteria:

R35 Causes severe burns
- if, when applied to healthy intact animal skin, full thickness destruction of skin tissue occurs as a result of up to three minutes exposure, or if this result can be predicted.

R34 Causes burns
- if, when applied to healthy intact animal skin, full thickness destruction of skin tissue occurs as a result of up to four hours exposure, or if this result can be predicted,
- organic hydroperoxides, except where evidence to the contrary is available.

Notes:

Where classification is based on results of a validated in vitro test R35 or R34 should be applied according to the capacity of the test method to discriminate between these.

Where classification is based upon consideration of extreme pH alone, R35 should be applied.

3.2.6. Irritant

Substances and preparations shall be classified as irritant and assigned the symbol 'Xi' and the indication of danger 'irritant' in accordance with the criteria given below.

69 J.R. Young, M.J. How, A.P. Walker and W.M.H. Worth (1988) "Classification as corrosive or irritant to skin of preparations containing acidic or alkaline substances, without testing on animals" Toxic. In Vitro 2(1): 19-26.

3.2.6.1. *Inflammation of the skin*

The following risk phrase shall be assigned in accordance with the criteria given:

R38 Irritating to skin

- Substances and preparations which cause significant inflammation of the skin which persists for at least 24 hours after an exposure period of up to four hours determined on the rabbit according to the cutaneous irritation test method cited in Annex V.

Inflammation of the skin is significant if:

(a) the mean value of the scores for either erythema and eschar formation or oedema formation, calculated over all the animals tested, is 2 or more; or

(b) in the case where the Annex V test has been completed using three animals, either erythema and eschar formation or oedema formation equivalent to a mean value of 2 or more calculated for each animal separately has been observed in two or more animals.

In both cases all scores at each of the reading times (24, 48 and 72 hr) for an effect should be used in calculating respective mean values.

Inflammation of the skin is also significant if it persists in at least two animals at the end of the observation time. Particular effects e.g. hyperplasia, scaling, discoloration, fissures, scabs and alopecia should be taken into account.

Relevant data may also be available from non-acute animal studies (see comments on R48, section 2.d). These are considered significant if the effects seen are comparable to those described above.

- Substances and preparations which cause significant inflammation of the skin, based on practical observations in humans on immediate, prolonged or repeated contact.

- Organic peroxides, except where evidence to the contrary is available.

Paresthesia:
Paresthesia caused in humans by skin contact with pyrethroid pesticides is not regarded as an irritant effect justifying classification as Xi; R38. The S-phrase S24 should however be applied for substances seen to cause this effect.

3.2.6.2. *Ocular lesions*

The following risk phrases shall also be assigned in accordance with the criteria given:

R36 Irritating to eyes

- Substances and preparations which, when applied to the eye of the animal, cause significant ocular lesions which occur within 72 hours after exposure and which persist for at least 24 hours.

Ocular lesions are significant if the mean scores of the eye irritation test cited in Annex V have any of the following values:

- cornea opacity equal to or greater than 2 but less than 3,

- iris lesion equal to or greater than 1 but not greater than 1.5,
- redness of the conjunctivae equal to or greater than 2.5,
- oedema of the conjunctivae (chemosis) equal to or greater than 2,

or, in the case where the Annex V test has been completed using three animals if the lesions, on two or more animals, are equivalent to any of the above values except that for iris lesion the value should be equal to or greater than 1 but less than 2 and for redness of the conjunctivae the value should be equal to or greater than 2.5.

In both cases all scores at each of the reading times (24, 48 and 72 hours) for an effect should be used in calculating the respective mean values.

- Substances or preparations which cause significant ocular lesions, based on practical experience in humans.
- Organic peroxides except where evidence to the contrary is available.

R41 Risk of serious damage to eyes

- Substances and preparations which, when applied to the eye of the animal cause severe ocular lesions which occur within 72 hours after exposure and which persist for at least 24 hours.

Ocular lesions are severe if the means of the scores of the eye irritation test in Annex V have any of the values:

- cornea opacity equal to or greater than 3,
- iris lesion greater than 1.5.

The same shall be the case where the test has been completed using three animals if these lesions, on two or more animals, have any of the values:

- cornea opacity equal to or greater than 3,
- iris lesion equal to 2.

In both cases all scores at each of the reading times (24, 48 and 72 hours) for an effect should be used in calculating the respective mean values.

Ocular lesions are also severe when they are still present at the end of the observation time.

Ocular lesions are also severe if the substance or preparation causes irreversible colouration of the eyes.

- Substances and preparations which cause severe ocular lesions, based on practical experience in humans.

Note:

When a substance or preparation is classified as corrosive and assigned R34 or R35, the risk of severe damage to eyes is considered implicit and R41 is not included in the label.

3.2.6.3. *Respiratory system irritation*

The following risk phrase shall be assigned in accordance with the criteria given:

R37 Irritating to respiratory system

Substances and preparations which cause serious irritation to the respiratory system based on:

- practical observation in humans
- positive results from appropriate animal tests.

Comments regarding the use of R37

In interpreting practical observations in humans, care should be taken to distinguish between effects which lead to classification with R48 (see section 3.2.4.) from those leading to classification with R37. Conditions normally leading to classification with R37 are reversible and usually limited to the upper airways.

Positive results from appropriate animal tests may include data obtained in a general toxicity test, including histopathological data from the respiratory system. Data from the measurement of experimental bradypnea may also be used to assess airway irritation.

3.2.7. Sensitisation

3.2.7.1. *Sensitisation by inhalation*

Substances and preparations shall be classified as sensitising and assigned the symbol 'Xn', the indication of danger 'Harmful' and the risk phrase R42 in accordance with the criteria given below.

R42 May cause sensitisation by inhalation

- if there is evidence that the substance or preparation can induce specific respiratory hypersensitivity;
- where there are positive results from appropriate animal tests; or
- if the substance is an isocyanate, unless there is evidence that the specific isocyanate does not cause respiratory hypersensitivity

Comments regarding the use of R42

Human evidence

Evidence that the substance or preparation can induce specific respiratory hypersensitivity will normally be based on human experience. In this context hypersensitivity is normally seen as asthma, but other hypersensitivity reactions such as rhinitis and alveolitis are also considered. The condition will have the clinical character of an allergic reaction. However, immunological mechanisms do not have to be demonstrated.

When considering the evidence from human exposure, it is necessary for a decision on classification to take into account in addition to the evidence from the cases:

- the size of the population exposed
- the extent of exposure.

The evidence referred to above could be:

- clinical history and data from appropriate lung function tests related to exposure to the substance, confirmed by other supportive evidence which may include:
- a chemical structure related to substances known to cause respiratory hypersensitivity;
- an *in vivo* immunological test (e.g. skin prick test);
- an *in vitro* immunological test (e.g. serological analysis);
- studies indicating other specific but non-immunological mechanisms of action, e.g. repeated low-level irritation, pharmacologically mediated effects; or
- data from a positive bronchial challenge test with the substance conducted according to accepted guidelines for the determination of a specific hypersensitivity reaction.

Clinical history should include both medical and occupational history to determine a relationship between exposure to a specific substance or preparation and development of respiratory hypersensitivity. Relevant information includes aggravating factors both in the home and workplace, the onset and progress of the disease, family history and medical history of the patient in question. The medical history should also include a note of other allergic or airway disorders from childhood, and smoking history.

The results of positive bronchial challenge tests are considered to provide sufficient evidence for classification on their own. It is however recognised that in practice many of the examinations listed above will already have been carried out.

Substances that elicit symptoms of asthma by irritation only in people with bronchial hyperreactivity should not be assigned R42.

Animal studies

Data from tests which may be indicative of the potential of a substance or preparation to cause sensitisation by inhalation in humans may include:

- IgE measurements (e.g. in mice), or
- specific pulmonary responses in guinea pigs.

3.2.7.2. *Sensitisation by skin contact*

Substances and preparations shall be classified as sensitising and assigned the symbol 'Xi', the indication of danger 'Irritant' and the risk phrase R43 in accordance with the criteria given below:

R43 May cause sensitisation by skin contact

- If practical experience shows the substance or preparation to be capable of inducing a sensitisation by skin contact in a substantial number of persons, or
- where there are positive results from an appropriate animal test.

Comments regarding the use of R43

Human evidence

The following evidence (practical experience) is sufficient to classify a substance or preparation with R43:

- Positive data from appropriate patch testing, normally in more than one dermatological clinic, or
- Epidemiological studies showing allergic contacts dermatitis caused by the substance or preparation. Situations in which a high proportion of those exposed exhibit characteristic symptoms are to be looked at with special concern, even if the number of cases is small, or
- Positive data from experimental studies in man (see also 3.1.1).

The following is sufficient to classify a substance with R43 when there is supportive evidence:

- Isolated episodes of allergic contact dermatitis, or
- Epidemiological studies where chance, bias or confounders have not been ruled out fully with reasonable confidence.

Supportive evidence may include:

- data from animal tests performed according to existing guidelines, with a result that does not meet the criteria given in the section on animal studies but is sufficiently close to the limit to be considered significant, or
- data from non-standard methods, or
- appropriate structure-activity relationships.

Animal studies

Positive results from appropriate animal tests are:

- in the case of the adjuvant type test method for skin sensitisation detailed in Annex V or in the case of other adjuvant-type test methods, a response of at least 30% of the animals is considered positive;
- for any other test method a response of at least 15% of the animals is considered positive.

3.2.7.3. *Immunological contact urticaria*

Some substances or preparations, which meet the criteria for R42 may in addition cause immunological contact urticaria. In these cases, information concerning contact urticaria should be included by the use of appropriate S-phrases, usually S24 and S36/37, and in the Safety Data Sheet.

For substances or preparations, which produce signs of immunological contact urticaria which do not fulfil the criteria for R42, consideration should be given to classification with R43.

There is no recognised animal model available to identify substances which cause immunological contact urticaria. Therefore, classification will normally be based on human evidence which will be similar to that for skin sensitisation (R43).

3.2.8. Other toxicological properties

Additional risk phrases shall be assigned in accordance with the following criteria (based on experience obtained during compilation of Annex I) to substances and preparations classified by virtue of 2.2.1. to 3.2.7. above and/or chapters 4 and 5:

R29 Contact with water liberates toxic gas

For substances and preparations which in contact with water or damp air, evolve very toxic/toxic gases in potentially dangerous amounts, e.g. aluminium phosphide, phosphorus pentasulphide.

R31 Contact with acids liberates toxic gas

For substances and preparations which react with acids to evolve toxic gases in dangerous amounts, e.g. sodium hypochlorite, barium polysulphide. For substances used by members of the general public, the use of S50 (do not mix with ... (to be specified by the manufacturer)) would be more suitable.

R32 Contact with acids liberates very toxic gas

For substances and preparations which react with acids to evolve very toxic gases in dangerous amounts; e.g. salts of hydrogen cyanide, sodium azide. For substances used by members of the general public, the use of S50 (do not mix with ... (to be specified by the manufacturer)) would be more suitable.

R33 Danger of cumulative effects

For substances and preparations when accumulation in the human body is likely and may cause some concern which, however, is not sufficient to justify the use of R48.

For comments on the use of this R-phrase see Section 4.2.3.3 for substances and Annex V, Part A.3. of Directive 1999/45/EC for preparations.

R64 May cause harm to breastfed babies

For substances and preparations which are absorbed by women and may interfere with lactation or which may be present (including metabolites) in breast milk in amounts sufficient to cause concern for the health of a breastfed child.

For comments on the use of this R-phrase see Section 4.2.3.3 for substances and Annex V, Part A.4. of Directive 1999/45/EC for preparations.

R66 Repeated exposure may cause skin dryness or cracking

For substances and preparations which may cause concern as a result of skin dryness, flaking or cracking but which do not meet the criteria for R38 based on either:

- practical observation after normal handling and use, or
- relevant evidence concerning their predicted effects on the skin.

See also paragraphs 1.6 and 1.7.

R67 Vapours may cause drowsiness and dizziness

For volatile substances and preparations containing such substances which cause clear symptoms of central nervous system depression by inhalation and which are not already classified with respect to acute inhalation toxicity (R20, R23, R26 , R68/20, R39/23 or R39/26).

The following evidence may be used:

(a) Data from animal studies showing clear signs of CNS depression such as narcotic effects, lethargy, lack of co-ordination (including loss of righting reflex) and ataxia either:

- at concentrations/exposure times not exceeding 20 mg/l/4h or,
- for which the ratio of the effect concentration at ≤ 4 h to the saturated vapour concentration (SVC) at 20ºC is ≤ 1/10.

(b) Practical experience in humans (e.g. narcosis, drowsiness, reduced alertness, loss of reflexes, lack of co-ordination, vertigo) from well documented reports under comparable exposure conditions to the effects specified above for animals.

See also Paragraphs 1.6 and 1.7.

For other supplementary risk phrases see Section 2.2.6.

4. CLASSIFICATION ON THE BASIS OF SPECIFIC EFFECTS ON HUMAN HEALTH

4.1. Introduction

4.1.1. This Chapter sets out the procedure for the classification of substances which may have the effects mentioned below. For preparations see Section 4.2.4.

4.1.2. If a manufacturer, distributor or importer has information available which indicates that a substance should be classified and labelled in accordance with the criteria given in Section 4.2.1, 4.2.2 or 4.2.3, he shall provisionally label the substance in accordance with these criteria, on the basis of the assessment of the evidence by a competent person.

4.1.3. The manufacturer, distributor or importer shall submit as soon as possible a document summarising all relevant information to one Member State in which the substance is placed on the market. Relevant information in this context comprises in particular all available published and unpublished information required for appropriate classification of the substance in question, on the basis of the intrinsic properties according to the categories laid down in Article 2 (2) and in accordance with the criteria in this Annex. The submitted summary document should include a bibliography containing all relevant references, including any relevant unpublished data.

4.1.4. Furthermore, a manufacturer, distributor or importer who has new data which are relevant to the classification and labelling of a substance in accordance with the criteria given in Section 4.2.1., 4.2.2. or 4.2.3., shall submit this data as soon as possible to one Member State in which the substance is placed on the market.

4.1.5. To obtain as quickly as possible a harmonised classification for the Community by the procedure defined in Article 28 of Directive 67/548/EEC, Member States which have relevant information available justifying the classification of a substance in one of these categories, whether submitted by the manufacturer or not, should forward such information together with suggestions for classification and labelling, to the Commission as soon as possible.

The Commission will forward to the other Member States the classification and labelling proposal that it receives. Any Member State may ask the Commission for the information it has received.

Any Member State which has good reason to believe that the suggested classification and labelling is inappropriate as far as the carcinogenic, mutagenic or reproductive toxicity effects are concerned shall notify the Commission thereof.

4.2. **Criteria for classification, indication of danger, choice of risk phrases**

4.2.1. Carcinogenic substances

For the purpose of classification and labelling, and having regard to the current state of knowledge, such substances are divided into three categories:

Category 1

Substances known to be carcinogenic to man. There is sufficient evidence to establish a causal association between human exposure to a substance and the development of cancer.

Category 2

Substances which should be regarded as if they are carcinogenic to man. There is sufficient evidence to provide a strong presumption that human exposure to a substance may result in the development of cancer, generally on the basis of:

- appropriate long-term animal studies,
- other relevant information.

Category 3

Substances which cause concern for man owing to possible carcinogenic effects but in respect of which the available information is not adequate for making a satisfactory assessment. There is some evidence from appropriate animal studies, but this is insufficient to place the substance in Category 2.

4.2.1.1. *The following symbols and specific risk phrases apply:*

Categories 1 and 2:

Substances classified as carcinogenic category 1 or 2 shall be assigned the symbol 'T' and the risk phrase

R45 May cause cancer

However, substances and preparations which present a carcinogenic risk only when inhaled, for example, as dust, vapour or fumes, (other routes of exposure e.g. by swallowing or in contact with skin do not present any carcinogenic risk), shall be assigned the symbol 'T' and the risk phrase

R49 May cause cancer by inhalation

Category 3:

Substances classified as carcinogenic category 3 shall be assigned the symbol 'Xn' and the risk phrase

R40 Limited evidence of a carcinogenic effect

4.2.1.2. *Comments regarding the categorisation of carcinogenic substances*

The placing of a substance into Category 1 is done on the basis of epidemiological data; placing into Categories 2 and 3 is based primarily on animal experiments.

For classification as a Category 2 carcinogen either positive results in two animal species should be available or clear positive evidence in one species, together with supporting evidence such as genotoxicity data, metabolic or biochemical studies, induction of benign tumours, structural relationship with other known carcinogens, or data from epidemiological studies suggesting an association.

Category 3 actually comprises 2 sub-categories:

(a) substances which are well investigated but for which the evidence of a tumour-inducing effect is insufficient for classification in Category 2. Additional experiments would not be expected to yield further relevant information with respect to classification;

(b) substances which are insufficiently investigated. The available date are inadequate, but they raise concern for man. This classification is provisional; further experiments are necessary before a final decision can be made.

For a distinction between Categories 2 and 3 the arguments listed below are relevant which reduce the significance of experimental tumour induction in view of possible human exposure. These arguments, especially in combination, would lead in most cases to classification in Category 3, even though tumours have been induced in animals:

- carcinogenic effects only at very high dose levels exceeding the 'maximal tolerated dose'. The maximal tolerated dose is characterised by toxic effects which, although not yet reducing lifespan, go along with physical changes such as about 10 % retardation in weight gain,
- appearance of tumours, especially at high dose levels, only in particular organs of certain species known to be susceptible to a high spontaneous tumour formation,
- appearance of tumours, only at the site of application, in very sensitive test systems (e.g., i.p. or s.c. application of certain locally active compounds), if the particular target is not relevant to man,
- lack of genotoxicity in short-term tests *in vivo* and *in vitro*,
- existence of a secondary mechanism of action with the implication of a practical threshold above a certain dose level (e.g., hormonal effects on target organs or on mechanisms of physiological regulation, chronic stimulation of cell proliferation),
- existence of a species - specific mechanism of tumour formation (e.g. by specific metabolic pathways) irrelevant for man.

For a distinction between Category 3 and no classification arguments are relevant which exclude a concern for man:

- a substance should not be classified in any of the categories if the mechanism of experimental tumour formation is clearly identified, with good evidence that this process cannot be extrapolated to man,
- if the only available tumour data are liver tumours in certain sensitive strains of mice, without any other supplementary evidence, the substance may not be classified in any of the categories,
- particular attention should be paid to cases where the only available tumour data are the occurrence of neoplasms at sites and in strains where they are well known to occur spontaneously with a high incidence.

4.2.2. Mutagenic substances

4.2.2.1. For the purposes of classification and labelling, and having regard to the current state of knowledge, such substances are divided into three categories:

Category 1

Substances known to be mutagenic to man.

There is sufficient evidence to establish a causal association between human exposure to a substance and heritable genetic damage.

Category 2

Substances which should be regarded as if they are mutagenic to man.

There is sufficient evidence to provide a strong presumption that human exposure to the substance may result in the development of heritable genetic damage, generally on the basis of:

- appropriate animal studies,
- other relevant information.

Category 3

Substances which cause concern for man owing to possible mutagenic effects. There is evidence from appropriate mutagenicity studies, but this is insufficient to place the substance in Category 2.

4.2.2.2. *The following symbols and specific risk phrases apply:*

Categories 1 and 2:

Substances classified as mutagenic category 1 or 2 shall be assigned the symbol 'T' and the risk phrase

R46 May cause heritable genetic damage

Category 3:

Substances classified as mutagenic category 3 shall be assigned the symbol 'Xn' and the risk phrase

R68 Possible risk of irreversible effects

4.2.2.3. *Comments regarding the categorisation of mutagenic substances*

Definition of terms:

A mutation is a permanent change in the amount or structure of the genetic material in an organism, resulting in a change of the phenotypic characteristics of the organism. The alterations may involve a single gene, a block of genes, or a whole chromosome. Effects involving single genes may be a consequence of effects on single DNA bases (point mutations) or of large changes, including deletions, within the gene. Effects on whole chromosomes may involve structural or numerical changes. A mutation in the germ cells in

sexually reproducing organisms may be transmitted to the offspring. A mutagen is an agent that gives rise to an enhanced occurrence of mutations.

It should be noted that substances are classified as mutagens with specific reference to inherited genetic damage. However, the type of results leading to classification of chemicals in Category 3: 'induction of genetically relevant events in somatic cells`, is generally also regarded as an alert for possible carcinogenic activity.

Method development for mutagenicity testing is an ongoing process. For many new tests no standardised protocols and evaluation criteria are presently available. For the evaluation of mutagenicity data the quality of the test performance and the degree of validation of the test method have to be considered.

Category 1

To place a substance in Category 1, positive evidence from human mutation epidemiology studies will be needed. Examples of such substances are not known to date. It is recognised that it is extremely difficult to obtain reliable information from studies on the incidence of mutations in human populations, or on possible increases in their frequencies.

Category 2

To place a substance in Category 2, positive results are needed from assays showing (a) mutagenic effects, or (b) other cellular interactions relevant to mutagenicity, in germ cells of mammals *in vivo*, or (c) mutagenic effects in somatic cells of mammals *in vivo* in combination with clear evidence that the substance or a relevant metabolite reaches the germ cells.

With respect to placement in Category 2, at present the following methods are appropriate:

2 (a) *in vivo* germ cell mutagenicity assays:

- specific locus mutation test,
- heritable translocation test,
- dominant lethal mutation test.

These assays actually demonstrate the appearance of affected progeny or a defect in the developing embryo.

2 (b) *in vivo* assays showing relevant interaction with germ cells (usually DNA):

- assays for chromosomal abnormalities, as detected by cytogenetic analysis, including aneuploidy, caused by malsegregation of chromosomes,
- test for sister chromatid exchanges (SCEs),
- test for unscheduled DNA synthesis (UDS),
- assay of (covalent) binding of mutagen to germ cell DNA,
- assaying other kinds of DNA damage.

These assays provide evidence of a more or less indirect nature. Positive results in these assays would normally be supported by positive results from *in vivo* somatic cell mutagenicity assays, in mammals or in man (see under Category 3, preferably methods as under 3 (a)).

2 (c) in *vivo* assays showing mutagenic effects in somatic cells of mammals (see under 3 (a)), in combination with toxicokinetic methods, or other methodologies capable of demonstrating that the compound or a relevant metabolite reaches the germ cells.

For 2 (b) and 2 (c), positive results from host-mediated assays or the demonstration of unequivocal effects in *in vitro* assays can be considered as supporting evidence.

Category 3

To place a substance in Category 3, positive results are needed in assays showing (a) mutagenic effects or (b) other cellular interaction relevant to mutagenicity, in somatic cells in mammals *in vivo*. The latter especially would normally be supported by positive results from *in vitro* mutagenicity assays.

For effects in somatic cells *in vivo* at present the following methods are appropriate:

3 (a) *in vivo* somatic cell mutagenicity assays:

- bone marrow micronucleus test or metaphase analysis,
- metaphase analysis of peripheral lymphocytes,
- mouse coat colour spot test.

3 (b) *in vivo* somatic cell DNA interaction assays:

- test for SCEs in somatic cells,
- test for UDS in somatic cells,
- assay for the (covalent) binding of mutagen to somatic cell DNA,
- assay for DNA damage, e.g. by alkaline elution, in somatic cells.

Substances showing positive results only in one or more *in vitro* mutagenicity assays should normally not be classified. Their further investigation using *in vivo* assays, however, is strongly indicated. In exceptional cases, e.g. for a substance showing pronounced responses in several *in vitro* assays, for which no relevant *in vivo* data are available, and which shows resemblance to known mutagens/carcinogens, classification in Category 3 could be considered.

4.2.3. Substances toxic to reproduction

4.2.3.1. For the purposes of classification and labelling and having regard to the present state of knowledge, such substances are divided into 3 categories:

Category 1

Substances known to impair fertility in humans

There is sufficient evidence to establish a causal relationship between human exposure to the substance and impaired fertility.

Substances known to cause developmental toxicity in humans

There is sufficient evidence to establish a causal relationship between human exposure to the substance and subsequent developmental toxic effects in the progeny.

Category 2

Substances which should be regarded as if they impair fertility in humans

There is sufficient evidence to provide a strong presumption that human exposure to the substance may result in impaired fertility on the basis of:

- clear evidence in animal studies of impaired fertility in the absence of toxic effects, or, evidence of impaired fertility occurring at around the same dose levels as other toxic effects but which is not a secondary non-specific consequence of the other toxic effects,
- other relevant information.

Substances which should be regarded as if they cause developmental toxicity to humans

There is sufficient evidence to provide a strong presumption that human exposure to the substance may result in developmental toxicity, generally on the basis of:

- clear results in appropriate animal studies where effects have been observed in the absence of signs of marked maternal toxicity, or at around the same dose levels as other toxic effects but which are not a secondary non-specific consequence of the other toxic effects,
- other relevant information.

Category 3

Substances which cause concern for human fertility

Generally on the basis of:

- results in appropriate animal studies which provide sufficient evidence to cause a strong suspicion of impaired fertility in the absence of toxic effects, or evidence of impaired fertility occuring at around the same dose levels as other toxic effects, but which is not a secondary non-specific consequence of the other toxic effects, but where the evidence is insufficient to place the substance in Category 2,
- other relevant information.

Substances which cause concern for humans owing to possible developmental toxic effects

Generally on the basis of:

- results in appropriate animal studies which provide sufficient evidence to cause a strong suspicion of developmental toxicity in the absence of signs of marked maternal toxicity, or at around the same dose levels as other toxic effects but which are not a secondary non-specific consequence of the other toxic effects, but where the evidence is insufficient to place the substance in Category 2,
- other relevant information.

4.2.3.2. *The following symbols and specific risk phrases apply:*

Category 1

for substances that impair fertility in humans:

Substances classified as toxic to reproduction category 1 shall be assigned the symbol 'T' and the risk phrase

R60 May impair fertility

for substances that cause developmental toxicity:

Substances classified as toxic to reproduction category 1 shall be assigned the symbol 'T' and the risk phrase

R61 May cause harm to the unborn child

Category 2

for substances that should be regarded as if they impair fertility in humans:

Substances classified as toxic to reproduction category 2 shall be assigned the symbol 'T' and the risk phrase

R60 May impair fertility

for substances that should be regarded as if they cause developmental toxicity in humans:

Substances classified as toxic to reproduction category 2 shall be assigned the symbol 'T' and the risk phrase

R61 May cause harm to the unborn child.

Category 3

for substances which cause concern for human fertility:

Substances classified as toxic to reproduction category 3 shall be assigned the symbol 'Xn' and the risk phrase

R62 Possible risk of impaired fertility

for substances which cause concern for humans owing to possible developmental toxic effects:

Substances classified as toxic to reproduction category 3 shall be assigned the symbol 'Xn' and the risk phrase

R63 Possible risk of harm to the unborn child.

4.2.3.3. *Comments regarding the categorisation of substances toxic to reproduction*

Reproductive toxicity includes impairment of male and female reproductive functions or capacity and the induction of non-inheritable harmful effects on the progeny. This may be classified under two main headings of 1. Effects on male or female fertility; 2. Developmental toxicity.

1 Effects on male or female fertility, includes adverse effects on libido, sexual behaviour, any aspect of spermatogenesis or oogenesis, or on hormonal activity or physiological response which would interfere with the capacity to fertilise, fertilisation itself or the development of the fertilised ovum up to and including implantation.

2 Developmental toxicity, is taken in its widest sense to include any effect interfering with normal development, both before and after birth. It includes effects induced or manifested prenatally as well as those manifested postnatally. This includes embrytoxic/fetotoxic effects such as reduced body weight, growth and developmental retardation, organ toxicity, death, abortion, structural defects (teratogenic effects), functional defects, peri-postnatal defects, and impaired postnatal mental or physical development up to and including normal pubertal development.

Classification of chemicals as toxic to reproduction is intended to be used for chemicals which have an intrinsic or specific property to produce such toxic effects. Chemicals should not be classified as toxic to reproduction where such effects are solely produced as a non-specific

secondary consequence of other toxic effects. Chemicals of most concern are those which are toxic to reproduction at exposure levels which do not produce other signs of toxicity.

The placing of a compound in Category 1 for effects on fertility and/or developmental toxicity is done on the basis of epidemiological data. Placing into Categories 2 or 3 is done primarily on the basis of animal data. Data from *in vitro* studies, or studies on avian eggs, are regarded as 'supportive evidence' and would only exceptionally lead to classification in the absence of *in vivo* data.

In common with most other types of toxic effect, substances demonstrating reproductive toxicity will be expected to have a threshold below which adverse effects would not be demonstrated. Even when clear effects have been demonstrated in animal studies the relevance for humans may be doubtful because of the doses administered, for example, where effects have been demonstrated only at high doses, or where marked toxicokinetic differences exist, or the route of administration is inappropriate. For these or similar reasons it may be that classification in Category 3, or even no classification, will be warranted.

Annex V to Directive 67/548/EEC specifies a limit test in the case of substances of low toxicity. If a dose level of at least 1000 mg/kg orally produces no evidence of effects toxic to reproduction, studies at other dose levels may not be considered necessary. If data are available from studies carried out with doses higher than the above limit dose, this data must be evaluated together with other relevant data. Under normal circumstances it is considered that effects seen only at doses in excess of the limit dose would not necessarily lead to classification as 'Toxic to reproduction`.

EFFECTS ON FERTILITY

For the classification of a substance into Category 2 for impaired fertility, there should normally be clear evidence in one animal species, with supporting evidence on mechanism of action or site of action, or chemical relationship to other known anti-fertility agents or other information from humans which would lead to the conclusion that effects would be likely to be seen in humans. Where there are studies in only one species without other relevant supporting evidence then classification in Category 3 may be appropriate.

Since impaired fertility may occur as a non-specific accompaniment to severe generalised toxicity or where there is severe inanition, classification into Category 2 should only be made where there is evidence that there is some degree of specificity of toxicity for the reproductive system. If it was demonstrated that impaired fertility in animal studies was due to failure to mate, then for classification into Category 2, it would normally be necessary to have evidence on the mechanism of action in order to interpret whether any adverse effect such as alteration in pattern of hormonal release would be likely to occur in humans.

DEVELOPMENTAL TOXICITY

For classification into Category 2 there should be clear evidence of adverse effects in well conducted studies in one or more species. Since adverse effects in pregnancy or postnatally may result as a secondary consequence of maternal toxicity, reduced food or water intake, maternal stress, lack of maternal care, specific dietary deficiencies, poor animal husbandry, intercurrent infections, and so on, it is important that the effects observed should occur in well conducted studies and at dose levels which are not associated with marked maternal toxicity. The route of exposure is also important. In particular, the injection of irritant material intraperitoneally may result in local damage to the uterus and its contents, and the results of such studies must be interpreted with caution and on their own would not normally lead to classification.

Classification into Category 3 is based on similar criteria as for Category 2 but may be used where the experimental design has deficiencies which make the conclusions less convincing, or where the possibility that the effects may have been due to non-specific influences such as generalised toxicity cannot be excluded.

In general, classification in Category 3 or no category would be assigned on an ad hoc basis where the only effects recorded are small changes in the incidences of spontaneous defects, small changes in the proportions of common variants such as are observed in skeletal examinations, or small differences in postnatal developmental assessments.

Effects during lactation

Substances which are classified as toxic to reproduction and which also cause concern due to their effects on lactation should in addition be labelled with R64 (see criteria in Section 3.2.8.).

For the purpose of classification, toxic effects on offspring resulting only from exposure via the breast milk, or toxic effects resulting from direct exposure of children will not be regarded as 'Toxic to reproduction`, unless such effects result in impaired development of the offspring.

Substances which are not classified as toxic to reproduction but which cause concern due to toxicity when transferred to the baby during the period of lactation should be labelled with R64 (see criteria in Section 3.2.8.). This R-phrase may also be appropriate for substances which affect the quantity or quality of the milk.

R64 would normally be assigned on the basis of :

(a) toxicokinetic studies that would indicate the likelihood that the substance would be present in potentially toxic levels in breast milk; and/or

(b) on the basis of results of one or two generation studies in animals which indicate the presence of adverse effects on the offspring due to transfer in the milk; and/or

(c) on the basis of evidence in humans indicating a risk to babies during the lactational period.

Substances which are known to accumulate in the body and which subsequently may be released into milk during lactation may be labelled with R33 and R64.

4.2.4. Procedure for the classification of preparations concerning specific effects on health

If a preparation contains one or more substances classified with respect to the criteria laid out above, it must be classified according to the criteria referred to in Annex II, Part A. 7. – 9. and Part B. 6. of Directive 1999/45/EC (the concentration limits are either in Annex I of this Directive, or in Annex II, Part B. 6. of Directive 1999/45/EC where the substance or substances under consideration do not appear in Annex I or appear in it without concentration limits).

5. CLASSIFICATION ON THE BASIS OF ENVIRONMENTAL EFFECTS

5.1. Introduction

The primary objective of classifying substances and preparations dangerous for the environment is to alert the user to the hazards these substances and preparations present to ecosystems. Although the present criteria refer to aquatic ecosystems it is recognised that certain substances and preparations may simultaneously or alternatively affect other ecosystems whose constituents may range from soil microflora and microfauna to primates.

The criteria set out below follow directly from the test methods set out in Annex V in so far as they are mentioned. The test methods required for the 'base set' referred to in Annex VII are limited and the information derived from them may be insufficient for an appropriate classification. Classification may require additional data derived from Level 1 (Annex VIII) or other equivalent studies. Furthermore, classified substances may be subject to review in the light of other new data.

For the purposes of classification and labelling and having regard to the current state of knowledge such substances and preparations are divided into two groups according to their acute and/or long-term effects in aquatic systems or their acute and/or long-term effects in non-aquatic systems.

5.1.1. The classification of substances is usually made on the basis of experimental data for acute aquatic toxicity, degradation, and log Pow (or BCF if available).

5.1.2. The classification of preparations shall normally be carried out on the basis of a conventional method referred to in Article 7 and Annex III, Parts A and B of Directive 1999/45/EC. In this case, the classification is based on the individual concentration limits

- in Annex I to Directive 67/548/EEC
- or in Annex III Part B to Directive 1999/45/EC where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits.

5.1.3. Normally, the classification of a preparation is made on the basis of a 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 a conventional method. 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 to Directive 67/548/EEC have been complied with. Furthermore, the tests are to be carried out on all three groups of species in conformity with the criteria in this Annex (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 Directive 1999/45/EC entered into force.

5.2. **Criteria for classification, indication of danger, choice of risk phrases**

The classification criteria for substances in Section 5.2.1. only apply to preparations where they have been tested in accordance with 5.1.3.

5.2.1. Aquatic environment

5.2.1.1. Substances shall be classified as dangerous for the environment and assigned the symbol 'N' and the appropriate indication of danger, and assigned risk phrases in accordance with the following criteria:

R50 Very toxic to aquatic organisms

and

R53 May cause long-term adverse effects in the aquatic environment

Acute toxicity:		96 hr LC_{50} (for fish)	$\leq$ 1 mg/l
	or	48 hr EC_{50} (for Daphnia)	$\leq$ 1 mg/l
	or	72 hr IC_{50} (for algae)	$\leq$ 1 mg/l

and

- the substance is not readily degradable

or

- the log Pow (log octanol/water partition coefficient) $\geq$ 3.0 (unless the experimentally determined BCF $\leq$ 100).

R50 Very toxic to aquatic organisms

Acute toxicity:		96 hr LC_{50} (for fish)	$\leq$ 1 mg/l
	or	48 hr EC_{50}(for Daphnia)	$\leq$ 1 mg/l
	or	72 hr IC_{50}(for algae)	$\leq$ 1 mg/l

R51 Toxic to aquatic organisms

and

R53 May cause long-term adverse effects in the aquatic environment

Acute toxicity:		96 hr LC_{50} (for fish)	1 mg/l < $LC_{50} \leq$ 10 mg/l
	or	48 hr EC_{50} (for Daphnia)	1 mg/l < $EC_{50} \leq$ 10 mg/l
	or	72 hr IC_{50} (for algae)	1 mg/l < $IC_{50} \leq$ 10 mg/l

and

- the substance is not readily degradable

or

- the log Pow $\geq$ 3.0 (unless the experimentally determined BCF $\leq$ 100).

5.2.1.2. Substances shall be classified as dangerous for the environment in accordance with the criteria set out below. Risk phrases shall also be assigned in accordance with the following criteria

R52 Harmful to aquatic organisms

and

R53 May cause long-term adverse effects in the aquatic environment

Acute toxicity:		96 hr LC_{50} (for fish)	10 mg/l < $LC_{50} \leq$ 100 mg/l
	or	48 hr EC_{50} (for Daphnia)	10 mg/l < $EC_{50} \leq$ 100 mg/l
	or	72 hr IC_{50} (for algae)	10 mg/l < $IC_{50} \leq$ 100 mg/l

and

the substance is not readily degradable.

This criterion applies unless there exists additional scientific evidence concerning degradation and/or toxicity sufficient to provide an adequate assurance that neither the substance nor its degradation products will constitute a potential long-term and/or delayed danger to the aquatic environment. Such additional scientific evidence should normally be based on the studies required at Level 1 (Annex VIII), or studies of equivalent value, and could include:

(i) a proven potential to degrade rapidly in the aquatic environment,

(ii) an absence of chronic toxicity effects at a concentration of 1.0 mg/litre, e.g. a no-observed effect concentration of greater than 1.0 mg/litre determined in a prolonged toxicity study with fish or Daphnia.

R52 Harmful to aquatic organisms

Substances not falling under the criteria listed above in this chapter, but which on the basis of the available evidence concerning their toxicity may nevertheless present a danger to the structure and/or functioning of aquatic ecosystems.

R53 May cause long-term adverse effects in the aquatic environment

Substances not falling under the criteria listed above in this chapter, but which, on the basis of the available evidence concerning their persistence, potential to accumulate, and predicted or observed environmental fate and behaviour may nevertheless present a long-term and/or delayed danger to the structure and/or functioning of aquatic ecosystems.

For example, poorly water-soluble substances, i.e. substances with a solubility of less than 1 mg/l will be covered by this criterion if :

(a) they are not readily degradable; and
(b) the log Pow $\geq$ 3.0 (unless the experimentally determined BCF $\leq$ 100).

This criterion applies to substances unless there exists additional scientific evidence concerning degradation and/or toxicity sufficient to provide an adequate assurance that neither the substance nor its degradation products will constitute a potential long-term and/or delayed danger to the aquatic environment.

Such additional scientific evidence should normally be based on the studies required at Level 1 (Annex VIII), or studies of equivalent value, and could include

(i) a proven potential to degrade rapidly in the aquatic environment;

(ii) an absence of chronic toxicity effects at the solubility limit e.g. a no-observed effect concentration of greater than the solubility limit determined in a prolonged toxicity study with fish or Daphnia.

5.2.1.3. *Comments on the determination of IC_{50} for algae and of degradability*

- where it can be demonstrated in the case of highly coloured substances that algal growth is inhibited solely as a result of a reduction in light intensity, then the 72h IC_{50} for algae should not be used as a basis for classification.

- Substances are considered readily degradable if the following criteria hold true.

(a) If in 28-day biodegradation studies the following levels of degradation are achieved

  - in tests based upon dissolved organic carbon: 70%,
  - in tests based upon oxygen depletion or carbon dioxide generation: 60 % of the theoretical maxima.

  These levels of biodegradation must be achieved within 10 days of the start of degradation, which point is taken as the time when 10% of the substance has been degraded.

  or

(b) if in those cases where only COD and BOD5 data are available when the ratio of BOD5/COD is greater than or equal to 0.5;

  or

(c) if other convincing scientific evidence is available to demonstrate that the substance can be degraded (biotically and/or abiotically) in the aquatic environment to a level of > 70% within a 28-day period.

5.2.2. Non - aquatic environment

5.2.2.1. Substances and preparations shall be classified as dangerous for the environment and assigned the symbol 'N' and the appropriate indication of danger, and assigned risk phrases in accordance with the following criteria:

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

Substances and preparations which on the basis of the available evidence concerning their toxicity, persistence, potential to accumulate and predicted or observed environmental fate and behaviour may present a danger, immediate or long-term and/or delayed, to the structure and/or functioning of natural ecosystems other than those covered under 5.2.1 above. Detailed criteria will be elaborated later.

5.2.2.2. Substances and preparations shall be classified as dangerous for the environment, and assigned the symbol 'N' and the appropriate indication of danger, where applicable, and assigned risk phrases in accordance with the following criteria:

R59 Dangerous for the ozone layer

Substances which on the basis of the available evidence concerning their properties and their predicted or observed environmental fate and behaviour may present a danger to the structure and/or the functioning of the stratospheric ozone layer. This includes the substances which are listed in Annex I to Council Regulation (EC) No 2037/2000 on substances that deplete the ozone layer (OJ No L 244, 29.9.2000, p.1) and its subsequent amendments.

Preparations shall be classified on the basis of a conventional method referred to in Article 7 and Annex III, Parts A and B of Directive 1999/45/EC.

6. CHOICE OF SAFETY ADVICE PHRASES

6.1. Introduction

Safety advice phrases (S-phrases) shall be assigned to dangerous substances and preparations in accordance with the following general criteria. In addition, for certain preparations, the safety advice listed in Annex V of Directive 1999/45/EC is mandatory.

Whenever the manufacturer is mentioned in Chapter 6 it refers to the person responsible for placing the substance or preparation on the market.

6.2. Safety phrases for substances and preparations

S1 *Keep locked up*

- Applicability:
  - very toxic, toxic and corrosive substances and preparations.
- Criteria for use:
  - *obligatory* for those substances and preparations mentioned above if sold to the general public.

S2 *Keep out of the reach of children*

- Applicability:

- all dangerous substances and preparations.

- Criteria for use:

  - *obligatory* for all dangerous substances and preparations sold to the general public, except for those only classified as dangerous for the environment.

S3 *Keep in a cool place*

- Applicability:

  - organic peroxides,

  - other dangerous substances and preparations having a boiling point ≤ 40° C.

- Criteria for use:

  - *obligatory* for organic peroxides unless S47 is used,

  - recommended for other dangerous substances and preparations having a boiling point ≤ 40°C.

S4 *Keep away from living quarters*

- Applicability:

  - very toxic and toxic substances and preparations.

- Criteria for use:

  - normally limited to very toxic and toxic substances and preparations when desirable to supplement S13; for example when there is an inhalation risk and the substance or preparation should be stored away from living quarters. The advice is not intended to preclude proper use of the substance or preparation in living quarters.

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

- Applicability:

  - spontaneously flammable solid substances and preparations.

- Criteria for use:

  - normally limited to special cases, e.g. sodium, potassium or white phosphorous.

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

- Applicability:

  - dangerous substances and preparations which must be kept under an inert atmosphere.

- Criteria for use:

  - normally limited to special cases, e.g. certain organo-metallic compounds.

S7 *Keep container tightly closed*

- Applicability:
  - organic peroxides,
  - substances and preparations which can give off very toxic, toxic, harmful or extremely flammable gases,
  - substances and preparations which in contact with moisture give off extremely flammable gases,
  - highly flammable solids.
- Criteria for use:
  - *obligatory* for organic peroxides,
  - recommended for the other fields of application mentioned above.

S8 *Keep container dry*

- Applicability:
  - substances and preparations which may react violently with water,
  - substances and preparations which on contact with water liberate extremely flammable gases,
  - substances and preparations which on contact with water liberate very toxic or toxic gases.
- Criteria for use:
  - normally limited to the fields of application mentioned above when necessary to reinforce warnings given by R14, R15 in particular, and R29.

S9 *Keep container in a well-ventilated place*

- Applicability:
  - volatile substances and preparations which may give off very toxic, toxic or harmful vapours,
  - extremely flammable or highly flammable liquids and extremely flammable gases.
- Criteria for use:
  - recommended for volatile substances and preparations which may give off very toxic, toxic or harmful vapours,
  - recommended for extremely flammable or highly flammable liquids or extremely flammable gases.

S12 *Do not keep the container sealed*

- Applicability:

- substances and preparations which will by giving off gases or vapours be liable to burst the container.

- Criteria for use:

  - normally limited to the special cases mentioned above.

S13 *Keep away from* food, *drink and animal feedingstuffs*

- Applicability:

  - very toxic, toxic and harmful substances and preparations.

- Criteria for use:

  - recommended when such substances and preparations are likely to be used by the general public.

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

- Applicability:

  - organic peroxides.

- Criteria for use:

  - *obligatory* for and normally limited to organic peroxides. However, may be useful in exceptional cases when incompatibility is likely to produce a particular risk.

S15 *Keep away from heat*

- Applicability:

  - substances and preparations which may decompose or which may react spontaneously under the effect of heat.

- Criteria for use:

  - normally limited to special cases, e.g. monomers, but not assigned if risk phrases R2, R3 and/or R5 have already been applied.

S16 *Keep away from sources of ignition - No smoking*

- Applicability:

  - extremely flammable or highly flammable liquids and extremely flammable gases.

- Criteria for use:

  - recommended for the substances and preparations mentioned above but not assigned if risk phrases R2, R3 and/or R5 have already been applied.

S17 *Keep away from combustible material*

- Applicability:
    - substances and preparations which may form explosive or spontaneously flammable mixtures with combustible material.
- Criteria for use:
    - available for use in special cases, e.g. to emphasise R8 and R9.

S18 *Handle and open container with care*

- Applicability:
    - substances and preparations liable to produce an overpressure in the container,
    - substances and preparations which may form explosive peroxides.
- Criteria for use:
    - normally limited to the above-mentioned cases when there is risk of damage to the eyes and/or when the substances and preparations are likely to be used by the general public.

S20 *When using do not eat or drink*

- Applicability:
    - very toxic, toxic and corrosive substances and preparations.
- Criteria for use:
    - normally limited to special cases (e.g. arsenic and arsenic compounds; fluoracetates) in particular when any of these are likely to be used by the general public.

S21 *When using do not smoke*

- Applicability:
    - substances and preparations which produce toxic products on combustion.
- Criteria for use
    - normally limited to special cases (e.g. halogenated compounds).

S22 *Do not breathe dust*

- Applicability:
    - all solid substances and preparations dangerous for health.
- Criteria for use:
    - *obligatory* for those substances and preparations mentioned above to which R42 is assigned,
    - recommended for those substances and preparations mentioned above which are

supplied in the form of an inhalable dust and for which the health hazards following inhalation are not known.

S23 *Do not breathe gas/fumes/vapour/spray (appropriate wording to be specified by the manufacturer)*

- Applicability:
  - all liquid or gaseous substances and preparations dangerous to health.
- Criteria for use:
  - *obligatory* for those substances and preparations mentioned above to which R42 is assigned,
  - *obligatory* for substances and preparations intended for use by spraying. Either S38 or S51 must be ascribed in addition,
  - recommended when it is necessary to draw the attention of the user to inhalation risks not mentioned in the risk phrases which have to be ascribed.

S24 *Avoid contact with skin*

- Applicability:
  - all substances and preparations dangerous for health.
- Criteria for use:
  - *obligatory* for those substances and preparations to which R43 has been ascribed, unless S36 has also been ascribed,
  - recommended when it is necessary to draw the attention of the user to skin contact risks not mentioned in the risk phrases (e.g. paresthesia) which have to be ascribed. However, may be used to emphasise such risk phrases.

S25 *Avoid contact with eyes*

- Applicability:
  - all substances and preparations dangerous to health.
- Criteria for use:
  - recommended when it is necessary to draw the attention of the user to eye contact risks not mentioned in the risk phrases which have to be applied. However, may be used to emphasise such risk phrases.
  - recommended for substances ascribed R34, R35, R36 or R41 which are likely to be used by the general public.

S26 *In case of contact with eyes, rinse immediately with plenty of water and seek medical advice*

- Applicability:

- corrosive or irritant substances and preparations.

- Criteria for use:

  - *obligatory* for corrosive substances and preparations and those to which R41 has already been ascribed,

  - recommended for irritant substances and preparations to which the risk phrase R36 has already been ascribed.

S27 *Take off immediately all contaminated clothing.*

- Applicability:

  - very toxic, toxic or corrosive substances and preparations.

- Criteria for use:

  - *obligatory* for very toxic substances and preparations to which R27 has been ascribed and which are likely to be used by the general public.

  - recommended for very toxic substances and preparations to which R27 has been ascribed used in industry. However, this safety phrase should not be used if S36 has been ascribed.

  - recommended for toxic substances and preparations to which R24 has been ascribed as well as corrosive substances and preparations which are likely to be used by the general public.

S28 *After contact with skin, wash immediately with plenty of ... (to be specified by the manufacturer).*

- Applicability:

  - very toxic, toxic or corrosive substances and preparations.

- Criteria for use:

  - *obligatory* for very toxic substances and preparations.

  - recommended for the other substances and preparations mentioned above, in particular when water is not the most appropriate rinsing fluid.

  - recommended for corrosive substances and preparations which are likely to be used by the general public.

S29 *Do not empty into drains*

- Applicability:

  - extremely or highly flammable liquids immiscible with water,

  - very toxic and toxic substances and preparations,

  - substances and preparations dangerous for the environment.

- Criteria for use:

- *obligatory* for substances and preparations dangerous for the environment and assigned the symbol 'N', which are likely to be used by the general public, unless this is the intended use.

- recommended for other substances and preparations mentioned above which are likely to be used by the general public, unless this is the intended use.

S30 *Never add water to this product*

- Applicability:

  - substances and preparations which react violently with water.

- Criteria for use:

  - normally limited to special cases (e.g. sulphuric acid) and may be used, as appropriate, to give the clearest possible information, either to emphasise R14 or as an alternative to R14.

S33 *Take precautionary measures against static discharges*

- Applicability:

  - extremely or highly flammable substances and preparations.

- Criteria for use:

  - recommended for substances and preparations used in industry which do not absorb moisture. Virtually never used for substances and preparations as placed on the market for use by the general public.

S35 *This material and its container must be disposed of in a safe way.*

- Applicability:

  - all dangerous substances and preparations

- Criteria for use:

  - recommended for substances and preparations where special guidance is needed to ensure proper disposal.

S36 *Wear suitable protective clothing*

- Applicability:

  - organic peroxides,

  - very toxic, toxic or harmful substances and preparations,

  - corrosive substances and preparations.

- Criteria for use:

  - *obligatory* for very toxic and corrosive substances and preparations,

- *obligatory* for those substances and preparations to which either R21 or R24 has been ascribed,

- *obligatory* for category 3 carcinogens, mutagens and substances toxic to reproduction unless the effects are produced solely by inhalation of the substance or preparation,

- *obligatory* for organic peroxides,

- recommended for toxic substances and preparations if the LD_{50} dermal value is unknown but the substance or preparation is likely to be toxic through skin contact,

- recommended for substances and preparations used in industry which are liable to damage health by prolonged exposure.

S37 *Wear suitable gloves*

- Applicability

  - very toxic, toxic, harmful or corrosive substances and preparations,

  - organic peroxides,

  - substances and preparations irritating to the skin or causing sensitisation by skin contact.

- Criteria for use

  - *obligatory* for very toxic and corrosive substances and preparations,

  - *obligatory* for those substances and preparations to which either R21, R24 or R43 has been ascribed,

  - *obligatory* for Category 3 carcinogens, mutagens and substances toxic to reproduction unless the effects are produced solely by inhalation of the substances and preparations,

  - *obligatory* for organic peroxides,

  - recommended for toxic substances and preparations if the LD_{50} dermal value is unknown but the substance or preparation is likely to be harmful by skin contact,

  - recommended for substances and preparations irritating to the skin.

S38 *In case of insufficient ventilation, wear suitable respiratory equipment*

- Applicability:

  - very toxic or toxic substances and preparations.

- Criteria for use:

  - normally limited to special cases involving the use of very toxic or toxic substances and preparations in industry or in agriculture.

S39 *Wear eye/face protection*

- Applicability :

    - organic peroxides,

    - corrosive substances and preparations, including irritants which give rise to risk of serious damage to the eyes.

    - very toxic and toxic substances and preparations.

- Criteria for use:

    - *obligatory* for those substances and preparations to which R34, R35 or R41 have been ascribed,

    - *obligatory* for organic peroxides,

    - recommended when it is necessary to draw the attention of the user to eye contact risks not mentioned in the risk phrases which have to be ascribed,

    - normally limited to exceptional cases for very toxic and toxic substances and preparations, where there is a risk of splashing and they are likely to be easily absorbed by the skin.

S40 *To clean the floor and all objects contaminated by this material use ... (to be specified by the manufacturer)*

- Applicability:

    - all dangerous substances and preparations.

- Criteria for use:

    - normally limited to those dangerous substances and preparations for which water is not considered to be a suitable cleansing agent (e.g. where absorption by powdered material, dissolution by solvent etc. is necessary) and where it is important for health and/or safety reasons to provide a warning on the label.

S41 *In case of fire and/or explosion do not breathe fumes*

- Applicability:

    - dangerous substances and preparations which on combustion give off very toxic or toxic gases.

- Criteria for use:

    - normally limited to special cases.

S42 *During fumigation/spraying wear suitable respiratory equipment (appropriate wording to be specified by the manufacturer)*

- Applicability:

    - substances and preparations intended for such use but which may endanger the health and safety of the user unless proper precautions are taken.

- Criteria for use:

- normally limited to special cases.

S43 *In case of fire use ... (indicate in the space the precise type of fire-fighting equipment. If water increases the risk add: Never use water)*

- Applicability:
  - extremely flammable, highly flammable and flammable substances and preparations.
- Criteria for use:
  - *obligatory* for substances and preparations which, in contact with water or damp air, evolve extremely flammable gases,
  - recommended for extremely flammable, highly flammable and flammable substances and preparations, particularly when they are immiscible with water.

S45 *In case of accident or if you feel unwell seek medical advice immediately (show the label where possible).*

- Applicability:
  - very toxic substances and preparations,
  - toxic and corrosive substances and preparations,
  - substances and preparations causing sensitisation by inhalation.
- Criteria for use:
  - *obligatory* for the substances and preparations mentioned above.

S46 *If swallowed, seek medical advice immediately and show this container or label*

- Applicability:
  - all dangerous substances and preparations other than those which are very toxic, toxic, corrosive or dangerous to the environment.
- Criteria for use:
  - *obligatory* for all dangerous substances and preparations mentioned above which are likely to be used by the general public, unless there is no reason to fear any danger from swallowing, particularly by children.

S47 *Keep at temperature not exceeding ... ° C (to be specified by the manufacturer)*

- Applicability:
  - substances and preparations which become unstable at a certain temperature.
- Criteria for use:
  - normally limited to special cases (e.g. certain organic peroxides).

S48 *Keep wetted with .... (appropriate material to be specified by the manufacturer)*

- Applicability:
    - substances and preparations which may become very sensitive to sparks, friction or impact if allowed to dry out.
- Criteria for use:
    - normally limited to special cases, e.g. nitrocelluloses.

S49 *Keep only in the original container*

- Applicability:
    - substances and preparations sensitive to catalytic decomposition.
- Criteria for use:
    - substances and preparations sensitive to catalytic decomposition e.g. certain organic peroxides.

S50 *Do not mix with ... (to be specified by the manufacturer)*

- Applicability:
    - substances and preparations which may react with the specified product to evolve very toxic or toxic gases,
    - organic peroxides.
- Criteria for use
    - recommended for substances and preparations mentioned above which are likely to be used by the general public, when it is a better alternative to R31 or R32,
    - *obligatory* with certain peroxides which may give violent reaction with accelerators or promoters.

S51 *Use only in well-ventilated areas*

- Applicability:
    - substances and preparations likely to or intended to produce vapours, dusts, sprays, fumes, mists, etc. which give rise to inhalation risks or to a fire or explosion risk
- Criteria for use:
    - recommended when use of S38 would not be appropriate. Thus important when such substances and preparations are likely to be used by the general public.

S52 *Not recommended for interior use on large surface areas*

- Applicability:

- volatile, very toxic, toxic and harmful substances and preparations containing them.

- Criteria for use:

  - recommended when damage to health is likely to be caused by prolonged exposure to these substances and preparations by reason of their volatilisation from large treated surfaces in the home or other enclosed places where persons congregate.

S53 *Avoid exposure - Obtain special instructions before use*

- Applicability:

  - substances and preparations that are carcinogenic, mutagenic and/or toxic to reproduction.

- Criteria for use:

  - *obligatory* for the above-mentioned substances and preparations to which at least one of the following R-phrases has been assigned : R45, R46, R49, R60 or R61.

S56 *Dispose of this material and its container to hazardous or special waste collection point.*

- Applicability:

  - all dangerous substances and preparations.

- Criteria for use:

  - recommended for all dangerous substances and preparations likely to be used by the general public for which special disposal is required.

S57 *Use appropriate containment to avoid environmental contamination*

- Applicability:

  - substances and preparations which have been assigned the symbol 'N'.

- Criteria for use:

  - normally limited to substances and preparations not likely to be used by the general public.

S59 *Refer to manufacturer for information on recovery/recycling*

- Applicability:

  - all dangerous substances and preparations.

- Criteria for use:

  - *obligatory* for substances and preparations dangerous for the ozone layer,

  - recommended for other substances and preparations for which recovery/recycling is recommended.

S60 *This material and its container must be disposed of as hazardous waste*

- Applicability:
  - all dangerous substances and preparations.
- Criteria for use:
  - recommended for substances and preparations not likely to be used by the general public and where S35 is not assigned.

S61 *Avoid release to the environment. Refer to special instructions/Safety data sheet*

- Applicability:
  - substances and preparations dangerous for the environment.
- Criteria for use:
  - normally used for substances and preparations which have been assigned the symbol 'N',
  - recommended for all substances and preparations classified dangerous for the environment not covered above.

S62 *If swallowed, do not induce vomiting: seek medical advice immediately and show this container or label.*

- Applicability:
  - substances and preparations classified as harmful with R65 in accordance with the criteria in section 3.2.3,
  - not applicable to substances and preparations which are placed on the market in aerosol containers (or in containers fitted with a sealed spray attachment), see sections 8 and 9.
- Criteria for use:
  - *obligatory* for substances and preparations mentioned above, if sold to, or likely to be used by the general public, except when S45 or S46 are obligatory.
  - recommended for the substances and preparations mentioned above when used in industry, except where S45 or S46 are obligatory.

S63 *In case of accident by inhalation: remove casualty to fresh air and keep at rest.*

- Applicability:
  - very toxic and toxic substances and preparations (gases, vapours, particulates, volatile liquids),
  - substances and preparations causing respiratory sensitisation.
- Criteria for use:

- *obligatory* for substances and preparations to which R26, R23 or R42 has been assigned which are likely to be used by the general public in a way which could result in inhalation.

S64 *If swallowed, rinse mouth with water, (only if the person is conscious).*

- Applicability:
  - corrosive or irritant substances and preparations.
- Criteria for use:
  - recommended for the above substances and preparations which are likely to be used by the general public and where the above treatment is suitable.

7. LABELLING

7.1. When a substance or preparation has been classified the appropriate label is determined with reference to the requirements of Article 23 and Article 10 of Directive 1999/45/EC for substances and preparations respectively. This section explains how the label is determined and, in particular, gives guidance on how to choose the appropriate risk and safety phrases.

The label contains the following information:

(a) for preparations the trade name or designation;
(b) for substances the name of the substance and for preparations the names of the substances present in the preparations in accordance with the rules set out in Article 10.2.3. of Directive 1999/45/EC;
(c) the name, full address and telephone number of the person responsible for placing the substance or preparation on the market, whether manufacturer, importer or distributor;
(d) the symbol(s) and indication(s) of danger;
(e) phrases indicating particular hazards (R-phrases);
(f) phrases indicating safety advice (S-phrases);
(g) for substances, the EC number, and in addition for substances appearing in Annex I, the word 'EC label';
(h) for preparations offered or sold to the general public the nominal quantity of the contents unless specified elsewhere on the package.

Note

For certain preparations there are additional labelling requirements set out in Article 10.1.2. and Annex V of Directive 1999/45/EC and in Article 20 of Directive 98/8/EC.

7.1.1. Final choice of risk and safety phrases

Although the final choice of the most appropriate risk and safety phrases is primarily governed by the need to give all necessary information, consideration should also be given in the clarity and impact of the label. With clarity in mind, the necessary information should be expressed in a minimum number of phrases.

In the case of substances which are irritant, highly flammable, flammable and oxidising, an indication of R-phrases and S-phrases need not be given where the package does not contain more than 125ml. This shall also apply in the case of the same volume of harmful substances not retailed to the general public.

For preparations, if the contents of the package do not exceed 125 ml:

- if classified as highly flammable, oxidising, irritant, with the exception of those assigned R41, or dangerous for the environment and assigned the 'N' symbol it shall not be necessary to indicate the R-phrases or the S-phrases,

- if classified as flammable or dangerous to the environment and not assigned the 'N' symbol it shall be necessary to indicate the R-phrases but it shall not be necessary to indicate the S-phrases.

7.1.2. Without prejudice to Article 16.4. of Directive 91/414/EEC and to Directive 98/8/EC, indications such as 'non-toxic', 'non-harmful', 'non-polluting', 'ecological' or any other statement indicating that the substance or preparation is not dangerous or likely to lead to underestimation of the dangers of the substance or preparation in question shall not appear on the label or packaging of substances or preparations subject to this Directive or to Directive 1999/45/EC.

7.2. **Chemical name(s) to be displayed on the label**

7.2.1. For substances listed in Annex I the label shall show the name of the substances under one of the designations given in Annex I.

For substances not listed in Annex I, the name is established according to an internationally recognised chemical nomenclature as defined in Section 1.4 above.

7.2.2. For preparations, the choice of names to be displayed on the label follows the rules of Article 10.2.3. of Directive 1999/45/EC.

Note:

Subject to Annex V, B. 9. of Directive 1999/45/EC,

- the name of the sensitising substance must be chosen in accordance with Section 7.2.1 of this Annex,

- in the case of concentrate preparations which are intended for the perfume industry:

  - the person responsible for placing them on the market may identify merely the one sensitising substance judged by him to be primarily responsible for the sensitisation hazard.

  - in the case of a natural substance, the chemical name may be of the type: 'essential oil of ...' 'extract of ...', rather than the name of the constituents of that essential oil or extract.

7.3. **Choice of danger symbols**

The design of the danger symbols and the wording of the indications of danger shall comply with those laid down in Annex II[70]. The symbol shall be printed in black on an orange-yellow background.

7.3.1. For substances appearing in Annex I the danger symbols and indications of danger shall be those shown in the Annex.

7.3.2. For dangerous substances not yet appearing in Annex I and for preparations, the danger symbols and indications of danger shall be assigned according to the rules laid down in this Annex.

70 This Annex corresponds to Schedule 2

Where more than one danger symbol is assigned to a substance or preparation:

- the obligation to indicate the symbol 'E' makes the symbols 'F+', 'F' and 'O' optional,

- the obligation to indicate the symbol 'T+' or 'T' makes the symbols 'Xn', 'Xi' and 'C' optional,

- the obligation to indicate the symbol 'C' makes the symbols 'Xn' and 'Xi' optional,

- if the symbol 'Xn' is assigned, the symbol 'Xi' is optional.

7.4. **Choice of Risk-phrases**

The wording of the R-phrases shall comply with that laid down in Annex III[71].

The combined R-phrases in Annex III shall be used where applicable.

7.4.1. For substances appearing in Annex I, the R-phrases shall be those shown in the Annex.

7.4.2. For substances not appearing in Annex I, R-phrases will be selected according to the following criteria and priorities:

(a) in the case of dangers which give rise to health effects:

(i) R-phrases corresponding to the category of danger illustrated by a symbol must appear on the label;

(ii) R-phrases corresponding to other categories of danger which are not illustrated by a symbol by virtue of Article 23;

(b) in the case of dangers arising from physicochemical properties:

- R-phrases corresponding to the category of danger illustrated by a symbol must appear on the label;

(c) in the case of dangers for the environment:

- the R-phrase(s) corresponding to the classification category 'dangerous for the environment' must appear on the label.

7.4.3. For preparations, R-phrases will be selected according to the following criteria and priorities:

(a) in the case of dangers which give rise to health effects:

(i) R-phrases which correspond to the category of danger illustrated by a symbol. In certain cases the R-phrases must be adopted according to the tables of Annex II, Part B of Directive 1999/45/EC. More specifically, the R-phrases of the constituent(s) which are responsible for the assignment of the preparation to a danger category must appear on the label.

(ii) R-phrases which correspond to other categories of danger which have been attributed to the constituents but which are not illustrated by a symbol by virtue of Article 10.2.4. of Directive 1999/45/EC;

(b) in the case of dangers arising from physicochemical properties:

71 This Annex corresponds to Schedule 3

the criteria described under 7.4.3 (a) are applicable, except that the risk phrases 'extremely flammable' or 'highly flammable' need not be indicated where they repeat the wording of the indication of danger used with a symbol.

(c) in the case of dangers for the environment

(i) the R-phrase(s) corresponding to the classification category 'dangerous for the environment' must appear on the label;

(ii) where the R-phrase R50 has been assigned in addition to a combined R-phrase R51/53 or R52/53 or to the R-phrase 53 alone, the combined R-phrase R50/53 shall be used.

As a general rule, for preparations a maximum of six R-phrases shall suffice to describe the risk; for this purpose the combined phrases listed in Annex III shall be regarded as single phrases. However, if the preparation falls within more than one danger category, those standard phrases shall cover all the principal hazards associated with the preparation. In some cases, more than six R-phrases may be necessary.

7.5. **Safety phrases**

The wording of S-phrases shall comply with that laid down in Annex IV[72].3e

The combined S-phrases in Annex IV shall be used where applicable.

7.5.1. For substances appearing in Annex I, the S-phrases shall be those shown in the Annex. Where no S-phrases are shown, the manufacturer/importer may include any appropriate S-phrase(s). For substances not in Annex I and for preparations, the manufacturer shall include S-phrases in accordance with the criteria given in Chapter 6 of this Annex.

7.5.2. Choice of safety phrases

The final choice of safety phrases must have regard to the risk phrases indicated on the label and to the intended use of the substance or preparation:

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

- in the case of S-phrases concerning disposal, one S-phrase shall be used, unless it is clear that disposal of the material and its container does not present a danger for human health or the environment. In particular, advice on safe disposal is important for substances and preparations sold to the general public,

- some R-phrases become superfluous if a careful selection is made of S-phrases and vice versa; S-phrases which obviously correspond to R phrases will appear on the label only if it is intended to emphasise a specific warning,

- particular attention must be given, in the choice of safety phrases, to the foreseen conditions of use of certain substances and preparations, e.g. spraying or other aerosol effects. Phrases should be chosen with the intended use in view,

- the safety phrases S1, S2 and S45 are obligatory for all very toxic, toxic and corrosive substances and preparations sold to the general public,

- the safety phrases S2 and S46 are obligatory for all other dangerous substances and preparations (except those only classified as dangerous for the environment) sold to the general public.

72 This Annex corresponds to Schedule 4

Where the phrases selected according to the strict criteria in 6.2 result in redundancy or ambiguity or are clearly unnecessary given the specific product/package then some phrases may be deleted.

7.6. **The EC number**

If a substance named on the label is listed in the European Inventory of Existing Commercial Chemical Substances (Einecs) or in the European List of Notified Substances (ELINCS), the Einecs or ELINCS number of the substances shall be shown on the Label. This requirement does not apply to preparations.

7.7 **Dimensions of the label for preparations**

The dimensions of the label shall be as follows:

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

Each symbol shall cover at least one-tenth of the surface area of the label but shall not be less than 1cm2. The label shall be firmly affixed to one or more surfaces of the packaging immediately containing the preparation.

The information required on the label shall stand out clearly from its background and shall be of such size and spacing as to be easily read.

8. **SPECIAL CASES: SUBSTANCES**

8.1. **Mobile gas cylinders**

For mobile gas cylinders the requirements concerning labelling are considered to be satisfied when they are in agreement with Article 23 or Article 24 (6) b[73] of Directive 67/548/EEC

However, by way of derogation from Article 24 (1) and (2), one of the following alternatives can be used for gas cylinders 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 ISO/DP 7225 (1994 edition) relating to 'Gas cylinders - Precautionary labels',

the information specified in Article 23 (2) may be provided on a durable information disc or label held captive on the cylinder.

73 This article corresponds to Regulation 22(2)(b)

8.2. **Gas containers intended for propane, butane or liquefied petroleum gas (LPG)**

These substances are classified in Annex I. Although classified in accordance with Article 2, they do not present a danger to human health when they are placed on the market in closed refillable cylinders or in non-refillable cartridges within the scope of 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 or cartridges must be labelled with the appropriate symbol and the R- and S-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 Article 27[74] of Directive 67/548/EEC. 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, as modified by Directive 93/112/EEC and Directive 2001/58/EC.

8.3. **Metals in massive form**

These substances are classified in Annex I or shall be classified in accordance with Article 6. However, some of these substances, although classified in accordance with Article 2 do not present a danger to human health by inhalation, ingestion or contact with skin or to the aquatic environment in the form in which they are placed on the market. Such substances do not require a label according to Article 23. However, all the information which should have appeared on the label shall be transmitted to the user by the person responsible for placing the metal on the market, in a format foreseen in Article 27.

8.4. **Substances classified with R65**

Substances 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.

9. **SPECIAL CASES: PREPARATIONS**

9.1. **Gaseous preparations (gas mixtures)**

For gaseous preparations, consideration must be given to:
the evaluation of the physicochemical properties,

- the evaluation of health hazards,
- the evaluation of the environmental hazards.

9.1.1. Evaluation of physicochemical properties

9.1.1.1. *Flammability*

The flammable properties of these preparations are determined in accordance with Article 5 of Directive 1999/45/EC according to the methods specified in Part A of Annex V to Directive 67/548/EEC.

74 This article corresponds to Regulation 24

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.

Coefficients of equivalency (Ki)

The values of the coefficients of equivalency Ki, 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 (new: 1996 edition) relating to 'Gases and gas mixtures - Determination of fire potential and oxidising ability for the selection of cylinder valve outlets'.

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 (new: 1996 edition) relating to 'Gases and gas mixtures - Determination of fire potential and oxidising ability for the selection of cylinder valve outlets'.

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 oxidising gases can be prepared safely. When estimating flammability these oxidising 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.

9.1.1.2. *Oxidising properties*

Given the fact that Annex V to Directive 67/548/EEC does not contain a method to determine the oxidising 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 oxidising potential of gases in a mixture with that of the oxidising 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 oxidising and the phrase R8 will be assigned.

Coefficients of equivalency between oxidising gases and oxygen

The coefficients used in the calculation to determine the oxidising capacity of certain gases in a mixture with respect to the oxidising capacity of oxygen in air, listed under 5.2. in the ISO Standard ISO 10156 edition 15. 12. 1990 (new: 1996 edition) relating to 'Gases and gas mixtures - Determination of fire potential and oxidising ability for the selection of cylinder valve outlets', 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.

9.1.2. Labelling

For mobile gas containers the requirements concerning labelling are considered to be satisfied when they are in agreement with Article 11. 6. (b) of Directive 1999/45/EC.

However, by way of derogation from Articles 11. 1. and 11. 2., 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 provided that 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 Article 10 may be provided on a durable information disc or label held captive on the containers.

9.2. **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 Articles 5, 6 and 7 of Directive

1999/45/EC, 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 R- and S-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 Article 14 of Directive 1999/45/EC. 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.

9.3. Alloys, preparations containing polymers, preparations containing elastomers

These preparations shall be classified according to the requirements of Articles 5, 6 and 7 and labelled according to the requirements of Article 10 of Directive 1999/45/EC.

However some of these preparations although classified in accordance with Articles 6 and 7 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 Article 10 or according to Annex V 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 Article 14 of the above-mentioned Directive.

9.4. 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.

9.5. Organic peroxides

Organic peroxides combine the properties of an oxidiser and a combustible substance in one molecule: when an organic peroxide decomposes, the oxidising part of the molecule reacts exothermically with the combustible (oxidisable) part. For the oxidising properties the existing methods in Annex V cannot be applied to the organic peroxides.

The following calculation method based on the presence of active oxygen must be used.

The available oxygen content (%) of an organic peroxide preparation is given by the formula:

$$16 \times \Sigma \left(n_i \times c_i / m_i \right)$$

where:

n_i = number of peroxygen groups per molecule of organic peroxide i,

c_i = concentration (mass %) of organic peroxide i,

m_i = molecular mass of organic peroxide i.

9.6. Additional labelling requirements for certain preparations

For certain preparations there are additional labelling requirements set out in Article 10.1.2. and Annex V of Directive 1999/45/EC and Article 20 of Directive 98/8/EC.

COMMISSION STATEMENT

With regard to Section 4.1.5. and in particular to the last paragraph of Section 4.1.5., the Commission states that, should it envisage making use of the procedure of Article 28 of Directive 67/548/EEC, it is prepared to consult in advance appropriate experts designated by Members States and having special qualifications with respect to either carcinogenicity, mutagenicity or reproductive toxicity.

This consultation will take place in the framework of the normal consultation procedure with national experts and/or in the framework of existing committees. The same will be the case when substances already included in Annex I must be reclassified in respect of their carcinogenic, mutagenic effects, or effects toxic to reproduction.

SCHEDULE 6

ANNEX VII. A

INFORMATION REQUIRED FOR THE TECHNICAL DOSSIER ("BASE SET") REFERRED TO IN ARTICLE 7 (1)

If it is not technically possible or if it does not appear scientifically necessary to give information, the reasons shall be clearly stated and be subject to acceptance by the competent authority.

The name of the body or bodies responsible for carrying out the studies shall be mentioned.

For intermediates with limited exposure the provisions under point 7 apply.

0. **IDENTITY OF MANUFACTURER AND THE IDENTITY OF THE NOTIFIER: LOCATION OF THE PRODUCTION SITE**

For substances manufactured outside the Community and for which, for the purpose of notification, the notifier has been designated as the manufacturer's sole representative, the identity and the addresses of the importers who will be bringing the substance into the Community.

1. IDENTITY OF THE SUBSTANCE

1.1 Name
1.1.1. Names in the IUPAC nomenclature
1.1.2 Other names (usual name, trade name, abbreviation)
1.1.3 CAS number and CAS name (if available)
1.2. Molecular and structural formula
1.3. Composition of the substance
1.3.1 Degree of purity (%)
1.3.2 Nature of impurities, including isomers and by-products
1.3.3 Percentage of (significant) main impurities
1.3.4 If the substance contains a stabilizing agent or an inhibitor or other additives, specify: nature, order of magnitude: ..... ppm, ... %
1.3.5 Spectral data (UV, IR, NMR or mass spectrum)
1.3.6 HPLC, GC
1.4 Methods of detection and determination

A full description of the methods used or the appropriate bibliographical references

Apart from methods of detection and determination, information shall be given on analytical methods which are known to the notifier and allows detection of a substance and its transformation products after discharge into the environment as well as determination of the direct exposure of humans.

2 INFORMATION ON THE SUBSTANCE

2.0. Production

Information given in the section should be sufficient to allow an approximate but realistic estimation of human and environmental exposure associated with the production process. Precise details of the production process, particularly those of a commercially sensitive nature, are not required.

2.0.1. Technological process used in production
2.0.2. Exposure estimates related to production:
- working environment
- environment

2.1. Proposed uses

Information given in this section should be sufficient to allow an approximate but realistic estimation of human and environmental exposure to the substances as associated with the proposed/expected uses.

2.1.1. Types of use: description of the function and the desired effects

2.1.1.1 Technological process(es) related to the use of the substance (where known)

2.1.1.2. Exposure estimate(s) related to use (where known):

- working environment
- environment

2.1.1.3. Form under which the substance is marketed: substance, preparation, product

2.1.1.4. Concentration of the substance in marketing preparations and products (where known)

2.1.2. Fields of application with approximate breakdown:

- industries
- farmers and skilled trades
- use by the public at large

2.1.3. Where known and where appropriate, the identity of the recipients of the substance

2.1.4. Waste quantities and composition of waste resulting from the proposed uses (where known)

2.2. Estimated production and/or imports for each of the anticipated uses or fields of application

2.2.1. Overall production and/or imports in tonnes per year:

- the first calendar year
- the following calendar years

For the substances manufactured outside the Community and for which, for the purpose of notification, the notifier has been designated as the manufacturer's sole representative, this information must be given for each of the importers identified under section 0 above.

2.2.2. Production and/or imports, broken down in accordance with 2.1.1 and 2.1.2 expressed as a percentage:

- the first calendar year
- the following calendar years

2.3. Recommended methods and precautions concerning:

2.3.1. Handling

2.3.2. Storage

2.3.3. Transport

2.3.4. Fire (nature of combustion gases or pyrolysis, where proposed uses justify this)

2.3.5. Other dangers, particularly chemical reaction with water

2.3.6. If relevant, information concerning the susceptibility of the substance to explode when presented in the form of a dust

2.4. Emergency measures in the case of accidental spillage

2.5. Emergency measures in the case of injury to persons (e.g. poisoning)

2.6. Packaging

3. PHYSICO-CHEMICAL PROPERTIES OF THE SUBSTANCE

3.0. State of the substance at 20 ^{o}C and 101,3 kPA

3.1 Melting-point

3.2 Boiling-point

3.3 Relative density

3.4 Vapour pressure

3.5 Surface tension

3.6 Water solubility

3.8. Partition coefficient n/octanol/water

3.9. Flash-point

3.10. Flammability

3.11. Explosive properties

3.12. Self-ignition temperature

3.13. Oxidizing properties

3.15` Granulometry:

For those substances which may be marketed in a form which gives rise to the danger of exposure by the inhalatory route, a test should be conducted to determine the particle size distribution of the substance as it will be marketed.

4. TOXICOLOGICAL STUDIES

4.1. Acute toxicity

For tests 4.1.1 to 4.1.3, substances other than gases shall be administered via at least two routes, one of which should be the oral route. The choice of the second route will depend on the nature of the substance and the likely route of human exposure. Gases and volatile liquids should be administered by the inhalation route.

4.1.1. Administered orally
4.1.2. Administered by inhalation
4.1.3. Administered cutaneously
4.1.5 Skin irritation
4.1.6 Eye irritation
4.1.7 Skin sensitization

4.2. Repeated dose

The route of administration should be the most appropriate having regard to the likely route of human exposure, the acute toxicity and the nature of the substance. In the absence of contra-indications the oral route is usually the preferred one.

4.2.1. Repeated dose toxicity (28 days)

4.3. Other effects

4.3.1. Mutagenicity

The substance shall be examined in two tests. One shall be a bacteriological (reverse mutation) test, with and without metabolic activation. The second shall be a non-bacteriological test to detect chromosome aberrations or damage. In the absence of contra-indications, this test should normally be conducted in vitro, both with and without metabolic activation. In the event of a positive result in either test, further testing according to the strategy described in Annex V should be carried out.

4.3.2. Screening for toxicity related to reproduction (for the record)
4.3.3. Assessment of the toxicokinetic behaviour of a substance to the extent that can be derived from base set data and other relevant information

5. ECOTOXICOLOGICAL STUDIES

5.1. Effects on organisms

5.1.1. Acute toxicity for fish
5.1.2. Acute toxicity for daphnia
5.1.3. Growth-inhibitor test on algae
5.1.6. Bacterial inhibitionIn those cases where biodegradation may be affected by the inhibitory effect of a substance on the bacteria, a test for bacterial inhibition should be carried out prior to undertaking the biodegradation.

5.2. Degradation

-biotic
-antibiotic:

If the substance is not readily biodegradable then consideration should be given to the need to carry out the following tests: hydrolysis as a function of pH.

5.3. Absorption/desorption screening test

6. POSSIBILITY OF RENDERING THE SUBSTANCE HARMLESS

6.1. For industry/skilled trades

6.1.1. Possibility of recycling
6.1.2. Possibility of neutralization of unfavourable effects
6.1.3. Possibility of destruction:

- controlled discharge
- incineration
- water purification station
- others

6.2. For the public at large
6.2.1. Possibility of recycling
6.2.2. Possibility of neutralization of unfavourable effects
6.2.3. Possibility of destruction:
- controlled discharge
- incineration
- water purification station
- others

7. REDUCED TEST PACKAGE FOR INTERMEDIATES AT QUANTITIES ≥1 TONNE / ANNUM

1. Without prejudice to other Community legislation, the following definitions apply:

"Intermediate" is a chemical substance that is solely manufactured for and consumed in or used for chemical processing in order to be transformed into another chemical substance(s);

"Emission" concerns the release of a substance from a system, for example when a system is breached. To guarantee a maximum level of protection for workers and the environment minimisation of emission through rigorous containment of the process must therefore be the primary aim;

"Exposure" is concerned with what happens to a substance after it has been emitted, whether this is into the wider environment or whether the substance can be potentially inhaled or come in contact with the skin of a member of the workforce. If emissions can be anticipated to occur, rigorous exposure control must be achieved by appropriate techniques, noting the need to adopt the precautionary principle in that physicochemical, toxicological and ecotoxicological properties which had not been tested shall be assumed as being hazardous;

"Integrated exhaust ventilation system" is an exhaust ventilation system of closed type which is used in combination with locks, enclosures, housings, containers etc. in order to restrict the chemical agents to the inner part of the closed functional unit. Process-related openings must be as small as possible. The power of extraction and the air ducting must be designed so that there is sufficient underpressure within the extraction unit to ensure that all of the gases, vapours and/or dusts that occur are fully captured and carried away. Back-flow of the extracted hazardous substances into the working area must be prevented. This means that hazardous substances are prevented from escaping from the closed functional unit into the working area;

"Highly effective exhaust ventilation" is an exhaust ventilation system of open and semi-open type which is dimensioned in such a way that chemical agents remain within the catchment area. This means that the occurrence of chemical agents in the workplace atmosphere can practically be excluded**;**

"Effective exhaust ventilation system" is an exhaust ventilation system of open and semi-open type which is dimensioned in such a way that the chemical agents remain within the catchment area, i.e., the occurrence of chemical agents in the workplace atmosphere can be largely excluded or proof of adherence to the limit value is furnished;

"Other exhaust ventilation system" is an exhaust ventilation system of open and semi-open type which is dimensioned in such a way that the occurrence of chemical agents in the workplace atmosphere cannot be excluded;

"Low-emission forms of use" are, for example:

- expendable packaging, i.e. the hazardous substance is enclosed in appropriate packaging and, without opening the packaging, is introduced into a reaction system together with this packaging.
- change in consistency, i.e., the substance is used, for example, in the form of a paste or a granulate instead of in powder form.
- master batch; this means that the hazardous substance is surrounded by a plastic matrix which prevents direct contact with the hazardous substance. The plastic matrix itself is not a

hazardous substance. Abrasion of the plastic matrix and therefore of the hazardous substance, is, however, possible.

"Emission-free forms of use" are, for example, master batches without abrasion, i.e., the plastic matrix is so resistant to abrasion that no hazardous substance can be released;

"Technically leakproof" is applied to a sub unit if a leak is not discernible during testing, monitoring or checking for leakproofness, e.g. using foaming agents or leak searching / indicating equipment performed for the particular use. Systems, sub systems and functional elements are technically leakproof, if the Rate of leakage is < 0.00001 mbar*l*s^{-1};

2. For intermediates, the notifier may request the competent authority to grant permission to apply a reduced test package (RTP). This RTP represents a minimum data set designed to produce a first preliminary risk assessment for any chemical intermediate to be placed on the market. Any additional test result might be required, in accordance with Article 16(1) of Directive 67/548/EEC, based on the outcome of the risk assessment.

3. Conditions for a application of a reduced test package

The notifier must demonstrate to the satisfaction of the competent authority where the substance is notified that the following conditions are fulfilled.

a) The substance is solely manufactured for and consumed in or used for chemical processing. Monomers are excluded. When processed the substance is transformed into chemically different molecules, not being polymers.
b) The substance is restricted to a maximum number of 2 users' sites. For example, it may be manufactured by one company and then transported to 1 or 2 others for processing. Note that if supply is intended to progress to more than 2 users' sites, the conditions for a RTP are no longer met and the dossier must be upgraded to the appropriate level.
c) The supply to the enterprise which uses the intermediate for further processing must be directly from the notifier and not through an intermediate supplier.
d) The substance must be rigorously contained by technical means during its whole lifecycle. This includes production, transportation, purification, cleaning and maintenance, sampling, analysis, loading and unloading of equipment/vessels, waste disposal/purification and storage. In general, an appropriate process would have all functional elements of the plant such as filling ports, emptying equipment etc. either of a closed construction type with assured leakproofness or of a closed construction type with integrated exhaust ventilation.
e) Where there is the potential for exposure, procedural and control technologies must be used which minimise emission and the resulting exposure.
f) In case of cleaning and maintenance works special procedures such as purging and washing must be applied before the system is opened or entered.
g) Transport operations will be in compliance with the requirements of Council Directive 94/55/EC[75] as amended from time to time.
h) In case of accident and where waste is generated following purification or cleaning and maintenance procedures, environmental exposure may occur. In either case, procedural and/or control technologies are used which minimise emissions and the resulting exposures.
i) A management system must exist which identifies the roles of the individuals in the organisation.
j) The packaging of the substance will be labelled according to Annex VI of 67/548/EEC and additionally with the following sentence: "Caution - substance not yet fully tested".
k) The notifier must operate a system of product stewardship and must monitor the users (a maximum of 2) to ensure compliance with the conditions listed above.

4. Technical dossier to be supplied for a reduced test package

A notifier requesting an RTP for a substance must supply the following technical dossier to the competent authority for all production and user sites:

a) A statement that the notifier and each user accepts the conditions listed in 3 above.
b) A description of the technical measures by which rigorous containment of the substance is achieved[76] including procedures for charging, sampling, transfer and cleaning. It is not necessary to

75 O.J. L319, 12.12.1994, p. 7.

provide details of the integrity of every seal or efficiency of integrated exhaust ventilation. However, whatever means are used to achieve rigorous containment of the process it is important that the information is available, if needed, to verify that the assertions made for achievement of control are true.

c) If the criteria for the assessment of closed systems during handling of chemical agents are not fulfilled, the notifier must submit exposure data based on representative monitoring data and/or reliable model calculations to enable the competent authority to make a decision whether to accept an RTP-request or not.

d) A detailed description of the processes at all sites involved in production and use. In particular, it must be stated whether production and/or processing wastes are discharged to waste-water, liquid or solid waste is incinerated, and how the cleaning and maintenance of all equipment is made.

e) A detailed assessment of the possible emissions and possible exposure to man and the environment during the whole life cycle, including details of the various chemical reactions involved in the process and the ways in which residues are dealt with.
Where emissions may lead to exposure, the means by which these are controlled must be described in sufficient detail to enable the competent authority to make a decision whether to accept the statement or to calculate an emission rate according to the EU Technical Guidance Document.

f) Changes which might affect exposure to man or the environment must be notified in advance, e.g. any change in the functional elements of the plant, new user or site.

g) The information prescribed for the RTP is the following:
Annex VII. B plus the following tests from this Annex:
- vapour pressure (3.4)
- explosive properties (3.11)
- self-ignition temperature (3.12)
- oxidising properties (3.13)
- granulometry (3.15)
- acute toxicity for daphnia (5.1.2)

The notifier must also include other relevant information to enable the competent authority to make an informed decision and to enable proper controls to be put in place by the user at the intermediate processing site. For example, if supplementary physicochemical and/or toxicological information and/or information about the environmental behaviour is available this data must also be submitted. Additionally, the notifier must review the available toxicity and ecotoxicity data on substances having close structural relationship to the notified substance. If relevant data are available, especially on chronic and reproductive toxicity and carcinogenicity, then a summary of these data must be provided.

h) Identities of the notifier, producer and the user(s).

5. Criteria for the assessment of closed systems during the handling of chemical agents

5.1 Use

An assessment index is used in the assessment of the plant. The assessment index classifies the handling of the substance and the resultant process-related exposure potential. The notifier shall examine the plant or plant unit is in order to determine the assessment index. Each individual functional element must be assessed.

Systems are regarded as closed if the assessment of all of the available functional elements corresponds to the assessment index 0.5 and if only functional elements are involved which are of closed type with assured leakproofness and/or equipped with integrated exhaust ventilation. In addition, direct skin contact must be excluded.

In the collection of examples relevant functional elements are indicated by 0.5 in bold type.

---

76 The type of construction and the technical specifications (e.g. leakproofness) of the closed functional element determines the effectiveness of the containment. To enable the competent authority to make a decision as to whether rigorous containment is achieved or not, it is essential that the notifier includes details on these aspects. The technical measures must normally fulfil the conditions of the "Criteria for the Assessment of Closed Systems during Handling of Chemical Agents", which are included for guidance in section 7.5 of these Regulations and Table 1 of Annex VIIA of Directive 67/548/EEC (As set down in Annex VB of Commission Directive 2001/59/EC: O.J. L225, 21.08.2001 p320 – 332)

Functional elements of partially open type with highly effective exhaust ventilation (also indicated by the assessment index 0.5, but in normal type) are not regarded as closed according to the meaning of this rule.

In the case of functional elements assigned the assessment index 1, the safe adherence to the limit value on a permanent basis is not always assured. Such functional elements are

1 - closed type, leakproofness not assured
1 - partially open type with effective exhaust ventilation.

In the case of functional elements assigned the assessment indices 2 and 4 the adherence to the limit values is not always assured. Such functional elements are

2 - of a partially open type, opening as intended with simple exhaust ventilation
2 - open with simple exhaust ventilation

4 - open type or partially open type
4 - natural ventilation

The catalogue of examples in Table 1 of Annex VIIA to Directive 67/548/EEC facilitates the classification of the functional elements. Functional elements which are not included in the collection of examples can be classified by means of conclusions drawn by analogy. The plant or plant unit is then classified using the index value of the functional element which has received the highest assessment index.

5.2 Checking

Use of this criterion requires adherence to the process parameters which have been laid down as well as the performance of the checks cited in the collection of examples (e.g. inspection and maintenance).

6. Application of a reduced test package

If the competent authority accepts the notifier's application for a RTP, then information from the tests and/or studies set out in point 7.4 above shall be required for the technical dossier referred to in Article 7 of Directive 67/548/EEC[77]. Note that for quantities below 1 tonne/annum the usual Annex VIIB/VIIC testing requirements apply.

77 This article corresponds to Regulation 10

ANNEX VII. B
INFORMATION REQUIRED FOR THE TECHNICAL DOSSIER ("BASE SET") REFERRED TO IN ARTICLE 8 (1) AND (3)

If it is not technically possible or if it does not appear scientifically necessary to give information, the reasons shall be clearly stated and subject to acceptance by the competent authority.

The name of the body or bodies responsible for carrying out the studies shall be mentioned.

In addition to the information requested below, Member States may, if they consider it necessary for the risk assessment, require that the notifier provides the following additional information: - vapour pressure, - daphnia acute toxicity test.

0. IDENTITY OF MANUFACTURER AND THE IDENTITY OF THE NOTIFIER: LOCATION OF THE PRODUCTION SITE

For substances manufactured outside the Community and for which, for the purpose of notification, the notifier has been designated as the manufacturer's sole representative, the identity and the addresses of the importers who will be bringing the substance into the Community

1. IDENTITY OF THE SUBSTANCE

1.1 Name
1.1.1. Names in the IUPAC nomenclature
1.1.2. Other names (usual name, trade name, abbreviation)
1.1.3. CAS number and CAS name (if available)
1.2. Molecular and structural formula
1.3. Composition of the substance
1.3.1. Degree of purity (%)
1.3.2. Nature of impurities, including isomers and by-products
1.3.3. Percentage of (significant) main impurities
1.3.4. If the substance contains a stabilizing agent or an inhibitor or other additives, specify: nature, order of magnitude: ..... ppm, ... %
1.3.5. Spectral data (UV, IR, NMR or mass spectrum)
1.3.6. HPLC, GC
2.3 Methods of detection and determination
A full description of the methods used or the appropriate bibliographical references
Apart from methods of detection and determination, information on analytical methods which are known to the notifier and which allow detection of a substance and its transformation products after discharge into the environment as well as determination of the direct exposure of humans

2. INFORMATION ON THE SUBSTANCE

2.0. Production
Information given in this section should be sufficient to allow an approximate but realistic estimation of human and environmental exposure, associated with the production process. Precise details of the production process, particularly those of a commercially sensitive nature, are not required.
2.0.1. Technological process(es) used in production
2.0.2. Exposure estimate related to production:
- working environment
- environment

2.1. Proposed uses
Information given in this section should be sufficient to allow an approximate but realistic

estimation of human and environmental exposure to the substances as associated with the proposed/expected uses.

2.1.1. Types of use: description of the function and the desired effects

2.1.1.1. Technological process(es) related to the use of the substance (where known)

2.1.1.2. Exposure estimate(s) related to the use of the substance (where known):
-working environment
-environment

2.1.1.3. Form under which the substance is marketed: substance, preparation, product

2.1.1.4. Concentration of the substance in marketed preparations and products (where known)

2.1.2. Fields of application with approximate breakdown:
- industries
- farmers and skilled trades
- use by the public at large

2.1.3. Where known and where appropriate, the identity of the recipients of the substance

2.2. Estimated production and/or imports for each of the anticipated uses or fields of application

2.2.1. Overall production and/or imports in tonnes per year:
- first calendar year
- the following calendar years

For substances manufactured outside the Community and for which, for the purposes of notification, the notifier has been designated as the manufacturer's sole representative, this information must be given for each of the importers identified under section 0 above.

2.2.2. Production and/or imports, broken down in accordance with 2.1.1 and 2.1.2 expressed as a percentage: - the first calendar year
- the following calendar years

2.3. Recommended methods and precautions concerning:

2.3.1. Handling

2.3.2. Storage

2.3.3. Transport

2.3.4. Fire (nature of combustion gases or pyrolysis, where proposed uses justify this)

2.3.5. Other dangers, particularly chemical reaction with water

2.4. Emergency measures in the case of accidental spillage

2.5. Emergency measures in the case of injury to persons (e.g. poisoning)

2.6. Packaging

3. PHYSICO-CHEMICAL PROPERTIES OF THE SUBSTANCE

3.0. State of the substance at 20 oC and 101,3 Kpa

3.1. Melting-point

3.2. Boiling-point

3.6. Water solubility

3.8. Partition coefficient n-octanol/water

3.9. Flash-point

3.10. Flammability

4. TOXICOLOGICAL STUDIES

4.1. Acute toxicity

For tests 4.1.1 to 4.1.2 one route of administration is sufficient. Substances other than gases should be tested by oral administration. Gases should be tested by inhalation.

4.1.1. Administered orally

4.1.2. Administered by inhalation

4.1.5. Skin irritation

4.1.6. Eye irritation

4.1.7. Skin sensitization

4.3. Other effects

4.3.1. MutagenicityThe substance should be examined in a bacteriological (reverse mutation) test with and without metabolic activation.

5. ECOTOXICOLOGICAL STUDIES

5.2. Degradation:
Biotic

ANNEX VII. C

INFORMATION REQUIRED FOR THE TECHNICAL DOSSIER ("BASE SET") REFERRED TO IN ARTICLE 8 (2)

If it is not technically possible or if it does not appear scientifically necessary to give information, the reasons shall be clearly stated and be subject to acceptance by the competent authority.

The name of the body or bodies responsible for carrying out the studies shall be mentioned.

0. IDENTITY OF MANUFACTURER AND THE NOTIFIER IF THESE ARE NOT THE SAME; LOCATION OF THE PRODUCTION SITE

For substances manufactured outside the Community and for which, for the purpose of notification, the notifier has been designated as the manufacturer's sole representative, the identity and the addresses of the importers who will be bringing the substance into the Community

1. IDENTITY OF THE SUBSTANCE

1.1. Name
1.1.1. Names in the IUPAC nomenclature
1.1.2. Other names (usual name, trade name, abbreviation)
1.1.3. CAS number and CAS name (if available)
1.2 Molecular and structural formula
1.3 Composition of the substance
1.3.1. Degree of purity (%)
1.3.2. Nature of impurities, including isomers and by-products
1.3.3. Percentage of (significant) main impurities
1.3.4. If the substance contains a stabilizing agent or an inhibitor or other additives, specify: nature, order of magnitude:..... ppm; ..... %
1.3.5. Spectral data (UV, IR, NMR or mass spectrum)
1.3.6. HPLC, GC
1.4. Methods of detection and determination

A full description of the methods used or the appropriate bibliographical references

Apart from methods of detection and determination, information on analytical methods which are known to the notifier and which allow detection of a substance and its transformation products after discharge into the environment as well as determination of the direct exposure of humans

2. INFORMATION ON THE SUBSTANCE

2.0. Production
Information given in this section should be sufficient to allow an approximate but realistic estimation of human and environmental exposure, associated with the production process. Precise details of the production process, particularly those of a commercially sensitive nature, are not required.
2.0.1. Technological process(es) used in production
2.0.2. Exposure estimate related to production:
- working environment
- environment

2.1. Proposed uses
Information given in this section should be sufficient to allow an approximate but realistic estimation of human and environmental exposure to the substances as associated with the proposed/expected uses.

2.1.1. Types of use: description of the function and the desired effects
2.1.1.1. Technological process(es) related to the use of the substance (where known)
2.1.1.2. Exposure estimate(s) related to the use of the substance (where known):
- working environment
- environment
2.1.1.3. Form under which the substance is marketed: - substance, preparation, product
2.1.1.4. Concentration of the substance in marketed preparations and products (where known)
2.1.2. Fields of application with approximate breakdown:
- industries
- farmers and skilled trades
- use by the public at large
2.1.3. Where known and where appropriate, the identity of the recipients of the substance
2.2. Estimated production and/or imports for each of the anticipated uses or fields of application
2.2.1. Overall production and/or imports in tonnes per year:
- the first calendar year
- the following calendar years

For substances manufactured outside the Community and for which, for the purposes of notification, the notifier has been designated as the manufacturer's sole representative, this information must be given for each of the importers identified under section 0 above

2.2.2. Production and/or imports, broken down in accordance with 2.1.1 and 2.1.2 expressed as a percentage:
- the first calender year
- the following calendar years

2.3. Recommended methods and precautions concerning:
2.3.1. Handling
2.3.2. Storage
2.3.3. Transport
2.3.4. Fire (nature of combustion gases or pyrolysis, where proposed uses justify this)
2.3.5. Other dangers, particularly chemical reaction with water
2.4. Emergency measures in the case of accidental spillage
2.5. Emergency measures in the case of injury to persons (e.g. poisoning)
2.6. Packaging

3. PHYSICO-CHEMICAL PROPERTIES OF THE SUBSTANCE

3.0. State of the substance at 20 oC and 101,3 kPa
3.9. Flash-point
3.10. Flammability

4. TOXICOLOGICAL STUDIES

4.1. Acute toxicity

One route of administration is sufficient. Substances other than gases should be tested by oral administration. Gases should be tested by inhalation.

4.1.1. Administered orally
4.1.2. Administered by inhalation.

ANNEX VII D

SPECIFIC PROVISIONS CONCERNING THE TECHNICAL DOSSIER ("BASE SET") CONTAINED IN THE NOTIFICATIONS REFERRED TO IN ARTICLE 12.

A. For the purpose of this Annex

- "homopolymer" is a polymer consisting of only one kind of monomer unit,
- "copolymer" is a polymer consisting of more than one kind of monomer unit,
- "polymer for which a reduced test package is acceptable",
- "RTP polymer", is a polymer that satisfies the criteria laid down in C.2,
- "family of polymers" is a group of polymers (either homopolymers or copolymers) with different number-average molecular weights or different compositions resulting from different ratios of monomer units. The difference in the number-average molecular weight or in the composition is determined not by unintentional process-related fluctuations but by deliberate alterations to the process conditions, the process itself remaining the same,
- "Mn" is the number-average molecular weight,
- "M" is the molecular weight.

B. Family approach

To avoid unnecessary testing, the grouping of polymers into families shall be possible. The concept consists of testing representative members of a family with:

- Mn variable for homopolymers, or
- composition variable with Mn approximately constant for copolymers, or
- for Mn > 1 000, Mn variable with composition approximately constant for copolymers.

In certain cases where there are dissimilarities in the effects seen in the representative members, depending on the Mn or composition-range, additional testing of other representative members shall be required.

C. Information required for the technical dossier referred to in Article 12.

If it is not technically possible or if it does not appear scientifically necessary to give information, the reasons shall be clearly stated and be subject to acceptance by the competent authorities.
Appropriate available information on the properties of the monomer(s) may be taken into account for the assessment of the properties of the polymer. Without prejudice to the provisions of Article 3 (1) of Directive 67/548/EEC the tests must be conducted according to methods recognized and recommended by the competent international bodies where such recommendations exist. The name of the body or bodies responsible for carrying out the studies shall be mentioned.

C.1. POLYMERS WITH STANDARD TEST PACKAGE

C.1.1. Polymers placed on the Community market in quantities of >=1 t/a or total quantities of >= 5 t
In addition to the information and tests referred to in Article 7 (1), laid down in Annex VII A, the following polymer-specific information is required:

1.I **DENTITY OF THE SUBSTANCE**
1.2.1. Number-average molecular weight
1.2.2. Molecular weight distribution (MWD)
1.2.3. Identity and concentration of starting monomers and starting substances which will be bound in the polymer
1.2.4. Indication of end groups and identity and frequency of reactive functional groups
1.3.2.1. Identity of non-reacted monomers
1.3.3.1 Percentage of non-reacted monomers

2. INFORMATION ON THE SUBSTANCE
2.1.1.5. Statement, with relevant information, if the polymer has been developed to be environmentally degradable

3. PHYSICO-CHEMICAL PROPERTIES OF THE SUBSTANCE

3.6.1. Water extractivity.

Without prejudice to Article 16 (1) of Directive 67/548/EEC, further tests may be required additionally in certain cases, e.g.:

- light-stability if the polymer is not specifically light-stabilized,
- long-term extractivity (leachate test); depending on the results of this test, appropriate tests on the leachate may be requested on a case by case basis.

C.1.2. Polymers placed on the Community market in quantities of < 1 t/a or total quantities of < 5 t but >= 100 kg/a or total quantities >= 500 kg

In addition to the information and tests referred to in Article 8 (1), laid down in Annex VII B, the following polymer-specific information is required:

1. **IDENTITY OF THE SUBSTANCE**

1.2.1. Number-average molecular weight
1.2.2. Molecular weight distribution (MWD)
1.2.3. Identity and concentration of starting monomers and starting substances which will be bound in the polymer
1.2.4. Indication of end groups and identity and frequency of reactive functional groups
1.3.2.1. Identity of non-reacted monomer
1.3.3.1. Percentage of non-reacted monomers

2. **INFORMATION ON THE SUBSTANCE**

2.1.1.5. Statement, with relevant information, if the polymer has been developed to be environmentally degradable

3. **PHYSICO-CHEMICAL PROPERTIES OF** THE SUBSTANCE

4.1.8 Water extractivity

C.1.3. Polymers placed on the Community market in quantities of < 100 kg/a or total quantities of < 500 kg

In addition to the information and tests referred to in Article 8 (2), laid down in Annex VII C, the following polymer-specific information is required:

1. **IDENTITY OF THE SUBSTANCE**

1.2.1. Number-average molecular weight
1.2.2. Molecular weight distribution (MWD)
1.2.3. Identity and concentration of starting monomers and starting substances which will be bound in the polymer
1.2.4. Indication of end groups and identity and frequency of reactive functional groups
1.3.2.1. Identity of non-reacted monomers
1.3.3.1. Percentage of non-reacted monomers

2. **INFORMATION ON THE SUBSTANCE**

2.1.1.5. Statement, with relevant information, if the polymer has been developed to be environmentally degradable

C2. POLYMERS FOR WHICH A REDUCED TEST PACKAGE IS ACCEPTABLE

Under certain conditions the base set test package for polymers can be reduced. Substances with a high number-average molecular weight, a low content of low molecular weight species and a low solubility/extractivity will be regarded as being non-bioavailable. Consequently, the following criteria shall be used to determine the polymers for which a reduced test package is acceptable:

For non-readily degradable polymers placed on the Community market in quantities of & ge; 1 t/a or total quantities of & ge; 5 t, the following criteria define those polymers for which a reduced test package is acceptable:

I. High number-average molecular weight (Mn) (1);
II. Extractivity in water (3.6.1)
< 10 mg/l excluding any contribution from additives and impurities;
III. Less than 1 % with M < 1 000; the percentage refers only to molecules (components) directly derived from and including monomer(s), excluding other components e.g. additives or impurities.

If all criteria are fulfilled, the polymer is regarded as a polymer for which a reduced test package is acceptable.

In the case of non-readily degradable polymers placed on the Community market in quantities < 1 t/a or total quantities of < 5 t it is sufficient that criteria I and II are fulfilled for the polymer to be considered a polymer for which a reduced test package is acceptable. If it is not possible to prove the criteria with the assigned tests, the notifier has to demonstrate compliance with the criteria by other means. Under certain circumstances toxicological and ecotoxicological tests may be required.

C.2.1. Polymers placed on the Community market in quantities of >= 1 t/a or total quantities of >= 5 t

0. Identity of manufacturer and the identity of the notifier: Location of the production site. For substances manufactured outside the Community and for which, for the purpose of notification, the notifier has been designated as the manufacturer's sole representative, the identity and the addresses of the importers who will be bringing the substance into the Community.

1. **IDENTITY OF THE SUB**STANCE
1.1. Name
1.1.1. Name in the IUPAC nomenclature
1.1.2. Other names (usual name, trade name, abbreviation) .
1.1.3. CAS number and CAS name if available
1.2 Molecular and structural formula
1.2.1 Number average molecular weight
1.2.2 Molecular weight distribution (MWD)
1.2.3. Identity and concentration of starting monomers and starting substances which will be bound in the polymer
1.2.4. Indication of end groups and identity and frequency of reactive functional groups
1.3. Composition of the substance
1.3.1. Degree of purity (%)
1.3.2. Nature of impurities, including by-products
1.3.2.1 Identity of non-reacted monomers
1.3.3. Percentage of (significant) main impurities
1.3.3.1. Percentage of non-reacted monomers
1.3.4. If the substances contains a stabilizing agent or an inhibitor or other additives, specify: nature, order of magnitude: . . . ppm, . . . %1.3.5. Spectral data (UV, IR, NMR or mass spectrum)
1.3.6.1. GPC1.
1.4. Methods of detection and determination
A full description of the methods used or the appropriate bibliographical references.Apart from methods of detection and determination, information shall be given on analytical methods which are known to the notifier and allow detection of a substance and its transformation products after discharge into the environment as well as determination of the direct exposure of humans.

2. **INFORMATION ON THE SUBSTANCE**
2.0. Production
Information given in the section should be sufficient to allow an approximate but realistic estimation of human and environmental exposure associated with the production process. Precise details of the production process, particularly those of a commercially sensitive nature, are not required.
2.0.1. Technological process in production.
2.0.2. Exposure estimates related to production:
- working environment
- environment
2.1. Proposed uses

Information given in this section should be sufficient to allow an approximate but realistic estimation of human and environmental exposure to the substances as associated with the proposed/expected uses.

2.1.1. Types of use: description of the function and the desired effect

2.1.1.1. Technological process(es) related to the use of the substance (where known)

2.1.1.2. Exposure estimate(s) related to the use (where known):

- working environment
- environment

2.1.1.3. Form under which the substance is marketed: substance, preparation, product

2.1.1.4. Concentration of the substance in marketing preparations and products (where known)

2.1.2. Fields of application with approximate breakdown:

- industries
- farmers and skilled trades
- use by the public at large

2.1.3. Where known and where appropriate, the identify of the recipients of the substance

2.1.4. Waste quantities and composition of waste resulting from the proposed uses (where known)

2.2. Estimated production and/or imports for each of the anticipated uses or fields of application

2.2.1. Overall production and/or imports in tonnes per year:

- the first calendar year
- the following calendar years

For the substances manufactured outside the Community and for which, for the purpose of notification, the notifier has been designated as the manufacturer's sole representative, this information must be given for each of the importers identified under section O above.

2.2.2. Production and/or imports, broken down in accordance with 2.1.1 and 2.1.2 expressed as a percentage: - the first calendar year- the following calendar years

2.3. Recommended methods and precautions concerning:

2.3.1. Handling

2.3.2. Storage

2.3.3. Transport

2.3.4. Fire (nature of combustion gases or pyrolysis, where proposed uses justify this)

2.3.5. Other dangers, particularly chemical reaction with water

2.3.6. If relevant, information concerning the susceptibility of the substance to explode when present in the form of a dust

2.4. Emergency measures in the case of accidental spillage

2.5 Emergency measures in the case of injury to persons (e. g. poisoning)

2.6. Packaging

3. **PHYSICO-CHEMICAL PROPERTIES OF THE SUBSTANCE**

3.0. State of the substance at 20° C and 101,3 kPa

3.1 Melting range (e. g. from the termal stability test)

3.3. Relative density

3.6.1. Water extractivity

3.10. Flammability

3.11. Explosive properties

3.12. Auto-flammability

3.15. Particle size:

For those substances which may be marketed in a form which gives rise to the danger of exposure by the inhalator route, a test should be conducted to determine the particle distribution of the substances as it will be marketed.

3.16. Thermal stability

3.17. Extractivity with:

- water at pH 2 and 9 at 37° C
- cyclohexane

4. **TOXICOLOGICAL STUDIES**

On a case by case basis and without delaying in acceptance of the notification, the competent authorities may, on the basis of the presence of reactive groups, structural/physical characteristics,

knowledge concerning the properties of low molecular weight components of the polymer or exposure potential, require certain tests to be carried out. In particular tests for inhalation toxicity (e. g. 4.1.2 or 4.2.1), may be required if exposure by the inhalatory route is considered possible.

5. **ECOTOXICOLOGICAL STUDIES**

On a case-by-case basis and without delaying the acceptance of the notification, the competent authorities may on the basis of the presence of reactive groups, structural/physical charateristics, knowledge concerning the properties of low molecular weight components of the polymer or exposure potential, require certain tests to be carried out. In particular, the following additional tests may be required:

- light-stability, if the polymer is not specifically light-stabilized
- long-term extractivity (leachate test). Depending on the results of this test, any appropriate test on the leachate may be requested on a case by case basis

6. **POSSIBILITY OF RENDERING THE SUBSTANCE HARMLESS**

6.1. For industry/skilled trades
6.1.1. Possibility of recycling
6.1.2. Possibility of neutralization of unfavourable effects
6.1.3. Possibility of destruction:
- controlled discharge
- incineration
- water purification station
- others

6.2. For the public at large
6.2.1. Possibility of recycling
6.2.2. Possibility of neutralization of unfavourable effects
6.2.3. Possibility of destruction:
- controlled discharge
- incineration
- water purification station
- others

C.2.2 Polymers placed on the Community market in quantities of < t/a or total quantities of < 5 t

0. **IDENTITY OF MANUFACTURER AND THE IDENTITY OF THE NOTIFIER: LOCATION OF THE PRODUCTION SITE**

For substances manufactured outside the Community and for which, for the purpose of notification, the notifier has been designated as the manufacturer's sole representative, the identity and the addresses of the importers who will be bringing the substance into the Community.

1. **IDENTITY OF THE SUBSTANCE**

1.1. Name
1.1.1. Name in the IUPAC nomenclature
1.1.2. Other names (usual name, trade name, abbreviation)
1.1.3. CAS number and CAS name (if available)
1.2. Molecular and structural formula
1.2.1. Number-average molecular weight
1.2.2. Molecular weight distribution (MWD)
1.2.3. Identity and concentration of starting monomers and starting substances which will be bound in the polymer
1.2.4. Indication of end groups and identity and frequency of reactive functional groups
1.3. Composition of the substance
1.3.1. Degree of purity (%)
1.3.2. Nature of impurities, including by-products
1.3.2.1. Identity of non-reacted monomers
1.3.3. Percentage of (significant) main impurities
1.3.3.1. Percentage of non-reacted monomers

1.3.4. If the substance contains a stabilizing agent or an inhibitor or other additives, specify: nature, order of magnitude: . . . ppm, . . . %
1.3.5. Spectral data (UV, IR, NMR or mass spectrum)
1.3.6.1. GPC
1.4. Methods of detection and determination
A full description of the methods used or the appropriate bibliographical references. Apart from methods of detection and determination, information shall be given on analytical methods which are known to the notifier and allow detection of a substance and its transformation products after discharge into the environment as well as determination of the direct exposure of humans.

2. **INFORMATION ON THE SUBSTANCE**
2.0. Production
Information given in the section should be sufficient to allow an approximate but realistic estimation of human and environmental exposure associated with the production process. Precise details of the production process, particularly those of a commercially sensitive nature, are not required
2.0.1. Technological process used in production
2.0.2. Exposure estimates related to production:
- working environment
- environment

2.1. Proposed uses
Information given in this section should be sufficient to allow an approximate but realistic estimation of human and environmental exposure to the substances as associated with the proposed/expected uses.
2.1.1. Types of uses: description of the function and the desired effects
2.1.1.1. Technological process(es) related to the use of the substance (where known)
2.1.1.2. Exposure estimate(s) related to the use (where known):
- working environment
- environment

2.1.1.3. Form under which the substance is marketed: substance, preparation, product
2.1.1.4. Concentration of the substance in marketing preparations and products (where known)
2.1.2. Fields of application with approximate breakdown:
- industries
- farmers and skilled trades
- use by the public at large

2.1.3. Where known and where appropriate, the identity of the recipients of the substance
2.1.4. Waste quantities and composition of waste resulting from the proposed uses (where known)
2.2. Estimated production and/or imports for each of the anticipated uses or fields of application
2.2.1. Overall production and/or imports in tonnes per year:
- the first calendar year
- the following calendar years

For the substances manfuactured outside the Community and for which, for the purpose of notification, the notifier has been designated as the manufacturer's sole representative, this information must be given for each of the importers identified under section 0 above.

2.2.2. Production and/or imports, broken down in accordance with 2.1.2 expressed as a percentage:
- the first calendar year
- the following calendar years

2.3. Recommended methods and precautions concerning:
2.3.1. Handling
2.3.2.Storage
2.3.3. Transport
2.3.4. Fire (nature of combustion gases or pyrolysis, where proposed uses justify this)
2.3.5. Other dangers, particularly chemical reaction with water
2.3.6. If relevant, information concerning the susceptibility of the substance to explode when present in the form of a dust
2.4. Emergency measures in the case of accidental spillage
2.5. Emergency measures in the case of injury to persons (e. g. poisoning)
2.6. Packaging

3. **PHYSICO-CHEMCIAL PROPERTIES OF THE SUBSTANCE**
3.0 State of the substance at 20 °C and 101,3 kPa
3.1. Melting range (e. g. from the termal stability test)
3.6.1. Water extractivity
3.10. Flammability

(1) The authorities receiving the notification shall decide on their own responsibility whether or not a polymer satisfies this criterion.

ANNEX VIII

ADDITIONAL INFORMATION AND TESTS REQUIRED UNDER ARTICLE 7 (2)

If it is not technically possible or if it does not appear scientifically necessary to give information, the reasons shall be clearly stated and be subject to acceptance by the competent authority.
The name of the body or bodies responsible for carrying out the studies shall be indicated.

LEVEL 1

Where, in accordance with the provisions of Annex VII.A related to intermediates, the relevant competent authority has authorised the application of a reduced test package to a chemical substance, the requirements of this section shall be reduced as follows.

When the quantity of the substance placed on the market reaches 10 tonnes per year per manufacturer or when the total quantity of the substance placed on the market reaches 50 tonnes per manufacturer; in this case the relevant competent authority shall require all those test and studies laid down in points 3 to 6 of Annex VII.A (excepting those already performed); in addition, the relevant competent authority may require those Level 1 tests and studies related to aquatic organisms.
When the quantity of the substance placed on the market reaches 100 tonnes per year per manufacturer or when the total quantity of the substance placed on the market reaches 500 tonnes per manufacturer; in this case the relevant competent authority shall require the Level 1 tests or studies related to reproductive toxicity. The relevant competent authority may decide that the classification of the substance as an intermediate qualifying for a reduced test package constitutes a good reason why one or more tests and studies, except those related to reproductive toxicity, are not appropriate.

Physico-chemical studies

Further studies on physico-chemical properties dependent upon the results of the studies laid down in Annex VII. Such further studies could include for example the development of analytical methods which make it possible to observe and detect a substance or its transformation products and studies on thermal decomposition products.

Toxicological studies

Fertility study (one species, one generation, male and female, most appropriate route of administration).

If there are equivocal findings in the first generation, study of a second generation is required.

Depending upon the dosing schedule it may be possible in this study to obtain an indication of teratogenicity. A positive indication should be examined in a formal teratology study.

- Teratology study (one species, most appropriate route of administration)
  This study is required if teratogenicity has not been examined in the fertility study.
- Sub-chronic and/or chronic toxicity study, including special studies (one species, male and female, most appropriate route of administration) shall be required if the results of the repeated-dose study in Annex VII or other relevant information demonstrate the need for further appropriate investigation.

The effects which would indicate the need for such a study could include for example:

(a) serious or irreversible lesions;
(b) a very low or absence of a "no effect" level;
(c) a clear relationship in chemical structure between the substance being studied and other substances which have been proved dangerous.

- Additional mutagenesis studies and/or screening study(ies) for carcinogenesis as prescribed in the testing strategy described in Annex V.

  When both tests in the base set are negative, further tests shall be conducted according to the specific properties and the purposed use of the substance.

When a test or both tests were positive in the base set, a supplementary study should include the same or different end points in other in vivo test methods.

- Basic toxicokinetic information.

Ecotoxicity studies
- Prolonged toxicity study with Daphnia magna (21 days)
- Test on higher plants
- Test on earthworms
- Further toxicity studies with fish
- Tests for species accumulation; one species, preferably fish
- Supplementary degradation study(ies), if sufficient degradation has not been proved by the studies laid down in Annex VII.
- Further studies on absorption/desorption dependent upon the results of the investigations laid down in Annex VII.

LEVEL 2

When the quantity of the substance placed on the market reaches 1,000 tonnes per year per manufacturer or when the total quantity of the substance placed on the market reaches 5,000 tonnes per manufacturer; additional studies mentioned in Level 1 or 2 would normally not be required. The relevant competent authority should however, consider additional tests and may require additional tests including the tests laid down in Levels 1 and 2 of this Annex.

Toxicological studies

The test programme shall cover the following aspects unless there are strong reasons to the contrary, supported by evidence, that it should not be followed:
- Chronic toxicity study
- Carcinogenicity study
- Fertility study (e.g. three-generation study); only if an effect on fertility has been established at level 1
- Developmental toxicity study on peri and postnatal effects
- Teratology study (species not employed in the respective level 1)
- Additional toxicokinetic studies which cover biotransformation, pharmacokinetics
- Additional tests to investigate organ or system toxicity.

Ecotoxicological studies

- Additional tests for accumulation, degradation, mobility and absorption/desorption
- Further toxicity studies with fish
- Toxicity studies with birds
- Additional toxicity studies with other organisms.

SCHEDULE 7

ANNEX IX

PART A

Provisions relating to child-proof fastenings

In addition to the provisions in Article 22(1)(e) of Directive 67/548/EEC[78] containers of whatever capacity containing substances presenting an aspiration hazard (Xn; R65) and classified and labelled according to paragraph 3.2.3 of Annex VI to this Directive, with the exception of substances placed on the market in the form of aerosols or in a container fitted with a sealed spray attachment, shall be fitted with 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 Organization (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 3.1, 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.

78 This article corresponds to Regulation 19(a)

PART B

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 8

Regulation 24

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 9

FEES PAYABLE BY NOTIFIER

Regulation 27

	Column 1 Subject matter	Column 2 Fee payable EUR
1.	For a notification under Regulation 10 (1) ("base set") (See notes 1 and 2)	€8,380
2.	For a re-notification submitted in accordance with Regulation 17 (1) (See notes 1 and 2)	€1,675
3.	For a notification of a substance notified at least 10 years previously (Regulation 12) (See notes 1 and 2)	€1,675
4.	For additional tests submitted under Regulation 10(3)*(a)* (>10 tonnes per year)	€8,380
5.	For additional tests submitted under Regulation 10(3)*(b)* (>100 tonnes per year)	€8,380
6.	For additional tests submitted under Regulation 10(3)(c) (>1000 tonnes per year)	€16,760
7.	For a notification under Regulation 11 (see note 3)	
	(a) quantity of the new substance equal to or more than 100kg (Regulation 11(1))	€1,675
	(b) quantity of the new substance up to 100kg[1] (Regulation 11(3))	€838
8.	For a successful application made by a notifier for an exemption relating to him under Regulation 15(3)	€838
Note 1.	Additional charge where notification particulars are not provided on an approved diskette -	€304
Note 2.	Additional charge where an adequate risk assessment is not included -	€3,809
Note 3.	Additional charge where an adequate risk assessment is not included -	€838

[1] Including a re-notification submitted in accordance with Regulation 17(1)

GIVEN under my Official Seal,

27 March 2003

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 for the first time Commission Directive 2001/58/EC amending for the second time Directive 91/155/EEC, relating to dangerous substances in implementation of Article 27 of Council Directive 67/548/EEC (safety data sheets) and Commission Directive 2001/59/EC, the 28th Adaptation to Technical Progress of Council Directive 67/548/EEC. (The provisions of Commission Directive 2001/58/EC relating to dangerous preparations in implementation of European Parliament and Council Directive 1999/45/EC will be transposed in separate Regulations.)

These Regulations also retranspose Council Directive 92/32/EEC, amending for the 7th time Directive 67/548/EEC, together with Council Directive 96/56/EC and Commission Directives 92/69/EEC (17th ATP), 93/21/EEC (18th ATP), 93/72/EEC (19th ATP), 93/101/EC (20th ATP), 94/69/EC (21st ATP), 96/54/EC (22nd ATP), 97/69/EC (23rd ATP), 98/73/EC (24th ATP), 98/98/EEC (25th ATP), 2000/32/EC (26th ATP) and 2000/33/EC (27th ATP). Related Commission Directives on Risk Assessment (93/67/EEC), on substances for which equivalent European Community notification or approval systems exist (93/90/EEC), data requirements for polymers (93/105/EC) and requirements for Safety Data Sheets (91/155/EEC, 93/112/EC) are also retransposed.

These Regulations revoke the European Communities (Dangerous Substances) (Classification, Packaging and Labelling) Regulations, 2000 (S.I. No. 393 of 2000).

The aim of these Regulations is to protect man and the environment from the harmful effects of both new substances and existing dangerous substances. The Regulations apply to all substances which are intended to be placed on the market either on their own or in a preparation with exceptions for certain categories of substances such as medicinal, cosmetic, pesticide, waste, etc., products which are covered by other Directives.

They require each manufacturer, importer or other person proposing to place any new chemical on the market for the first time to submit to the competent authority a notification dossier containing details of tests to which the substance has been subjected and the proposed classification and labelling of the substance.

The Regulations also require suppliers to put warning labels on containers for dangerous substances and to ensure that the containers are properly designed, constructed and secured to prevent spillage or seepage during normal use. Safety data sheets must be supplied for dangerous substances covered by these Regulations.

Commission Directive 2001/59/EC adapts to technical progress for the 28th time Annexes I, III, V, VI, VII and VIII of Directive 67/548/EEC.

- The Directive adds a number of additional dangerous substances to Annex I, the list of substances classified and labelled as dangerous in the European Community, amends the classification and labelling of a number of other dangerous substances already included in Annex 1, and deletes a number of existing entries in the Annex.
- In addition, the Foreword to Annex I is updated. It is provided for the first time as Schedule 1 to the Regulations.
- Additional risk phrases are included in Annex III of the Directive and are set out in Schedule 3 to the Regulations.
- Safety advice is set out in Annex VI and is set out in Schedule 5 to the Regulations.
- Additional test methods are incorporated into Annex V.
- Annex VI, the general classification and labelling guide, is set out in Schedule 5 to the Regulations.
- Annex VII is amended to contain details of the reduced test package (RTP) which can be submitted for intermediates with limited exposure and is set out in Schedule 6 to the Regulations.
- Annex VIII is amended to detail additional tests that may be required for intermediates with limited exposure marketed in higher volumes. The Irish Competent Authority shall produce guidelines on this Reduced Test Package.
- Annex IX contains provisions relating to child-proof fastenings and tactile warning devices and is set out in Schedule 7 to the Regulations.
- Schedule 8 to the Regulations sets out the obligatory headings for safety data sheets.

The Fees payable by the notifier are set out in Schedule 9 to the Regulations.

The Hazardous Substances Assessment Unit of the Health and Safety Authority, 10 Hogan Place, Dublin 2. is the competent authority to which notifications under these Regulations should be sent.

Price €15.49

dscplnregs2k3