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(Information)

COUNCIL

COMMON POSITION (EC) No 54/98

adopted by the Council on 24 September 1998

with a view to the adoption of Directive 98/. . ./EC of the European Parliament and of the Council concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations

(98/C 360/01)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal of the Commission [1],

Having regard to the opinion of the Economic and Social Committee [2],

Acting in accordance with the procedure laid down in Article 189b of the Treaty [3],

(1) Whereas Council Directive 88/379/EEC of 7 June 1988 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations [4] has been amended on several occasions; whereas on the occasion of further amendments, the said Directive should, for reasons of clarity, be recast;

(2) Whereas, in spite of Community provisions, the rules applying to certain dangerous preparations in the Member States exhibit considerable differences as regards classification, packaging and labelling; whereas these differences constitute a barrier to trade, create unequal competition conditions and directly affect the functioning of the internal market; whereas it is therefore necessary to remove this barrier to trade by approximating the relevant legislation existing in the Member States;

(3) Whereas measures for the approximation of the provisions of the Member States affecting the establishment and functioning of the internal market must, in so far as they concern health, safety and protection of man and the environment, adopt a high level of protection as a basis; whereas this Directive must, at the same time, ensure protection for the general public, and, in particular, persons who come into contact with dangerous preparations in the course of their work or in the pursuit of a hobby, protection for consumers and for the environment;

(4) Whereas containers containing certain categories of dangerous preparations offered or sold to the general public must be fitted with child-resistant fastenings and/or carry a tactile warning of danger; whereas certain preparations not falling within these categories of danger may nevertheless, owing to their composition, present a danger for children; whereas the packaging of such preparations should therefore be equipped with child-resistant fastenings;

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[1] OJ C 283, 26.9.1996, p. 1 and OJ C 337, 7.11.1997, p. 45.
[2] OJ C 158, 26.5.1997, p. 76.
[3] Opinion of the European Parliament of 26 June 1997 (OJ C 222, 21.7.1997, p. 26), Council Common Position of 24 September 1998 and Decision of the European Parliament of . . . (not yet published in the Official Journal).
[4] OJ L 187, 16.7.1988, p. 14. Directive as last amended by Commission Directive 96/65/EC (OJ L 265, 18.10.1996, p. 15).

(5) Whereas it is necessary to provide concentration limits expressed as a volume/volume percentage in the case of preparations marketed in gaseous form;

(6) Whereas this Directive contains special labelling provisions applicable to certain preparations; whereas, to ensure an adequate level of protection for man and the environment, special labelling provisions must also be introduced for certain preparations which, although not dangerous within the meaning of this Directive, may nevertheless present a danger to the user;

(7) Whereas on 30 April 1992 the Council adopted Directive 92/32/EEC amending for the seventh time Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances [1]; whereas on 27 April 1993 the Commission adopted Directive 93/21/EEC [2] adapting to technical progress for the 18th time Council Directive 67/548/EEC [3]; whereas new criteria developed for classifying and labelling substances dangerous for the environment were introduced by those Directives, together with the appropriate symbols, indications of danger, risk phrases and safety advice required to appear on labelling; whereas provisions should be adopted at Community level on the classification and labelling of preparations to take account of their effects on the environment and whereas it is therefore necessary to introduce a method for assessing the hazards of a given preparation for the environment either by a calculation method, or by determining the ecotoxicological properties by test methods under certain conditions;

(8) Whereas the number of animals used for experiments should be reduced to a minimum, in accordance with the provisions of Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes [4]; whereas Article 7(2) of that Directive stipulates that an experiment shall not be performed if another scientifically satisfactory method of obtaining the results sought, not entailing the use of an animal, is reasonably and practically available; whereas, therefore, this Directive makes use of the results of assessments of toxicological and ecotoxicological properties only when these are already known and entails no obligation to conduct further experiments on animals;

(9) Whereas it is necessary to define what human experience might be considered for the evaluation of the health hazards of a preparation; whereas, if clinical studies may be accepted, it is taken as given that such studies comply with the Helsinki Declaration and OECD guidelines for good clinical practice;

(10) Whereas the characteristics of alloys are such that it may not be possible accurately to determine their properties using currently available conventional methods; whereas it is therefore necessary to develop a specific method of classification which takes into account their particular chemical properties; whereas the Commission, in consultation with Member States, will examine this need and submit a proposal, if appropriate, before the implementation date of this Directive;

(11) Whereas classification, packaging and labelling of plant protection products covered by Council Directive 78/631/EEC of 26 June 1978 on the approximation of the laws of the Member States relating to the classification, packaging and labelling of dangerous preparations (pesticides) [5] need to be revised taking into account technical and scientific developments as well as regulatory developments following implementation of Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market [6];

(12) Whereas Directive 91/414/EEC and Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market [7], in contrast to the provisions applicable to chemical preparations covered by this Directive, provide for an authorisation procedure for each product on the basis of a dossier presented by the applicant and an assessment carried out by the competent authority in each Member State; whereas furthermore that authorisation procedure includes a control relating specifically to the classification, packaging and labelling of each product before it is placed on the market; whereas it is appropriate, as part of a clear and transparent information process, to classify and label plant protection products according to the provisions of this Directive, and also to provide instructions for use in accordance with the results of the evaluation carried out in the framework of Directive 91/414/EEC and to ensure that the labelling satisfies the high level of protection sought

[1] OJ L 154, 5.6.1992, p. 1.
[2] OJ L 110, 4.5.1993, p. 20.
[3] OJ 196, 16.8.1967, p. 1.
[4] OJ L 358, 18.12.1986, p. 1.
[5] OJ L 206, 29.7.1978, p. 13. Directive as last amended by Council Directive 92/32/EEC.
[6] OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 96/68/EC (OJ L 277, 30.10.1996, p. 25).
[7] OJ L 123, 24.4.1998, p 1.

by both this Directive and Directive 91/414/EEC; whereas, in addition, a safety data sheet has to be established for plant protection products in accordance with this Directive;

(13) Whereas it is appropriate to provide, in relation to environmental labelling, that specific exemptions or specific provisions may be decided upon in specific cases where it can be demonstrated that the overall environmental impact of the product types in question is lower than that of corresponding product types;

(14) Whereas, although munitions are not covered by this Directive, explosives marketed to produce an explosive or pyrotechnic effect may, through their chemical composition, present dangers to health; whereas it is therefore necessary as part of a transparent information process to classify them and assign to them a safety data sheet in accordance with the provisions of this Directive and also to label them in accordance with the international rules used for the transport of dangerous goods;

(15) Whereas, in order to take account of certain preparations which, although they are not considered dangerous under this Directive, may nevertheless present a danger for users, it is necessary to extend certain provisions of this Directive to cover such preparations;

(16) Whereas the label constitutes a basic tool for users of the dangerous preparations in so far as it provides them with the initial essential concise information; whereas it nevertheless needs to be supplemented by a two-fold system of more detailed information, consisting firstly of the safety data sheet, intended for professional users as defined by Commission Directive 91/155/EEC of 5 March 1991 defining and laying down the detailed arrangements for the system of specific information relating to dangerous preparations in implementation of Article 10 of Directive 88/379/EEC [1] and secondly of the bodies appointed by the Member States which are responsible for the provision of information solely for medical purposes, both preventive and curative;

(17) Whereas, on the basis of information to be supplied by the Member States and the various parties concerned, the Commission will submit a report to the European Parliament and the Council within two years of the entry into force of this Directive on experience with the present overall approach to labelling of dangerous preparations and in particular on its understanding and application by users, experience with publicity campaigns and educational and training programmes; whereas, on the basis of this report, the Commission will, if appropriate, submit the necessary proposals;

(18) Whereas it is necessary to require safety data sheets providing proportionate information on the dangers to man and the environment arising from preparations not classified as dangerous within the meaning of this Directive but containing substances classified as dangerous or having a Community exposure limit; whereas the Commission, on the basis of information submitted by Member States, will review Directive 91/155/EEC and submit proposals, if appropriate, before the expiry of the date for implementation of this Directive;

(19) Whereas, in the case of preparations classified as dangerous within the meaning of this Directive, it is appropriate to permit Member States to allow certain derogations with respect to labelling where the packaging is too small, or otherwise unsuitable for labelling, or where such small packaging or such small quantities are involved that there is no reason to fear any danger to man or the environment; whereas in such cases appropriate consideration should also be given to the approximation of the relevant provisions at Community level; whereas the Commission will therefore examine the needs for harmonisation and, if appropriate, submit proposals;

(20) Whereas the confidentiality of certain substances contained in the preparations should be guaranteed and whereas it is therefore necessary to institute a system which allows the person responsible for placing the preparation on the market to request confidentiality for such substances;

(21) Whereas the provisions of this Directive will have regard to the commitment entered into by the Community and its Member States, in accordance with the goals for sustainable development set under Agenda 21, Chapter 19, at the UNCED conference held in June 1992 in Rio de Janeiro, to strive for the future harmonisation of systems for the classification of dangerous substances and preparations;

(22) Whereas the Commission should be given the powers necessary to adapt all the Annexes to this Directive to technical progress;

(23) Whereas the adoption of this Directive should not affect the obligations of the Member States concerning the deadlines for transposition into national law and for application of the Directives indicated in Annex VIII;

[1] OJ L 76, 22.3.1991, p. 35. Directive as last amended by Commission Directive 93/112/EEC (OJ L 314, 16.12.1993, p. 38).

(24) Whereas the Directives indicated in Annex VIII should be repealed, subject to certain conditions; whereas the conditions for repealing the Directives indicated in Annex VIII should be specified for Austria, Finland and Sweden in order to take account of the present level of their legislation, in particular as regards the protection of health and the protection of the environment,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Objectives and scope

1. This Directive aims at the approximation of the laws, regulations and administrative provisions of the Member States relating to:

— the classification, packaging and labelling of dangerous preparations, and to

— the approximation of specific provisions for certain preparations which may present hazards, whether or not they are classified as dangerous within the meaning of this Directive,

when such preparations are placed on the market of the Member States.

2. This Directive shall apply to preparations which:

— contain at least one dangerous substance within the meaning of Article 2,

and

— are considered dangerous within the meaning of Articles 5, 6 or 7.

3. The specific provisions set out:

— in Article 9 and defined in Annex IV,

— in Article 10 and defined in Annex V, and

— in Article 14

shall also apply to preparations which are not considered dangerous within the meaning of Articles 5, 6 or 7 but may nevertheless present a specific hazard.

4. Without prejudice to Directive 91/414/EEC, the Articles on classification, packaging, labelling and safety data sheets of this Directive shall apply to plant protection products.

5. This Directive 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 [1];

(b) cosmetic products as defined in Directive 76/768/EEC [2];

(c) mixtures of substances which, in the form of waste, are covered by Directives 75/442/EEC [3] and 78/319/EEC [4];

(d) foodstuffs;

(e) animal feedingstuffs;

(f) preparations containing radioactive substances as defined by Directive 80/836/Euratom [5];

(g) medical devices which are invasive or used in direct physical contact with the human body in so far as Community measures lay down provisions for the classification and labelling of dangerous substances and preparations which ensure the same level of information provision and protection as this Directive.

6. This Directive shall not apply to:

— the carriage of dangerous preparations by rail, road, inland waterway, sea or air,

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

Article 2

Definitions

1. For the purposes of this Directive:

(a) '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 products 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;

(b) 'preparations': means mixtures or solutions composed of two or more substances;

[1] OJ 22, 9.2.1965, p. 369. Directive as last amended by Directive 93/39/EEC (OJ L 214, 24.8.1993, p. 22).
[2] OJ L 262, 27.9.1976, p. 169. Directive as last amended by Directive 97/18/EC (OJ L 114, 1.5.1997, p. 43).
[3] OJ L 194, 25.7.1975, p. 39. Directive as last amended by Commission Decision 96/350/EC (OJ L 135, 6.6.1996, p. 32).
[4] OJ L 84, 31.3.1978, p. 43.
[5] OJ L 246, 17.9.1980, p. 1. Directive as amended by Directive 84/467/Euratom (OJ L 265, 5.10.1984, p. 4).

(c) '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 consists of less than a simple weight majority of molecules of the same molecular weight. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. In the context of this definition a 'monomer unit' means the reacted form of a monomer in a polymer;

(d) '(. . .)';

(e) 'placing on the market': means making available to third parties. Importation into the Community customs territory shall be deemed to be placing on the market for the purposes of this Directive;

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

(g) '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;

(h) 'Einecs' means the European Inventory of Existing Commercial Chemical Substances. This inventory contains the definitive list of all chemical substances deemed to be on the Community market on 18 September 1981.

2. The following are 'dangerous' within the meaning of this Directive:

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

(b) 'oxidising substances and preparations': 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': 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':

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

— 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, or

— liquid substances and preparations having a very low flash-point, or

— substances and preparations which, in contact with water or damp air, evolve extremely flammable gases in dangerous quantities;

(e) 'flammable substances and preparations': liquid substances and preparations having a low flash-point;

(f) 'very toxic substances and preparations': 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': 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': 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': substances and preparations which may, on contact with living tissues, destroy them;

(j) 'irritant substances and preparations': 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': 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 of preparation, characteristic adverse effects are produced;

(l) 'carcinogenic substances and preparations': 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': 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': 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 and/or an impairment of male or female reproductive functions or capacity;

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

Article 3

Determination of dangerous properties of preparations

1. The evaluation of the hazards of a preparation shall be based on the determination of:

— physico-chemical properties,

— properties affecting health,

— environmental properties.

These different properties shall be determined in accordance with the provisions laid down in Articles 5, 6 and 7.

Where laboratory tests are conducted, they shall be carried out on the preparation as placed on the market.

2. Where the determination of dangerous properties is carried out in accordance with Articles 5, 6 and 7, all dangerous substances within the meaning of Article 2 and in particular those which:

— are listed in Annex I to Directive 67/548/EEC,

— are listed in Elincs in accordance with Article 21 of Directive 67/548/EEC,

— are classified and labelled provisionally by the person responsible for the placing on the market in accordance with Article 6 of Directive 67/548/EEC,

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

— are covered by Article 8 of Directive 67/548/EEC,

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

shall be taken into consideration in accordance with the provisions laid down in the method used.

3. For the preparations covered by this Directive, dangerous substances as referred to in paragraph 2 which are classified as dangerous on the basis of their health and/or environmental effects, whether they are present as impurities or additives, shall be taken into consideration when their concentrations are equal to, or greater than, those defined in the following table unless lower values are given in Annex I to Directive 67/548/EEC, or in Part B of Annex II to this Directive or in Part B of Annex III thereto, unless otherwise specified in Annex V to this Directive.

Category of danger of the substance	Concentration to take into consideration for	
	Gaseous preparations % vol/vol	Other preparations % w/w
Very toxic	≥ 0,02	≥ 0,1
Toxic	≥ 0,02	≥ 0,1
Carcinogenic Category 1 or 2	≥ 0,02	≥ 0,1
Mutagenic Category 1 or 2	≥ 0,02	≥ 0,1
Toxic for reproduction Category 1 or 2	≥ 0,02	≥ 0,1
Harmful	≥ 0,2	≥ 1
Corrosive	≥ 0,02	≥ 1
Irritant	≥ 0,2	≥ 1
Sensitising	≥ 0,2	≥ 1
Carcinogenic Category 3	≥ 0,2	≥ 1
Mutagenic Category 3	≥ 0,2	≥ 1
Toxic for reproduction Category 3	≥ 0,2	≥ 1
Dangerous for the environment N		≥ 0,1
Dangerous for the environment ozone	≥ 0,1	≥ 0,1
Dangerous for the environment		≥ 1

Article 4

General principles of classification and labelling

1. The classification of dangerous preparations according to the degree and specific nature of the hazards involved shall be based on the definitions of categories of danger laid down in Article 2.

2. The general principles of the classificaiton and labelling of preparations shall be applied in accordance with the criteria laid down in Annex VI to Directive 67/548/EEC, save where alternative criteria referred to in Article 5, 6, 7 or 10 and the relevant Annexes to this Directive are applied.

Article 5

Evaluation of the hazards deriving from physico-chemical properties

1. The hazards of a preparation deriving from its physico-chemical properties shall be assessed by determining, by means of the methods specified in Part A of Annex V to Directive 67/548/EEC, the physico-chemical properties of the preparation necessary for appropriate classification and labelling in accordance with the criteria laid down in Annex VI to that Directive.

2. By way of derogation from paragraph 1:

the determination of the explosive, oxidising, extremely flammable, highly flammable, or flammable properties is not necessary provided that:

— none of the constituents possesses such properties and that, on the basis of the information available to the manufacturer, the preparation is unlikely to present hazards of this kind,

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

— preparations placed on the market in the form of aerosols satisfy the provisions of Article 9a of Directive 75/324/EEC [1].

3. For certain cases for which the methods laid down in Part A of Annex V to Directive 67/548/EEC are not appropriate, alternative calculation methods are laid down in Part B of Annex I to this Directive.

4. Certain exemptions from the application of the methods laid down in Part A of Annex V to Directive 67/548/EEC are referred to in Part A of Annex I to this Directive.

5. The hazards deriving from the physico-chemical properties of a preparation covered by Directive 91/414/EEC shall be assessed by determining the physico-chemical properties of the preparation necessary for appropriate classification in accordance with the criteria set out in Annex VI to Directive 67/548/EEC. These properties shall be determined by means of the methods laid down in Part A of Annex V to Directive 67/548/EEC unless other internationally recognised methods are acceptable in accordance with the provisions of Annexes II and III to Directive 91/414/EEC.

Article 6

Evaluation of health hazards

1. The health hazards of a preparation shall be assessed by one or more of the following procedures:

(a) by a conventional method described in Annex II;

(b) by determining the toxicological properties of the preparation necessary for appropriate classification in accordance with the criteria in Annex VI to Directive 67/548/EEC. These properties shall be determined by means of the methods laid down in Part B of Annex V to Directive 67/548/EEC, 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.

2. Without prejudice to the 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 1(a), or on the basis of existing test results on animals, the methods outlined in paragraph 1(b) may be used, provided they are justified or specifically authorised under Article 12 of Directive 86/609/EEC.

When a toxicological property is established by the methods outlined in paragraph 1(b) to obtain new data, the test shall be conducted in compliance with the principles of good laboratory practice provided for in Directive 87/18/EEC of 18 December 1986 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances [2] and the provisions of Directive 86/609/EEC, in particular Articles 7 and 12 thereof.

Subject to the provisions of paragraph 3, where a toxicological property has been established on the basis of both the methods outlined in paragraphs 1(a) and 1(b), the results from the methods outlined in paragraph 1(b) shall be used for classifying the preparation, except in the case of carcinogenic, mutagenic

[1] OJ L 147, 9.6.1975, p. 40. Directive as last amended by Directive 94/1/EC (OJ L 23, 28.1.1994, p. 28).

[2] OJ L 15, 17.1.1987, p. 29.

or toxic effects for reproduction for which only the method outlined in 1(a) shall be used.

Any of the toxicological properties of the preparation which are not assessed by the method outlined in paragraph 1(b) shall be assessed in accordance with the method outlined in paragraph 1(a).

3. Furthermore, where it can be demonstrated:

— by epidemiological studies, by scientifically valid case studies as specified by Annex VI to Directive 67/548/EEC 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 paragraph 1, then the preparation shall be classified according to its effects on man,

— that, owing to effects such as potentiation, a conventional assessment would underestimate the toxicological hazard, those effects shall be taken into account in classifying the preparation,

— that, owing to effects such as antagonism, a conventional assessment would overestimate the toxicological hazard, those effects shall be taken into account in classifying the preparation.

4. For preparations of a known composition, with the exception of those covered by Directive 91/414/EEC, classified in accordance with paragraph 1(b), a new evaluation of health hazard by the methods outlined in either paragraph 1(a) or (b) shall be performed whenever:

— changes of composition of the inital concentration, as a weight/weight or volume/volume percentage, of one or more of the dangerous constituents are introduced by the manufacturer, in accordance with the following table:

Initial concentration range of the constituent	Permitted variation in initial concentration of the constituent
≤ 2,5 %	±30 %
> 2,5 ≤ 10 %	±20 %
> 10 ≤ 25 %	±10 %
> 25 ≤ 100 %	± 5 %

— changes of composition involving the substitution or addition of one or more constituents, which may or may not be dangerous within the meaning of the definitions set out in Article 2, are introduced by the manufacturer.

This new evaluation will apply unless there is valid scientific justification for considering that a re-evaluation of the hazard will not result in a change of classification.

Article 7

Evaluation of environmental hazards

1. The hazards of a preparation for the environment shall be assessed by one or more of the following procedures:

(a) by a conventional method described in Annex III to this Directive;

(b) by determining the hazardous properties of the preparation for the environment necessary for appropriate classification in accordance with the criteria set out in Annex VI to Directive 67/548/EEC. These properties shall be determined by means of the methods laid down in Part C of Annex V to Directive 67/548/EEC 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. Without prejudice to the testing requirements set out in Directive 91/414/EEC, the conditions for application of the test methods are described in Part C of Annex III to this Directive.

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

Where the environmental hazards have been assessed in compliance with both the procedures mentioned above, the results of the methods referred to in paragraph 1(b) shall be used for classifying the preparation.

3. For preparations of a known composition, with the exception of those covered by Directive 91/414/EEC, classified in accordance with the method outlined in paragraph 1(b), a new evaluation of environmental hazard either by the method outlined in paragraph 1(a) or that outlined in paragraph 1(b) shall be performed whenever:

— changes of composition of the initial concentration, as a weight/weight or volume/volume percentage, of one or more of the dangerous constituents are introduced by the manufacturer, in accordance with the following table:

Initial concentration range of the constituent	Permitted variation in initial concentration of the constituent
≤ 2,5 %	±30 %
> 2,5 ≤ 10 %	±20 %
> 10 ≤ 25 %	±10 %
> 25 ≤ 100 %	± 5 %

— changes of composition involving the substitution or addition of one or more constituents, which may or may not be dangerous within the meaning of the definitions set out in Article 2, are introduced by the manufacturer.

This new evaluation will apply unless there is valid scientific justification for considering that a re-evaluation of the hazard will not result in a change of classification.

Article 8

Obligations and duties of the Member States

1. Member States shall take all necessary measures to ensure that the preparations covered by this Directive cannot be placed on the market unless they comply with it.

2. In order to ensure compliance with this Directive, the authorities of the Member States may request information on the composition of the preparation and any other pertinent information from any person responsible for placing the preparation on the market.

3. Member States shall take all necessary measures to ensure that those responsible for placing the preparation on the market hold at the disposal of the authorities of the Member States:

— the data used for the classification and labelling of the preparation,

— any pertinent information relating to packaging requirements in accordance with Article 9(1)(3), including the test certificate issued in accordance with Part A of Annex IX to Directive 67/548/EEC,

— the data used for establishing the safety data sheet, in accordance with Article 14.

4. Member States and the Commission shall exchange information concerning the name and full address of the national authority (authorities) responsible for communicating and exchanging information relating to the practical application of this Directive.

Article 9

Packaging

1. Member States shall take all necessary measures to ensure that:

1. preparations within the meaning of Article 1(2) and preparations covered by Annex IV pursuant to Article 1(3) cannot be placed on the market unless their packaging satisfies the following requirements:

   — it shall be so designed and constructed that its contents cannot escape; this requirement shall not apply where special safety devices are prescribed,

   — the materials constituting the packaging and fastenings must not be susceptible to adverse attack by the contents, or liable to form dangerous compounds with the contents,

   — packaging and fastenings must be strong and solid throughout to ensure that they will not loosen and will safely meet the normal stresses and strains of handling,

   — containers fitted with replaceable fastening devices shall be so designed that the packaging can be refastened repeatedly without the contents escaping.

2. containers which contain preparations within the meaning of Article 1(2) and preparations covered by Annex IV puorsuant to Article 1(3) offered or sold to the general public do not have:

   — either a shape and/or graphic decoration likely to attract or arouse the active curiosity of children or to mislead consumers, or

   — a presentation and/or a designation used for foodstuffs or animal feedingstuffs or medicinal or cosmetic products.

3. containers which contain certain preparations offered or sold to the general public covered by Annex IV to this Directive:

   — are fitted with child-resistant fastenings,

   and/or

   — carry a tactile warning of danger.

The devices must conform to the technical specifications given in Parts A and B of Annex IX to Directive 67/548/EEC.

2. The packaging of preparations shall be deemed to satisfy the requirements of paragraph 1(1), first, second and third indents, if it complies with the requirements for carriage of dangerous goods by rail, road, inland waterway, sea or air.

Article 10

Labelling

1. Member States shall take all necessary measures to ensure that:

1. (a) preparations within the meaning of Article 1(2) cannot be placed on the market unless the labelling on their packaging satisfies all the requirements of this Article and the specific provisions of Parts A and B of Annex V;

   (b) preparations within the meaning of Article 1(3) as defined in Parts B and C of Annex V cannot be placed on the market unless the labelling on their packaging satisfies the requirements of paragraph 2(1) and (2) and the specific provisions of Parts B and C of Annex V.

2. With respect to plant protection products subject to Directive 91/414/EEC, the labelling requirements in accordance with this Directive shall be accompanied by the following wording:

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

   This labelling shall be without prejudice to the information required in accordance with Article 16 of, and Annex V to, Directive 91/414/EEC.

2. The following information shall be clearly and indelibly marked on any package:

1. the trade name or designation of the preparation;

2. the name, full address and telephone number of the person established in the Community who is responsible for placing the preparation on the market, whether it be the manufacturer, the importer or the distributor;

3. the chemical name of the substance or substances present in the preparation in accordance with the following detailed rules:

   1. for preparations classified T^+, T, X_n in accordance with Article 6, only the substances T^+, T, X_n present in concentrations equal to, or greater than, the lowest limit (limit X_n) for each of them laid down in Annex I to Directive 67/548/EEC or, failing that, Part B of Annex II to this Directive have to be taken into consideration;

   2. for preparations classified C in accordance with Article 6, only C substances present in concentration equal to, or greater than, the lowest limit (limit X_i) laid down in Annex I to Directive 67/548/EEC or, failing that, Part B of Annex II to this Directive have to be taken into consideration;

   3. the name of the substances which have given rise to the classification of the preparation in one or more of the following danger categories:

      — carcinogen category 1, 2 or 3,

      — mutagen category 1, 2 or 3,

      — toxic for reproduction category 1, 2 or 3,

      — very toxic, toxic or harmful due to non-lethal effects after a single exposure,

      — toxic or harmful due to severe effects after repeated or prolonged exposure,

      — sensitising,

      shall be mentioned on the label.

      The chemical name shall be one of the designations listed in Annex I to Directive 67/548/EEC or an internationally recognised chemical nomenclature if no corresponding designation is yet listed in that Annex;

   4. As a consequence of the above provisions the name of any substance which led to the classification of the preparation in the following danger categories:

      — explosive,

      — oxidising,

      — extremely flammable,

      — highly flammable,

      — flammable,

      — irritant,

      — dangerous for the environment,

      need not be mentioned on the label unless the substance has to be mentioned pursuant to points 3.1, 3.2 or 3.3;

   5. As a general rule, a maximum of four chemical names shall suffice to identify the substances primarily responsible for the major health hazards which have given rise to the classification and the

choice of the corresponding phrases referring to the risk involved. In some cases, more than four chemical names may be necessary;

4. The danger symbol(s) and indication(s) of danger:

The danger symbols, where specified in this Directive, and indications of the dangers involved in the use of the preparation, shall be in accordance with the wording of Annexes II and VI to Directive 67/548/EEC and shall be applied in accordance with the evaluation of the hazards carried out in accordance with Annexes I, II and III to this Directive.

Where more than one danger symbol must be assigned to a preparation the obligation to apply the symbol:

— T shall make the symbols C and X optional unless otherwise specified in Annex I to Directive 67/548/EEC,

— C shall make the symbol X optional,

— E shall make the symbols F and O optional,

— X_n shall make the symbol X_i optional.

The symbol(s) shall be printed in black on an orange-yellow background;

5. The risk phrases (R phrases):

The indications concerning special risks (R phrases) shall comply with the wording in Annexes III and VI to Directive 67/548/EEC and shall be assigned in accordance with the results of the hazard evaluation carried out in accordance with Annexes I, II, and III to this Directive.

As a general rule, a maximum of six R phrases shall suffice to describe the risks; for this purpose, the combined phrases listed in Annex III to Directive 67/548/EEC 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.

The standard phrases 'extremely flammable' or 'highly flammable' need not be used where they describe an indication of danger used in accordance with point 4.

6. The safety advice (S phrases):

The indications giving safety advice (S phrases) shall comply with the wording in Annex IV and with Annex VI to Directive 67/548/EEC and shall be assigned in accordance with the results of the hazard evaluation carried out in accordance with Annexes I, II and III to this Directive.

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 to Directive 67/548/EEC shall be regarded as single phrases. However, in some cases more than six S phrases may be necessary.

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

7. The nominal quantity (nominal mass or nominal volume) of the contents in the case of preparations offered or sold to the general public.

3. For certain preparations classified as dangerous within the meaning of Article 7, by way of derogation from paragraph 2(4), (5) and (6) of this Article, exemptions to certain provisions on environmental labelling or specific provisions in relation to environmental labelling may be determined in accordance with the procedure referred to in Article 20, where it can be demonstrated that there would be a reduction in the environmental impact. These exemptions or specific provisions are defined and laid down in Part A or B of Annex V.

4. If the contents of the package do not exceed 125 ml:

— in the case of preparations that are 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,

— in the case of preparations that are classified as flammable or dangerous for 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.

5. Without prejudice to Article 16(4) of Directive 91/414/EEC, indications such as 'non-toxic', 'non-harmful', 'non-polluting', 'ecological' or any other statement indicating that the preparation is not dangerous or likely to lead to underestimation of the dangers of the preparation in question shall not appear on the packaging or labelling of any preparation subject to this Directive.

Article 11

Implementation of the labelling requirements

1. Where the particulars required by Article 10 appear on a label, that label shall be firmly affixed to one or more surfaces of the packaging so that those particulars can be read horizontally when the package is set down normally. The dimensions of the label are laid down in Annex VI to Directive 67/548/EEC and the label is intended solely for provision of the information required by this Directive and if necessary of any supplementary health or safety information.

2. A label shall not be required when the particulars are clearly shown on the package itself, as specified in paragraph 1.

3. The colour and presentation of the label — or, in the case of paragraph 2, of the package — shall be such that the danger symbol and its background stand out clearly from it.

4. The information required on the label under Article 10 shall stand out clearly from its background and shall be of such size and spacing as to be easily read.

Specific provisions regarding the presentation and format of this information shall be laid down in Annex VI to Directive 67/548/EEC.

5. Member States may make the placing on the market of preparations covered by this Directive within their territories subject to use of their official language or languages in respect of the labelling thereof.

6. For the purposes of this Directive, labelling requirements shall be deemed to be satisfied:

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

(b) in the case of a single package:

— if such a package is labelled in accordance with international rules on the transport of dangerous goods and with Article 10(2)(1), (2), (3), (5) and (6); for preparations classified according to Article 7, the provisions of Article 10(2)(4) shall additionally apply with respect to the property in question when it has not been so identified on the label,

or

— where appropriate, for particular types of packaging such as mobile gas cylinders, if the specific requirements referred to in Annex VI to Directive 67/548/EEC are complied with.

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

Article 12

Exemptions from the labelling and packaging requirements

1. Articles 9, 10 and 11 shall not apply to explosives placed on the market with a view to obtaining an explosive or pyrotechnic effect.

2. For certain dangerous preparations within the meaning of Article 5, 6 or 7 defined in Annex VII which, in the form in which they are placed on the market, do not present any physico-chemical risk, or risk to health or to the environment, Articles 9, 10 and 11 shall not apply.

3. Member States may also:

(a) permit the labelling required by Article 10 to be applied in some other appropriate manner on packages which are either too small or otherwise unsuitable for labelling in accordance with Article 11(1) and (2);

(b) by way of derogation from Articles 10 and 11 permit the packaging of dangerous preparations which are classified as harmful, extremely flammable, highly flammable, flammable, irritant or oxidising to be unlabelled or to be labelled in some other way, if they contain such small quantities that there is no reason to fear any danger to persons handling such preparations or to other persons;

(c) by way of derogation from Articles 10 and 11, for preparations classified according to Article 7, permit the packaging of dangerous preparations to be unlabelled or labelled in some other way if they contain such small quantities that there is no reason to fear any dangers to the environment;

(d) by way of derogation from Articles 10 and 11 permit the packaging of dangerous preparations which are not mentioned in (b) or (c) to be labelled in some other appropriate way, if the packages are too

small for the labelling provided for in Articles 10 and 11 and there is no reason to fear any danger to persons handling such preparations or to other persons.

Where this paragraph is applied, the use of symbols, indications of danger, risk (R) phrases or safety (S) phrases different to those laid down in this Directive shall not be permitted.

4. If a Member State makes use of the options provided for in paragraph 3, it shall forthwith inform the Commission and Member States thereof. Where it is appropriate, measures shall be decided upon in the framework of Annex V and in accordance with the provisions of Article 20.

Article 13

Distance selling

Any advertisement for a preparation within the meaning of this Directive which enables a member of the general public to conclude a contract for purchase without first having sight of the label for that preparation must make mention of the type or types of hazard indicated on the label. This requirement is without prejudice to Directive 97/7/EC of the European Parliament and of the Council of 20 May 1997 on the protection of consumers in respect of distance contracts [1].

Article 14

Safety data sheet

1. The safety data sheet information is principally intended for use by professional users and must enable them to take the necessary measures as regards the protection of health, safety and the environment at the place of work.

2. 1. Member States shall take all the necessary measures to ensure that:

(a) the person responsible for placing on the market a preparation within the meaning of Article 1(2) provides a safety data sheet;

(b) the person responsible for placing on the market a preparation provides on request of a professional user a safety data sheet providing proportionate information for preparations not classified as dangerous within the meaning of Articles 5, 6 and 7 but containing in an individual concentration of ≥ 1 % by weight for non-gaseous preparations and ≥ 0,2 % by volume for gaseous preparations at least:

— one substance posing health or environmental hazards, or

— one substance for which there are Community workplace exposure limits;

2. The safety data sheet and its supply must comply with the provisions of Directive 91/155/EEC;

3. The necessary amendments required to adapt to technical progress Directive 91/155/EEC shall be adopted in accordance with the procedure laid down in Article 20 of this Directive.

In particular, the necessary amendments to take account of provisions in point 1(b) shall be adopted before the date specified in Article 22(1);

4. The safety data sheet may be supplied on paper or electronically, provided that the addressee has the necessary means of receiving it.

Article 15

Confidentiality of chemical names

Where the person responsible for placing the preparation on the market can demonstrate that the disclosure on the label or safety data sheet of the chemical identity of a substance which is exclusively classified as:

— irritant with the exception of those assigned R41 or irritant in combination with one or more of the other properties mentioned in point 3.4 of Article 10(2), or

— harmful or harmful in combination with one or more of the properties mentioned in point 3.4 of Article 10(2) presenting acute lethal effects alone

will put at risk the confidential nature of his intellectual property, he may, in accordance with the provisions of Annex VI, be permitted to refer to that substance either by means of a name that identifies the most important functional chemical groups or by means of an alternative name. This procedure may not be applied where the substance concerned has been assigned a Community exposure limit.

[1] OJ L 144, 4.6.1997, p. 19.

Where the person responsible for placing a preparation on the market wishes to take advantage of confidentiality provisions, he shall make a request to the competent authority of the Member State in which the preparation is to be first placed on the market.

This request must be made in accordance with the provisions of Annex VI and must provide the information required in the form in Part A of that Annex. The competent authority may nevertheless request further information from the person responsible for placing the preparation on the market if such information appears necessary in order to evaluate the validity of the request.

The authority of the Member State receiving a request for confidentiality shall notify the applicant of its decision. The person responsible for placing the preparation on the market shall forward a copy of this decision to each of the Member States where he wishes to market the product.

Confidential information brought to the attention of the authorities of a Member State or of the Commission shall be treated in accordance with Article 19(4) of Directive 67/548/EEC.

Article 16

Rights of Member States regarding safety of workers

This Directive shall not affect the right of Member States to specify, in compliance with the Treaty, the requirements they deem necessary to ensure that workers are protected when using the dangerous preparations in question, provided that this does not mean that the classification, packaging, and labelling of dangerous preparations are modified in a way not provided for in this Directive.

Article 17

Bodies responsible for receiving information relating to health

Member States shall appoint the body or bodies responsible for receiving information, including chemical composition, relating to preparations placed on the market and considered dangerous on the basis of their health effects or on the basis of their physico-chemical effects.

Member States shall take the necessary steps to ensure that the appointed bodies provide all the requisite guarantees for maintaining the confidentiality of the information received. Such information may only be used to meet any medical demand by formulating preventive and curative measures, in particular in case of emergency.

Member States shall ensure that the information is not used for other purposes.

Member States shall ensure that the appointed bodies have at their disposal all the information required from the manufacturers or persons responsible for marketing to carry out the tasks for which they are responsible.

Article 18

Free movement clause

Without prejudice to the provisions set out in other Community legislation, Member States may not prohibit, restrict or impede the placing on the market of preparations because of their classification, packaging, labelling or safety data sheets if such preparations comply with the provisions laid down in this Directive.

Article 19

Safeguard clause

1. Where a Member State has detailed evidence that a preparation, although satisfying the provisions of this Directive, constitutes a hazard for man or the environment on grounds relating to the provisions of this Directive, it may provisionally prohibit the placing on the market of that preparation or subject it to special conditions in its territory. It shall immediately inform the Commission and the other Member States of such action and give reasons for its decision.

2. In the case referred to in paragraph 1, the Commission shall consult the Member States as soon as possible.

3. The Commission shall take a decision in accordance with the procedure laid down in Article 20.

Article 20

Adaptation to technical progress

Amendments required to adapt the Annexes to this Directive to technical progress shall be adopted in accordance with the procedure laid down in Article 29(4)(b) of Directive 67/548/EEC.

Article 21

Repeal of Directives

1. The Directives listed in Part A of Annex VIII are hereby repealed, without prejudice to the obligation of the Member States concerning the deadlines for transposition into national law and for application of the Directives indicated in Part B of Annex VIII.

2. The Directives listed in Part A of Annex VIII shall apply to Austria, Finland and Sweden subject to provisions laid down in Part C of that Annex and pursuant to the Treaty.

3. References to the repealed Directives shall constitute references to this Directive and should be read in accordance with the correlation table set out in Annex IX.

Article 22

Transposition

1. Member States shall adopt and publish before . . .[1] the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith inform the Commission thereof.

2. Member States shall apply the laws, regulations and administrative provisions referred to in paragraph 1:

(a) to preparations not within the scope of Directive 91/414/EEC or Directive 98/8/EC as from . . .[2]; and

(b) to preparations within the scope of Directive 91/414/EEC or Directive 98/8/EC as from . . .[3].

3. When Member States adopt such measures, they shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The methods of making such reference shall be laid down by Member States.

Article 23

Entry into force

This Directive shall enter into force on the day of its publication in the *Official Journal of the European Communities*.

Article 21(2) shall apply from 1 January 1999.

Article 24

Adressees

This Directive is addressed to the Member States.

Done at Brussels, . . .

For the European Parliament	*For the Council*
The President	*The President*

(1) 36 months after the entry into force of this Directive.
(2) 36 months after the entry into force of this Directive.
(3) 60 months after the entry into force of this Directive.

ANNEX I

METHODS FOR THE EVALUATION OF PHYSICO-CHEMICAL PROPERTIES OF PREPARATIONS IN ACCORDANCE WITH ARTICLE 5

PART A

Exemptions to test methods of Annex V — Part A to Directive 67/548/EEC

See point 2.2.5 of Annex VI to Directive 67/548/EEC.

PART B

Alternative calculation methods

B.1. *Non-gaseous preparations*

Method for the determination of oxidising properties of preparations containing organic peroxides.

See point 2.2.2.1 of Annex VI to Directive 67/548/EEC.

B.2. *Gaseous preparations*

1. Method for the determination of oxidising properties:
   See point 9.1.1.2 of Annex VI to Directive 67/548/EEC.
2. Method for the determination of flammability properties:
   See point 9.1.1.1 of Annex VI to Directive 67/548/EEC.

ANNEX II

METHODS FOR THE EVALUATION OF HEALTH HAZARDS OF PREPARATIONS IN ACCORDANCE WITH ARTICLE 6

Introduction

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

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

The health effects of a preparation are to be assessed in accordance with Article 6(1)(a) by the conventional method described in Parts A and B of this Annex using individual concentration limits:

(a) where the dangerous substances listed in Annex I to Directive 67/548/EEC are assigned concentration limits necessary for the application of the method of assessment described in Part A of this Annex, these concentration limits must be used;

(b) where the dangerous substances do not appear in Annex I to Directive 67/548/EEC or appear there without the concentration limits necessary for the application of the method of evaluation described in Part A of this Annex, the concentration limits must be assigned in accordance with the specifications in Part B of this Annex.

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

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

— either by a symbol and one or more risk phrases, or

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

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

Where they are not given in Annex I to Directive 67/548/EEC, the concentration limits to be taken into account for the application of this conventional method are those set out in Part B of this Annex.

PART A

Procedure for evaluation of health hazards

The evaluation proceeds stepwise as follows.

1. *The following preparations are to be classified as very toxic:*

1.1. Owing to their acute lethal effects and assigned the symbol 'T+', the indication of danger 'very toxic' and the risk phrases R26, R27 or R28:

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

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration; or

(b) the concentration specified at point 1 in Part B of this Annex (Tables I and IA) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

1.1.2. Preparations containing more than one substance classified as very toxic in lower individual concentrations than the limits specified under 1.1.1(a) or (b) if:

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

where:

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

L_{T+} = the very toxic limit specified for each very toxic substance, expressed as a percentage by weight or by volume.

1.2. Owing to their non-lethal irreversible effects after a single exposure and assigned the symbol 'T+', the indication of danger 'very toxic' and the risk phrase R39/route of exposure.

Preparations containing at least one dangerous substance that produces such effects in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration; or

(b) the concentration specified at point 2 in Part B of this Annex (Tables II and IIA) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without limits.

2. *The following preparations shall be classified as toxic:*

2.1. Owing to their acute lethal effects and assigned the symbol 'T', the indication of danger 'toxic' and the risk phrases R23, R24 or R25.

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

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration; or

(b) the concentration specified at point 1 in Part B of this Annex (Tables I and IA) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

2.1.2. Preparations containing more than one substance classified as very toxic or toxic in lower individual concentrations than the limits specified under point 2.1.1(a) or (b) if:

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

where:

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

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

L_T = the respective toxic limit specified for each very toxic or toxic substance, expressed as a percentage by weight or by volume;

2.2. Owing to their non-lethal irreversible effects after a single exposure and assigned the symbol T, the indication of danger 'toxic' and the risk phrase R39/route of exposure.

Preparations containing at least one dangerous substance classified as very toxic or toxic that produce such effects in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration; or

(b) the concentration specified at point 2 in Part B of this Annex (Tables II and IIA) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

2.3. Owing to their long-term effects and assigned the symbol T, the indication of danger 'toxic' and the risk phrase R48/route of exposure.

Preparations containing at least one dangerous substance that produces such effects in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

(b) the concentration specified at point 3 in Part B of this Annex (Tables III and IIIA) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

3. *The following preparations shall be classified as harmful:*

3.1. Owing to their acute lethal effects and assigned the symbol X_n and the indication of danger 'harmful' and the risk phrases R20, R21 or R22.

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

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration; or

(b) the concentration specified at point 1 in Part B of this Annex (Tables I and IA) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

3.1.2. Preparations containing more than one substance classified as very toxic, toxic or harmful in lower individual concentrations than the limits specified under point 3.3.1(a) or (b) if:

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

where:

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

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

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

L_{Xn} = the respective harmful limit specified for each very toxic, toxic or harmful substance, expressed as percentage by weight or by volume;

3.2. Owing to their acute effects to the lungs if swallowed and assigned the symbol X_n and the indication of danger 'harmful' and the risk phrase R65.

Preparations classified as harmful according to the criteria specified in point 3.2.3 of Annex VI to Directive 67/548/EEC. In applying the conventional method according to point 3.1 no account shall be taken of the classification of a substance as R65.

3.3. Owing to their non-lethal irreversible effects after a single exposure and assigned the symbol X_n, the indication of danger 'harmful' and the risk phrase R40/route of exposure.

Preparations containing at least one dangerous substance classified as very toxic, toxic or harmful that produces such effects in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

(b) the concentration specified at point 2 in Part B of this Annex (Tables II and IIA) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits.

3.4. Owing to their long-term effects and assigned the symbol X_n, the indication of danger 'harmful' and the risk phrase R48/route of exposure.

Preparations containing at least one dangerous substance classified as toxic or harmful that produces such effects in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration; or

(b) the concentration specified at point 3 in Part B of this Annex (Tables III and IIIA) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits.

4. *The following preparations are to be classified as corrosive:*

4.1. and assigned the symbol C, the indication of danger 'corrosive' and the risk phrase R35.

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

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration; or

(b) the concentration specified at point 4 in Part B of this Annex (Tables IV and IVA) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits.

4.1.2. Preparations containing more than one substance classified as corrosive to which is assigned phrase R35 in lower individual concentrations than the limits specified under point 4.1.1(a) or (b) if:

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

where:

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

$L_{C,\,R35}$ = the corrosive limit R35 specified for each corrosive substance to which is assigned phrase R35, expressed as a percentage by weight or by volume;

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

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

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration; or

(b) the concentration specified at point 4 in Part B of this Annex (Tables IV and IVA) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits.

4.2.2. Preparations containing more than one of the substances classified as corrosive to which is assigned the phrase R35 or R34 in lower individual concentrations than the limits specified under point 4.2.1(a) or (b) if:

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

where:

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

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

$L_{C,\,R34}$ = the respective corrosive limit R34 specified for each corrosive substance to which is assigned phrase R35 or R34, expressed as a percentage by weight or by volume.

5. *The following preparations are to be classified as irritants:*

5.1. liable to cause serious eye damage and assigned the symbol X_i, the indication of danger 'irritant' and the risk phrase R41.

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

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration; or

(b) the concentration specified at point 4 in Part B of this Annex (Tables IV and IVA) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

5.1.2. Preparations containing more than one of the substances classified as irritant and to which is assigned phrase R41, or classified as corrosive and to which is assigned phrase R35 or R34, in lower individual concentrations than the limits specified under point 5.1.1(a) or (b) if:

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

where:

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

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

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

$L_{X_i,\,R41}$ = the respective irritant limit R41 specified for each corrosive substance to which is assigned phrase R35 or R34 or irritant substance to which is assigned phrase R41, expressed as percentage by weight or by volume;

5.2. Irritant to eyes and assigned the symbol X_i, the indication of danger 'irritant' and the risk phrase R36.

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

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration; or

(b) the concentration specified at point 4 in Part B of this Annex (Tables IV and IVA) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits.

5.2.2. Preparations containing more than one substance classified as irritant to which is assigned phrase R41 or R36, or as corrosive and to which is assigned phrase R35 or R34, in lower individual concentrations than the limits specified under point 5.2.1(a) or (b) if:

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

where:

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

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

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

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

$L_{X_i,\,R36}$ = the respective irritant limit R36 specified for each corrosive substance to which is assigned phrase R35 or R34 or irritant substance to which is assigned phrase R41, or R36 expressed as percentage by weight or by volume;

5.3. Irritant to skin and assigned the symbol X_i, the indication of danger 'irritant' and the risk phrase R38.

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

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration; or

(b) the concentration specified at point 4 in Part B of this Annex (Tables IV and IVA) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits.

5.3.2. Preparations containing more than one of the substances classified as irritant and to which is assigned phrase R38, or as corrosive and to which is assigned phrase R35 or R34 in lower individual concentrations than the limits specified under point 5.3.1(a) or (b) if:

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

where:

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

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

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

$L_{X_i,\,R38}$ = the respective irritant limit R38 specified for each corrosive substance to which is assigned phrase R35 or R34 or irritant substance to which is assigned phrase R38, expressed as percentage by weight or by volume;

5.4. Irritant to respiratory system and assigned the symbol X_i, the indication of danger 'irritant' and the risk phrase R37.

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

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration; or

(b) the concentration specified at point 4 in Part B of this Annex (Tables IV and IVA) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits.

5.4.2. Preparations containing more than one substance classified as irritant and to which is assigned phrase R37 in lower individual concentrations than the limits specified under point 5.4.1(a) or (b) if:

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

where:

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

$L_{X_i,\,R37}$ = the irritant limit R37 specified for each irritant substance to which is assigned phrase R37, expressed as percentage by weight or by volume.

5.4.3. Gaseous preparations containing more than one of the substances classified as irritant to which is assigned phrase R37 or as corrosive and to which is assigned phrase R35 or R34 in lower individual concentrations than the limits specified under point 5.4.1(a) or (b) if:

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

where:

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

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

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

$L_{X_i,\,R37}$ = the respective irritant limit R37 specified for each gaseous corrosive substance to which is assigned phrase R35 or R34 or gaseous irritant substance to which is assigned phrase R37, expressed as percentage by weight or by volume.

6. *The following preparations are to be classified as sensitising:*

6.1. by skin contact and assigned the symbol X_i, the indication of danger 'irritant' and the risk phrase R43.

Preparations containing at least one substance classified as sensitising and to which is assigned phrase R43 that produces such effects in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration; or

(b) the concentration specified at point 5 in Part B of this Annex (Table V and VA) where the substance or substances donot appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

6.2. by inhalation and assigned the symbol X_n, the indication of danger 'harmful' and the risk phrase R42.

Preparations containing at least one substance classified as sensitising to which is assigned phrase R42 that produces such effects in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration; or

(b) the concentration specified at point 5 in Part B of this Annex (Table V and VA) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits.

7. *The following preparations are to be classified as carcinogenic:*

7.1. those of category 1 or 2 which are assigned the symbol T and the phrase R45 or R49.

Preparations containing at least one substance producing such effects, classified as carcinogenic and to which is assigned phrase R45 or R49 which denotes carcinogenic substances in categories 1 and 2, in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration; or

(b) the concentration specified at point 6 in Part B of this Annex (Tables VI and VIA) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

7.2. those of category 3 which are assigned the symbol X_n and the phrase R40.

Preparations containing at least one substance producing such effects classified as carcinogenic and to which is assigned phrase R40 which denotes carcinogenic substances in category 3, in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration; or

(b) the concentration specified at point 6 in Part B of this Annex (Tables VI and VIA) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits.

8. *The following preparations are to be classified as mutagenic:*

8.1. those of category 1 or 2 which are assigned the symbol T and the phrase R46.

Preparations containing at least one substance producing such effects, classified as mutagenic and to which is assigned phrase R46 which denotes mutagenic substances in categories 1 and 2, in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration; or

(b) the concentration specified at point 6 in Part B of this Annex (Tables VI and VIA) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

8.2. those of category 3 which are assigned the symbol X_n and the phrase R40.

Preparations containing at least one substance, producing such effects, classified as mutagenic and to which is assigned phrase R40 which denotes mutagenic substances in category 3, in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration; or

(b) the concentration specified at point 6 in Part B of this Annex (Tables VI and VIA) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits.

9. *The following preparations are to be classified as toxic for reproduction:*

9.1. those of category 1 or 2 which are assigned the symbol T and the phrase R60 (fertility).

Preparations containing at least one substance producing such effects, classified as toxic for reproduction and to which is assigned phrase R60 which denotes substances toxic for reproduction of categories 1 and 2, in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration; or

(b) the concentration specified at point 6 in Part B of this Annex (Tables VI and VIA) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

9.2. those of category 3 which are assigned the symbol X_n and the phrase R62 (fertility).

Preparations containing at least one substance producing such effects, classified as toxic for reproduction and to which is assigned phrase R62 which denotes substances toxic for reproduction of category 3, in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration; or

(b) the concentration specified at point 6 in Part B of this Annex (Tables VI and VIA) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

9.3. those of category 1 or 2 which are assigned the symbol T and the phrase R61 (development).

Preparations containing at least one substance producing such effects, classified as toxic for reproduction and to which is assigned phrase R61 which denotes substances toxic for reproduction of categories 1 and 2, in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration; or

(b) the concentration specified at point 6 in Part B of this Annex (Tables VI and VIA) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

9.4. those of category 3 which are assigned the symbol X_n and the phrase R63 (development).

Preparations containing at least one substance producing such effects, classified as toxic for reproduction and to which is assigned phrase R63 which denotes substances toxic for reproduction of category 3, in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration; or

(b) the concentration specified at point 6 in Part B of this Annex (Tables VI and VIA) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits.

PART B

Concentration limits to be used in evaluation of health hazards

For each health effect, the first table (Tables I to VI) sets out the concentration limits (expressed as a weight/weight percentage) to be used for non-gaseous preparations and the second table (Tables IA to VIA) sets out the concentration limits (expressed as a volume/volume percentage) to be used for gaseous preparations. These concentration limits are used in the absence of specific concentration limits for the substance under considerateion in Annex I to Directive 67/548/EEC.

1. *Acute lethal effects:*

1.1. Non-gaseous preparations:

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

Table I

Classification of the substance	Classification of the preparation		
	T^+	T	X_n
T^+ with R26, R27, R28	Concentration ≥ 7 %	1 % ≤ concentration < 7 %	0,1 % ≤ concentration < 1 %
T with R23, R24, R25		Concentration ≥ 25 %	3 % ≤ concentration < 25 %
X_n with R20, R21, R22			Concentration ≥ 25 %

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

— the label shall include one or more of the abovementioned R phrases according to the classification used,

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

1.2. Gaseous preparations:

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

Table IA

Classification of the substance (gas)	Classification of the gaseous preparation		
	T^+	T	X_n
T^+ with R26, R27, R28	Concentration ≥ 1 %	0,2 % ≤ concentration < 1 %	0,02 % ≤ concentration < 0,2 %
T with R23, R24, R25		Concentration ≥ 5 %	0,5 % ≤ concentration < 5 %
X_n with R20, R21, R22			Concentration ≥ 5 %

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

— the label shall include one or more of the abovementioned R phrases according to the classification used,

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

2. *Non-lethal irreversible effects after a single exposure:*

2.1. Non-gaseous preparations:

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

Table II

Classification of the substance	Classification of the preparation		
	T^+	T	X_n
T^+ with R39/route of exposure	Concentration ≥ 10 % R39(*) obligatory	1 % ≤ concentration < 10 % R39(*) obligatory	0,1 % ≤ concentration < 1 % R40(*) obligatory
T with R39/route of exposure		Concentration ≥ 10 % R39(*) obligatory	1 % ≤ Concentration < 10 % R40(*) obligatory
X_n with R40/route of exposure			Concentration ≥ 10 % R40(*) obligatory

(*) In order to indicate the route of administration/exposure (route of exposure) the combined R phrases listed under points 3.2.1, 3.2.2 and 3.2.3 of the labelling guide (Annex VI to Directive 67/548/EEC) are to be used.

2.2. Gaseous preparations:

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

Table IIA

Classification of the substance (gas)	Classification of the gaseous preparation		
	T^+	T	X_n
T^+ with R39/route of exposure	Concentration ≥ 1 % R39(*) obligatory	0,2 % ≤ concentration < 1 % R39(*) obligatory	0,02 % ≤ concentration < 0,2 % R40(*) obligatory
T with R39/route of exposure		Concentration ≥ 5 % R39(*) obligatory	0,5 % ≤ concentration < 5 % R40(*) obligatory
X_n with R40/route of exposure			Concentration ≥ 5 % R40(*) obligatory

(*) In order to indicate the route of administration/exposure (route of exposure) the combined R phrases listed under points 3.2.1, 3.2.2 and 3.2.3 of the labelling guide (Annex VI to Directive 67/548/EEC) are to be used.

3. *Severe effects after repeated or prolonged exposure:*

3.1. Non-gaseous preparations:

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

Table III

Classification of the substance	Classification of the preparation	
	T	X_n
T with R48/route of exposure	Concentration ≥ 10 % R48 (*) obligatory	1 % ≤ concentration < 10 % R48 (*) obligatory
X_n with R48/route of exposure		Concentration ≥ 10 % R48 (*) obligatory

(*) In order to indicate the route of administration/exposure (route of exposure) the combined R phrases listed under points 3.2.1, 3.2.2 and 3.2.3 of the labelling guide (Annex VI to Directive 67/548/EEC) are to be used.

3.2. Gaseous preparations:

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

Table IIIA

Classification of the substance (gas)	Classification of the gaseous preparation	
	T	X_n
T with R48/route of exposure	Concentration ≥ 5 % R48 (*) obligatory	0,5 % ≤ concentration < 5 % R48 (*) obligatory
X_n with R48/route of exposure		Concentration ≥ 5 % R48 (*) obligatory

(*) In order to indicate the route of administration/exposure (route of exposure) the combined R phrases listed under points 3.2.1, 3.2.2 and 3.2.3 of the labelling guide (Annex VI to Directive 67/548/EEC) are to be used.

4. *Corrosive and irritant effects including serious damage to the eye:*

4.1. Non-gaseous preparations:

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

Table IV

Classification of the substance	Classification of the preparation			
	C with R35	C with R34	X_i with R41	X_i with R36, R37, R38
C with R35	Concentration ≥ 10 % R35 obligatory	5 % ≤ concentration < 10 % R34 obligatory	5 % (*)	1 % ≤ concentration < 5 % R36/38 obligatory

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

(*) According to the labelling guide (Annex VI to Directive 67/548/EEC), corrosive substances assigned risk phrases R35 or R34 must also be considered as being assigned phrase R41. Consequently, if the preparation contains corrosive substances with R35 or R34 below the concentration limits for a classification of the preparation as corrosive, such substances can contribute to a classification of the preparation as irritant with R41 or irritant with R36.

4.2. Gaseous preparations:

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

Table IVA

Classification of the substance (gas)	Classification of the gaseous preparation			
	C with R35	C with R34	X_i with R41	X_i with R36, R37, R38
C with R35	Concentration ≥ 1 % R35 obligatory	0,2 % ≤ concentration < 1 % R34 obligatory	0,2 % (*)	0,02 % ≤ concentration < 0,2 % R36/37/38 obligatory
C with R34		Concentration ≥ 5 % R34 obligatory	5 % (*)	0,5 % ≤ concentration < 5 % R36/37/38 obligatory
X_i with R41			Concentration ≥ 5 % R41 obligatory	0,5 % ≤ concentration < 5 % R36 obligatory
X_i with R36, R37, R38				Concentration ≥ 5 % R36, R37, R38 obligatory as appropriate

(*) According to the labelling guide (Annex VI to Directive 67/548/EEC), corrosive substances assigned risk phrases R35 or R34 must also be considered as being assigned phrase R41. Consequently, if the preparation contains corrosive substances with R35 or R34 below the concentration limits for a classification of the preparation as corrosive, such substances can contribute to a classification of the preparation as irritant with R41 or irritant with R36.

5. *Sensitising effects:*

5.1. Non-gaseous preparations:

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

— the symbol X_n and phrase R42 if this effect can be produced by inhalation,

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

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

Table V

Classification of the substance	Classification of the preparation	
	sensitising with R42	sensitising with R43
sensitising with R42	Concentration ≥ 1 % R42 obligatory	
sensitising with R43		Concentration ≥ 1 % R43 obligatory

5.2. Gaseous preparations:

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

— the symbol X_n and phrase R42 if this effect can be produced by inhalation,

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

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

Table VA

Classification of the substance (gas)	Classification of the gaseous preparation	
	sensitising with R42	sensitising with R43
sensitising with R42	Concentration ≥ 0,2 % R42 obligatory	
sensitising with R43		Concentration ≥ 0,2 % R43 obligatory

6. *Carcinogenic/mutagenic/toxic effects for reproduction:*

6.1. Non-gaseous preparations:

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

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

Table VI

Classification of the substance	Classification of the preparation	
	Categories 1 and 2	Category 3
Carcinogenic substances of category 1 or 2 with R45 or R49	Concentration ≥ 0,1 % carcinogenic R45, R49 obligatory as appropriate	
Carcinogenic substances of category 3 with R40		Concentration ≥ 1 % Carcinogenic R40 obligatory
Mutagenic substances of category 1 or 2 with R46	Concentration ≥ 0,1 % Mutagenic R46 obligatory	
Mutagenic substances of category 3 with R40		Concentration ≥ 1 % Mutagenic R40 obligatory
Substances 'toxic for reproduction' of category 1 or 2 with R60 (fertility)	Concentration ≥ 0,5 % Toxic for reproduction (fertility) R60 obligatory	
Substances 'toxic for reproduction' of category 3 with R62 (fertility)		Concentration ≥ 5 % Toxic for reproduction (fertility) R62 obligatory
Substances 'toxic for reproduction' of category 1 or 2 with R61 (development)	Concentration ≥ 0,5 % Toxic for reproduction (development) R61 obligatory	
Substances 'toxic for reproduction' of category 3 with R63 (development)		Concentration ≥ 5 % Toxic for reproduction (development) R63 obligatory

6.2. Gaseous preparations:

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

Carcinogenic categories 1 and 2:	T; R45 or R49
Carcinogenic category 3:	X_n; R40

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

Table VIA

Classification of the substance (gas)	Classification of the gaseous preparation	
	Categories 1 and 2	Category 3
Carcinogenic substances of category 1 or 2 with R45 or R49	Concentration ≥ 0,1 % Carcinogenic R45, R49 obligatory as appropriate	
Carcinogenic substances of category 3 with R40		Concentration ≥ 1 % Carcinogenic R40 obligatory
Mutagenic substances of category 1 or 2 with R46	Concentration ≥ 0,1 % Mutagenic R46 obligatory	
Mutagenic substances of category 3 with R40		Concentration ≥ 1 % Mutagenic R40 obligatory
Substances 'toxic for reproduction' of category 1 or 2 with R60 (fertility)	Concentration ≥ 0,2 % toxic for reproduction (fertility) R60 obligatory	
Substances 'toxic for reproduction' of category 3 with R62 (fertility)		Concentration ≥ 1 % toxic for reproduction (fertility) R62 obligatory
Substances 'toxic for reproduction' of category 1 or 2 with R61 (development)	Concentration ≥ 0,2 % toxic for reproduction (development) R61 obligatory	
Substances 'toxic for reproduction' of category 3 with R63 (development)		Concentration ≥ 1 % toxic for reproduction (development) R63 obligatory

ANNEX III

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

Introduction

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

Part A gives the calculation procedure according to Article 7(1)(a) and gives the R phrases to be assigned to the classification of the preparation.

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

In accordance with Article 7(1)(a) the environmental hazards of a preparation shall be assessed by the conventional method described in Parts A and B of this Annex, using individual concentration limits:

(a) where the dangerous substances listed in Annex I to Directive 67/548/EEC are assigned concentration limits necessary for the application of the method of assessment described in Part A of this Annex, these concentration limits must be used;

(b) where the dangerous substances do not appear in Annex I to Directive 67/548/EEC or appear there without the concentration limits necessary for the application of the method of evaluation described in Part A of this Annex, the concentration limits shall be assigned in accordance with the specification in Part B of this Annex.

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

PART A

Procedure for the evaluation of environmental hazards

(a) *Aquatic environment*

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

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

The following preparations are to be classified as dangerous for the environment:

1. and assigned the symbol N, the indication of danger 'dangerous for the environment' and the risk phrases R50 and R53 (R50—53):

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

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration; or

(b) the concentration specified in Part B of this Annex (Table 1) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

1.2. preparations containing more than one substance classified as dangerous for the environment and to which is assigned phrases R50—53 in lower individual concentrations than the limits specified under point 1.1(a) or (b) if:

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

where:

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

$L_{N,\ R50—53}$ = the limit R50—53 for each substance dangerous for the environment to which is assigned the phrases R50—53, expressed as percentage by weight;

2. and assigned the symbol N, the indication of danger 'dangerous for the environment' and the risk phrases R51 and R53 (R51—53) unless the preparation is already classified according to point 1;

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

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration; or

(b) the concentration specified in Part B of this Annex (Table 1) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

2.2. preparations containing more than one of the substances classified as dangerous for the environment and to which is assigned phrases R50—53 or R51—53 in lower individual concentrations than the limits specified under point 2.1(a) or (b) if:

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

where:

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

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

$L_{N,\ R51—53}$ = the respective limit R51—53 for each substance dangerous for the environment to which is assigned phrases R50—53 or R51—53, expressed as percentage by weight;

3. and assigned the risk phrases R52 and R53 (R52—53) unless the preparation is already classified according to point 1 or 2.

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

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration; or

(b) the concentration specified in Part B of this Annex (Table 1) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

3.2. preparations containing more than one substance classified as dangerous for the environment and to which is assigned phrases R51—53 or R50—53 or R52—53 in lower individual concentrations than the limits specified under point 3.1(a) or (b) if:

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

where:

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

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

$P_{R52—53}$ = the percentage by weight of each substance dangerous for the environment to which is assigned phrases R52—53 in the preparation

$L_{R52—53}$ = the respective limit R52—53 for each substance dangerous for the environment to which is assigned phrases R50—53 or R51—53 or R52—53, expressed as percentage by weight;

4. and assigned the symbol N, the indication of danger 'dangerous for the environment' and the risk phrase R50 unless the preparation is already classified according to point 1.

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

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration; or

(b) the concentration specified in Part B of this Annex (Table 2) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

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

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

where:

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

$L_{N,\,R50}$ = the limit R50 for each substance dangerous for the environment to which is assigned phrases R50, expressed as percentage by weight;

4.3. preparations containing one or more than one of the substances classified as dangerous for the environment and to which is assigned phrase R50 not meeting the criteria under point 4.1 or 4.2 and containing one or more than one substance classified as dangerous for the environment and to which is assigned phrases R50—53 if:

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

where:

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

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

$L_{N,\,R50}$ = the respective limit R50 for each substance dangerous for the environment to which is assigned phrases R50 or R50—53, expressed as percentage by weight

5. and assigned the risk phrase R52 unless the preparation is already classified according to point 1, 2, 3 or 4:

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

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration; or

(b) the concentration specified in Part B of this Annex (Table 3) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

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

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

where:

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

L_{R52} = the limit R52 for each substance dangerous for the environment to which is assigned phrase R52, expressed as percentage by weight

6. and assigned the risk phrase R53 unless the preparation is already classified according to point 1, 2 or 3:

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

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration; or

(b) the concentration specified in Part B of this Annex (Table 4) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

6.2. preparations containing more than one substance classified as dangerous for the environment and to which is assigned phrase R53 in lower individual concentrations than the limits specified under point 6.1(a) or (b) if:

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

where:

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

L_{R53} = the limit R53 for each substance dangerous for the environment to which is assigned phrase R53, expressed as percentage by weight;

6.3. preparations containing one or more than one of the substances classified as dangerous for the environment and to which is assigned phrase R53 not meeting the criteria under point 6.2 and containing one or more than one substance classified as dangerous for the environment and to which is assigned phrases R50—53 or R51—53 or R52—53 if:

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

where:

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

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

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

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

L_{R53} = the respective limit R53 for each substance dangerous for the environment to which is assigned phrase R53 or R50—53 or R51—53 or R52—53, expressed as percentage by weight;

(b) *Non-aquatic environment*

1. OZONE LAYER

I. Conventional method for the evaluation of preparations dangerous for the ozone layer:

The following preparations are to be classified as dangerous for the environment:

1. and assigned the symbol N, the indication of danger 'dangerous for the environment' and the risk phrase R59:

1.1. preparations containing one or more substances classified as dangerous to the environment and to which is assigned the symbol N and the risk phrase R59 in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration; or

(b) the concentration specified in Part B of this Annex (Table 5) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits

2. and assigned the risk phrase R59:

2.1. preparations containing one or more substances classified as dangerous to the environment and to which is assigned R59 in individual concentrations equal to or greater than:

(a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration; or

(b) the concentration specified in Part B of this Annex (Table 5) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits

2. TERRESTRIAL ENVIRONMENT

I. Evaluation of preparations dangerous for the terrestrial environment

Classification of preparations using the risk phrases below will follow after the detailed criteria for use of the phrases have been incorporated in Annex VI to Directive 67/548/EEC.

R54 Toxic to flora

R55 Toxic to fauna

R56 Toxic to soil organisms

R57 Toxic to bees

R58 May cause long-term adverse effects in the environment.

PART B

Concentration limits to be used for the evaluation of environmental hazards

I. *For the aquatic environment*

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

Table 1

Acute aquatic toxicity and long-term adverse effects

Classification of the substance	Classification of the preparation		
	N, R50—53	N, R51—53	R52—53
N, R50—53	Concentration ≥ 25 %	2,5 % ≤ Concentration < 25 %	0,25 % ≤ Concentration < 2,5 %
N, R51—53		Concentration ≥ 25 %	2,5 % ≤ Concentration < 25 %
R52—53			Concentration ≥ 25 %

Table 2

Acute aquatic toxicity

Classification of the substance	Classification of the preparation N, R50
N, R50	Concentration ≥ 25 %
N, R50—53	Concentration ≥ 25 %

Table 3

Aquatic toxicity

Classification of the substance	Classification of the preparation R52
R52	Concentration ≥ 25 %

Table 4

Long-term adverse effects

Classification of the substance	Classification of the preparation R53
R53	Concentration ≥ 25 %
N, R50—53	Concentration ≥ 25 %
N, R51—53	Concentration ≥ 25 %
R52—53	Concentration ≥ 25 %

II. *For the non-aquatic environment*

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

Table 5

Dangerous for the ozone layer

Classification of the substance	Classification of the preparation N, R59
N with R59	Concentration ≥ 0,1 %

Classification of the substance	Classification of the preparation R59
R59	Concentration ≥ 0,1 %

PART C

Test methods for the evaluation of the hazards for the aquatic environment

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

The results of these tests on the preparation may only modify the classification concerning acute aquatic toxicity which would have been obtained by the application of the conventional method.

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 the three species in conformity with the criteria of Annex VI to Directive 67/548/EEC (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.

ANNEX IV

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

PART A

Containers to be fitted with child-resistant fastenings

1. Containers of whatever capacity, containing preparations offered or sold to the general public and labelled as very toxic, toxic or corrosive in accordance with Article 10 and under the conditions laid down in Article 6 of this Directive, are to be fitted with child-resistant fastenings.

2. Containers of whatever capacity containing preparations presenting an aspiration hazard (X_n, R65) and classified and labelled according to point 3.2.3 of Annex VI to Directive 67/548/EEC with the exception of preparations placed on the market in the form of aerosols or in a container fitted with a sealed spray attachment.

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

Number	Identification of the substance			Concentration limit
	CAS Reg Number	Name	Einecs Number	
1	67-56-1	Methanol	2006596	≥ 3 %
2	75-09-2	Dichloromethane	2008389	≥ 1 %

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

PART B

Containers to be fitted with a tactile warning of danger

Containers of whatever capacity, containing preparations offered or sold to the general public and labelled as very toxic, toxic, corrosive, harmful, extremely flammable or highly flammable in accordance with Article 10 and under the conditions laid down in Articles 5 and 6 of this Directive, are to carry a tactile warning of danger.

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

ANNEX V

SPECIAL PROVISIONS CONCERNING THE LABELLING OF CERTAIN PREPARATIONS

A. For preparations classified as dangerous within the meaning of Articles 5, 6 and 7

1. *Preparations sold to the general public:*

1.1. The labels on packages containing such preparations, in addition to the specific safety advice, must bear the relevant safety advice S1, S2, S45 or S46 in accordance with the criteria laid down in Annex VI to Directive 67/548/EEC.

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

2. *Preparations intended for use by spraying:*

The package label containing such preparations must compulsorily bear the safety advice S23 accompanied by safety advice S38 or S51 assigned to it in accordance with the criteria laid down in Annex VI to Directive 67/548/EEC.

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

When a preparation contains at least one substance assigned the phrase R33, the label of the preparation must carry the wording of this phrase as set out in Annex III to Directive 67/548/EEC, when the concentration of this substance present in the preparation is equal to or higher than 1 %, unless different values are set in Annex I to Directive 67/548/EEC.

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

When a preparation contains at least one substance assigned phrase R64, the label of the preparation must carry the wording of this phrase as set out in Annex III to Directive 67/548/EEC, when the concentration of this substance present in the preparation is equal to or higher than 1 %, unless different values are set in Annex I to Directive 67/548/EEC.

B. For preparations irrespective of their classification within the meaning of Articles 5, 6 and 7

1. *Preparations containing lead*

1.1. Paint and varnishes

Labels of packages of paints and varnishes containing lead in quantities exceeding 0,15 % (expressed as weight of metal) of the total weight of the preparation, as determined in accordance with ISO standard 6503/1984, must show the following particulars:

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

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

'Warning! Contains lead'.

2. *Preparations containing cyanoacrylates*

2.1. Adhesives

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

'Cyanoacrylate

Danger

Bonds skin and eyes in seconds

Keep out of the reach of children'.

Appropriate advice on safety must accompany the package.

3. *Preparations containing isocyanates*

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

'Contains isocyanates

See information supplied by the manufacturer'

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

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

'Contains epoxy constituents

See information supplied by the manufacturer'

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

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

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

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

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

'Warning! Contains cadmium

Dangerous fumes are formed during use

See information supplied by the manufacturer

Comply with the safety instructions'

7. *Preparations available as aerosols*

Without prejudice to the provisions of this Directive, preparations available as aerosols are also subject to the labelling provisions in accordance with points 2.2 and 2.3 of the Annex to Directive 75/324/EEC.

8. *Preparations containing substances not yet tested completely*

Where a preparation contains at least one substance which, in accordance with Article 13(3) of Directive 67/548/EEC, bears the inscription 'Warning — substance not yet tested completely', the label of the preparation must bear the inscription 'Warning — this preparation contains a substance not yet tested completely' if this substance is present in a concentration ⩾ 1 %.

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

The packaging of preparations containing at least one substance classified as sensitising and being present in a concentration equal to or greater than 0,1 % or in a concentration equal to or greater than that specified under a specific note for the substance in Annex I to Directive 67/548/EEC must bear the inscription:

'Contains "name of sensitising substance"

May produce an allergic reaction in persons already sensitised'

10. *Liquid preparations containing halogenated hydrocarbons*

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

'Can become highly flammable in use'

or 'Can become flammable in use'

C. **For preparations not classified within the meaning of Articles 5, 6 and 7 but containing at least one dangerous substance**

Preparations not intended for the general public

The label on the packaging of the preparations referred to in Article 14(2)(1)(b) must bear the following inscription:

'Safety data sheet available for professional user on request'

ANNEX VI

CONFIDENTIALITY FOR THE CHEMICAL IDENTITY OF A SUBSTANCE

PART A

Information to be communicated in the request for confidentiality

Introductory notes:

A. Article 15 indicates the conditions in which the person responsible for placing a preparation on the market may avail himself of the confidentiality.

B. To avoid multiple requests for confidentiality relating to the same substance used in different preparations, a single request for confidentiality may suffice if a certain number of preparations have:

— the same dangerous constituents present in the same concentration range,

— the same classification and labelling,

— the same expected uses.

A single alternative denomination must be used to mask the chemical identity of the same substance in the preparations concerned. Furthermore, the request for confidentiality must contain all information indicated in the following request, without forgetting the name or the trade name of each preparation.

C. The alternative designation used on the label must be the same as that given unter heading 2 'Composition/information on ingredients' of the Annex to Directive 91/155/EEC as last amended by Directive 93/112/EEC [1].

This implies that the alternative designation used will contain enough information about the substance to ensure risk-free handling.

D. In making the request to use an alternative designation the person responsible for placing on the market must take into account the need to provide enough information for necessary health and safety precautions to be taken in the workplace and to ensure that risks from handling the preparation can be minimised.

Request for confidentiality

In accordance with Article 15 the request for confidentiality must obligatorily contain the following information:

1. Name and full address (including telephone number) of the person established in the Community who is responsible for placing the preparation on the market (manufacturer, importer or distributor).

2. Precise identification of the substance(s) for which confidentiality is proposed and the alternative designation.

CAS No	Einecs No	Chemical name according to international nomenclature and classification (Annex I to Council Directive 67/548/EEC or provisional classification)	Alternative designation
(a) (b) (c)			

NB:
Where substances are classified provisionally, accompanying information (bibliographical references) should be provided as evidence that the provisional classification takes account of all existing pertinent information available on the properties of the substance.

[1] OJ L 314, 16.12.1993, p. 38.

3. Justification for confidentiality (probability — plausibility).

4. Designation(s) or commercial name(s) of the preparation(s).

5. Is the designation or commercial name the same for all the Community?

YES ☐ NO ☐

If no, specify the designation(s) or commercial name(s) used in the different Member States:

Austria:

Belgium:

Denmark:

Germany:

Greece:

Finland:

France:

Spain:

Sweden:

Ireland:

Italy:

Luxembourg:

Netherlands:

Portugal:

United Kingdom:

6. Composition of the preparation(s) defined in point 2 of the Annex to Directive 91/155/EEC.

7. Classification of the preparation(s) according to Article 6 of this Directive.

8. Labelling of the preparation(s) according to Article 10 of this Directive.

9. Intended uses for the preparation(s).

10. Safety data sheet(s) conforming to Directive 91/155/EEC.

PART B

Lexicon guide for establishing the alternative designations (generic names)

1. **Introductory note:**

The lexicon-guide is based on the procedure for the classification of dangerous substances (division of substances into families) which appears in Annex I to Directive 67/548/EEC.

Alternative designations to those based on this guide may be used. However, in all cases the names chosen must provide enough information to ensure the preparation can be handled without risk and that necessary health and safety precautions can be taken in the workplace.

The families are defined in the following manner:

— inorganic or organic substances whose properties are identified by having a common chemical element as their chief characteristic. The family name is derived from the name of the chemical element. These families are identified as in Annex I by the atomic number of the chemical element (001 to 103),

— organic substances whose properties are identified by having a common functional group as their chief characteristics.

The family name is derived from the functional group name.

These families are identified by the conventional number found in Annex I (601—650).

Sub-families bringing together substances with a common specific character have been added in certain cases.

2. **Establishing the generic name:**

General principles

For the purposes of establishing the generic name, the following general approach, involving two successive stages, is adopted:

(i) identification of the functional groups and chemical elements present in the molecule;

(ii) determination of the extent to which account should be taken of the most important functional groups and chemical elements.

The identified functional groups and elements taken into account are the names of the families and sub-families set out in point 3 in the form of a non-restrictive list.

3. **Division of substances into families and sub-families:**

Family Number Annex I to Directive 67/548/EEC	Families / Sub-families
001	Hydrogen compounds Hydrides
002	Helium compounds
003	Lithium compounds
004	Beryllium compounds
005	Boron compounds Boranes Borates
006	Carbon compounds Carbamates Inorganic carbon compounds Salts of hydrogen cyanide Urea and derivatives
007	Nitrogen compounds Quaternary ammonium compounds Acid nitrogen compounds Nitrates Nitrites
008	Oxygen compounds
009	Fluorine compounds Inorganic fluorides
010	Neon compounds

Family Number Annex I to Directive 67/548/EEC	Families / Sub-families
011	Sodium compounds
012	Magnesium compounds Organometallic magnesium derivatives
013	Aluminium compounds Organometallic aluminium derivatives
014	Silicon compounds Silicones Silicates
015	Phosphorus compounds Acid phosphorus compounds Phosphonium compounds Phosphoric esters Phosphates Phosphites Phosphoramides and derivatives
016	Sulphur compounds Acid sulphur compounds Mercaptans Sulphates Sulphites
017	Chlorine compounds Chlorates Perchlorates
018	Argon compounds
019	Potassium compounds
020	Calcium compounds
021	Scandium compounds
022	Titanium compounds
023	Vanadium compounds
024	Chromium compounds Chromium VI compounds
025	Manganese compounds
026	Iron compounds
027	Cobalt compounds

Family Number Annex I to Directive 67/548/EEC	Families / Sub-families
028	Nickel compounds
029	Copper compounds
030	Zinc compounds Organometallic zinc derivatives
031	Gallium compounds
032	Germanium compounds
033	Arsenic compounds
034	Selenium compounds
035	Bromine compounds
036	Krypton compounds
037	Rubidium compounds
038	Strontium compounds
039	Yttrium compounds
040	Zirconium compounds
041	Niobium compounds
042	Molybdenum compounds
043	Technetium compounds
044	Ruthenium compounds
045	Rhodium compounds
046	Palladium compounds
047	Silver compounds
048	Cadmium compounds
049	Indium compounds
050	Tin compounds Organometallic tin derivatives
051	Antimony compounds
052	Tellurium compounds

Family Number Annex I to Directive 67/548/EEC	Families / Sub-families
053	Iodine compounds
054	Xenon compounds
055	Caesium compounds
056	Barium compounds
057	Lanthanum compounds
058	Cerium compounds
059	Praseodymium compounds
060	Neodymium compounds
061	Promethium compounds
062	Samarium compounds
063	Europium compounds
064	Gandolinium compounds
065	Terbium compounds
066	Dysprosium compounds
067	Holmium compounds
068	Erbium compounds
069	Thulium compounds
070	Ytterbium compounds
071	Lutetium compounds
072	Hafnium compounds
073	Tantalum compounds
074	Tungsten compounds
075	Rhenium compounds
076	Osmium compounds
077	Iridium compounds
078	Platinum compounds

Family Number Annex I to Directive 67/548/EEC	Families / Sub-families
079	Gold compounds
080	Mercury compounds Organometallic mercury derivatives
081	Thallium compounds
082	Lead compounds Organometallic lead derivatives
083	Bismuth compounds
084	Polonium compounds
085	Astate compounds
086	Radon compounds
087	Francium compounds
088	Radium compounds
089	Actinium compounds
090	Thorium compounds
091	Protactinium compounds
092	Uranium compounds
093	Neptunium compounds
094	Plutonium compounds
095	Americium compounds
096	Curium compounds
097	Berkelium compounds
098	Californium compounds
099	Einsteinium compounds
100	Fermium compounds
101	Mendelevium compounds
102	Nobelium compounds
103	Lawrencium compounds

Family Number Annex I to Directive 67/548/EEC	Families / Sub-families
601	Hydrocarbons Aliphatic hydrocarbons Aromatic hydrocarbons Alicyclic hydrocarbons Polycyclic aromatic hydrocarbons (PAH)
602	Halogenated hydrocarbons (1) Halogenated aliphatic hydrocarbons (1) Halogenated aromatic hydrocarbons (1) Halogenated alicyclic hydrocarbons (1)
603	Alcohols and derivatives Aliphatic alcohols Aromatic alcohols Alicyclic alcohols Alcanolamines Epoxy derivatives Ethers Glycolethers Glycols and polyols
604	Phenols and derivatives Halogenated phenol derivatives (1)
605	Aldehydes and derivatives Aliphatic aldehydes Aromatic aldehydes Alicyclic aldehydes Aliphatic acetals Aromatic acetals Alicyclic acetals
606	Ketones and derivatives Aliphatic Ketones Aromatic Ketones (2) Alicyclic Ketones
607	Organic acids and derivatives Aliphatic acids Halogenated aliphatic acids (1) Aromatic acids Halogenated aromatic acids (1) Alicyclic acids Halogenated alicyclic acids (1) Aliphatic acid anhydrides Halogenated aliphatic acid anhydrides Aromatic acid anhydrides Halogenated aromatic acid anhydrides (1) Alicyclic acid anhydrides Halogenated alicyclic acid anhydrides (1) Salts of aliphatic acid Salts of halogenated aliphatic acid (1) Salts of aromatic acid

Family Number Annex I to Directive 67/548/EEC	Families / Sub-families
607 *(cont'd)*	Salts of halogenated aromatic acid (1) Salts of alicyclic acid Salts of halogenated alicyclic acid (1) Esters of aliphatic acid Esters of halogenated alicyclic acid (1) Esters of aromatic acid Esters of halogenated aromatic acid (1) Esters of alicyclic acid Esters of halogenated alicyclic acid (1) Esters of glycol ether Acrylates Methacrylates Lactones Acyl halogenides
608	Nitriles and derivatives
609	Nitro compounds
610	Chlornitrated compounds
611	Azoxy and azo compounds
612	Amine compounds Aliphatic amines and derivatives Alicyclic amines and derivatives Aromatic amines and derivatives Aniline and derivatives Benzidine and derivatives
613	Heterocyclic bases and derivatives Benzimidazole and derivatives Imidazol and derivatives Pyrethrinoids Quinoline and derivatives Triazine and derivatives Triazole and derivatives
614	Glycosides and alkaloids Alkaloid and derivatives Glycosides and derivatives
615	Cyanates and isocyanates Cyanates Isocyanates
616	Amides and derivatives Acetamide and derivatives Anilides

Family Number Annex I to Directive 67/548/EEC	Families / Sub-families
617	Organic peroxides
647	Enzymes
648	Complex coal derivatives Acid extract Alkaline extract Anthracene oil Anthracene oil extract residue Anthracene oil fraction Carbolic oil Carbolic oil extract residue Coal liquids, liquid solvent extraction Coal liquids, liquid solvent extraction solvents Coal oil Coal tar Coal tar extract Coal tar solids residue Coke (coal tar) low temperature, high temperature pitch Coke (coal tar), high temperature pitch Coke (coal tar), mixed coal high temperature pitch Crude benzole Crude phenols Crude tar bases Distillate bases Distillate phenols Distillates Distillates (coal), liquid solvent extraction, primary Distillates (coal), solvent extraction, hydrocracked Distillates (coal), solvent extraction, hydrocracked hydrogenated middle Distillates (coal), solvent extraction, hydrocracked middle Extract residues (coal), low temperature coal tar alkaline Fresh oil Fuels, diesel, coal solvent extraction, hydrocracked, hydrogenated Fuels, jet aircraft, coal solvent extraction, hydrocracked, hydrogenated Gasoline, coal solvent extraction, hydrocracked naphtha Heat treatment products Heavy anthracene oil Heavy anthracene oil redistillate Light oil Light oil extract residues, high boiling Light oil extract residues, intermediate boiling Light oil extract residues, low boiling Light oil redistillate, high boiling Light oil redistillate, intermediate boiling Light oil redistillate, low boiling Methylnaphthalene oil Methylnaphthalene oil extract residue

Family Number Annex I to Directive 67/548/EEC	Families / Sub-families
648 *(cont'd)*	Naphtha (coal), solvent extraction, hydrocracked Naphthalene oil Naphthalene oil extract residue Naphthalene oil redistillate Pitch Pitch redistillate Pitch residue Pitch residue, heat treated Pitch residue, oxidised Pyrolysis products Redistillates Residues (coal), liquid solvent extractions Tar brown coal Tar brown coal, low temperature Tar oil, high boiling Tar oil, intermediate boiling Wash oil Wash oil extract residue Wash oil redistillate
649	Complex oil derivatives Crude oil Petroleum gas Low boiling point naphtha Low boiling point modified naphtha Low boiling point cat-cracked naphtha Low boiling point cat-reformed naphtha Low boiling point thermally cracked naphtha Low boiling point hydrogen-treated naphtha Low boiling point naphtha — unspecified Straight-run kerosine Kerosine — unspecified Cracked gas oil Gas oil — unspecified Heavy fuel oil Grease Unrefined or mildly refined base oil Base oil — unspecified Distillate aromatic extract Distillate aromatic extract (treated) Foots oil Slack wax Petrolatum
650	Various substances [3]

[1] Specify according to the family corresponding to halogen.
[2] Quinones included.
[3] Do not use this family. Instead, use the families or sub-families mentioned above.

4. **Practical application:**

After having conducted a search to see if the substance belongs to one or more families or sub-families on the list, the generic name can be established in the following way:

4.1. If the name of a family or sub-family is sufficient to characterise the chemical elements or important functional groups, this name will be chosen as the generic name.

Examples:

— 1,4 dihydroxybenzen
family 604: phenols and derivatives
generic name: phenol derivatives

— Butanol
family 603: alcohols and derivatives
sub-family: aliphatic alcohols
generic name: aliphatic alcohol

— 2-Isopropoxyethanol
family 603: alcohols and derivatives
sub-family: glycolethers
generic name: glycolether

— methacrylate
family 607: organic acids and derivatives
sub-family: acrylates
generic name: acrylate

4.2. If the name of a family or sub-family is not sufficient to characterise the chemical elements of important functional groups, the generic name will be a combination of the corresponding different family or sub-family names.

Examples:

— chlorobenzene
family 602: halogenated hydrocarbons
sub-family: halogenated aromatic hydrocarbons
family 017: chlorine compounds
generic name: chlorinated aromatic hydrocarbon

— 2,3,6-trichlorophenylacetic acid
family 607: organic acids
sub-family: halogenated aromatic acids
family 017: chlorine compounds
generic name: chlorinated aromatic acid

— 1-chloro-1-nitropropane
family 610: chloronitrated derivatives
family 601: hydrocarbons
sub-family: aliphatic hydrocarbons
generic name: chlorinated aliphatic hydrocarbon

— tetrapropyl dithiopyrophosphate
family 015: phosphorus compounds
sub-family: phosphoric esters
family 016: sulphur compounds
generic name: thiophosphoric ester

NB:

In the case of certain elements, notably metals, the name of the family or sub-family may be indicated by the words ‘organic’ or ‘inorganic’.

Examples:

— dimercury chloride
family 080: mercury compounds
generic name: inorganic mercury compound

— barium acetate:
family 056: barium compounds
generic name: organic barium compound

— ethyl nitrite
  family 007: nitrogen compounds
  sub-family: nitrites
  generic name: organic nitrite

— sodium hydrosulphite
  family 016: sulphur compounds
  generic name: inorganic sulphur compound

(The examples cited are substances taken from Annex I to Directive 67/548/EEC (19th adaptation) in respect of which requests for confidentiality may be submitted).

ANNEX VII

PREPARATIONS COVERED BY ARTICLE 12(2)

Preparations as specified by point 9.3 of Annex VI to Directive 67/548/EEC.

ANNEX VIII

PART A

Directives repealed in accordance with Article 21

— Directive 78/631/EEC on the approximation of the laws of the Member States relating to the classification, packaging and labelling of dangerous preparations (pesticides)

— Directive 88/379/EEC on the approximation of the laws of the Member States relating to the classification, packaging and labelling of dangerous preparations and its following adaptations to technical progress:

  — Directive 89/178/EEC [1]

  — Directive 90/492/EEC [2]

  — Directive 93/18/EEC [3]

  — Directive 96/65/EC

— Directive 90/35/EEC [4] defining in accordance with Article 6 of Directive 88/379/EEC the category of preparations the packaging of which must be fitted with child-resistant fastenings and/or carry a tactile warning of danger

— Directive 91/442/EEC [5] on dangerous preparations the packaging of which must be fitted with child-resistant fastenings

PART B

Deadlines for transposition and for application in accordance with Article 22

Directive	Deadline for transposition	Deadline for application
78/631/EEC	1 January 1981	1 January 1981
88/379/EEC	7 June 1991	7 June 1991
89/178/EEC	1 December 1990	1 June 1991
90/492/EEC	1 June 1991	8 June 1991
93/18/EEC	1 July 1994	1 July 1994
90/35/EEC	1 August 1992	1 November 1992
91/442/EEC	1 August 1992	1 November 1992
96/65/EC	31 May 1998	31 May 1998

PART C

Special provisions for Austria, Finland and Sweden concerning the application of the following Directives in accordance with Article 21

1. Austria, Finland and Sweden do not transpose or apply Council Directive 78/631/EEC of 26 June 1978 on the approximation of the laws of the Member States relating to the classification, packaging and labelling of dangerous preparations (pesticides), as last amended by Directive 92/32/EEC.

(1) OJ L 64, 8.3.1989, p. 18.
(2) OJ L 275, 5.10.1990, p. 55.
(3) OJ L 104, 29.4.1993, p. 46.
(4) OJ L 19, 24.1.1990, p. 14.
(5) OJ L 238, 27.8.1991, p. 25.

2. Austria is to apply Council Directive 88/379/EEC of 7 June 1988 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous preparations, as last amended by Directive 96/65/EC under the following conditions:

   The following provisions of Directive 88/379/EEC will not apply to Austria

   (a) Article 13 in conjunction with Articles 3 and 7 with respect to preparations containing substances listed in Appendix 1;

   (b) Article 13 in conjunction with Article 7 with respect to labelling respecting the Austrian provisions on

   — safety advice for waste disposal,

   — pictogram for waste disposal until two years after the entry into force of this Directive,

   — safety advice for counter-measures in case of accidents;

   (c) Article 13 in conjunction with Article 7(1)(c) concerning the chemical names of dangerous substances present in dangerous preparations, until two years after the entry into force of this Directive.

3. Sweden is to apply Council Directive 88/379/EEC of 7 June 1988 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous preparations, as last amended by Directive 96/65/EC under the following conditions:

   The following provisions of Directive 88/379/EEC will not apply to Sweden:

   (a) Article 13 in conjunction with Articles 3 and 7 with respect to preparations

   — containing substances listed in Appendix 2,

   — containing substances presenting neurotoxic effects and defatting effects on the skin not covered by criteria for classification of Annex VI to Directive 67/548/EEC, and by risk phrases of Annex III to Directive 67/548/EEC,

   — containing substances presenting acutely toxic effects not covered by criteria for classification of Annex VI to Directive 67/548/EEC, and by risk phrases of Annex III to Directive 67/548/EEC, until two years after the entry into force of this Directive,

   — which are not classified as dangerous according to the 'måttligt skadliga' (Swedish: 'moderately harmful') criteria of Directive 88/379/EEC;

   (b) Article 13 in conjunction with Articles 3 and 7 with respect to

   — the criteria for classification and labelling of preparations containing carcinogenic substances classified on the basis of criteria in point 4.2.1 of Annex VI to Directive 67/548/EEC,

   — labelling of preparations classified as carcinogenic, category 3, with a special R-phrase instead of R-phrase 40.

Appendix 1

Substances referred to in Annex VIII Part C point 2 (Austria)

Name of the substance	Index number in Annex I to Directive 67/548/EEC
Linuron	006-021-00-1
Trichlorosilan	014-001-00-9
Phosphorus trichloride	015-007-00-4
Phosphorus pentachloride	015-008-00-X
Phosphorus oxychloride	015-009-00-5
Sodium polysulphides	016-010-00-3
Disulphur dichloride	016-012-00-4
Thionyl chloride	016-015-00-0
Calcium hypochlorite	017-012-00-7
Potassium hydroxide	019-002-00-8
2-Dimethylaminoethanol	603-047-00-0
2-Diethylaminoethanol	603-048-00-6
Diethanolamine	603-071-00-1
N-Methyl-2-ethanolamine	603-080-00-0
2-Ethylhexan-1,3-diol	603-087-00-9
Isophorone	606-012-00-8
6-Methyl-1,3-dithiolo(4,5-b)chinoxalin-2-one	606-036-00-9
Acetic anhydride	607-008-00-9
Methyl formate	607-014-00-1
Ethyl formate	607-015-00-7
Acrylic acid	607-061-00-8
Chloroacetyl chloride	607-080-00-1
Nitrofen	609-040-00-9
Quintozen; Pentachloronitrobenzol	609-043-00-5
Dichlofluanid	616-006-00-7
Cumene hydroperoxide	617-002-00-8
Monocrotophos	015-072-00-9
Edifenphos	015-121-00-4
Triazophos	015-140-00-8
Methanol	603-001-00-X
Trifenmorph; 4-Tritylmorpholin	613-052-00-X
Diuron	006-015-00-9
Fenbutanin oxide	050-017-00-2
1-Butanol, 2-Butanol, iso-Butanol	603-004-00-6

Appendix 2

Substances referred to in Annex VIII Part C point 3 (Sweden)

Name of the substance	Index number in Annex I to Directive 67/548/EEC
Acetone	606-001-00-8
Butanone	606-002-00-3
Amyl formate	607-018-00-3
Ethyl acetate	607-022-00-5
n-Butylacetate	607-025-00-1

Name of the substance	Index number in Annex I to Directive 67/548/EEC
sec-Butylacetate	607-026-00-7
tert-Butylacetate	607-026-00-7
iso-Butylacetate	607-026-00-7
Butylformate	607-017-00-8
Cyclohexane	601-017-00-1
1,4-Dimethylcyclohexane	601-019-00-2
Diethyl ether	603-022-00-4
Ethyl methyl ether	603-020-00-3
Amyl acetate	607-130-00-2
Ethyl lactate	607-129-00-7
Amyl propionate	607-131-00-8
2,4-Dimethylpentan-3-one	606-028-00-5
Di-n-propylether	603-045-00-X
Di-n-propyl ketone	606-027-00-X
Ethyl propionate	607-028-00-8
Heptane	601-008-00-2
Hexane (mixture of isomers) containing less than 5 % n-hexane)	601-007-00-7
Isopropyl acetate	607-024-00-6
Isopropyl alcohol	603-003-00-0
4-Methoxy-4-methylpentane-2-one	606-023-00-8
Methyl acetate	607-021-00-X
Methyl cyclohexane	601-018-00-7
5-Methylhexane-2-one	606-026-00-4
Methylacetate	607-092-00-7
4-Methylpentan-2-one	606-004-00-4
Methyl propionate	607-027-00-2
Octane	601-009-00-8
Pentane	601-006-00-1
Pentan-3-one	606-006-00-5
Propan-1-ol	603-003-00-0
Propyl acetate	607-024-00-6
Propyl formate	607-016-00-2
Propyl propionate	607-030-00-9
Sodium bisulphite = polysulphite	016-010-00-3
Toluene-2,4-diisocyanate	615-006-00-4
Toluene-2,6-diisocyanate	615-006-00-4
Cadmiumfluoride	048-006-00-2
1,2-Epoxy-3(tolyloxy)-propane	603-056-00-X
Diphenylmethane-2,2′-diisocyanate	615-005-00-9
Diphenylmethane-2,4′-diisocyanate	615-005-00-9
Diphenylmethane-4,4′-diisocyanate	615-005-00-9
Hydroquinone	604-005-00-4
Hydroxypropylacrylate	607-108-00-2
Turpentine	650-002-00-6
Butyl methyl ketone (2-Hexanone)	606-030-00-6
Hexane	601-007-00-7
Vanadium pentoxide	023-001-00-8
Sodium nitrate	
Zinc oxide	

ANNEX IX

CORRELATION TABLE

This Directive	88/379/EEC
Article 1	Article 1
1.1	1.1
1.2	1.2
1.3	
1.4	
1.5	1.3
Article 2	Article 2
Article 3	Article 3(6)
Article 4	Article 3(1)
	Article 4
Article 5	Article 3(2)
5.1	3.2
5.1 3rd indent	3.2 paragraph 3(b)
5.2 to 5.3	
5.4	
Article 6	Article 3(3)
6.1	3.3 paragraphs (a) and (b)
6.2	
6.3	3.3 paragraphs 3 and 4
6.4	3.4
6.5	3.5 paragraphs 1 to 3
Article 7	
Article 8	Article 5
8.1	5.1
8.2	5.2
8.3	5.3
8.4	
Article 9	Article 6
9.1	6.1 paragraph (a)
9.2	6.1 paragraph (b)
9.3	6.2 and 6.3 second paragraph
Article 10	Article 7
10.1.1 to 1.2	
10.2	7.1
10.2.3	7.1 paragraph (c)
10.2.4	7.1 paragraph (d)
10.2.5	7.4
Article 11	Article 8

This Directive	88/379/EEC
Article 12	Article 9
Article 13	
Article 14	Article 10
Article 15	Article 7
Article 16	Article 11
Article 17	Article 12
Article 18	Article 13
Article 19	Article 14
Article 20	Article 15
Article 21	
Article 22	Article 16
Article 23	Article 16(3)
Article 24	Article 17

CORRELATION TABLE

This Directive	88/379/EEC	90/35/EEC	91/442/EEC	93/18/EEC
Annex I.A	Article 3(2)(2)			
Annex I.B				
Annex II.A Introduction Paragraphs 1 to 3				Annex I Introduction
Annex II.A Introduction (4)				
Annex II.A.1	Article 3(5)(a)			
Annex II.A.1.1.1	Article 3(5)(a)(i)			
Annex II.A.1.1.2	Article 3(5)(a)(ii)			
Annex II.A.1.2	Article 3(5)(a)(iii)			
Annex II.A.2	Article 3(5)(b)			
Annex II.A.2.1.1	Article 3(5)(b)(i)			

This Directive	88/379/EEC	90/35/EEC	91/442/EEC	93/18/EEC
Annex II.A.2.1.2	Article 3(5)(b)(ii)			
Annex II.A.2.2	Article 3(5)(b)(iii)			
Annex II.A.2.3	Article 3(5)(b)(iv)			
Annex II.A.3	Article 3(5)(c)			
Annex II.A.3.1.1	Article 3(5)(c)(i)			
Annex II.A.3.1.2	Article 3(5)(c)(ii)			
Annex II.A.3.2	Article 3(5)(c)(iii)			
Annex II.A.3.3	Article 3(5)(c)(iv)			
Annex II.A.4	Article 3(5)(d)			
Annex II.A.4.1.1	Article 3(5)(d)(i)			
Annex II.A.4.1.2	Article 3(5)(d)(ii)			
Annex II.A.4.2.1	Article 3(5)(e)(i)			
Annex II.A.4.2.2	Article 3(5)(e)(ii)			
Annex II.A.5	Article 3(5)(f)			
Annex II.A.5.1.1	Article 3(5)(f)(i)			
Annex II.A.5.1.2	Article 3(5)(f)(ii)			
Annex II.A.5.2.1	Article 3(5)(h)(i)			
Annex II.A.5.2.2	Article 3(5)(h)(ii)			
Annex II.A.5.3.1	Article 3(5)(g)(i)			
Annex II.A.5.3.2	Article 3(5)(g)(ii)			
Annex II.A.5.4.1	Article 3(5)(i)(i)			
Annex II.A.5.4.2	Article 3(5)(i)(ii)			
Annex II.A.6				
Annex II.A.6.1	Article 3(5)(g)(iii)			
Annex II.A.6.2	Article 3(5)(c)(v)			
Annex II.A.7.1	Article 3(5)(j)			Annex I.6
Annex II.A.7.2	Article 3(5)(k)			
Annex II.A.8.1	Article 3(5)(l)(m)			
Annex II.A.8.2	Article 3(5)(n) Article 3(5)(o)(p)			
Annex II.A.9.1 to 9.4				

This Directive	88/379/EEC	90/35/EEC	91/442/EEC	93/18/EEC
Annex II.B Introduction				Annex I Introduction
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Annex II.B.1.1				Annex I.1.1
Annex II.B.1.2				Annex I.1.2
Annex II.B.2				Annex I.2
Annex II.B.2.1				Annex I.2.1
Annex II.B.2.2				Annex I.2.2
Annex II.B.3				Annex I.3
Annex II.B.3.1				Annex I.3.1
Annex II.B.3.2				Annex I.3.2
Annex II.B.4				Annex I.4
Annex II.B.4.1				Annex I.4.1
Annex II.B.4.2				Annex I.4.2
Annex II.B.5				Annex I.5
Annex II.B.5.1				Annex I.5.1
Annex II.B.5.2				Annex I.5.2
Annex II.B.6				Annex I.6
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Annex III.C				
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Annex IV.A.2			Article 2; Annex (a)	
Annex IV.A.3			Article 1; Annex (b)	
Annex V.A.1				Annex II.A.1
Annex V.A.2				Annex II.A.2
Annex V.A.3				Annex II.A.3
Annex V.A.4				Annex II.A.4
Annex V.B.1				Annex II.B.1

This Directive	88/379/EEC	90/35/EEC	91/442/EEC	93/18/EEC
Annex V.B.2				Annex II.B.2
Annex V.B.3				Annex II.B.3
Annex V.B.4				Annex II.B.4
Annex V.B.5				Annex II.B.5
Annex V.B.6				Annex II.B.6
Annex V.B.7	Article 3.2(3)(b)			
Annex V.B.8	Article 3.5(4)			
Annex V.C				
Annex VI				
Annex VII				
Annex VIII				
Annex IX				

STATEMENT OF THE COUNCIL'S REASONS

I. INTRODUCTION

1. On 18 July 1996 the Commission sent the Council a proposal, based on Article 100a of the EC Treaty, on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations.

2. The European Parliament delivered its first reading opinion on 26 June 1997. Further to that opinion, the Commission submitted an amended proposal on 23 September 1997.

   The Economic and Social Committee delivered its opinion on 20 March 1997.

3. On 24 September 1998, the Council adopted by unanimity its common position in accordance with Article 189b of the Treaty.

II. OBJECTIVE

4. The Commission proposal recasts Directive 88/379/EEC to provide a more consistent approach across the sectors; to rationalise and update existing Community legislation; to simplify the processes for adaptation to technical progress; and to address the issues concerning the Accession Member States. In doing so the draft proposal:

   — extends the scope of the current Directive to encompass plant protection products (i.e. pesticides) which are currently subject to separate legislation which would be repealed by this proposal,

   — extends the scope to include provisions for environmental classification and labelling,

   — extends certain requirements to preparations containing levels of dangerous substances below that where normal hazard classification would be triggered.

III. ANALYSIS OF THE COMMON POSITION

5. The proposal has been examined in the Council since 1996. Compared to the Commission's amended proposal the text has been changed in various points.

   Many of the amendments suggested by the European Parliament have been incorporated in the common position. As regards other amendments the Council has either accepted these amendments in principle or has taken them into consideration in its common position.

6. As regards Amendment 1 (accepted by the Commission) concerning a Commission report and, if appropriate, necessary Commission proposals, related to labelling requirements on dangerous preparations (recital 17), the Council welcomes this amendment and has incorporated it in a reworded form in the common position. The Council notes that the Commission is, by accepting this recital, committing itself to launch, as soon as possible, a study on the comprehensibility of labels to the users.

7. Furthermore, the Council has accepted Amendment 2 (Article 1(1)) concerning a clarification of the objectives and scope (this amendment is also accepted by the Commission). Along the same lines the Council has also accepted Amendment 3

(Article 1(3)) specifying that the scope covers non-dangerous preparations which may present a specific hazard (this amendment is accepted by the Commission). However, Amendments 2 and 3 have been integrated into the text in a slightly reworded form.

8. Concerning Amendment 5 (Article 4(2)) the Council has in a reworded form accepted this clarification of the general principles of classification and labelling (the Commission has accepted this amendment).

9. The Council accepts in principle Amendment 6 (Article 6(2)) introducing relevant restrictions on animal testing in cases where alternative methods are available. The amendment also clarifies that tests in question shall be conducted in compliance with the principles of good laboratory practice and protection of animal welfare (the Commission has accepted the amendment in a reworded form).

10. The Council accepts Amendment 7 (Article 9(2)) which lays down the practice already existing between transport and supply packages (Amendment 7 is accepted by the Commission). This amendment has been slightly reworded by the Council.

11. The Council has accepted the principles expressed in Amendment 14 (this amendment is accepted by the Commission) related to labelling requirements applicable to preprations classified as dangerous for the environment, when they are supplied in small packages (Article 10(4)). However the Council has further clarified the European Parliament amendment; to ensure that where the warning symbol is not required the appropriate R-phrase is given instead.

12. Finally, as regards labelling requirements, the Council has incorporated with minor editorial modifications Amendment 15 (accepted by the Commission) prohibiting the use of information on the label such as 'ecological' which might lead to an underestimation of the hazards. In addition the Council has clarified the text by making a reference to provisions on plant protection products, which will continue to allow 'positive' environmental labelling like 'not dangerous to bees' (Article 10(5)).

13. In relation to safety data sheets (Article 14), this provision has been modified to make clear that safety data sheets are principally intended for professional users. For non-classified preparations, the Council has considered that information provided on safety data sheets for such products should be proportionate to risks. It has also accepted Amendment 40 of the European Parliament, extending provisions concerning non-dangerous preparations to cover preparations which contain substances dangerous to the environment (which was not accepted by the Commission). The Council has also thought it appropriate to require safety data sheets for plant protection products.

14. As regards the Annexes, the following amendments have been accepted by the Council:

— Amendment 18 introducing to Annex III, Part B, Table V, a lower concentration limit (0,1 % instead of 0,5 %) for classification of preparations containing ozone-depleting substances (the amendment is also accepted by the Commission),

— Amendment 19 (which was also accepted by the Commission), introducing an editorial improvement of the introduction of Annex III (methods for the evaluation of the environmental hazards of preparations in accordance with Article 7),

— Amendment 21 concerning Annex IV, Part B (accepted by the Commission) which removes the requirement for a tactile danger warning (a special warning for blind persons) on aerosols classified as extremely flammable and highly flammable (this amendment is introduced at the request of the European Blind Association).

15. The Council accepts Amendment 27 suggesting that the reference to Directive 96/65/EC should be added to the list of Directives that need to be repealed (this amendment was accepted by the Commission).

16. The following amendments were not accepted by the Council:

— Amendment 4 (Article 3(3)); the Council does not find it appropriate introducing changes to the application of the conventional methods, and it fears that this amendment eventually will lead to unnecessary animal testing because the conventional method would be unworkable (the European Parliament amendment is not accepted by the Commission),

— Amendments 8, 9, 11 and 12 (Article 10); the Council feels that these amendments would not improve the level of protection of the user (the Commission has not accepted those amendments),

— Amendment 16 (Article 13); it is the Council's opinion that this provision should only apply to the specific situation of offering a product for sale on the market through the so-called 'distance selling'. The Article has been reworded to bring it in line with the provisions of Directive 97/7/EC on distance contracts (the Commission has not accepted this amendment),

— Amendment 17 (Article 20) concerning the type of committee procedure applicable when adaptation to technical progress is taking place within the Commission. However, the European Parliament suggests a type IIIa — committee procedure [1]. The Council thinks some parts of the adaptation to technical progress would involve highly sensitive political questions, and on this basis it considers that a type IIIb — committee is more appropriate (Amendment 17 has been accepted by the Commission who wants a IIIa — committee).

17. As regards the annexes, the following amendments were not accepted:

— as regards Amendment 13 (Article 10(2) point 3.5) concerning the labelling of chemical names primarily responsible for health hazards, the Council has not accepted this amendment (this amendment is not accepted by the Commission).

— Amendment 20 (Annex III, Part C) provides that the existing test results should be applicable for the assessment of effects dangerous for the environment. Since this is already the case, the Council considers this amendment superfluous (the Commission has not accepted this amendment),

— Amendment 22 (Annex V, Part B) concerns the specific warning on the label on sensitising effects to persons. The Council has modified this warning which now states that the allergic effect due to low concentrations of sensitisers may be expected in persons already sensitised (the Commission has accepted this amendment),

— Amendment 24 (Annex V, Part C) dealing with the availability of safety data sheets (SDS). The Council does not find it appropriate to specify the type of preparations for which the obligation to provide a SDS is applied. Furthermore, the Council wants to specify that SDS is available for professional users on request (the Commission accepted this amendment in a slightly modified form),

— Amendment 25 (Annex V, Part D) related to labelling provisions on plant protection products (PPP). The Council has not accepted this amendment because labelling requirements on PPP's have been further elaborated in the legal text itself (Article 10(1)(2)). Article 10(1)(2) states that the label of a PPP must bear an

[1] OJ L 197, 18.7.1987, p. 33.

inscription specifying that risk to man and the environment can be avoided when the user complies with the instructions for use. The label will also have normal hazard information and the symbols indicating danger (the Commission accepted this amendment),

— Amendment 26 (Annex V, Part D) concerning labelling provisions on biocides. The Council does not find it appropriate to include a specific provision on biocides in the present Directive because such specific provisions are laid down in Directive 98/8/EC on biocides (the Commission has not accepted this amendment).

18. In addition, the Council has introduced new provisions on:

— Articles 6 and 7 concerning evaluation of health hazards and evaluation of environmental hazards; this provision would make it possible to introduce into Annexes II and III other conventional methods. This might be necessary for alloys,

— Article 15 concerning confidentiality of chemical names; this provision now covers both labelling and safety data sheets, and the Council has introduced a less bureaucratic notification procedure,

— Article 21 concerning Accession Treaty arrangements; this provision allows Sweden, Finland and Austria not to transpose the existing (old) Community *acquis* in the beginning of 1999.

IV. CONCLUSION

19. The Council considered that, in view of the above objective, it has endeavoured to retain and strengthen the provisions which guarantee a high level of health and environmental protection.

In trying to achieve this the Council has included many of the European Parliament amendments and has taken into consideration other amendments.