SUBSIDIARY LEGISLATION 427.28

DANGEROUS SUBSTANCES AND PREPARATIONS REGULATIONS

16th January, 2007

LEGAL NOTICE 10 of 2007, as amended by Legal Notices 221 and 309 of 2007, and 267 of 2009.

Citation.

1. The title of these regulations is the Dangerous Substances and Preparations Regulations.

General provision.

2. Preparations that fail to comply with the provisions of these regulations shall not be placed on the market by manufacturers or importers.

Scope.

3. These regulations implement the provisions of Commission Directive 1999/45/EC of the 31st May, 1991 as amended by Commission Directive 2001/60/EC of the 7th August, 2001.

Applicability.

4.1. These regulations shall apply to:

- the classification, packaging and labelling of dangerous preparations, and to
- those preparations which may present hazards, whether or not they are classified as dangerous within the meaning of those regulations, when such preparations are placed on the market.

4.2. These regulation shall apply to preparations which:

- contain at least one dangerous substance within the meaning of regulation 5, and
- are considered dangerous within the meaning of regulations 8, 9 or 10.

4.3. The specific provisions set out -

- in regulation 11 and defined in the Fourth Schedule,
- in regulation 12 and defined in the Fifth Schedule, and
- in regulation 16

shall also apply to preparations which are not considered dangerous within the meaning of regulations 8, 9 or 10 but may nevertheless present a specific hazard.

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4.4.1 Without prejudice to other provisions implementing the requirements of the Plant Protection Products Regulations, the regulations on classification, packaging, labelling and safety datasheets of these Regulations shall apply to plant protection products.

S.L. 430.03

4.4.2 Without prejudice to other provisions implementing the requirements of the Biocides Regulations, the regulations on classification, packaging, labelling and safety datasheets of these regulations shall apply to biocide products.

4.5. These regulations shall not apply to the following preparations in the finished state, intended for the final user:

(*a*) medicinal products for human or veterinary use, as defined in the Act;

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(*b*) cosmetic products as defined in the Cosmetic Products Regulations;

(*c*) mixtures of substances which, in the form of waste, are covered by provisions implementing the requirements of the Waste Management (Permit and Control) Regulations;

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(*d*) foodstuffs;

(*e*) animal feedingstuffs;

(*f*) preparations containing radioactive substances as defined by the Nuclear Safety and Radiation Protection Regulations;

S.L. 365.15

(*g*) medical devices which are invasive or used in direct physical contact with the human body in so far as other 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 these regulations.

4.6. These regulations 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.

Definitions.

5.1. In these regulations, the following definitions shall apply, unless the context otherwise requires:

(*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;

(*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 number of monomer units. In the

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

(*d*) "placing on the market" means making available to third parties. Importation into customs territory shall be deemed to be placing on the market for the purposes of these regulations;

(*e*) "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;

(*f*) "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;

(*g*) "Einecs" means the European Inventory of Existing Commercial Chemical Substances. This inventory contain the definitive list of all chemical substances deemed to on the market within the European Community on 18 September 1981.

5.2. The following are "dangerous" within the meaning of these regulations:

(*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 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 or 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 to enter the environment, would or could present an immediate or delayed danger for one or more components of the environment.

5.3. "Directive 67/548/EEC" shall mean Directive 67/548/EEC of the European Community or equivalent provisions.

Determination of dangerous properties of preparations. *Amended by: L.N. 267 of 2009.*

6.1. 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 regulations 8, 9 and 10. Where laboratory tests are conducted, they shall be carried out on the preparation as placed on the market.

6.2. Where the determination of dangerous properties is carried out in accordance with regulations 8, 9 and 10, all dangerous substances within the meaning of regulation 5.2. and in particular those which -

- are listed in Part 3 of Annex VI to Regulation (EC) No. 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures,
- are listed in ELINCS in accordance with the Dangerous Substances (Notification) Regulations, S.L. 427.14
- are classified and labelled provisionally by the person responsible for the placing on the market in accordance with the Dangerous Substances (Notification) Regulations, S.L. 427.14
- are classified and labelled in accordance with the Dangerous Substances (Notification) Regulations, and are not yet included in ELINCS, S.L. 427.14
- are covered by the Dangerous Substances (Notification) Regulations, S.L. 427.14
- are classified and labelled in accordance with the Dangerous Substances (Notification) Regulations, S.L. 427.14

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

6.3. For preparations covered by these regulations, dangerous substances as referred to in regulation 5.2. 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 concentration are equal to, or greater than, those defined in the following table unless lower values are given in Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures, or in Part B of the Second Schedule or in Part B of the Third Schedule, unless otherwise specified in the Fifth Schedule.

Category of danger of the substance	Concentration to take into consideration for	
	Gaseous preparations	Other preparations
	% vol/vol	% w/w
Very toxic	≥ 0.02	≥ 0.1
Toxic	≥ 0.02	≥ 0.1
Carcinogenic Category 1 or 2	≥ 0.02	≥ 0.1
Mutagenic 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

General principles of classification and labelling.

7.1. 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 regulation 5.2.

7.2. The general principles of the classification 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 regulations 8, 9, 10 or 13 and the relevant Schedules of these regulations are applied.

Evaluation of the hazards deriving from physico-chemical properties.

8.1. The hazards of a preparation deriving from its physico-chemical properties shall 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.

8.2. By way of derogation from regulation 8.1:

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,
- preparation placed on the market in the form of aerosols satisfy the provisions of the Aerosol Dispensers Regulations. S.L. 427.26

8.3. 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 the First Schedule.

8.4. 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 the First Schedule.

8.5. The hazards deriving from the physico-chemical properties of a preparation covered by the Plant Protection Products Regulations, or equivalent provisions shall be assessed by determining the physcio-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 the Second and Third Schedules to the Plant Protection Products Regulations. S.L. 430.01

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

(*a*) by a conventional method described in the Second Schedule;

(*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 the First and Second Schedules to the Plant Protection Products Regulations. S.L. 430.01

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9.2. Without prejudice to the requirements of the Plant Protection Products Regulations, or equivalent provisions, 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 regulation 9.1.(*a*), or on the basis of existing test results on animals, the methods outlined in regulation 9.1.(*b*) may be used, provided they are justified or specifically authorised under the Animal Welfare Act.

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9.2.1. When a toxicological property is established by the methods outlined in regulation 7.1.(*b*) to obtain new data, the test shall be conducted in compliance with the principles of good laboratory practice provided for in the Good Laboratory Practice Regulations, and the provisions in the Animal Welfare Act.

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9.2.2. Subject to the provisions of regulation 9.3., where a toxicological property has been established on the basis of both the methods outlined in regulations 9.1.(*a*) and (*b*), the results from the methods outlined in regulation 9.1.(*b*) shall be used for classifying the preparation, except in the case of carcinogenic, mutagenic or toxic effects for reproduction for which only the method outlined in 9.1.(*a*) shall be used.

9.2.3. Any of the toxicological properties of the preparation which are not assessed by the method outlined in regulation 9.1.(*b*) shall be assessed in accordance with the method outlined in regulation 9.1.(*a*).

9.3. 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 methods outlined in regulation 9.1., 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.

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9.4. For preparations of a known composition, with the exception of those covered by the Plant Protection Products Regulations, or equivalent provisions, classified in accordance with regulation 9.1.(*b*), a new evaluation of health hazard by the methods outlined in either regulation 9.1.(*a*) or (*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 following table:

Initial concentration range of the constituent	Permitted variation in initial concentration of the constituent
$\leq$ 2.5%	± 30 %
> 2.5 $\leq$ 10%	± 20%
> 10 $\leq$ 25%	± 10%
> 25 $\leq$ 100%	± 5%

- changes of composition involving the substitution or addition of one or more constituents, which may or may not be dangerous within the definitions set out in regulation 5.2, 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.

Evaluation of environmental hazards.

10.1. 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 the Third Schedule;

(*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 provisions of the Second and Third Schedule of the Plant Protection Products Regulations. Without prejudice to the testing requirements set out in the Plant Protection Products Regulations, the conditions for application of the test methods are described in Part C of the Third Schedule.

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10.2. When an ecotoxicological property is established by one of the methods outlined in regulation 10.1.(*b*) to obtain new data, the test shall be conducted in compliance with the principles of good laboratory practice provided for in the Good Laboratory Practice Regulations and the provisions in the Animal Welfare Act. Where the environmental hazards have been assessed in compliance with both the procedures mentioned above, the results of the methods referred to in regulation 10.1.(*b*) shall be used for classifying the preparation.

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10.3. For preparations of a known composition, with the exception of those covered by the Plant Protection Products Regulations or equivalent provisions, classified in accordance with method outlined in regulation 10.1.(*b*), a new evaluation of environmental hazard either by the method outlined in regulation 8.1.(*a*) or that outlined in regulation 8.1.(*b*) shall be performed

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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 following table:

Initial concentration range of the constituent	Permitted variation in initial concentration of the constituent
$\leq$ 2.5%	± 30 %
> 2.5 $\leq$ 10%	± 20%
> 10 $\leq$ 25%	± 10%
> 25 $\leq$ 100%	± 5%

- changes of composition involving the substitution or addition of one or more constituents, which may or may not be dangerous within the definitions set out in regulation 5.2, 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.

Prohibition of marketing.

11.1. Preparations covered by these regulations cannot be placed on the market unless they comply with it.

11.2. In order to ensure compliance with these regulations, the Director 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.

11.3. The Director shall take all necessary measures to ensure that those responsible for placing the preparation on the market hold at his disposal:

- the data used for the classification and labelling of the preparation,
- any pertinent information relating to packaging requirements in accordance with regulation 12.1.3, 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 regulation 15.

Packaging.

12.1. Preparations within the meaning of regulation 4.2. and preparations covered by the Fourth Schedule pursuant to regulation 4.3. 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 devices are prescribed,
- the materials constituting the packaging and fastening 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 fastened repeatedly without the contents escaping.

12.2. Containers which contain preparations within the meaning of regulation 4.2. and preparations covered by the Fourth Schedule pursuant to regulation 4.3. offered or sold to the general public must 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.

12.3. Containers which contain certain preparations offered or sold to the general public covered by the Fourth Schedule must:

- be 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.

12.4. The packaging of preparations shall be deemed to satisfy the requirements of regulations 12.1. to 12.3. if it complies with the requirements for carriage of dangerous goods by rail, road, inland, waterway, sea or air.

Labelling. *Amended by: L.N. 267 of 2009.*

13.1. Preparations within the meaning of regulation 4.2. cannot be placed on the market unless the labelling on their packaging satisfies all the requirements of regulation 13.2. and the specific provisions of Part A and B of the Fifth Schedule.

Preparations within the meaning of regulation 4.3. as defined in Parts B and C of the Fifth Schedule cannot be placed on the market unless the labelling on their packaging satisfies the requirements of regulations 13.2.1. and 13.2.2. and the specific provisions of Parts B and C of the Fifth Schedule.

13.1.1. With respect to plant protection products subject to the Plant Protection Products Regulations, or equivalent provisions, the labelling requirements in accordance with these regulations shall be accompanied by the following wording: S.L. 430.01

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

This labelling shall be without prejudice to the information required by the Plant Protection Products Regulations. S.L. 430.01

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

13.2.1. the trade name or designation of the preparation;

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

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

- for preparations classified as T+, T, Xn in accordance with regulation 9, only the substances T+, T, Xn present in concentrations equal to, or greater than, the lowest limit (limit Xn) for each of them laid down in Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures or, failing that, Part B of the Second Schedule have to be taken into consideration;
- for preparations classified C in accordance with regulation 9, only C substances present in concentrations equal to, or greater than, the lowest limit (limit Xi) laid down in Annex I to Directive 67/548/EEC or failing that, Part B of the Second Schedule have to be taken into consideration;
- the name of the substances which have given rise to the classification of the preparation in one or more of the following hazard 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.

- As a consequence of the above provisions the name of any substance which led to the classification of the preparation in the following hazard 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 the first, second or third indents of regulation 13.2.3.

- 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.

13.2.4. The danger symbol(s), where specified in these regulations, and indication(s) of hazards 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 the First, Second and Third Schedules.

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

- T shall make the symbols C and Xn optional unless otherwise specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures,
- C shall make the symbol Xi optional,
- E shall make the symbol F and O optional,
- Xn shall make the symbol Xi optional.

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

13.2.5. 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 results of the hazard evaluation carried out in accordance with the First, Second and Third Schedules.

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 paragraph 13.2.4.

13.2.6. The indications giving safety advice (S phrases) shall comply with the wording in the Fourth Schedule 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 the First, Second and Third Schedules.

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.

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

13.3. For certain preparations classified as dangerous within the meaning of regulation 10, by way of derogation from regulations 13.2.4., 13.2.5., and 13.2.6., exemptions to certain provisions on the environmental labelling or specific provisions in relation to the environmental labelling may be determined in accordance with the procedure referred to in Article 20 of Directive 1999/45/EC, 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 the Fifth Schedule.

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

- 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.

13.5. Without prejudice to regulation 43(3) of the Plant Protection Products Regulations, 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 under-estimation of the dangers of the preparation in question shall not appear on the packaging or labelling of any preparation subject to these regulations.

Implementation of the labelling requirements.

14.1. Where the particulars required by regulation 13 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.

14.2. A label shall not be required when the particulars are clearly shown on the package itself, as specified in regulation 14.1.

14.3. The colour and presentation of the label - or, in the case of regulation 14.2, of the package - shall be such that the danger symbol and its background stand out clearly from it.

14.4. The information required on the label under regulation 13 shall stand out clearly from its background and shall be of such size and spacing as to be easily read.

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

14.5. Preparations covered by these regulations must be labelled in at least one of the official languages of Malta.

14.6. For the purposes of these regulations, labelling requirements shall be deemed to be satisfied:

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

(*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 regulations 13.2.1, 13.2.2, 13.2.3, 13.2.5 and 13.2.6; for preparations classified according to regulation 10, the provisions of regulation 13.2.4 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.

Exemptions from the labelling and packaging requirements.

15.1. Regulations 12, 13 and 14 shall not apply to explosives placed on the market with a view to obtaining an explosive or pyrotechnic effect.

15.2. For certain dangerous preparations within the meaning of regulations 8, 9 or 10 defined in the Seventh Schedule 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, regulations 12, 13 and 14 shall not apply.

15.3. The Director may also, on the advice of the Malta Standards Authority:

(*a*) permit the labelling required by regulation 13 to be applied in some other appropriate manner on packages which are either too small or otherwise unsuitable for labelling in accordance with regulation 14.1 and 14.2;

(*b*) by way of derogation from regulations 13 and 14 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 regulations 13 and 14, for preparations classified according to regulation 10, 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 regulations 13 and 14 permit the packaging of dangerous preparations which are not mentioned in paragraphs (*b*) or (*c*) to be labelled in some other appropriate way, if the packages are too small for the labelling provided for in paragraphs 13 and 14 and there is no reason to fear any danger to persons handling such preparations or to other persons.

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

Distance selling.

16.1. Any advertisement for a preparation within the meaning of these regulations 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 the provisions of the Consumer Affairs Act on the protection of consumers in respect of distance contracts.

Cap. 378.

Safety data sheet.

17. (*Deleted by: L.N. 221 of 2007*)

Confidentiality of chemical names.

18.1. 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 the fourth indent of regulation 13.2.3, or
- harmful or harmful in combination with one or more of the properties mentioned in the fourth indent of regulation 13.2.3 presenting acute lethal effects alone,

will put at risk the confidential nature of his intellectual property, he may, in accordance with the provisions of the Sixth Schedule 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 an exposure limit by the European Community.

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 Director.

This request must be made in accordance with the provisions of the Sixth Schedule and must provide the information required in the form in Part A of that Schedule. The Director 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 Director, when receiving a request for confidentiality shall notify the applicant of his decision.

The Director shall recognise a decision pursuant to a request for confidentiality taken by the competent authority of a Member State of the European Community, provided that a copy of such decision has been duly forwarded to him by the person responsible for placing the preparation on the Maltese market.

Confidential information brought to the attention of the Director shall be treated in accordance with the provisions of the Dangerous Substances (Notification) Regulations. S.L. 427.14

19.1. These regulations shall apply without prejudice to other requirements deemed 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 these regulations. Safety of workers.

20.1. Where the Director has detailed evidence that a preparation, although satisfying the provisions of these regulations, constitutes a hazard for man or the environment on grounds relating to the provisions of these regulations, he may, on the advice of the Directorate responsible for chemicals within the Malta Standards Authority, provisionally prohibit the placing on the market of that preparation or subject it to special conditions. Safeguard clause.

FIRST SCHEDULE

Methods for the evaluation of physico-chemical properties of preparations in accordance with regulation 8

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 Dircctivc 67/548/EEC.

PART B

Alternative calculation methods

B.1. Non-gaseous preparations

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

   See point 2.2.2.1 of Annex VI to Dircctive 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.

Amended by: L.N. 267 of 2009.

SECOND SCHEDULE

Methods for the evaluation of health hazards of preparations in accordance with regulation 9

Introduction

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

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

The health effects of a preparation are to be assessed in accordance with paragraph 7.1(*a*) by the conventional method described in Parts A and B of this Schedule using indvidual concentration limits.

(*a*) where the dangerous substances listed in Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the

Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures are assigned concentration limits necessary for the application of the method of assessment described in Part A of this Schedule, these concentration limits must be used;

(*b*) where the dangerous substances do not appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures or appear there without the concentration limits necessary for the application of the method of evaluation described in Part A of this Schedule, the concentration limits must be assigned in accordance with the specifications in Part B of this Schedule.

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

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

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

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 Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures, the concentration limits to be taken into account for the application of this conventional method are those set out in Part B of this Schedule.

PART A

Procedure for evaluation of health hazards

The evaluation proceeds stepwise as follows:

1. 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 Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures for the substance or substances under consideration, or

(*b*) the concentration specified at point 1 in Part B of this Schedule (Table I and I A) where the substance or substances do not appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures 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:

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

where:

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

L_{T+} is the very toxic limit specified for each very toxic substance, expressed as a percentage by height 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 Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures for the substance or substances under consideration, or

(*b*) the concentration specified at point 2 in Part B of this Schcdule (Table II and II A) where the substance or substances do not appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures or appear in it without concentration 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 Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures for the substance or substances under consideration, or

(*b*) the concentration specified at point 1 in Part B of this Schedule (Table I and I A) where the substance or substances do not appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures or appear in it without concentration limits;

2.1.2. preparations containing more than one substance classified as very toxic or toxic in lower individual concentrations than the limits specified under 2.1.1(*a*) or

(*b*) if:

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

where:

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

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

L_T is 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 Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures for the substance or substances under consideration, or

(*b*) the concentration specified at point 2 in Part B of this Schedule (Table II and II A) where the substance or substances do not appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures 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 Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures for the substance or substances under consideration, or

(*b*) the concentration specified at point 3 in Part B of this Schedule (Table III and III A) where the substance or substances do not appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures 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 Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures for the substance or substances under consideration, or

(*b*) the concentration specified at point 1 in Part B of this Schedule (Table I and I A) where the substance or substances do not appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures or appear in it without concentration limits.

3.1.2. preparations containing more than one substance classified as very toxic, toxic or harmful in lower individual concentrations than the limits specified under 3.1.1(*a*) or (*b*) if:

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

where:

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

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

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

L_{Xn} is 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 paragraph 3.2.3 of Annex VI to Directive 67/548/EEC. In applying the conventional method according to the above paragraph 3.1 no account shall be taken of the classification of a substance as R65;

3.3. 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 R65/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 Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures for the substance or substances under consideration, or

(*b*) the concentration specified at point 2 in Part B of this Schedule (Table II and II A) where the substance or substances do not appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling

and packaging of substances and mixtures 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 Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures for the substance or substances under consideration, or

(*b*) the concentration specified at point 3 in Part B of this Schedule (Table III and III A) where the substance or substances do not appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures 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 classfied as corrosive to which is assigned the phrase R35 in individual concentrations equal to or greater than:

(*a*) either the concentration specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures for the substance or substances under consideration, or

(*b*) the concentration specified at point 4 in Part B of this Schedule (Table IV and IV A) where the substance or substances do not appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures or appear in it without concentration limits.

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

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

where:

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

$L_{C,R35}$ is 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 Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures for the substance or substances under consideration, or

(*b*) the concentration specified at point 4 in Part B of this Schedule (Table IV and IV A) where the substance or substances do not appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures or appear in it without concentration limits;

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

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

where:

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

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

$L_{C,R34}$ is 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 Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures for the substance or substances under consideration, or

(*b*) the concentration specified at point 4 in Part B of this Schedule (Table IV and IV A) where the substance or substances do not appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures 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 classificd as corrosive and to which is assigned phrase R35 or R34, in lower individual concentrations than the limits

specified under 5.1.1(*a*) or (*b*) if:

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

where:

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

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

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

$L_{Xi,R41}$ is 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 Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures for the substance or substances under consideration, or

(*b*) the concentration specified at point 4 in Part B of this Schedule (Table IV and IV A) where the substance or substances do not appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures or appear in it without concentration limits;

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

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

where:

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

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

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

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

$L_{Xi,R36}$ is 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 Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures for the substance or substances under consideration, or

(*b*) the concentration specified at point 4 in Part B of this Schedule (Table IV and IV A) where the substance or substances do not appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures or appear in it without concentration limits;

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

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

where:

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

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

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

$L_{Xi,R38}$ is 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 Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures for the substance or substances under consideration, or

(*b*) the concentration specified at point 4 in Part B of this Schedule (Table IV and IV A) where the substance or the substances do not appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the

classification, labelling and packaging of substances and mixtures or appear in it without concentration limits;

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

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

where:

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

$L_{Xi,R37}$ is the 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 5.4.1(*a*) or (*b*) if:

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

where

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

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

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

$L_{Xi,R37}$ is 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 Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures for the substance or substances under consideration, or

(*b*) the concentration specified at point 5 in Part B of this Schedule (Table V and V A) where the substance or substances do not appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures 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 Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures for the substance or substances under consideration, or

(*b*) the concentration specified at point 5 in Part B of this Schedule (Table V and V A) where the substance or substances do not appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures or appear in it without concentration limits.

7. The following preparattions 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 category 1 and category 2, in individual concentrations equal to or greater than:

(*a*) either the concentration specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures for the substance or substances under consideration, or

(*b*) the concentration specified at point 6 in Part B of this Schedule (Table VI and VI A) where the substance or substances do not appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures 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 Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures for the substance or substances under consideration, or

(*b*) the concentration specified at point 6 in Part B of this Schedule (Table VI and VI A) where the substance or substances do not appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the

classification, labelling and packaging of substances and mixtures 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 category 1 and category 2, in individual concentrations equal to or greater than:

(*a*) either the concentration specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures for the substance or substances under consideration, or

(*b*) the concentration specified at point 6 in Part B of this Schedule (Table VI and VI A) where the substance or substances do not appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures or appear in it without concentration limits;

8.2. those of category 3 which are assigned the symbol "X_n" and the phrase R68.

preparations containing at least one substance, producing such effects, classified as mutagenic and to which is assigned phrase R68 which denotes mutagenic substances in category, 3, in individual concentrations equal to or greater than:

(*a*) either the concentration specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures for the substance or substances under consideration, or

(*b*) the concentration specified at point 6 in Part B of this Schedule (Table VI and VI A) where the substance or substances do not appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures 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 category 1 and category 2, in individual concentrations equal to or greater than:

(*a*) either the concentration specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures for the substance or substances under consideration, or

(*b*) the concentration specified at point 6 in Part B of this Schedule (Table VI and VI A) where the substance or substances do not appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures 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 Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures for the substance or substances under consideration, or

(*b*) the concentration specified at point 6 in Part B of this Schedule (Table VI and VI A) where the substance or substances do not appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures 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 contaning at least one substance producing such effects, classified as toxic for reproduction and to which is assigned phrase R61 which denotes substances toxic for reproduction of category 1 and category 2, in individual concentrations equal to or greater than:

(*a*) either the concentration specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures for the substance or substances under consideration, or

(*b*) the concentration specified at point 6 in Part B of this Schedule (Table VI arnd VI A) where the substance or substances do not appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures 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 Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of

substances and mixtures for the substance or substances under consideration, or

(*b*) the concentration specified at point 6 in Part B of this Schedule (Table VI and VI A) where the substance or substances do not appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures or appear in it without concentration limits.

PART B

Concentration limits to be used in evaluation of health hazards

For each health effect, the first table (Tables I to VI) sets out the concentration limits (expressed as a weight/weight percentage) to be used for non-gaseous preparations and the second table (Tables I A to VI A) sets out the concentration limits (expressed as a volume/volume percentage) to be used for gaseous preparations. These concentrauon limits are used in the absence of specific concentration limits for the substance under consideration in Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures.

1. Acute lethal effects

1.1. Non-gaseous preparations

The concentration limits fixed in Table 1, expressed as a weight/weight percentage, determine the classification of the preparation in relation to the individual concentration of the substancc(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 $\geq$ 7%	1% $\leq$ concentration < 7%	1% $\leq$ concentration < 1%
T with R23, R24, R25		concentration $\geq$ 25%	3% $\leq$ concentration $\leq$ 25%
X_n with R20, R21, R22			concentration $\geq$ 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 I A below determine the classification of the gaseous preparations in relation to the individual concentration of the gas(es) present whose classification is also shown.

Table I A

Classification of the substance (gas)	Classification of the gaseous preparation		
	T^+	T	X_n
T^+ with R26, R27, R28	concentration $\geq$ 1%	0.2% $\leq$ concentration < 1%	0.02% $\leq$ concentration < 0.2%
T with R23, R24, R25		concentration $\geq$ 5%	0.5% $\leq$ concentration $\leq$ 5%
X_n with R20, R21, R22			concentration $\geq$ 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, R68/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 $\geq$ 10% R39(*) obligatory	1% $\leq$ concentration < 10% R39(*) obligatory	0.1% $\leq$ concentration < 1% R68(*) obligatory
T with R39/route of exposure		concentration $\geq$ 10% R39(*) obligatory	1% $\leq$ concentration $\leq$ 10% R68(*) obligatory
X_n with R68/route of exposure			concentration $\geq$ 10% R68(*) 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, R68/route of exposure), the individual concentration limits specified in Table II A, expressed as a volume/volume percentage, determine, when appropriate, the classification of the preparation.

Table II A

Classification of the substance (gas)	Classification of the gaseous preparation		
	T^+	T	X_n
T^+ with R39/route of exposure	concentration $\geq$ 1% R39(*) obligatory	0.2% $\leq$ concentration < 1% R39(*) obligatory	0.02% $\leq$ concentration < 0.2% R68(*) obligatory

T with R39/route of exposure		concentration ≥ 5% R39(*) obligatory	0.5% ≤ concentration ≤ 5% R68(*) obligatory
X_n with R68/route of exposure			concentration ≥ 5% R68(*) obligatory
(*) 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 (R 48/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 III A below, expressed as a volume/volume percentage, determine, when appropriate, the classification of the preparation.

Table III A

Classification of the substance	Classification of the preparation	
	T	X_n
T with R48/route of exposure	concentration ≥ 5% R48(*) obligatory	0.5% ≤ concentration < 5% R48(*) obligatory
X_n with R48/route of exposure		concentration ≥ 5% R48(*) obligatory
(*) 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 R 34	X_i with R41	X_i with R36, R37, R38
C with R35	concentration $\geq$ 10% R35 obligatory	5% $\leq$ concentration < 10% R34 obligatory	5% (*)	1% $\leq$ concentration < 5% R36/38 obligatory
C with R 34		concentration $\geq$ 10% R34 obligatory	10% (*)	5% $\leq$ concentration < 10% R36/38 obligatory
X_i with R41			concentration $\geq$ 10% R41 obligatory	5% $\leq$ concentration < 10% R36 obligatory
X_i with R36, R37, R38				concentration $\geq$ 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.

Note: Simple application of the conventional method to preparations containing substances classified as corrosive or irritant may result in under-classification or over-classification of the hazard, if other relevant factors (e.g. pH of the preparation) are not taken into account. Therefore, in classifying for corrosivity, consider the advice given in paragraph 3.2.5 of Annex VI to Directive 67/548/EEC and in the second and third indents of regulation 7.3 of these regulations.

4.2. Gaseous preparations

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

Table IV A

Classification of the substance (gas)	Classification of the gaseous preparation			
	C with R35	C with R 34	X_i with R41	X_i with R36, R37, R38
C with R35	concentration $\geq$ 1% R35 obligatory	0.2% $\leq$ concentration < 1% R34 obligatory	0.2% (*)	0.02% $\leq$ concentration < 0.2% R36/38 obligatory
C with R 34		concentration $\geq$ 5% R34 obligatory	5% (*)	0.5% $\leq$ concentration < 5% R36/38 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.

Note: Simple application of the conventional method to preparations containing substances classified as corrosive or irritant may result in under-classification or over-classification of the hazard, if other relevant factors (e.g. pH of the preparation) are not taken into account. Therefore, in classifying for corrosivity, consider the advice given in paragraph 3.2.5 of Annex VI to Directive 67/548/EEC and in the second and third indents of regulation 7.3 of these regulations.

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 phrse R43 if this effect can be produced through contact with the skin.

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

Table V A

Classification of the substance (gas)	Classification of the 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 Tatble 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
Catrcinogenic category 3:	X_n; R40
Mutagcnic categories 1 and 2:	T; R46
Mutagenic category 3:	X_n; R68
Toxic for reproduction fertility categories 1 and 2:	T; R60
Toxic for reproduction development categories 1 and 2:	T; R61
Toxic for reproduction fertility category 3:	X_n; R62
Toxic for reproduction development category 3:	X_n; R63

Table VI

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 (unless already assigned R45(*))
mutagenic substances of category 1 or 2 with R46	concentration ≥ 0.1% mutagenic R46 obligatory	
mutagenic substances of category 3 with R68		concentration ≥ 1% mutagenic R68 obligatory (unless already assigned R46)
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 (unless already assigned R60)

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 (unless already assigned R61)
(*) In cases where the preparation is assigned R49 and R40, both R phrases shall be kept, because R40 does not distinguish between the exposure routes, whereas R49 is only assigned for the inhalation route.		

6.2. Gaseous preparations

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

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

Table VI A

Classification of the substance	Classification of the preparation	
	Categories 1 and 2	Category 3
carcinogenic substances of category 1 or 2 with R45 or R49	concentration ≥ 0.1% carcinogenic R45, R49 obligatory as appropriate	
carcinogenic substances of category 3 with R40		concentration ≥ 1% carcinogenic R40 obligatory (unless already assigned R45(*))
mutagenic substances of category 1 or 2 with R46	concentration ≥ 0.1% mutagenic R46 obligatory	
mutagenic substances of category 3 with R68		concentration ≥ 1% mutagenic R68 obligatory (unless already assigned R46)
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 (unless already assigned R60)

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 (unless already assigned R61)
(*) In cases where the preparation is assigned R49 and R40, both R phrases shall be kept, because R40 does not distinguish between the exposure routes, whereas R49 is only assigned for the inhalation route.		

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THIRD SCHEDULE

Methods for the evaluation of the environmental hazards of preparations in accordance with regulation 10

Introduction

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

Part A gives the calculation procedure according to regulation 10.1(*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 regulation 10.1(*a*) the environmental hazards of a preparation shall be assessed by the conventional method described in Parts A and B of this Schedule, using individual concentration limits.

(*a*) Where the dangerous substances listed in Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures are assigned concentration limits necessary for the application of the method of assessment described in Part A of this Schedule, these concentration limits must be used.

(*b*) Where the dangerous substances do not appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures or appear there without the concentration limits necessary for the application of the method of evaluation described in Part A of this Schedule, the concentration limits shall be assigned in accordance with the specification in Part B of this Schedule.

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

PART A

Procedure for the evaluation of environmental hazards

(*a*) Aquatic environment

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

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

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 Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures for the substance or substances under consideration, or

(*b*) the concentration specified in Part B of this Schedule (Table 1) where the substance or substances do not appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures or appear in it without concentration limits;

1.2. preparations containing more than one substance classified as dangerous for the environment and to which is assigned phrases R50-53 in lower individual concentrations than the limits specified under 1.1.1(*a*) or (*b*) if:

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

where:

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

$L_{N,R50\text{-}53}$ is 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 1.1 above;

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 Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of

substances and mixtures for the substance or substances under consideration, or

(*b*) the concentration specified in Part B of this Schedule (Table 1) where the substance or substances do not appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures 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 1.2.(*a*) or (*b*) if:

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

where:

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

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

$L_{N,R51\text{-}53}$ is 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 1.1 or 1.2 above;

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

(*a*) either the concentration specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures for the substance or substances under consideration, or

(*b*) the concentration specified in Part B of this Schedule (Table 1) where the substance or substances do not appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures or appear in it without concentration limits;

3.2. preparations containing more than one of the substances classified as dangerous for the environment and to which is assigned phrases R51-53 or R50-53 or R52-53 in lower individual concentrations than the limits specified under 1.3.1(*a*) or (*b*) if:

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

where:

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

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

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

L_{R52-53} is 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 1.1 above:

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

(*a*) either the concentration specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures for the substance or substances under consideration, or

(*b*) the concentration specified in Part B of this Schedule (Table 2) where the substance or substances do not appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures 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 1.4.1(*a*) or (*b*) if:

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

where:

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

$L_{N,R50}$ is the limit R50 for each substance dangerous for the environment to which is assigned phrase 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 1.4.1 or 1.4.2 and containing one or more than one substance classified as dangerous for the environment and to which is assigned phrases R50-53 if:

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

where:

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

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

$L_{N,R50}$ is the perspective 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 1.1, 1.2, 1.3, or 1.4 above:

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 Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures for the substance or substances under consideration, or

(*b*) the concentration specified in Part B of this Schedule (Table 3) where the substance or substances do not appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures 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 1.5.1(*a*) or (*b*) if:

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

where:

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

L_{R52} is the limit 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 1.1, 1.2 or 1.3 above:

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

(*a*) either the concentration specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures for the substance or substances under consideration, or

(*b*) the concentration specified in Part B of this Schedule (Table 4) where the substance or substances do not appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures 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 1.6.1(*a*) or (*b*) if:

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

where:

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

L_{R53} is the limit 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 1.6.2 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:

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

where:

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

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

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

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

L_{R53} is 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

1. 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 Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures for the substance or substances under consideration, or

(*b*) the concentration specified in Part B of this Schedule (Table 5) where

the substance or substances do not appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures or appear in it without concentration limits;

(2) TERRESTRIAL ENVIRONMENT

1. Evaluation of preparations dangerous for the terrestrial environment

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

PART B

Concentration limits to be used for the evaluation of environmental hazards

1. 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 1a

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	See Table 1b	See Table 1b	See Table 1b
N,R51-53		$C_n \geq 25\%$	$2.5\% \leq C_n < 25\%$
R52-53			$C_n \geq 25\%$

Preparations containing a substance classified with N,R50-53, the concentration limits and the resulting classification given in Table 1b are applicable

Table 1b

Acute aquatic toxicity and long-term adverse effects

LC_{50} or EC_{50} value ("$L(E)C_{50}$") of substance classified as N,R50-53 (mg/l)	Classification of the preparation		
	N,R50-53	N,R51-53	R52-53
$0.1 < L(E)C_{50} \leq 1$	$C_n \geq 25\%$	$2.5\% \leq C_n < 25\%$	$0.25\% \leq C_n < 2.5\%$
$0.01 < L(E)C_{50} \leq 0.1$	$C_n \geq 2.5\%$	$0.25\% \leq C_n < 2.5\%$	$0.025\% \leq C_n < 0.25\%$
$0.001 < L(E)C_{50} \leq 0.01$	$C_n \geq 0.25\%$	$0.025\% \leq C_n < 0.25\%$	$0.0025\% \leq C_n < 0.025\%$
$0.0001 < L(E)C_{50} \leq 0.001$	$C_n \geq 0.025\%$	$0.0025\% \leq C_n < 0.025\%$	$0.00025\% \leq C_n < 0.0025\%$
$0.00001 < L(E)C_{50} \leq 0.0001$	$C_n \geq 0.0025\%$	$0.00025\% \leq C_n < 0.0025\%$	$0.000025\% \leq C_n < 0.00025\%$
For preparations containing subdstances with a lower LC_{50} or EC_{50} value than 0.00001 mg/l, the corresponding concentration limits are calculated accordingly (in factor 10 intervals).			

Table 2

Acute aquatic toxicity

LC_{50} or EC_{50} value ("$L(E)C_{50}$") of substance classified as N,R50-53 (mg/l)	Classification of the preparation
	N,R50-53
$0.1 < L(E)C_{50} \leq 1$	$C_n \geq 25\%$
$0.01 < L(E)C_{50} \leq 0.1$	$C_n \geq 2.5\%$
$0.001 < L(E)C_{50} \leq 0.01$	$C_n \geq 0.25\%$
$0.0001 < L(E)C_{50} \leq 0.001$	$C_n \geq 0.025\%$
$0.00001 < L(E)C_{50} \leq 0.0001$	$C_n \geq 0.0025\%$
For preparations containing subdstances with a lower LC_{50} or EC_{50} value than 0.00001 mg/l, the corresponding concentration limits are calculated accordingly (in factor 10 intervals).	

Table 3

Aquatic toxicity

Classification of the substance	Classification of the preparation R52 R52
R52	$C_n \geq 25\%$

Table 4

Long-term adverse effects

Classification of the substance	Classification of the preparation R53 R53
R53	$C_n \geq 25\%$
N,R50-53	$C_n \geq 25\%$
N,R51-53	$C_n \geq 25\%$
R52-53	$C_n \geq 25\%$

II For the non-aquatic environment

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

Table 5

Dangerous for the ozone layer

Classification of the substance	Classification of the preparation N, R59
N with R59	$C \geq 0.1\%$

PART C

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

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

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

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

Dircctive 67/548/EEC have been complied with.

Furthermore, the tests are to be carried out on all 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 or a test result was already available before Directive 1999/45/EC entered into force.

FOURTH SCHEDULE

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 regulation 11 and under the conditions laid down in regulation 7, are to 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 paragraph 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 in a concentration equal to or greater than the maximum individual concentration specified.

No	Identification of the substance			Concentration limit
	CAS Re No	Name	Einecs No	
1	67-56-1	Methanol	2006596	$\geq$ 3%
2	75-09-2	Dichloromethane	2008389	$\geq$ 1%

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

PART B

Containers to be fitted with a tactile warning of danger

Containers of whatever capacity, containing preparations offered or sold to the general public and labelled as very toxic, toxic, corrosive, harmful, extremely flammable or highly flammable in accordance with regulation 11 and under the conditions laid down in regulations 6 and 7, 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.

FIFTH SCHEDULE

Amended by:
L.N. 267 of 2009.

Special provisions concerning the labelling of certain preparations

A. For preparations classified as dangerous within the meaning of regulations 8, 9 and 10

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 cumulutive effects

When a preparation contains at least one substance assigned the phrase R33, the label on the packaging 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 Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures.

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 on the packaging 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 Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures.

B. For preparations irrespective of their classification within the meaning of regulations 8, 9 and 10

1. Preparations containing lead

1.1. Paint and varnishes

The label on the packaging 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 label on 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 label on the packaging 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 $\leq$ 700

The label on the packaging of preparations containing epoxy constituents with an average molecular weight $\leq$ 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 label on 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 label on 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 these regulations, preparations available as aerosols are also subject to the labelling provisions in accordance with

points 2.2 and 2.3 of the Annex to Directive 75/324/EEC as last amended by Directive 94/1/EC.

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 "Caution - substance not yet tested completely", the label of the preparation must bear the inscription "Caution - this preparation contains a substance not yet tested completely" if this substance is present in a concentration $\geq$ 1%.

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

The label on 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 Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures must bear the inscription:

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

10. Liquid preparations containing halogenated hydrocarbons

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

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

11. Preparatious containing a substance assigned phrase R67: vapours may cause drowsiness and dizziness

When a preparation contains one or more substances assigned the phrase R67, the label of the preparation must carry the wording of this phrase as set out in Annex III to Directive 67/548/EEC, when the total concentration of these substances present in the preparation is equal to or higher than 15%, unless:

- the preparation is already classified with phrases R20, R23, R26, R68/20, R39/23 or R39/26,
- or the preparation is in a package not exceeding 125 ml.

12. Cements and cement preparations

The label on the packaging of cements and cement preparations containing more than 0,0002% soluble chromium (VI) of the total dry weight of the cement must bear the inscription:

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

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

C. For preparations not classified within the meaning of regulations 8, 9 and 10 but containing at least one dangerous substance

1. Preparations not intended for the general public

The label on the packaging of the preparations referred to in regulation 17.3 must bear the following inscription:

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

Amended by:
L.N. 309 of 2007;
L.N. 267 of 2009.

SIXTH SCHEDULE

Confidentiality for the chemical identity of a substance

PART A

Information to be communicated in the request for confidentiality

Introductory notes

A. Regulation 18 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 under heading 2 "Composition/information on ingredients" of the Annex to Directive 91/155/EEC as last amended by Directive 93/112/EEC.

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 regulation 18 the request for confidentiality must obligatorily contain the following information:

1. Name and full address (including telephone number) of the person established in Malta or within the European 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 (Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures or provisional classification)	Alternative designation
(a)			
(b)			
(c)			
N.B: 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.			

3. Justification for confidentiality (probabiliy - plausibility).

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

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

YES ☐ NO ☐

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

Belgium:

Bulgaria:

Czech Republic

Denmark:

Germany:

Estonia

Greece:

Spain:

France:

Ireland:

Italy:

Cyprus:

Latvia:

Lithuania:

Luxembourg:

Hungary:

Malta:

Netherlands:

Austria:

Poland:

Portugal:

Romania:

Slovenia:

Slovakia:

Finland:

Sweden:

United Kingdom:

6. Composition of the preparation(s) defined in point 2 of the Annex to Directive 91/155/EEC as last amended by Directive 93/112/EEC.

7. Classification of the preparation(s) according to regulation 7.

8. Labelling of the preparation(s) according to regulation 11.

9. Intended uses for the preparation(s).

10. Safety data sheet(s) conforming to Directive 91/155/EEC as last amended by Directive 93/112/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 Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures.

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 Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures 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 Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures (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 abd 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 No Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures	Families & Sub-families
001	Hydrogen compounds Hydrides
002	Helium compounds
003	Lithium compounds
004	Beryllium compounds
005	Boron compounds - Boranes - Borates
006	Carbon compounds - Carbantates - 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
011	Sodium compounds
012	Magnesium compounds

Family No Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures	Families & Sub-families
	- 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
028	Nickel compounds
029	Copper compounds
030	Zinc compounds
	- Organometallic zinc derivatives

Family No Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures	Families & Sub-families
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
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	Gadolinium compounds
065	Terbium compounds

Family No Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures	Families & Sub-families
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
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	Astatine 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

Family No Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures	Families & Sub-families
100	Fermium compounds
101	Mendelevium compounds
102	Nobelium compounds
103	Lawrencium compounds
601	Hydrocarbons - Aliphatic hydrocarbons - Aromatic hydrocarbons - Alicyclic hydrocarbons - Polycyclic aromatic hydrocarbons (PAH)
602	Halogenated hydrocarbons (*) - Halogenated aliphatic hydrocarbons (*) - Halogenated aromatic hydrocarbons (*) - Halogenated alicyclic hydrocarbons (*)
	(*) Specify according to the family corresponding to halogen.
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 (*)
	(*) Specify according to the family corresponding to halogen.
605	Aldehydes and derivatives - Aliphatic aldehydes - Aromatic aldehydes - Alicyclic aldehydes
	- Aliphatic acetals - Aromatic acetals - Alicyclic acetals
606	Ketones and derivatives - Aliphatic ketones - Aromatic ketones (*)

Family No Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures	Families & Sub-families
	- Alicyclic ketones
	(*) Quinones included
607	Organic acids and derivatives
	- Aliphatic acids
	- Halogenated aliphatic acids (*)
	- Aromatic acids
	- Halogenated aromatic acids (*)
	- Alicyclic acids
	- Halogenated alicyclic acids (*)
	- Aliphatic acid anhydrides
	- Halogenated aliphatic acid anhydrides (*)
	- Aromatic acid anhydrides
	- Halogenated aromatic acid anhydrides (*)
	- Alicyclic acid anhydrides
	- Halogenated alicyclic acid anhydrides (*)
	- Salts of aliphatic acid
	- Salts of halogenated aliphatic acid (*)
	- Salts of aromatic acid
	- Salts of halogenated aromatic acid (*)
	- Salts of alicyclic acid
	- Salts of halogenated alicyclic acid (*)
	- Esters of aliphatic acid
	- Esters of halogenated aliphatic acid (*)
	- Esters of aromatic acid
	- Esters of halogenated aromatic acid (*)
	- Esters of alicyclic acid (*)
	- Esters of halogenated alicyclic acid (*)
	- Esters of glycol ether
	- Acrylates
	- Methacrylates
	- Lactones
	- Acyl halogenides
	(*) Specify according to the family corresponding to halogen.
608	Nitriles and derivatives
609	Nitro compounds
610	Chlornitrated compounds

Family No Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures	Families & Sub-families
611	Azoxy and azo compounds
612	Amine compounds - Aliphatic amines and derivatives - Alicyclic amines and derivatives
	- Aromatic amines and derivatives - Aniline and its derivatives - Benzidine and its derivatives
613	Heterocyclic bases and derivatives - Benzimidazole and derivatives - Imidazol and derivatives - Pyretbrinoids - 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
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

Family No Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures	Families & Sub-families
	- 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 - Naphtha (coal), solvent extraction, hydrocracked

Family No Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures	Families & Sub-families
	- 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 kerosene - Kerosene - unspecified - Cracked gas oil - Gas oil - unspecified - Heavy fuel oil - Grease - Unrefined or mildly refined base oil - Base oil - unspecified

Family No Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures	Families & Sub-families - Distillate aromatic extract - Distillate aromatic extract (treated) - Foots oil - Slack wax
	- Petrolatum
650	Various substances - Do not use this family. Instead, use the families or subfamilies 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 dihydroxybenzene
  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: glycotethers
  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 Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures in respect of which requests for confidentiality may be submitted).

SEVENTH SCHEDULE

Preparations covered by regulation 15.2

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