# COMMISSION DIRECTIVE 93/112/EC

## of 10 December 1993

## amending Commission Directive 91/155/EEC defining and laying down detailed arrangements for the system of specific information relating to dangerous preparations in implementation of Article 10 of Council Directive 88/379/EEC

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 88/379/EEC of 7 June 1988 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (1), as last amended by Commission Directive 93/18/EEC (2) and in particular Article 10 (2) thereof,

Whereas Article 10 (2) of Directive 88/379/EEC provides that the Commission shall make detailed arrangements for the implementation of a system of information in the form of safety data sheets relating to dangerous preparations; whereas, therefore, Commission Directive 91/155/EEC (3) laid down such detailed arrangements;

Whereas Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions of dangerous substances (4), as last amended by Commission Directive 92/21/EEC (5) and in particular Article 27 thereof, provides that the Commission shall make general rules for the elaboration distribution, contents and format of safety data sheets in relation to dangerous substances;

Whereas it is appropriate that the arrangements in relation to safety data sheets be the same for substances and for preparations; whereas this approach was foreseen by Directive 91/155/EEC; whereas, therefore, it is necessary to amend Directive 91/155/EEC in this sense;

Whereas it is necessary to make certain changes to the Annex in order to ensure protection of the environment;

Whereas given the amendments made to Directive 91/155/EEC Article 4 thereof should accordingly be repealed;

Whereas the provisions of this Directive are in accordance with the opinion of the Committee for the adaptation to technical progress of the directives on the removal of technical barriers to trade in dangerous substances and preparations,

HAS ADOPTED THIS DIRECTIVE:

*Article 1*

Directive 91/155/EEC is hereby amended as follows:

1. Article 4 is repealed.
2. The Annex is replaced by the Annex to this Directive.

*Article 2*

1. Member States shall adopt and publish the provisions necessary to comply with this Directive by 1 January 1995 at the latest and shall forthwith inform the Commission thereof.

2. These provisions shall take effect from 1 January 1995.

However, information systems of the safety data sheet type in use in some Member States may continue to be used until 1 July 1995.

3. When Member States adopt these provisions, these shall contain a reference to this Directive or shall be accompanied by such a reference at the time of their official publication. The procedure for such reference shall be adopted by the Member States.

*Article 3*

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

Done at Brussels, 10 December 1993.

*For the Commission*

Yannis PALEOKRASSAS

*Member of the Commission*

(1) OJ No L 187, 16. 7. 1988, p. 14.
(2) OJ No L 104, 29. 4. 1993, p. 46.
(3) OJ No L 76, 22. 3. 1991, p. 35.
(4) OJ No 196, 16. 8. 1967, p. 1.
(5) OJ No L 110, 4. 5. 1993, p. 20.

*ANNEX*

## GUIDE TO THE COMPILATION OF SAFETY DATA SHEETS

The following explanatory notes are intended as a guide. Their purpose is to ensure that the content of each of the mandatory headings listed in Article 3 will enable professional users to take the necessary measures relating to protection of health and safety at the workplace, and to protect the environment.

The information must be written in a clear and concise manner.

Additional information may prove necessary in some cases in view of the wide range of properties of the substances and preparations. If in other cases it emerges that information from certain properties is of no significance or that it is technically impossible to provide the reasons for this must be clearly stated.

Although the order of headings is not obligatory, the sequence given in Article 3 is recommended.

When a safety data sheet has been revised, the changes should be brought to the attention of the recipient.

### 1. Identification of the substance/preparation and of the company/undertaking

1.1. *Identification of the substance or preparation:*

The term used for identification must be identical to that provided on the label as set out in Annex VI to Directive 67/548/EEC.

Other means of identification available may also be indicated.

1.2. *Company/undertaking identification:*

— identification of the person established within the Community responsible for placing the substance or preparation on the market whether it be the manufacturer, importer or distributor,

— full address and telephone number of this person.

1.3. In addition to the abovementioned information, supply the emergency telephone number of the company and/or official advisory body in accordance with Article 12 of Directive 88/379/EEC.

### 2. Composition/information on ingredients

The information given should enable the recipient to identify readily the risks attached to the substance or preparation.

In the case of a preparation:

(a) it is not necessary to give the full composition (nature of the ingredients and their concentration);

(b) however, the following substances shall be indicated, together with their concentration or concentration range, if they are present in concentrations equal to or greater than those laid down in Article 3 (6) (a) of Directive 88/379/EEC (unless a lower limit is considered more appropriate):

— substances presenting a health hazard within the meaning of Directive 67/548/EEC,

and

— at least substances subject to recognized exposure limit values pursuant to Community provisions but which are not covered by the above Directive;

(c) the classification (either from Article 6 of or Annex I to Directive 67/548/EEC) of the above substances shall be given in the form of the symbols and R phrases which are assigned in accordance with their health hazards;

(d) if, in accordance with the provisions of Article 7 (1) of Directive 88/379/EEC, the identity of certain substances is to be kept confidential, their chemical nature shall be described in order to ensure safe handling. The name must be the same as that which derives from the above procedure.

3. **Hazards identification**

Indicate clearly and briefly the most important hazards the substance or preparation presents, in particular the critical hazards to man and the environment.

Describe the most important adverse human health effects and symptoms relating to the uses and possible misuses of the substance or preparation that can be reasonably foreseen.

The information should be compatible with that shown on the product label but need not repeat it.

4. **First-aid measures**

Describe the first-aid measures ; however, it is important to specify whether immediate medical attention is required.

The information on first aid must be brief and easy to understand by the victim, bystanders and first aiders. The symptoms and effects should be briefly summarized. The instructions should indicate what is to be done on the spot in the case of an accident and whether delayed effects can be expected after exposure.

Subdivide the information according to the different routes of exposure, i. e. inhalation, skin and eye contact and ingestion, under different subheadings.

Indicate whether professional assistance by a doctor is needed or advisable.

For some substances or preparations it may be important to emphasize that special means to provide specific and immediate treatment must be available at the workplace.

5. **Fire-fighting measures**

Refer to requirements for fighting a fire caused by the substance or preparation, or arising in its vicinity by indicating :

— suitable extinguishing media,

— extinguishing media which must not be used for safety reasons,

— special exposure hazards arising from the substance or preparation itself, combustion products, resulting gases,

— special protective equipment for fire-fighters.

6. **Accidental release measures**

Depending on the substance or preparation involved, information may be needed on :

— *personal precautions such as :*

removal of ignition sources, provision for sufficient ventilation/respiratory protection, control of dust, prevention of skin and eye contact,

— *environmental precautions such as :*

keeping away from drains, surface- and ground-water and soil, possible need to alert the neighbourhood,

— *methods for cleaning up such as :*

use of absorbant material (e. g. sand, diatonic soil, acid binder, universal binder, sawdust . . .) reduction of gases/fumes with water, dilution.

Also consider the need for indications such as : 'never use, neutralize with, . . .'.

*NB :* If appropriate refer to points 8 and 13.

7. **Handling and storage**

7.1. *Handling*

Consider precautions for safe handling including advice on technical measures such as : local and general ventilation, measures to prevent aerosol and dust generation and fire, and any specific requirement or rules relating to the substance or preparation (e. g. procedures or equipment which are prohibited or recommended) and if possible give a brief description.

7.2. *Storage*

Consider the conditions for safe storage such as : specific design for storage rooms or vessels (including retention walls and ventilation), incompatible materials, conditions of storage (temperature and humidity limit/range, light, inert gas . . .), special electrical equipment and prevention of static electricity.

Give advice if relevant on quantity limits under storage conditions. In particular indicate any special requirements such as the type of material used in the packaging/containers of the substance or preparation.

8. **Exposure controls/personal protection**

For the purposes of this document exposure control means the full range of precautionary measures to be taken during use in order to minimize worker exposure.

Engineering measures should be taken before personal protection equipment is necessary. Therefore give information on the system design, e. g. enclosure. This information should complement that already given to point 7.1.

Indicate, with their reference, any specific control parameters such as limit values or biological standards. Give information on the recommended monitoring procedures and indicate the reference.

Where personal protection is needed, specify the type of equipment to provide adequate and suitable protection :

— *respiratory protection :*

in the case of dangerous gases, vapours or dust, consider the need for appropriate protectice equipment, such as self-contained breathing apparatus, adequate masks and filters,

— *hand protection :*

specify the type of gloves to be worn when handling the substance or preparation. If necessary indicate any additional skin and hand protection measures,

— *eye protection :*

specify the tpye of eye protection equipment required such as : safety glasses, safety goggles, face shield,

— *skin protection :*

If it is necessary to protect a part or the body other than the hands, specify the type and quality of protection equipment required, such as : apron, boots and full protective suit. If necessary, indicate specific hygiene measures.

Reference shall be made where appropriate to the relevant CEN standards.

9. **Physical and chemical properties**

This section includes the following information, where applicable, on the substances or preparation.

| | |
|---|---|
| *Appearance :* | indicate the physical state (solid, liquid, gas) and the colour of the substance of preparation as supplied. |
| *Odour :* | if odour is perceptible, give a brief description of it. |
| *pH :* | indicate the pH of the substance or preparation as supplied or of an aqueous solution ; in the latter case, indicate the concentration. |
| *Boiling point/boiling range :*<br>*Melting point/melting range :*<br>*Flash point :*<br>*Flammability (solid, gas) :*<br>*Autoflammability :*<br>*Explosive properties :*<br>*Oxidizing properties :*<br>*Vapour pressure :*<br>*Relative density :*<br>*Solubility :* — *water solubility*<br>— *fat solubility (solvent-oil to be specified) :* | Within the meaning of Directive 67/548/EEC |
| *Partition coefficient : n-octanol/water :* | |
| *Other data :* | indicate important safety parameters, such as vapour density, miscibility, evaporation rate, conductivity, viscosity, etc. |

The above properties should be determined in accordance with the specifications of Part A of Annex V to Directive 67/548/EEC or any other comparable method.

10. **Stability and reactivity**

State the stability of the substance or preparation and the possibility of hazardous reactions occurring under certain conditions.

*Conditions to avoid:*

List those conditions such as temperature, pressure, light, shock, etc., which may cause a dangerous reaction and if possible give a brief description.

*Materials to avoid:*

List materials such as water, air, acids, bases, oxidizing agents or any other specific substance which may cause a dangerous reaction and if possible give a brief description.

*Hazardous decomposition products:*

List hazardous materials produced in dangerous amounts upon decomposition.

*N.B.* Address specifically:

- the need for and the presence of stabilizers,
- the possibility of a hazardous exothermic reaction,
- safety significance, if any, of a change in physical appearance of the substance or preparation,
- hazardous decomposition products, if any, formed upon contact with water,
- possibility of degradation to unstable products.

11. **Toxicological information**

This section deals with the need for a concise but complete and comprehensible description of the various toxicological (health) effects which can arise if the user comes into contact with the substance or preparation.

Include dangerous-to-health effects from exposure to the substance or preparation, based on both experiences and conclusions from scientific experiments. Include information on the different routes of exposure (inhalation, ingestion, skin and eye contact), and describe the symptoms related to the physical, chemical and toxicological characteristics.

Include known delayed and immediate effects and also chronic effects from short- and long-term exposure: for example sensitization, carcinogenicity, mutagenicity and reproductive toxicity including teratogenicity and narcosis.

Taking account of the information already provided under point 2, 'Composition/information on ingredients', it may be necessary to make reference to specific health effects of certain components in preparations.

12. **Ecological information**

Identify effects, behaviour and environmental fate owing to the nature of the substance or preparation and its reasonably foreseeable uses. Information of the same kind shall be supplied for dangerous products arising from the degradation of substances and preparations.

Examples of relevant ecological information are listed below:

| | |
|---|---|
| mobility: | — known or predicted distribution to environmental compartments,<br>— surface tension,<br>— absorption/desorption,<br>— other physical-chemical properties, see section 9; |
| degradability: | — biotic and abiotic degradation,<br>— aerobic and anaerobic degradation,<br>— persistence; |
| accumulation: | — bioaccumulation potential,<br>— biomagnification; |
| Short and long term effects on: | |
| ecotoxicity: | — aquatic organisms,<br>— soil organisms,<br>— plants and terrestrial animals; |
| other adverse effects: | — ozone depletion potential,<br>— photochemical ozone creation potential,<br>— global warming potential,<br>— effects on waste water treatment plants; |

*Remarks*

Ensure that information relevant to the environment is provided in other sections of the safety data sheet, especially advice for controlled release, accidental release measures and disposal considerations in points 6, 7, 13 and 15.

Pending criteria for evaluation of the environmental impact of a preparation, information relating to the factors above shall be given for substances classified as dangerous for the environment which are present in the preparation.

13. **Disposal considerations**

If the disposal of the substance or preparation (surplus or waste resulting from the foreseeable use) presents a danger, a description of these residues and information on their safe handling shall be given.

Indicate the appropriate methods of disposal of both the substance or preparation and any contaminated packaging (incineration, recycling, landfilling, etc.).

*Comment*

Refer to any Community provisions relating to waste. In their absence, it is useful to remind the user that national or regional provisions may be in force.

14. **Transport information**

Indicate any special precautions which a user needs to be aware of or needs to comply with in connection with transport or conveyance either within or outside his premises.

Additional information provided for by the United Nations recommendation and other international agreements on the transport and packaging of dangerous goods may also be given.

15. **Regulatory information**

Give the information on the label according to the Directives relating to the classification, packaging and labelling of dangerous substances and preparations.

If the substance or preparation covered by this safety data sheet is the subject of specific provisions in relation to protection of man or the environment at Community level (e.g. restrictions on marketing and use, limit values for exposure at the place of work) these provisions should, as far as possible, be stated. The attention of recipients should also be drawn to the existence of national laws that implement these provisions.

It is also recommended that the data sheet should remind recipients to refer to any other national measures that may be relevant.

16. **Other information**

Indicate any other information which might be of importance for safety and health and for the protection of the environment, for example :

— training advice,

— recommended uses and restrictions,

— further information (written reference and/or technical contact point),

— sources of key data used to compile the data sheet.

Also give the date of issue of the data sheet, if not stated elsewhere.