

ANNEX II

GUIDE TO THE COMPILATION OF SAFETY DATA SHEETS

This Annex sets out the requirements for a Safety Data Sheet that is provided for a substance or a preparation in accordance with Article 31. The Safety Data Sheet provides a mechanism for transmitting appropriate safety information on classified substances and preparations, including information from the relevant Chemical Safety Report(s) down the supply chain to the immediate downstream user(s). The information provided in the Safety Data Sheet shall be consistent with the information in the Chemical Safety Report, where one is required. Where a Chemical Safety Report has been performed, the relevant exposure scenario(s) shall be placed into an annex of the Safety Data Sheet, to make reference to them under the relevant headings of the Safety Data Sheet easier.

The purpose of this Annex is to ensure consistency and accuracy in the content of each of the mandatory headings listed in Article 31, so that the resulting Safety Data Sheets will enable users to take the necessary measures relating to protection of human health and safety at the workplace, and protection of the environment.

The information provided by Safety Data Sheets shall also meet the requirements set out in Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work. In particular, the Safety Data Sheet shall enable the employer to determine whether any hazardous chemical agents are present in the workplace, and to assess any risk to the health and safety of workers arising from their use.

The information in the Safety Data Sheet shall be written in a clear and concise manner. The Safety Data Sheet shall be prepared by a competent person who shall take into account the specific needs of the user audience, as far as it is known. Persons placing substances and preparations on the market shall ensure that competent persons have received appropriate training, including refresher training.

For preparations not classified as dangerous, but for which a Safety Data Sheet is required according to Article 31, proportionate information shall be provided under each heading.

Additional information may be 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 on certain properties is of no significance or that it is technically impossible to provide, the reasons for this shall be clearly stated under each heading. Information shall be provided for each hazardous property. If it is stated that a particular hazard does not apply, clearly differentiate between cases where no information is available to the classifier, and cases where negative test results are available.

Give the date of issue of the Safety Data Sheet on the first page. When a safety data sheet has been revised, the changes shall be brought to the attention of the recipient and identify it as "Revision: (date)".

Note

Safety data sheets are also required for certain special substances and preparations (e.g. metals in massive form, alloys, compressed gases, etc.) listed in chapters 8 and 9 of Annex VI to Directive 67/548/EEC, for which there are labelling derogations.

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

1.1. Identification of the substance or preparation

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

For substances subject to registration, the term shall be consistent with that provided under registration and the registration number assigned under Article 20(1) of this Regulation shall also be indicated.

Other means of identification available may also be indicated.

1.2. Use of the substance/preparation

Indicate the uses of the substance or preparation as far as they are known. Where there are many possible uses, only the most important or common uses need to be listed. This shall include a brief description of what it actually does, e.g. flame retardant, anti-oxidant, etc.

Where a Chemical Safety Report is required, the Safety Data Sheet shall contain information on all the identified uses relevant to the recipient of the Safety Data Sheet.

This information shall be consistent with the identified uses and exposure scenarios set out in the annex to the Safety Data Sheet.

1.3. Company/undertaking identification

Identify the person responsible for placing the substance or preparation on the market within the Community, whether it is the manufacturer, importer or distributor. Give the full address and telephone number of this person as well as the e-mail address of the competent person responsible for the Safety Data Sheet.

In addition, where this person is not located in the Member State where the substance or preparation is placed on the market, give a full address and telephone number for the person responsible in that Member State, if possible.

For registrants, the person identified shall be consistent with the information on the identity of the manufacturer or importer provided in the registration.

1.4. Emergency telephone

In addition to the above mentioned information, supply the emergency telephone number of the company and/or relevant official advisory body (this may be the body responsible for receiving information relating to health, which is referred to in Article 17 of Directive 1999/45/EC). Specify if this phone number is available only during office hours.

2. HAZARDS IDENTIFICATION

Give here the classification of the substance or preparation which arises from application of the classification rules in Directives 67/548/EEC or 1999/45/EC. Indicate clearly and briefly the hazards the substance or preparation presents to man and the environment.

Distinguish clearly between preparations which are classified as dangerous and preparations which are not classified as dangerous according to Directive 1999/45/EC.

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

It may be necessary to mention other hazards, such as dustiness, cross-sensitisation, suffocation, freezing, high potency for odour or taste or environmental effects such as hazards to soil-dwelling organisms, ozone depletion, photochemical ozone creation potential, etc., which do not result in classification but which may contribute to the overall hazards of the material.

The information shown on the label shall be given under heading 15.

The classification of the substance shall be consistent with the classification provided to the classification and labelling inventory according to Title XI.

3. COMPOSITION/INFORMATION ON INGREDIENTS

The information given shall enable the recipient to identify readily the hazards of the components of the preparation. The hazards of the preparation itself shall be given under heading 2.

- 3.1. It is not necessary to give the full composition (nature of the ingredients and their concentration), although a general description of the components and their concentrations can be helpful.
- 3.2. For a preparation classified as dangerous according to Directive 1999/45/EC, the following substances shall be indicated, together with their concentration or concentration range in the preparation:
- (a) substances presenting a health or environmental hazard within the meaning of Directive 67/548/EEC, if they are present in concentrations equal to or greater than the lowest of:
- the applicable concentrations defined in the table of Article 3(3) of Directive 1999/45/EC, or
 - the concentration limits given in Annex I to Directive 67/548/EEC, or
 - the concentration limits given in Part B of Annex II to Directive 1999/45/EC, or

- the concentration limits given in Part B of Annex III Directive 1999/45/EC, or
 - the concentration limits given in Annex V to Directive 1999/45/EC, or
 - the concentration limits given in an agreed entry in the classification and labelling inventory established under Title XI of this Regulation;
- (b) substances for which there are Community workplace exposure limits, which are not already included under point (a);
- (c) substances that are persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII, if the concentration of an individual substance is equal to or greater than 0,1 %.

3.3. For a preparation not classified as dangerous according to Directive 1999/45/EC, the substances shall be indicated, together with their concentration or concentration range, if they are present in an individual concentration of either:

- (a) ≥ 1 % by weight for non-gaseous preparations and $\geq 0,2$ % by volume for gaseous preparations and
- the substances present a health or environmental hazard within the meaning of Directive 67/548/EEC¹; or
 - the substances are assigned Community workplace exposure limits;

or

¹ Where the person responsible for placing the preparation on the market can demonstrate that the disclosure in the 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 properties mentioned in point 2.3.4 of Article 10 of Directive 1999/45/EC, or harmful or harmful in combination with one or more of the properties mentioned in point 2.3.4 of Article 10 of Directive 1999/45/EC presenting acute lethal effects alone, will put at risk the confidential nature of his intellectual property, he may, in accordance with the provisions of Part B of Annex VI to Directive 1999/45/EC, 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.

(b) $\geq 0,1$ % by weight and the substances are persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII.

- 3.4. The classification (derived either from Articles 4 and 6 of Directive 67/548/EEC, from Annex I to Directive 67/548/EEC or from an agreed entry in the classification and labelling inventory established under Title XI of this Regulation) of the above substances shall be given, including the symbol letters and R phrases which are assigned in accordance with their physicochemical, human health and environmental hazards. The R phrases do not need to be written out in full here: reference shall be made to heading 16, where the full text of each relevant R phrase shall be listed. If the substance does not meet the classification criteria, the reason for indicating the substance in section 3 shall be described, such as "PBT-substance" or "substance with a Community workplace exposure limit".
- 3.5. The name and the Registration number, assigned under Article 20(1) of this Regulation, EINECS or ELINCS number, if available, of the above substances shall be given in accordance with Directive 67/548/EEC. The CAS number and IUPAC name (if available) may also be helpful. For substances listed by a generic name, according to Article 15 of Directive 1999/45/EC or the footnote to Section 3.3 of this Annex, a precise chemical identifier is not necessary.
- 3.6. If, in accordance with the provisions of Article 15 of Directive 1999/45/EC or the footnote to Section 3.3 of this Annex, the identity of certain substances is to be kept confidential, their chemical nature shall be described in order to ensure safe handling. The name used shall be the same as that which derives from the above procedures.

4. FIRST AID MEASURES

Describe the first-aid measures.

Specify first whether immediate medical attention is required.

The information on first aid shall be brief and easy to understand by the victim, bystanders and first-aiders. The symptoms and effects shall be briefly summarised. The instructions shall 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 emphasise that special means to provide specific and immediate treatment shall 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 shall 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 absorbent material (e.g. sand, diatomaceous earth, acid binder, universal binder, sawdust, etc.), reduction of gases/fumes with water, dilution.

Also consider the need for indications such as: "never use, neutralise with ...".

Note

If appropriate refer to headings 8 and 13.

7. HANDLING AND STORAGE

Note

Information in this section shall relate to the protection of human health, safety and the environment. It shall assist the employer in devising suitable working procedures and organisational measures according to Article 5 of Directive 98/24/EC.

Where a chemical safety report or a registration is required, the information in this section shall be consistent with the information given, for the identified uses and exposure scenarios set out in the annex to the Safety Data Sheet.

7.1. Handling

Specify precautions for safe handling including advice on technical measures such as:

- containment, local and general ventilation, measures to prevent aerosol and dust generation and fire, measures required to protect the environment (e.g. use of filters or scrubbers on exhaust ventilation, use in a bunded area, measures for collection and disposal of spillages, etc.) and any specific requirements 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

Specify 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, etc.) 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.

7.3. Specific use(s)

For end products designed for specific use(s), recommendations shall refer to the identified use(s) and be detailed and operational. If possible, reference shall be made to industry – or sector – specific approved guidance.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Exposure limit values

Specify currently applicable specific control parameters including occupational exposure limit values and/or biological limit values. Values shall be given for the Member State where the substance or preparation is placed on the market. Give information on currently recommended monitoring procedures.

Where a Chemical Safety Report is required, the relevant DNELs and PNECs for the substance shall be given for the exposure scenarios set out in the annex to the Safety Data Sheet.

For preparations, it is useful to provide values for those constituent substances which are required to be listed in the Safety Data Sheet according to heading 3.

8.2. Exposure controls

For the purposes of this document exposure control means the full range of specific risk management measures to be taken during use in order to minimise worker and environmental exposure. Where a chemical safety report is required, a summary of the risk management measures shall be given in Section 8 of the Safety Data Sheet for the identified uses set out in the Safety Data Sheet.

8.2.1. Occupational exposure controls

This information will be taken into account by the employer in carrying out an assessment of risk to the health and safety of workers for the substance or preparation under Article 4 of Directive 98/24/EC, which requires, in the order of priority:

- design of appropriate work processes and engineering controls, the use of adequate equipment and materials,
- the application of collective protection measures at source, such as adequate ventilation and appropriate organisational measures, and
- where exposure cannot be prevented by other means the use of individual protection measures, such as personal protection equipment.

Therefore provide suitable and adequate information on these measures to enable a proper risk assessment to be carried out under Article 4 of Directive 98/24/EC. This information shall complement that already given under heading 7.1.

Where individual protection measures are needed, specify in detail which equipment will provide adequate and suitable protection. Take into account Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment¹ and make reference to the appropriate CEN standards:

(a) Respiratory protection

For dangerous gases, vapours or dust, specify the type of protective equipment to be used, such as:

- self contained breathing apparatus, adequate masks and filters.

(b) Hand protection

Specify clearly the type of gloves to be worn when handling the substance or preparation, including:

- the type of material,
- the breakthrough time of the glove material, with regard to the amount and duration of dermal exposure.

If necessary indicate any additional hand protection measures.

¹ OJ L 399, 30.12.1989, p. 18. Directive as last amended by Regulation (EC) No 1882/2003.

(c) Eye protection

Specify the type of eye protection equipment required such as:

- safety glasses, safety goggles, face shield.

(d) Skin protection

If it is necessary to protect a part of 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 any additional skin protection measures and specific hygiene measures.

8.2.2. Environmental exposure controls

Specify the information required by the employer to fulfil his commitments under Community environmental protection legislation.

Where a chemical safety report is required, a summary of the risk management measures that adequately control exposure of the environment to the substance shall be given for the exposure scenarios set out in the annex to the Safety Data Sheet.

9. PHYSICAL AND CHEMICAL PROPERTIES

To enable proper control measures to be taken, provide all relevant information on the substance or preparation, particularly the information listed under heading 9.2. The information in this section shall be consistent with the information provided in a registration where one is required.

9.1. General information

Appearance

Indicate the physical state (solid, liquid, gas) and the colour of the substance or preparation as supplied.

Odour

If odour is perceptible, give a brief description of it.

9.2. Important health, safety and environmental information

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

Flash point

Flammability (solid, gas)

Explosive properties

Oxidising properties

Vapour pressure

Relative density

Solubility

Water solubility

Partition coefficient: n-octanol/water

Viscosity

Vapour density

Evaporation rate

9.3. Other information

Indicate other important safety parameters, such as, miscibility, fat solubility (solvent – oil to be specified), conductivity, melting point/melting range, gas group (useful for Directive 94/9/EC of the European Parliament and the Council of 23 March 1994 on the approximation of the laws of the Member States concerning equipment and protective systems intended for use in potentially explosive atmospheres¹), auto-ignition temperature, etc.

¹ OJ L 100, 19.4.1994, p. 1. Directive as amended by Regulation (EC) No 1882/2003.

Note 1

The above properties shall be determined in accordance with the specifications laid down in the Commission Regulation on testing methods referred to in Article 13(3) or any other comparable method.

Note 2

For preparations, information shall normally be given on the properties of the preparation itself. However, if it is stated that a particular hazard does not apply, clearly differentiate between cases where no information is available to the classifier, and cases where negative test results are available. If it is considered necessary to give information about the properties of individual components, please indicate clearly what the data refers to.

10. STABILITY AND REACTIVITY

State the stability of the substance or preparation and the possibility of hazardous reactions occurring under certain conditions of use and also if released into the environment.

10.1. 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.

10.2. Materials to avoid

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

10.3. Hazardous decomposition products

List hazardous materials produced in dangerous amounts upon decomposition.

Note

Address specifically:

- the need for and the presence of stabilisers,
- 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.

The information shall include dangerous-to-health effects from exposure to the substance or preparation, based on the conclusion from, for example, test data and experience. The information shall also include, where appropriate, delayed, immediate and chronic effects from short- and long-term exposure such as sensitisation, narcosis, carcinogenicity, mutagenicity and reproductive toxicity (developmental toxicity and fertility). It shall also 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.

Taking account of the information already provided under heading 3, composition/information on ingredients, it may be necessary to make reference to specific health effects of certain substances in the preparation.

The information in this section shall be consistent with the information provided for in a registration where required and/or in a Chemical Safety Report where required and shall give information on the following groups of potential effects:

- toxicokinetics, metabolism and distribution,
- acute effects (acute toxicity, irritation and corrosivity),
- sensitisation,
- repeated dose toxicity, and
- CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction).

For substances subject to registration, summaries of the information derived from the application of Annexes VII to XI of this Regulation shall be given. The information shall also include the result of the comparison of the available data with the criteria given in Directive 67/548/EEC for CMR, categories 1 and 2, following paragraph 1.3.1 of Annex I of this Regulation.

12. ECOLOGICAL INFORMATION

Describe the possible effects, behaviour and environmental fate of the substance or preparation in air, water and/or soil. Where available, give relevant test data (e.g. LC_{50} fish ≤ 1 mg/l).

The information in this section shall be consistent with the information provided for in a registration where required and/or in a Chemical Safety Report where required.

Describe the most important characteristics likely to have an effect on the environment owing to the nature of the substance or preparation and likely methods of use. Information of the same kind shall be supplied for dangerous products arising from the degradation of substances and preparations. This may include the following:

12.1. Ecotoxicity

This shall include relevant available data on aquatic toxicity, both acute and chronic for fish, crustaceans, algae and other aquatic plants. In addition, toxicity data on soil micro- and macro-organisms and other environmentally relevant organisms, such as birds, bees and plants, shall be included when available. Where the substance or preparation has inhibitory effects on the activity of micro-organisms, the possible impact on sewage treatment plants shall be mentioned.

For substances subject to registration, summaries of the information derived from the application of Annexes VII to XI shall be included.

12.2. Mobility

The potential of the substance or the appropriate constituents of a preparation¹, if released to the environment, to transport to groundwater or far from the site of release.

Relevant data might include:

- known or predicted distribution to environmental compartments,
- surface tension,
- absorption/desorption.

For other physicochemical properties see heading 9.

¹ This information cannot be given for the preparation because it is substance specific. It should therefore be given, where available and appropriate, for each constituent substance in the preparation which is required to be listed in the Safety Data Sheet according to the rules under Section 3 of this Annex.

12.3. Persistence and degradability

The potential of the substance or the appropriate constituents of a preparation¹ to degrade in relevant environmental media, either through biodegradation or other processes such as oxidation or hydrolysis. Degradation half lives shall be quoted where available. The potential of the substance or appropriate constituents of a preparation¹ to degrade in sewage treatment plants shall also be mentioned.

12.4. Bioaccumulative potential

The potential of the substance or the appropriate constituents of a preparation¹ to accumulate in biota and, eventually, to pass through the food chain, with reference to the octanol-water partition coefficient (K_{ow}) and bioconcentration factor (BCF), if available.

12.5. Results of PBT assessment

Where a Chemical Safety Report is required, the results of the PBT assessment as set in the Chemical Safety Report shall be given.

12.6. Other adverse effects

If available, include information on any other adverse effects on the environment, e.g. ozone depletion potential, photochemical ozone creation potential, endocrine disrupting potential and/or global warming potential.

Remarks

Ensure that information relevant to the environment is provided under other headings of the Safety Data Sheet, especially advice for controlled release, accidental release measures, transport and disposal considerations under headings 6, 7, 13, 14 and 15.

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.

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

Where a Chemical Safety Report is required, the information on the waste management measures that adequately control exposure of humans and the environment to the substance shall be consistent with the exposure scenarios set out in the annex to the Safety Data Sheet.

Note

Refer to any relevant 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. Where relevant, provide information on the transport classification for each of the modal regulations: IMDG (sea), ADR (Council Directive 94/55/EC of 21 November 1994 on the approximation of the laws of the Member States with regard to the transport of dangerous goods by road¹), RID (Council Directive 96/49/EC of 23 July 1996 on the approximation of the laws of the Member States with regard to the transport of dangerous goods by rail²), ICAO/IATA (air). This might include *inter alia*:

- UN number,
- class,
- proper shipping name,
- packing group,
- marine pollutant,
- other applicable information.

¹ OJ L 319, 12.12.1994, p. 7. Directive as last amended by Commission Directive 2004/111/EC (OJ L 365, 10.12.2004, p. 25).

² OJ L 235, 17.9.1996, p. 25. Directive as last amended by Commission Directive 2004/110/EC (OJ L 365, 10.12.2004, p. 24).

15. REGULATORY INFORMATION

Indicate if a Chemical Safety Assessment has been carried out for the substance (or a substance in the preparation).

Give the health, safety and environmental information shown on the label according to Directives 67/548/EEC and 1999/45/EC.

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. authorisations given under Title VII or restrictions under Title VIII) these provisions shall, as far as is possible, be stated.

Also mention, where possible, the national laws which implement these provisions and any other national measures that may be relevant.

16. OTHER INFORMATION

Indicate any other information which the supplier assesses as being of importance for the health and safety of the user and for the protection of the environment, for example:

- list of relevant R phrases. Write out the full text of any R phrases referred to under headings 2 and 3 of the Safety Data Sheet,
- training advice,
- recommended restrictions on use (i.e. non-statutory recommendations by supplier),

- further information (written references and/or technical contact point),
- sources of key data used to compile the Safety Data Sheet.

For a revised Safety Data Sheet, indicate clearly the information, which has been added, deleted or revised (unless this has been indicated elsewhere).
