L.N. 393 of 2002

PRODUCT SAFETY ACT (ACT V OF 2001)

Dangerous Substances and Preparations (Safety Data Sheets) Regulations, 2002

IN exercise of the powers conferred by article 39 of the Product Safety Act, the Minister for Economic Services, on the advice of the Malta Standards Authority, has made the following regulations:

Citation and commencement.

1.1 The title of these regulations is the Dangerous Substances and Preparations (Safety Data Sheets) Regulations, 2002.

1.2 These regulations shall come into effect as from 1st January, 2003.

Applicability.

2.1 These regulations shall come into force:

(a) in the case of preparations not within the scope of Council Directive 91/414/EEC (1) on the placing of plant protection products on the market, or Council Directive 98/8/EC (2) on the placing of biocidal products on the market, as from the 1st January, 2003;

(b) in the case of preparations within the scope of Directive 91/414/EEC or Directive 98/8/EC, as from the 30th July, 2004.

2.2 These regulations shall apply without prejudice to other provisions regarding dangerous substances and preparations and occupational health and safety.

Obligation to supply safety data sheets.

3.1 The person who is responsible for placing a chemical substance or preparation on the market, whether the manufacturer, importer or distributor, shall supply the recipient, who is a professional user of the substance or preparation, with a safety data sheet containing the information set out in regulation 5 and the Schedule to these

[1] OJ L 230, 19.8.1991, p.1
[2] OJ L 123, 24.4.1998, p.1

regulations, if the substance or preparation is classified as dangerous according to the Dangerous Substances (Notification) Regulations (L.N. 318 of 2001) or the Dangerous Substances and Preparations Regulations (L.N. 163 of 2001).

3.2 Any person who is responsible for placing a preparation on the market, whether the manufacturer, importer or distributor, shall supply, on request of a professional user, a safety data sheet providing proportionate information as set out in regulation 5 and the Schedule to these regulations, if the preparation is not classified as dangerous according to regulations 6, 7 and 8 of the Dangerous Substances and Preparations Regulations (L.N. 163 of 2001), but the preparation contains in an individual concentration of ≥ 1 % by weight for non-gaseous preparations and ≥ 0,2 % by volume for gaseous preparations at least one substance posing health or environmental hazards, or one substance for which there are workplace exposure limits established by the European Community.

3.3 The information shall be provided free of charge at the latest when the substance or preparation is first supplied and thereafter following any revision due to any significant new information regarding safety and protection of health and the environment. The new dated version, identified as 'Revision: ... (date)' shall be provided free of charge to all former recipients who received the substance or preparation within the preceding 12 months.

3.4 The safety data sheet need not be supplied where dangerous substances or preparations offered or sold to the general public are furnished with sufficient information to enable users to take the necessary measures as regards the protection of health and safety. However, a safety data sheet must be supplied at the request of an industrial user.

Language requirements.

4.1 The safety data sheet referred to in regulation 3 hereof must be supplied in at least one of the following languages: Maltese, English, Italian.

Safety data sheet headings.

5.1 The safety data sheet referred to in regulation 3 hereof shall contain the following obligatory headings:

a) identification of the substance/preparation and of the company/undertaking;

b) composition/information on ingredients;

c) hazards identification;

d) first-aid measures;

e) fire-fighting measures;

f) accidental release measures;

g) handling and storage;

h) exposure controls/personal protection;

i) physical and chemical properties;

j) stability and reactivity;

k) toxicological information;

l) ecological information;

m) disposal considerations;

n) transport information;

o) regulatory information;

p) other information.

5.2 It shall be incumbent on the person placing the substance or preparation on the market to supply the information specified under these headings. This information shall be compiled in accordance with the Explanatory Notes in the Annex to Commission Directive 91/155/EEC defining and laying down the detailed arrangements for the system of specific information relating to dangerous preparations, and reproduced as the Schedule to these Regulations.

5.3 The safety data sheet shall be dated.

Provision of information to the Malta Standards Authority.

6.1 The Directorate responsible for chemicals within the Malta Standards Authority may require any person who is responsible for placing a substance or preparation on the market, whether the manufacturer, importer or distributor, to provide, free of charge, an updated copy of the safety data sheet for that substance or preparation.

SCHEDULE

GUIDE TO THE COMPILATION OF SAFETY DATA SHEETS

(reproduced from the Annex to Commission Directive 91/155/EEC, as amended by Commission Directive 2001/58/EC)

The purpose of this Annex is to ensure consistency and accuracy in the content of each of the mandatory headings listed in Article 3, so that the resulting safety data sheets will enable professional users to take the necessary measures relating to protection of health and safety at the workplace, and protection of the environment.

The information provided by safety data sheets should meet the requirements set out in Council Directive 98/24/EC (3) 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 should 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 must be written in a clear and concise manner. The safety data sheet should be prepared by a competent person who should take into account the specific needs of the user audience, as far as it is known. Persons placing substances and preparations on the market should 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 14(2.1)(b) of Directive 1999/45/EC, proportionate information should 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 must be clearly stated under each heading. Information must 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 should be brought to the attention of the recipient.

[3] OJ L 131, 5.5.1998, p. 11.

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 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. **Use of the substance/preparation**

Indicate the intended or recommended 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 be listed. This should include a brief description of what it actually does, e.g. flame retardant, anti-oxidant, etc.

1.3. **Company/undertaking identification**

Identify the person responsible for placing the substance or preparation on the market within the European Community, whether it be the manufacturer, importer or distributor. Give the full address and telephone number of this person.

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.

1.4. **Emergency telephone**

In addition to the abovementioned 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).

2. COMPOSITION/INFORMATION ON INGREDIENTS

The information given should enable the recipient to identify readily the hazards of the components of the preparation. The hazards of the preparation itself should be given under heading 3.

2.1. 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.

2.2. 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:

(i) 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 those laid down in the table set out in Article 3(3) of Directive 1999/45/EC (unless lower limits are given in Annex I to Directive 67/548/EEC or in Annexes II, III or V to Directive 1999/45/EC);

(ii) and substances for which there are Community workplace exposure limits, which are not already included under (i).

2.3. For a preparation not classified as dangerous according to Directive 1999/45/EC, the following substances shall be indicated, together with their concentration or concentration range, if they are present in an individual concentration of ≥ 1 % by weight for non-gaseous preparations and $\geq 0{,}2$ % by volume for gaseous preparations:

– substances presenting a health or environmental hazard within the meaning of Directive 67/548/EEC (4);

– and substances for which there are Community workplace exposure limits.

2.4. The classification (deriving either from Articles 4 and 6 or from Annex I to Directive 67/548/EEC) of the above substances shall be given, including the symbol letters and R phrases which are assigned in accordance with their physicochemical, health and environmental hazards. The R phrases do not need to be written out in full here: reference should be made to heading 16, where the full text of each relevant R phrase shall be listed.

2.5. The name and the Einecs or Elincs number of the above substances should 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,

4 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 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.

according to Article 15 of Directive 1999/45/EC or the footnote to point 2.3 of this Annex, a precise chemical identifier is not necessary.

2.6. If, in accordance with the provisions of Article 15 of Directive 1999/45/EC or the footnote to point 2.3 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 must be the same as that which derives from the above procedures.

3. 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, suffocation, freezing or environmental effects such as hazards to soil-dwelling organisms, etc., which do not result in classification but which may contribute to the overall hazards of the material.

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

4. FIRST AID MEASURES

Describe the first-aid measures.

Specify first 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 summarised. 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 emphasise 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 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 should relate to the protection of health, safety and the environment. It should assist the employer in devising suitable working procedures and organisational measures according to Article 5 of Directive 98/24/EC.

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 should refer to the intended use(s) and be detailed and operational. If possible, reference should 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 should be given for the Member State where the substance or preparation is placed on the market. Give information on currently recommended monitoring procedures. 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 2.

8.2. **Exposure controls**

For the purposes of this document exposure control means the full range of specific protection and prevention measures to be taken during use in order to minimise worker and environmental exposure.

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 the design of appropriate work processes and engineering controls, the use of adequate equipment and materials, the application of collective protection measures at source, and finally 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 should complement that already given under heading 7.1.

Where personal protection is needed, specify in detail which equipment will provide adequate and suitable protection. Take into account Council Directive 89/686/EEC ([5]) and make reference to the appropriate CEN standards:

8.2.1.1. 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.

8.2.1.2. 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.

8.2.1.3. Eye protection

Specify the type of eye protection equipment required such as: safety glasses, safety goggles, face shield.

8.2.1.4. Skin protection

5 OJ L 399, 30.12.1989, p. 18.

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.

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.

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.

9.3. **Other information**

Indicate other important safety parameters, such as, miscibility, conductivity, melting point/melting range, gas group (useful for European Parliament and Council Directive 94/9/EC) (6), auto-ignition temperature etc.

Note 1

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.

(6) OJ L 100, 19.4.1994, p. 1.

Note 2

For preparations, information should 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.

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 sensitisation, narcosis, carcinogenicity, mutagenicity and reproductive toxicity (developmental toxicity and fertility).

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

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. LC50 fish $\leq$ 1 mg/l).

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 should include relevant available data on aquatic toxicity, both acute and chronic for fish, daphnia, algae and other aquatic plant. In addition, toxicity data on soil micro- and macro-organisms and other environmentally relevant organisms, such as birds, bees and plants, should 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 should be mentioned.

12.2. **Mobility**

The potential of the substance or the appropriate constituents of a preparation (7), if released to the environment, to transport to groundwater or far from the site of release.

(7) 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 heading 2 of this Annex.

Relevant data might include:

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

For other physicochemical properties see heading 9.

12.3. **Persistence and degradability**

The potential of the substance or the appropriate constituents of a preparation (7) to degrade in relevant environmental media, either through biodegradation or other processes such as oxidation or hydrolysis. Degradation half lives should be quoted where available. The potential of the substance or appropriate constituents of a preparation (7) to degrade in sewage treatment plants should also be mentioned.

12.4. **Bioaccumulative potential**

The potential of the substance or the appropriate consituents of a preparation (1) to accumulate in biota and pass through the food chain, with reference to the Kow and BCF, if available.

12.5. **Other adverse effects**

If available, include information on any other adverse effects on the environment, e.g. ozone depletion potential, photochemical ozone creation 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.)

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 (road, Council Directive 94/55/EC ([8])), RID (rail, Council Directive 96/49/EC ([9])), ICAO/IATA (air).

This might include *inter alia*:

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

15. REGULATORY INFORMATION

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. restrictions on marketing and use set out in Council Directive 76/769/EEC ([10])) these provisions should, 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.

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[8] OJ L 319, 12.12.1994, p. 7.

[9] OJ L 235, 17.9.1996, p. 25.

[10] OJ L 262, 27.9.1976, p. 201.

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 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).

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