

amended safety data sheet directive (2001/58/EC)

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Brussels
June 2002

ABSTRACT

This report outlines the requirements of the amended EU Safety Data Sheet Directive and reviews the implications for the oil industry. A copy of the amended Safety Data Sheet Directive is included as an appendix.

KEYWORDS

Safety data sheet, legislation

INTERNET

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SUMMARY

This report provides a detailed comparison of the amended Safety Data Sheet Directive (amended July 2001) with the requirements of the earlier SDS Directive (Commission Directive 91/155/EC). Where appropriate, additional guidance is suggested that may be useful to consider by authors of SDSs in the oil industry.

1. INTRODUCTION

CONCAWE has previously published guidance [1] on the Safety Data Sheet Directive (SDS) [2] and more recently has published guidance [3] on the revised Dangerous Preparations Directive (DPD) [4]. The SDS Directive was amended for the second time on 27 July 2001 [5] as a consequence of revisions to the DPD and in an effort to improve the quality and usefulness of SDSs in the EU. A copy of the new SDS Directive is included in the Appendices.

This report provides a summary of the changes to the SDS Directive and a detailed comparison of the Annex of the amended SDS Directive with the Annex of the earlier SDS Directive. Where appropriate, additional guidance is suggested that may be useful to consider by authors of SDSs in the oil industry.

Member States are required to comply with the new requirements of the SDS Directive no later than 30 July 2002.

2. SUMMARY OF CHANGES

Significantly, Article 1 has been revised such that SDSs will now need to be supplied to the professional user by the person responsible for placing a preparation on the market, if the preparation is classified as Dangerous for the Environment according to the DPD.

Another consequence of the changes to Article 1 is that professional users will be entitled to request an SDSs for preparations not classified as dangerous, but which contain concentrations $\geq 1\%$ by weight ($\geq 0,2\%$ by volume for gaseous preparations) of at least one substance posing health or environmental hazards, or one substance for which there are Community workplace exposure limits (i.e. EU Indicative Occupational Exposure Limit Values [6]). For those preparations not classified as dangerous but for which a SDS is required, proportionate information under each heading is required.

The Annex of the former SDS Directive is replaced in entirety with the Annex in the amended SDS Directive and in many sections will require significantly more comprehensive information. New linkages are made in the Annex to the Chemical Agents Directive [7] and non-specific EU Environmental Protection legislation. It is envisaged that the information provided by the SDS should assist the employer in meeting his obligations of the Chemical Agents Directive and EU Environmental Protection legislation. There is also a new requirement for the provision of occupational exposure limits for the Member State in which the product is placed on the market. Requirements for recommendations for personal protective equipment have also been made more precise.

While the Annex of the amended SDS Directive is still referred to as a 'guide' to the compilation of SDSs, it should be recognised that some Member States may incorporate the Annex as legally binding in their respective national legislation, or may require further information to be included in various sections of the SDS consistent with their current national legislation.

The preamble to the Annex states that SDSs should be prepared by a competent person, having relevant experience and training. It is possible that Member States may define the criteria for assessing the competency of the author of the SDS.

Another significant change to the Annex is that information will need to be provided on SDSs for each hazardous property. If the information is not of significance or is impossible to provide, the reasons for this must be clearly stated. If it is stated that a particular hazard does not apply, differentiation needs to be provided between those cases where no information is available and cases where negative test results are available.

The date of issue of the SDS must now be given on the first page.

3. CHANGES IN THE ANNEX TO THE EU SAFETY DATA SHEET DIRECTIVE

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

Additional requirements to indicate the common intended or recommended use of the substance/preparation have been introduced in section 1.2. In addition, CONCAWE suggests that, where known, companies consider identifying specific non-intended uses of substance/preparations (i.e., use of gasoline or diesel fuel as solvents) in this section.

Section 1.3 now requires that, where the person responsible for placing the substance/preparation on the market within the Community is not located in the Member State, the full address and telephone number of the person responsible for marketing the substance/preparation within the specific Member State should be identified, where possible.

In addition to the requirement to supply the emergency telephone number of the companies and/or relevant official advisory body, companies may wish to list those poison centres that have been identified by Member States in accordance with the requirements of the DPD. Inclusion of an emergency telephone number for environmental emergencies may also be a consideration.

3.2. COMPOSITION / INFORMATION ON INGREDIENTS

This section has been revised to refer specifically to components of a preparation. As previously, there is no mandatory expectation that full compositional details of the preparation are given, but a statement has now been added that a general component description and concentrations could be helpful.

For a preparation classified as dangerous, the requirement to identify individual substances and their concentration/concentration range that are themselves dangerous within the meaning of the Dangerous Substances Directive (DSD) [8], or have a Community workplace exposure limit, has now been extended to include the identification of substances with an environmental hazard.

For preparations not classified as dangerous, but which contain substances having a health or environmental hazard within the meaning of the DSD or a Community workplace exposure limit and are present in concentrations $\geq 1\%$ by weight ($\geq 0.2\%$ by volume for gaseous substances), the identity of the substances, together with their concentration or concentration range, must be provided.

As this section is specific to preparations, there is no requirement to disclose the composition of complex substances. However, CONCAWE supports the identification in this section of key individual constituents (i.e. those individual constituents listed in Annex I of the DSD as dangerous, or for which there exists a Community workplace exposure limit, as given in lists of EU Indicative Limit Values or EU Binding Limit Values) of complex substances.

The classification of the identified substances (i.e. symbol letters and R phrases) has been extended to include physico-chemical and environmental properties, but it

is specifically stated that there is no requirement to write out in full the R phrases in section 2. Instead, reference should be made to Section 16 where the full text of the relevant R phrases should be listed.

Further guidance is now given as to how substances in section 2 should be defined. The Annex I name (for those substances appearing in Annex I) or a name based on internationally recognised chemical nomenclature and the European Inventory of Existing Chemical Substances (EINECS) or European List of New Chemical Substances (ELINCS) number should be given. The Chemical Abstract Service (CAS) number and the International Union of Pure and Applied Chemistry (IUPAC) name are optional.

Provisions for withholding the specific chemical identity of a substance exist but are limited. For preparations not classified as dangerous, the provisions for confidentiality may be found in the footnote to point 2.3 of the Annex. For those preparations classified as dangerous, the provisions for confidentiality may be found in Article 15 of the DPD.

The DPD requires that the packaging of those preparations not classified as dangerous, but which contain at least one substance classified as sensitising, should identify that substance if it is present in a concentration $\geq 0.1\%$ by weight. The SDS Directive does not specify that this information is required in Section 2 of the SDS. However, CONCAWE recommends that sensitisers that are present in concentrations $\geq 0.1\%$ by weight may be listed in this section, together with their actual concentration or concentration range.

3.3. HAZARDS IDENTIFICATION

There is a requirement to list the classification of the substance or preparation that arises from application of the classification rules in the DSD or the DPD. The hazard(s) that the substance or preparation presents to man or the environment should also be indicated.

A statement is required to distinguish clearly between preparations which are classified as dangerous based on their physicochemical, health and environmental properties and those preparations which are not classified as dangerous but for which a SDS is required.

In addition to the reporting of important adverse human health effects, there is now also a need to describe important adverse physicochemical and environmental effects and symptoms relating to the use and possible misuse of substances/preparations. Reference to other hazards which do not result in classification but which may contribute to the overall hazard of the material should be considered. Examples could include:

- freezing burns from contact with LPG
- groundwater contamination concerns associated with MTBE
- carcinogenicity of used motor oils
- static electricity concerns associated with fuels
- respiratory irritation associated with overexposure to oil mist
- slip hazard from oil mist deposited on surfaces

3.4. FIRST AID MEASURES

There are no new requirements in this section.

Some useful sources of information for this section include CONCAWE's report on first aid emergencies and medical advice [9], published literature, national toxic substances information centres and company doctors.

If special R-phrases point out special hazards caused by the product via different routes of exposure, detailed first aid measures should be identified as well.

3.5. FIRE-FIGHTING MEASURES

There are no revisions to this section.

For petroleum substances and preparations, consider the use of the following extinguishing media:

- Foam
- Dry powder
- Carbon dioxide
- Sand
- Water fog

It is worthy to consider that full water jet should not be used as extinguishing media based on safety concerns.

It should be pointed out that, in the event of fire, product fumes or vapours can spread quickly and may be ignited by remote ignition sources. Consider whether resulting vapours are heavier or lighter than air.

Containers at risk can be cooled with water spray jet. Any fire residues and contaminated fire-fighting water should be collected and disposed of in accordance with local regulations.

Guidance should be given to fire-fighters to use breathing apparatus if exposed to smoke and gases/fumes.

Respirators (filtering devices) should not be used in confined spaces where the environment is Immediately Dangerous to Life or Health (IDLH) or there is a risk of oxygen deficiency. In these circumstances, breathing apparatus should always be used.

3.6. ACCIDENTIAL RELEASE MEASURES

There are no revisions to this section.

It may be useful to consider providing guidance on who (i.e., neighbourhoods, regulatory authorities) the employer / professional user may need to notify in the event of an accidental release.

3.7. HANDLING AND STORAGE

There are several amendments and additions to this section. Firstly, there is reference to the Chemical Agents Directive, and the need for handling and storage information to be relevant to the requirements of Article 5 of this Directive (relating to the prevention of risks associated with hazardous chemicals in the workplace).

Suggestions for safe handling have now been extended to include environmental protection in relation to exhaust ventilation, collection and disposal of spillages, etc. However, more comprehensive information on dealing with spillages should be contained in Section 6 of the SDS.

Another paragraph has now been added to section 7 concerning industry or sector specific approved guidance where substances or preparations have particular uses. The handling advice for petroleum products included in the CONCAWE product dossiers [10-19] may be a useful source of information. Where such specific uses exist, then the handling and storage recommendations must refer to the intended use. In addition, Member States may already have national guidance in place for particular materials/uses, and therefore data sheet compilers should check with national, industrial, labour or environmental organisations in each territory where their products are supplied.

3.8. EXPOSURE CONTROLS/PERSONAL PROTECTION

New requirements for this section include the provision of:

- exposure limits for the Member State where the product is placed on the market,
- specific information on exposure controls that is sufficient to allow an assessment of risk to health and safety of workers according to the Chemical Agents Directive, and to allow employers to meet their obligations under Community environmental protection legislation.

3.8.1. Exposure limit values

It is necessary to specify the current occupational exposure limit values or biological limit values for the Member State where the substance or preparation is placed on the market. Information on recommended monitoring procedures should also be given.

For preparations, information on the exposure limit values for the dangerous constituents identified in heading 2 should be given, together with details of suitable monitoring methods. Similarly, for petroleum substances, information on the exposure limit values for the dangerous constituents identified in heading 2 should be given, together with details of suitable monitoring methods.

Many Member States have regulatory bodies which publish lists of Occupational Exposure Limit values. Whilst these may vary, the introduction of the EU Indicative Limit Values and Binding Limit Values Directives will lead to harmonisation of limit values in the longer term. A partial listing of sources of some Member State regulatory limit values and publicly available recommended monitoring methods which could be referred to in SDSs are provided in Appendix 1. Useful information on national legislation affecting the workplace can be found through the Member

State pages of the European Agency for Safety and Health at Work website (at the time of writing this report the following link can be used: http://europe.osha.eu.int/good_practice/risks/ds/oei).

3.8.2. Exposure Controls

Information should be provided not only on personal protection measures but also on prevention measures, such as the design and organisation of systems of work and the use of engineering controls, to minimise worker and environmental exposure.

3.8.2.1. Occupational exposure controls

The information on protection and prevention measures should be suitable and adequate to enable employers to carry out a proper risk assessment required by Article 4 of the Chemical Agents Directive. This information should complement that already provided under heading 7.1.

Where advice is provided on the use of personal protective equipment (PPE), the requirements of the PPE Directive [20] should be taken into account, that is, PPE should be certified according to EC examination and be 'CE' marked. When specifying PPE, reference should be made to the appropriate European Committee for Standardization (CEN) standard.

It is not possible to provide Member Companies with specific advice on the type of PPE to be used for the range of petroleum products available on the market. However, details of the relevant CEN standards covering a wide range of PPE are provided in Appendices 2-5 for respiratory protection, hand protection, eye protection and skin protection, respectively. These should be referenced against the PPE recommended in individual product SDSs.

3.8.2.2. Environmental exposure controls

This is an additional heading and it requires provision of information to the employer to fulfil his commitments under Community environmental protection legislation to be specified.

The requirements of relevant EU environmental protection legislation such as the Water Framework Directive [21], European Pollutant Emission Register [22] and the Directive on limiting VOC's [23], should be considered in assessing what additional information may be needed by the employer to fulfil his obligations under Community environmental protection legislation.

3.9. PHYSICAL AND CHEMICAL PROPERTIES

The specific listing of the physical and chemical properties that must be reported has not changed, although the section has now been revised to contain three sub-sections. Other physical and chemical properties such as freezing point, pour point, bulk density, etc. may also be given.

One should be mindful of the new requirement that information must be provided on SDSs for each property. If the information is not of significance or is impossible to provide, the reasons for this must be clearly stated. If it is stated that a particular

property does not apply, differentiation needs to be provided between those cases where no information is available and cases where negative test results are available.

3.10. STABILITY AND REACTIVITY

The requirements for information in this section are unchanged.

3.11. TOXICOLOGICAL INFORMATION

The requirements for information in this section are unchanged.

CONCAWE reports and product dossiers provide a useful source of reference.

3.12. ECOLOGICAL INFORMATION

Although the data requirements for this section are basically unchanged, the section has now been formatted into a number of sub-sections. Text has been added to provide more detailed guidance on the information that should be provided.

CONCAWE reports, particularly the Environmental Data Report [24], and product dossiers provide a useful source of reference.

Information relevant to the environment should be provided under headings of the SDS, especially advice for controlled release, accidental release measures, transport and disposal considerations under headings 6, 7, 13, 14 and 15.

3.13. DISPOSAL CONSIDERATIONS

This section has had no major revision; a few words have been changed or added to make the requirements clearer. Sufficient information should be provided in this section to enable the user to dispose of the product safely and in accordance with the appropriate regulations.

3.14. TRANSPORT INFORMATION

Previously the SDS Directive was not specific with regard to the information required in this section, referring to United Nations recommendations and other international agreements. This major revision defines, where relevant, the classifications needed for conveyance by road, rail, air and water. Thus the UN number, Class, Proper Shipping Name, Packing Group and Marine Pollutant classifications are now recommended.

It should be noted that the modal regulations listed in the Annex are not static and are subject to revision.

3.15. REGULATORY INFORMATION

As with the previous Directive, health, safety and environmental information shown on the label according to the DSD and the DPD must be provided here.

It should be noted that for those non-hazardous preparations requiring disclosure of their hazardous component substances in Section 2, the phrase 'Safety Data Sheet available for professional user on request' must appear on the label.

It should be also noted that Annex V of the DPD requires that the packaging of preparations, whether classified as dangerous or not, which contain at least one substance classified as sensitising, should identify the sensitiser if it is present at a concentration of $\geq 0.1\%$ by weight. Since relevant health and safety information on the label needs to be presented in this section, CONCAWE recommends that special information required by Annex V of the DPD on the packaging, for example the presence of sensitisers in non-dangerous preparations, also be included in this section.

3.16. OTHER INFORMATION

Again, additional and relevant environmental data has been added to the content of this section. Where R phrases have been referred to in Sections 2 and 3, these must be written out in full here. To minimise any reader confusion in the case of a SDS for a preparation, it is recommended that a clear distinction be made between those R phrases that are associated with the overall preparation and those that are associated with constituents of the preparation.

There has always been a requirement for the identification of significant revisions to a SDS, and the new Directive provides guidance that this information could be placed in Section 16 unless it has been indicated elsewhere in the SDS.

This section no longer includes the identification of recommended uses, which is now included in Section 1.2. However, the identification of any recommended restrictions for use that are considered appropriate by the supplier is retained.

4. IMPLEMENTATION DATES

Member States are required to comply with the new requirements of the SDS Directive no later than 30 July 2002.

5. REFERENCES

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3. CONCAWE (2000) Revised dangerous preparations Directive (1999/45/EC) – implications for petroleum products. Report No. 00/56. Brussels: CONCAWE
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5. EU (2001) Commission Directive 2001/58/EC of 27 July 2001 amending for the second time Directive 91/155/EEC defining and laying down the detailed arrangements for the system of specific information relating to dangerous preparations in implementation of Article 14 of European Parliament and Council Directive 1999/45/EC and relating to dangerous substances in implementation of Article 27 of Council Directive 67/548/EEC (safety data sheets). Official Journal of the European Communities No. L212, 07.08.2001
6. EU (2000) Commission Directive 2000/39/EC of 8 June 2000 establishing a first list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work. Official Journal of the European Communities No. L142, 16.06.2000
7. EU (1998) Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC). Official Journal of the European Communities No. L131, 05.05.1998
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10. CONCAWE (1992) Aromatic extracts. Product Dossier No. 92/101. Brussels: CONCAWE
11. CONCAWE (1992) Liquefied petroleum gas. Product Dossier No. 92/102. Brussels: CONCAWE
12. CONCAWE (1992) Gasolines. Product Dossier No. 92/103. Brussels: CONCAWE

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13. CONCAWE (1992) Bitumens and bitumen derivatives. Product Dossier No. 92/104. Brussels: CONCAWE
 14. CONCAWE (1993) Petroleum coke. Product Dossier No. 93/105. Brussels: CONCAWE
 15. CONCAWE (1994) Kerosines/jet fuels. Product Dossier No. 94/106. Brussels: CONCAWE
 16. CONCAWE (1995) Gas oils (diesel fuels/heating oils). Product Dossier No. 95/107. Brussels: CONCAWE
 17. CONCAWE (1997) Lubricating oil basestocks. Product Dossier No. 97/108. Brussels: CONCAWE
 18. CONCAWE (1998) Heavy fuel oils. Product Dossier No. 98/109. Brussels: CONCAWE
 19. CONCAWE (1999) Petroleum waxes and related products. Product Dossier No. 99/110. Brussels: CONCAWE
 20. EU (1989) Council Directive of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment (89/686/EEC). Official Journal of the European Communities No. L399, 30.12.1989
 21. EU (2000) Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy. Official Journal of the European Communities No. L327, 22.12.2000
 22. EU (2000) Commission Decision of 17 July 2000 on the implementation of a European pollutant emission register (EPER) according to Article 15 of Council Directive 96/61/EC concerning integrated pollution prevention and control (IPPC) (2000/479/EC). Official Journal of the European Communities No. L192, 28.07.2000
 23. EU (1999) Council Directive 1999/13/EC of 11 March 1999 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain activities and installations. Official Journal of the European Communities No. L85, 29.03.1999
 24. CONCAWE (2001) Environmental classification of petroleum substances – summary data and rationale. Report No. 01/54. Brussels: CONCAWE

APPENDIX 1

SOURCES FOR MEMBER STATE OELS AND RECOMMENDED MONITORING METHODS

Table 1 Listing of sources for some Member State Occupational Exposure Limits

Member State	Regulatory Body	Occupational Exposure Limits	Internet web address
Austria	Bundesministerium für Arbeit und Soziales	MAK-Werte-Liste	http://www.bgbl.at/BGBL/BASIS/bgblmeta/www/bgbl/sf
Belgium	Ministère de l'Emploi et du Travail	Valeurs Limites d'Exposition Professionnelle	Not available on-line
Denmark	Ministry of Labour	Grænseværdier for stoffer og materialer	http://www.arbejdstilsynet.dk
Finland	Ministry of Social Affairs and Health	HTP-arvot	Not available on-line
France	Ministère de l'Emploi et de la Solidarité	Valeurs limites d'exposition professionnelle aux agents chimiques en France	http://www.inrs.fr/home/ENhome/presentation.html
Germany	Ausschuss für Gefahrstoffe (AGS)	TRGS 900, 901, 903, 905, 907 and 954	Not available on-line
Netherlands	Minister van Sociale zaken en Werkgelegenheid	De Nationale MAC-lijst	Not available on-line
Spain	Instituto Nacional de Seguridad e Higiene en el Trabajo	Valores Límite Ambientales	http://www.mtas.es/insh/practice/vlas.htm#anexoc
Sweden	Arbetsmiljöverket	Hygieniska Gränsvärden	http://www.av.se/regler/afs/2000_03.pdf
UK	Health and Safety Executive	MELs - Maximum Exposure Limits OESs - Occupational Exposure Standards	Not available on-line

Table 2 Listing of some examples of publicly available recommended monitoring methods

Source	Sampling and Analytical Methods	Country
Heath and Safety Executive (HSE)	Methods for the Determination of Hazardous Substances (MDHS)	UK
National Institute of Occupational Safety and Health (NIOSH)	Manual of Analytical Methods http://www.cdc.gov/niosh/nmam/nmammenu.html	USA
Occupational Safety and Health Administration (OSHA)	Sampling and Analytical Methods http://www.osha-slc.gov/dts/sltc/methods/index.html	USA
Berufsgenossenschaftliches Institut für Arbeitssicherheit (BIA)	http://www.hvbg.de/d/bia/pub/grl/grle.htm	Germany
L'Institut National de Recherche et de Sécurité (INRS)	Dossiers http://www.inrs.fr/indexnosdoss.html	France

APPENDIX 2

GUIDANCE ON RESPIRATORY PROTECTION

Respiratory protection

There are two classes of respiratory protection:

- Respirator (filtering device) - filters or cleans contaminated air from the workplace before it is inhaled by the wearer. Respirators are not suitable for use in IDLH environments including oxygen-deficient atmospheres.
- Breathing Apparatus (BA) - delivers breathable air or oxygen to the wearer from an independent source. BA may be suitable for IDLH environments including oxygen-deficient atmospheres.

The following information on the selection of suitable respirators and filter types may be useful:

- Disposable filtering half masks to protect against particles are detailed in EN 149 [1]. They are classified according to their filtering efficiency. There are three classes FFP1, FFP2 and FFP3, the latter offering the highest level of protection.
They are designated as EN 149 (2001) FFP1, FFP2 or FFP3 respirators.
- Valved filtering half masks (EN 405) [2] protect against gases or gases and particles. The integral construction of these devices means they are maintenance free and should be regarded as disposable. The types of gas filtering EN 405 half masks are as follows:

Type FFA	For use against certain organic gases and vapours with boiling points higher than 65°C as specified by the manufacturer
Type FFB	For use against certain inorganic gases and vapours as specified by the manufacturer (excluding carbon monoxide)
Type FFE	For use against sulphur dioxide and other acid gases and vapours as specified by the manufacturer
Type FFK	For use against ammonia and organic ammonia derivatives as specified by the manufacturer
Type FFAX	For use against certain low boiling organic compounds as specified by the manufacturer
Type FFSX	For use against certain named gases and vapours

These are further classified according to their capacity:

- Class 1 - Low capacity, e.g. FFA1
- Class 2 - Medium capacity, e.g. FFB2

The valved filtering half masks can be used with multi-type gas filters or with combined gas and particle filters (P1, P2 or P3). An example designation of this type of respirator/filter combination is EN 405, FFA2P2.

- Half mask and quarter mask respirators (EN 140) [3] may be used with gas filters or combined filters conforming to EN 141 [4], EN 143 [5] or EN 371 [6].

The EN 141 standard details the gas filters which are available in the following types:

Type A	For use against certain organic gases and vapours with boiling points higher than 65°C as specified by the manufacturer
Type B	For use against certain inorganic gases and vapours as specified by the manufacturer (excluding carbon monoxide)
Type E	For use against sulphur dioxide and other acid gases and vapours as specified by the manufacturer
Type K	For use against ammonia and organic ammonia derivatives as specified by the manufacturer

The Type A, B, E and K gas filters are classified according to their capacity as follows:

- Class 1 - Low capacity filters
- Class 2 - Medium capacity filters
- Class 3 - High capacity filters

The EN 143 standard specifies particle filters according to their filtering efficiency. There are three classes of particle filters: P1, P2 and P3 in ascending order of filtering efficiency.

EN 371 is the standard for Type AX filters. These are for use against certain low boiling organic compounds as specified by the manufacturer. According to this standard, low boiling organic compounds have a boiling point of $\leq 65^{\circ}\text{C}$.

Examples of these types of combined filter designations are ABEK2P3 or AXP2.

- Full facemasks are specified in EN 136 [7]. There are three types of full face masks which reflect the intended area of application:

- Class 1 - Light duty use
- Class 2 - General use
- Class 3 - Special use

When used as a negative pressure system, the mask may have filters conforming to EN 141, EN 143 or EN 371 attached to it. An example designation for this is EN 136 Class 2 A2P3.

In selecting the type of respirator and filter, consideration should be given to ensure that the recommended protection factor for the selected equipment is sufficient to protect against the expected airborne concentration in the working environment. Assigned protection factors (APFs) have been published by the British Standards Institution in BS 4275 [8].

References

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4. CEN (2000) Respiratory protective devices – gas filters and combined filters – requirements, testing, marking. EN 141:2000. Brussels: Comité Européen de Normalisation
5. CEN (2000) Respiratory protective devices – particle filters – requirements, testing, marking. EN 143:2000. Brussels: Comité Européen de Normalisation
6. CEN (1992) Respiratory protective devices - AX gas filters and combined filters against low-boiling point organic compounds – requirements, testing, marking. EN 371:1992. Brussels: Comité Européen de Normalisation
7. CEN (1998) Respiratory protective devices – full face masks – requirements, testing, marking. EN 136:1998. Brussels: Comité Européen de Normalisation
8. BSI (1997) Guide to implementing an effective respiratory protective device programme. BS 4275:1997. London: British Standards Institution

APPENDIX 3

GUIDANCE ON HAND PROTECTION

The general requirements for gloves are provided in EN 420 [1].

Gloves approved to EN 374 offer protection against chemicals and microorganisms. The methods of testing are found in the following parts:

Penetration	EN 374-2 [2]
Permeation	EN 374-3 [3]
Degradation	Test method in preparation

A 'Protection Index' is given in EN 374-1 [4] based on breakthrough times for each combination of protective glove/test chemical. The index is as follows:

Measured Breakthrough Time	Protection Index
> 10 min	Class 1
> 30 min	Class 2
> 60 min	Class 3
> 120 min	Class 4
> 240 min	Class 5
> 360 min	Class 6

In order to be able to specify the type of material and the breakthrough time of the recommended glove material, it is necessary to contact glove suppliers or consult their 'Chemical Resistance Guides'. More detailed information on specific gloves and breakthrough times is available on the websites of most major glove suppliers.

For petroleum products whose properties require the use of a preferred type of glove material, such material should be specified. If certain materials are not recommended or their use is discouraged, this should also be stated. It may be necessary to advise on the frequency of changing gloves if immersion or prolonged contact is likely.

References

1. CEN (1994) General requirements for gloves. EN 420:1994. Brussels: Comité Européen de Normalisation
2. CEN (1994) Protective gloves against chemicals and micro-organisms. Part 2. Determination of resistance to penetration. EN 374-2:1994. Brussels: Comité Européen de Normalisation
3. CEN (1994) Protective gloves against chemicals and micro-organisms. Part 3. Determination of resistance to permeation by chemicals. EN 374-3:1994. Brussels: Comité Européen de Normalisation
4. CEN (1994) Protective gloves against chemicals and micro-organisms. Part 1. Terminology and performance requirements. EN 374-1:1994. Brussels: Comité Européen de Normalisation

APPENDIX 4

GUIDANCE ON EYE PROTECTION

Eye protection must be approved to EN 166 [1].

To prevent exposure to chemical splashes, unvented chemical goggles or a full-face shield should be worn. Chin guards can be attached to face shields to prevent splashes deflecting up from work surfaces.

References

1. CEN (1995) Personal eye-protection – specifications. EN 166:1995. Brussels: Comité Européen de Normalisation

APPENDIX 5

GUIDANCE ON SKIN PROTECTION

Chemical protection of the body is provided by protective clothing conforming to the following standards: EN 465 [1] - Type 4, EN 466/A1 [2] - Type 3 or EN 467 [3]. This includes full chemical suits and chemical hoods.

The test methods used to determine the resistance of clothing materials to permeation by liquids, penetration by a jet liquid, and leak-tightness of gas tight suits are described in EN 369 [4], EN 463 [5] and EN 464 [6] respectively.

References

1. CEN (1995) Protective clothing – protection against liquid chemicals – performance requirements for chemical protective clothing with spray-tight connections between different parts of the clothing (type 4 equipment). EN 465:1995. Brussels: Comité Européen de Normalisation
2. CEN (1998) Protective clothing – protection against liquid chemicals – performance requirements for chemical protective clothing with liquid-tight connections between different parts of the clothing (type 3 equipment) – Amendment 1. EN 466/A1:1998. Brussels: Comité Européen de Normalisation
3. CEN (1995) Protective clothing – protection against liquid chemicals – performance requirements for garments providing protection to parts of the body. EN 467:1995. Brussels: Comité Européen de Normalisation
4. CEN (1993) Protective clothing – protection against liquid chemicals – test method: resistance of materials to permeation by liquids. EN 369:1993. Brussels: Comité Européen de Normalisation
5. CEN (1994) Protective clothing for use against liquid chemicals - test method: determination of resistance to penetration by a jet of liquid (jet test). EN 463:1994. Brussels: Comité Européen de Normalisation
6. CEN (1994) Protective clothing for use against liquid and gaseous chemicals including aerosols and solid particles - test method: determination of leak-tightness of gas-tight suits (internal pressure test). EN 464:1994. Brussels: Comité Européen de Normalisation

APPENDIX 6

DIRECTIVE 2001/58/EC

COMMISSION DIRECTIVE 2001/58/EC**of 27 July 2001****amending for the second time Directive 91/155/EEC defining and laying down the detailed arrangements for the system of specific information relating to dangerous preparations in implementation of Article 14 of European Parliament and Council Directive 1999/45/EC and relating to dangerous substances in implementation of Article 27 of Council Directive 67/548/EEC (safety data sheets)****(Text with EEA relevance)**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations ⁽¹⁾, and in particular Article 14 thereof,Having regard to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances ⁽²⁾, as last amended by Commission Directive 2000/33/EC ⁽³⁾, and in particular Article 27 thereof,

Whereas:

- (1) Article 14 of Directive 1999/45/EC provides that the person responsible for placing on the market certain specified preparations must provide a safety data sheet.
- (2) Article 27 of Directive 67/548/EEC provides that the person responsible for placing dangerous substances on the market must also provide a safety data sheet.
- (3) Safety data sheet information is principally intended for use by professional users and must enable them to take the necessary measures as regards the protection of health, safety and the environment at the place of work.
- (4) Safety data sheets for dangerous substances and certain preparations, and their supply must comply with the provisions of Commission Directive 91/155/EEC ⁽⁴⁾, as amended by Directive 93/112/EC ⁽⁵⁾.
- (5) Article 14(2.1)(b) of Directive 1999/45/EC introduces a new requirement for persons responsible for placing preparations on the market to provide on the request of professional users a safety data sheet containing proportionate information for preparations not classified as dangerous within the meaning of Articles 5, 6 and 7 of Directive 1999/45/EC, but which contain in an indi-

vidual concentration of $\geq 1\%$ by weight for non-gaseous preparations and $\geq 0,2\%$ by volume for gaseous preparations at least one substance posing health or environmental hazards, or one substance for which there are Community workplace exposure limits.

- (6) Directive 1999/45/EC also introduces a requirement for preparations to be classified and labelled for their effects on the environment.
- (7) It is therefore necessary to amend Directive 91/155/EEC accordingly, as specified in Article 14(2.3) of Directive 1999/45/EC, before 30 July 2002.
- (8) Article 4 of Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risk related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) ⁽⁶⁾ requires employers to determine whether any hazardous chemical agents are present at the workplace, and to assess any risk to the health and safety of workers arising from the presence of those chemical agents, taking into consideration the information provided by the supplier via safety data sheets; it is therefore opportune to amend the Annex to Directive 91/155/EEC accordingly.
- (9) It is known from recent enforcement activities and studies in the Member States that many safety data sheets are of poor quality and do not provide adequate information for the user; one way of improving the quality of safety data sheets is to improve the guidance given to compilers of safety data sheets set out in the Annex to Directive 91/155/EEC; it is therefore opportune to amend the Annex to Directive 91/155/EEC accordingly; the Commission and the Member States will consider other means by which the quality of safety data sheets can be improved further in future.
- (10) The measures provided for in 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 established under Article 20 of Directive 1999/45/EC,

⁽¹⁾ OJ L 200, 30.7.1999, p. 1.⁽²⁾ OJ 196, 16.8.1967, p. 1.⁽³⁾ OJ L 136, 8.6.2000, p. 90.⁽⁴⁾ OJ L 76, 22.3.1991, p. 35.⁽⁵⁾ OJ L 314, 16.12.1993, p. 38.⁽⁶⁾ OJ L 131, 5.5.1998, p. 11.

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 91/155/EEC is amended as follows:

1. Article 1(1) is replaced by the following:

1. (a) 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 Article 3 and the Annex to this Directive, if the substance or preparation is classified as dangerous according to Directive 67/548/EEC or European Parliament and Council Directive 1999/45/EC (*).
- (b) 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 Article 3 and the Annex to this Directive, if the preparation is not classified as dangerous according to Articles 5, 6 and 7 of Directive 1999/45/EC, but the preparation contains in an individual concentration of $\geq 1\%$ by weight for non-gaseous preparations and $\geq 0,2\%$ by volume for gaseous preparations at least one substance posing health or environmental hazards, or one substance for which there are Community workplace exposure limits.

(*) OJ L 200, 30.7.1999, p. 1.'

2. The Annex referred to in Article 3 is replaced by the Annex to this Directive.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 30 July 2002 at the latest. They shall forthwith inform the Commission thereof.

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

- (a) to preparations not within the scope of 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 30 July 2002;
- (b) and to preparations within the scope of Directive 91/414/EEC or Directive 98/8/EC as from 30 July 2004.

3. When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

Article 3

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Communities*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 27 July 2001.

For the Commission

Erkki LIIKANEN

Member of the Commission

⁽¹⁾ OJ L 230, 19.8.1991, p. 1.

⁽²⁾ OJ L 123, 24.4.1998, p. 1.

ANNEX

'ANNEX

GUIDE TO THE COMPILATION OF SAFETY DATA SHEETS

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 ⁽¹⁾ 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.

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 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⁾ OJ L 131, 5.5.1998, p. 11.

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 $\geq 1\%$ 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⁽¹⁾;

— 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 Eines 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, 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.

⁽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 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.

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⁽¹⁾ 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.

⁽¹⁾ OJ L 399, 30.12.1989, p. 18.

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

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.

*Boiling point/boiling range:**Flash point:**Flammability (solid, gas):**Explosive properties:**Oxidising properties:**Vapour pressure:**Relative density:**Solubility:*

— *water solubility:*

— *fat solubility (solvent - oil to be specified):*

*Partition coefficient: n-octanol/water:**Viscosity:**Vapour density:**Evaporation rate:*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 ⁽¹⁾), auto-ignition temperature etc.

⁽¹⁾ OJ L 100, 19.4.1994, p. 1.

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.

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 ⁽¹⁾, 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.

12.3. **Persistence and degradability**

The potential of the substance or the appropriate constituents of a preparation ⁽¹⁾ 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 ⁽¹⁾ to degrade in sewage treatment plants should also be mentioned.

12.4. **Bioaccumulative potential**

The potential of the substance or the appropriate constituents of a preparation ⁽¹⁾ to accumulate in biota and pass through the food chain, with reference to the K_{ow} 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.

⁽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 heading 2 of this Annex.

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 ⁽¹⁾), RID (rail, Council Directive 96/49/EC ⁽²⁾), 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 ⁽³⁾) 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.

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).'

⁽¹⁾ OJ L 319, 12.12.1994, p. 7.

⁽²⁾ OJ L 235, 17.9.1996, p. 25.

⁽³⁾ OJ L 262, 27.9.1976, p. 201.