

UN/SCEGHS/5/INF.6/Add1

**Sub-Committee of Experts on the Globally
Harmonized System of Classification
and Labelling of Chemicals**
(Fifth session, 7-9 July 2003,
agenda item 2)

First report of the inter-sessional Working Group on SDS

Draft Guidance document circulated by Australia on SDS

Comments by CEFIC

Comments by CEFIC on the draft Guidance document circulated by the Correspondence group on SDS and submitted to the fifth session of the SCE GHS under reference UN/SCEGHS/5/INF.6 are presented in the present document .

DRAFT GUIDANCE DOCUMENT ON THE PREPARATION OF SAFETY DATA SHEETS (SDS)

CEFIC SUGGESTIONS ARE INCLUDED IN THE TEXT AND HIGHLIGHTED

THE RATIONALE FOR THE SUGGESTED MODIFICATIONS ARE HIGHLIGHTED IN YELLOW

FOREWORD

1. The Globally Harmonized System of Classification and Labelling of Chemicals (GHS) is the culmination of more than a decade of work. There were many individuals involved, from a multitude of countries, international organizations, and stakeholder organizations. Their work spanned a wide range of expertise, from toxicology to fire protection, and ultimately required extensive goodwill and the willingness to compromise, in order to achieve this system.

2. The work began with the premise that existing systems should be harmonized in order to develop a single, globally harmonized system to address classification of chemicals, labels, and safety data sheets. This was not a totally novel concept since harmonization of classification and labelling was already largely in place for physical hazards and acute toxicity in the transport sector, based on the work of the United Nations Economic and Social Council's Committee of Experts on the Transport of Dangerous Goods (UNCEDTG). Harmonization had not been achieved in the workplace or consumer sectors, however, and transport requirements in countries were often not harmonized with those of other sectors in that country.

3. The international mandate that provided the impetus for completing this work was adopted in the 1992 United Nations Conference on Environment and Development (UNCED), as reflected in Agenda 21, para.19.27

"A globally harmonized hazard classification and compatible labelling system, including national safety data sheets and easily understandable symbols, should be available, if feasible, by the year 2000".

4. The work was coordinated and managed under the auspices of the Interorganization Programme for the Sound Management of Chemicals (IOMC) Coordinating Group for the Harmonization of Chemical Classification Systems (CG/HCCS). The technical focal points for completing the work were the International Labour Organization (ILO); the Organization for Economic Cooperation and Development (OECD); and the United Nations Economic and Social Council's Sub Committee of Experts on the Transport of Dangerous Goods (UNSCETDG).

5. Once completed in 2001, the work was transmitted by the IOMC to the new United Nations Economic and Social Council's Sub-Committee of Experts on the Globally Harmonized System of Classification (UNSCEGHS) established by the Council's resolution 1999/65 of 26 October 1999 as a subsidiary body of the former UNCETDG, renamed at the same occasion "Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals" (UNCETDG/GHS). The Committee and its sub-committees work on a biennium basis and the first task of the UNSCEGHS was to make the GHS available for worldwide use and application. The GHS document¹, elaborated from the original proposal by IOMC and approved by the Committee at its first session (11-13 December 2002) is intended to serve as the initial basis for global implementation of the GHS. Nevertheless, the system should be dynamic, and be revised and made more efficient as experience is gained in implementation.

6. The UNSCEGHS is responsible for maintaining the GHS and promoting its implementation. It will provide additional guidance as needs arise, while maintaining stability in the system to encourage its adoption. Under its auspices, the GHS document will be revised and updated to reflect national, regional and international experiences in implementing requirements into national, regional and international laws, as well as experiences of those doing the classification and labelling.

7. The UNSCEGHS, at its fourth session (9-11 December 2002), established a number of inter sessional correspondence working groups to develop guidance material on hazard communication. The correspondence working group on safety data sheets was established with Australia as lead country. The objective of the group was to give guidance and more information to help fill in the SDS forms, as detailed in this guidance document.

¹ United Nations, *Globally Harmonized System of Classification and Labelling of Chemicals*, New York and Geneva, 2003.

8. Bearing in mind that, in paragraph 22 (c) of its Plan of Action adopted in Johannesburg on 4 September 2002, the World Summit on Sustainable Development encouraged countries to implement the new GHS as soon as possible with a view to having the system fully operational by 2008, the Committee hopes that countries and international organizations concerned with chemical safety will adopt it in the near future. Availability of information about chemicals, their hazards, and ways to protect people, will provide the foundation for national programs for the safe management of chemicals. Widespread management of chemicals in countries around the world will lead to safer conditions for the global population and the environment, while allowing the benefits of chemical use to continue. Harmonization will also have benefits in terms of facilitating international trade, by promoting greater consistency in the national requirements for chemical hazard classification and communication that companies engaged in international trade must meet.

9. This publication has been prepared by the secretariat of the United Nations Economic Commission for Europe (UN/ECE) which provides secretariat services to the Economic and Social Council's Sub-Committee of Experts on the Classification and Labelling of Chemicals.

10. Additional information, including corrigenda to this publication, if any, may be found on the UN/ECE Transport Division web site: <http://www.unece.org/trans/danger/danger.htm>.

TABLE OF CONTENTS

	Page
PREFACE	vii
CHAPTER 1 TITLE, PURPOSE, SCOPE AND APPLICATION	1
CHAPTER 2 DEFINITIONS AND ABBREVIATIONS	3
CHAPTER 3 GENERAL GUIDANCE FOR COMPILING AN SDS	9
CHAPTER 4 PREPARATION OF THE SDS	13

PREFACE

1. The SDS provides comprehensive information about a chemical substance or mixture for use in workplace chemical control regulatory frameworks. Both employers and workers use it as a source of information about hazards, including environmental hazards, and to obtain advice on safety precautions. The information acts as a reference source for the management of hazardous chemicals in the workplace. The SDS is product related and, usually, is not able to provide specific information that is relevant for any given workplace where the product may finally be used, although where products have specialised end uses the SDS information may be more workplace-specific. The information therefore enables the employer (i) to develop an active programme of worker protection measures, including training, which is specific to the individual workplace and (ii) to consider any measures which may be necessary to protect the environment.
2. In addition, the SDS provides an important source of information for other target audiences in the GHS. So certain elements of information may be used by those involved with the transport of dangerous goods, emergency responders (including poison centres), those involved in the professional use of pesticides and consumers. However, these audiences receive additional information from a variety of other sources such as the UN Recommendations on the Transport of Dangerous Goods, Model Regulations document and package inserts for consumers and will continue to do so. The introduction of a harmonized labelling system therefore, is not intended to affect the primary use of the SDS which is for workplace users.
3. This document provides guidance on the preparation of an SDS under the Globally Harmonized System of the Classification and Labelling of Chemicals (GHS, [chapter 1-5](#)). Compliance with this guidance document will ensure the SDS is prepared in accordance with the recommended GHS format.
4. The adoption of this guidance document is dependant on importing countries requirements for GHS implementation. Timing of the implementation of this guidance document will depend on transitional arrangements put in place by individual countries. It is hoped that the application of the GHS worldwide will eventually lead to a fully harmonized situation.

CHAPTER 1

TITLE, PURPOSE, SCOPE AND APPLICATION

1.1 TITLE

1.1.1 This guidance document may be cited as the *Guidance Document on the Preparation of Safety Data Sheets (SDS)*.

1.2 PURPOSE

1.2.1 The purpose of this guidance document is to provide advice on the preparation of Safety Data Sheets (SDS) under the requirements of the GHS. The aim is to provide consistent health, physical and environmental advice to persons who could be exposed to hazardous chemicals.

1.3 SCOPE AND APPLICATION

1.3.1 An SDS should be produced for all substances and mixtures which meet the harmonized criteria for physical, health or environmental hazards under the GHS and for all mixtures which contain substances that meet the criteria for carcinogenic, toxic to reproduction or target organ systemic toxicity in concentrations exceeding the cut-off limits for SDS specified by the criteria for mixtures (See section 3.2). The competent authority may choose also to require SDSs for mixtures not meeting the criteria for classification as hazardous but which contain hazardous substances in certain concentrations (See section 3.2).

CHAPTER 2

DEFINITIONS AND ABBREVIATIONS

For the purposes of the GHS:

ADR means the European Agreement concerning the International Carriage of Dangerous Goods by Road, as amended;

Aerosols means any non-refillable receptacles made of metal, glass or plastics and containing a gas compressed, liquefied or dissolved under pressure, with or without a liquid, paste or powder, and fitted with a release device allowing the contents to be ejected as solid or liquid particles in suspension in a gas, as a foam, paste or powder or in a liquid state or in a gaseous state. Aerosol includes aerosol dispensers;

Alloy means a metallic material, homogeneous on a macroscopic scale, consisting of two or more elements so combined that they cannot be readily separated by mechanical means. Alloys are considered to be mixtures for the purpose of classification under the GHS;

ASTM means the "American Society of Testing and Materials";

BCF means "bioconcentration factor";

BOD/COD means "biochemical oxygen demand/chemical oxygen demand";

CA means "competent authority";

Carcinogen means a chemical substance or a mixture of chemical substances which induce cancer or increase its incidence;

CAS means "Chemical Abstract Service";

CBI means "confidential business information";

Chemical identity means a name that will uniquely identify a chemical. This can be a name that is in accordance with the nomenclature systems of the International Union of Pure and Applied Chemistry (IUPAC) or the Chemical Abstracts Service (CAS), or a technical name;

Competent authority means any national body(ies) or authority(ies) designated or otherwise recognized as such in connection with the Globally Harmonized System of Classification and Labelling of Chemicals (GHS);

Compressed gas means a gas which when packaged under pressure is entirely gaseous at -50 °C; including all gases with a critical temperature \leq -50 °C;

Contact sensitizer means a substance that will induce an allergic response following skin contact. The definition for "contact sensitizer" is equivalent to "skin sensitizer";

Corrosive to metal means a substance or a mixture which by chemical action will materially damage, or even destroy, metals;

Critical temperature means the temperature above which a pure gas cannot be liquefied, regardless of the degree of compression;

Dermal Corrosion: see *skin corrosion*;

Dermal irritation: see *skin irritation*;

Dissolved gas means a gas which when packaged under pressure is dissolved in a liquid phase solvent;

EC₅₀ means the effective concentration of substance that causes 50% of the maximum response;

EC Number or (ECN^o) is a reference number used by the European Communities to identify dangerous substances, in particular those registered under EINECS;

ECOSOC means the Economic and Social Council of the United Nations;

EINECS means "European Inventory of Existing Commercial Chemical Substances";

ErC₅₀ means EC₅₀ in terms of reduction of growth rate;

EU means the "European Union";

Explosive article means an article containing one or more explosive substances;

Explosive substance means a solid or liquid substance (or mixture of substances) which is in itself capable by chemical reaction of producing gas at such a temperature and pressure and at such a speed as to cause damage to the surroundings. Pyrotechnic substances are included even when they do not evolve gases;

Eye irritation means the production of changes in the eye following the application of test substance to the anterior surface of the eye, which are fully reversible within 21 days of application;

Flammable gas means a gas having a flammable range with air at 20 °C and a standard pressure of 101.3 kPa;

Flammable liquid means a liquid having a flash point of not more than 93 °C;

Flammable solid means a solid which is readily combustible, or may cause or contribute to fire through friction;

Flash point means the lowest temperature (corrected to a standard pressure of 101.3 kPa) at which the application of an ignition source causes the vapours of a liquid to ignite under specified test conditions;

FAO means the "Food and Agriculture Organization of the United Nations";

Gas means a substance which (i) at 50 °C has a vapour pressure greater than 300 kPa; or (ii) is completely gaseous at 20 °C at a standard pressure of 101.3 kPa;

GESAMP means the "Joint Group of Experts on the Scientific Aspects of Marine Environmental Protection of IMO/FAO/UNESCO/WMO/WHO/IAEA/UN/UNEP";

GHS means the "Globally Harmonized System of Classification and Labelling of Chemicals";

Hazard category means the division of criteria within each hazard class, e.g. oral acute toxicity includes five hazard categories and flammable liquids includes four hazard categories. These categories compare hazard severity within a hazard class and should not be taken as a comparison of hazard categories more generally;

Hazard class means the nature of the physical, health or environmental hazard, e.g. flammable solid, carcinogen, oral acute toxicity;

Hazard statement means a statement assigned to a hazard class and category that describes the nature of the hazards of a hazardous product, including, where appropriate, the degree of hazard;

IAEA means the "International Atomic Energy Agency";

IARC means the "International Agency for the Research on Cancer";

ILO means the "International Labour Organization";

IMO means the "International Maritime Organization";

Initial boiling point means the temperature of a liquid at which its vapour pressure is equal to the standard pressure (101.3 kPa), i.e. the first gas bubble appears;

IOMC means the "Inter-organization Programme on the Sound Management of Chemicals";

IPCS means the "International Programme on Chemical Safety";

ISO means the "International Standards Organization";

IUPAC means the "International Union of Pure and Applied Chemistry";

Label means an appropriate group of written, printed or graphic information elements concerning a hazardous product, selected as relevant to the target sector (s), that is affixed to, printed on, or attached to the immediate container of a hazardous product, or to the outside packaging of a hazardous product;

Label element means one type of information that has been harmonized for use in a label, e.g. pictogram, signal word;

LC₅₀ (50% lethal concentration) means the concentration of a chemical in air or of a chemical in water which causes the death of 50% (one half) of a group of test animals;

LD₅₀ means the amount of a chemical, given all at once, which causes the death of 50% (one half) of a group of test animals;

L(E)C₅₀ means LC₅₀ or EC₅₀;

Liquefied gas means a gas which when packaged under pressure, is partially liquid at temperatures above -50 °C. A distinction is made between:

(i) High pressure liquefied gas: a gas with a critical temperature between -50 °C and +65 °C; and

(ii) Low pressure liquefied gas: a gas with a critical temperature above +65 °C;

Liquid means a substance or mixture which at 50 °C has a vapour pressure of not more than 300 kPa (3 bar), which is not completely gaseous at 20 °C and at a standard pressure of 101.3 kPa, and which has a melting point or initial melting point of 20 °C or less at a standard pressure of 101.3 kPa. A viscous substance or mixture for which a specific melting point cannot be determined shall be subjected to the ASTM D 4359-90 test; or to the test for determining fluidity (penetrometer test) prescribed in section 2.3.4 of Annex A of the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR);

MARPOL means the "International Convention for the Prevention of Pollution from Ships";

Mixture means a mixture or a solution composed of two or more substances in which they do not react;

Mutagen means an agent giving rise to an increased occurrence of mutations in populations of cells and /or organisms;

Mutation means a permanent change in the amount or structure of the genetic material in a cell;

NGO means "non-governmental organization";

NOEC means the "no observed effect concentration";

OECD means the "Organization for Economic Cooperation and Development";

Organic peroxide means a liquid or solid organic substance which contains the bivalent -O-O- structure and may be considered a derivative of hydrogen peroxide, where one or both of the hydrogen atoms have been replaced by organic radicals. The term also includes organic peroxide formulations (mixtures);

Oxidizing gas means any gas which may, generally by providing oxygen, cause or contribute to the combustion of other material more than air does;

Oxidizing liquid means a liquid which, while in itself not necessarily combustible, may, generally by yielding oxygen, cause, or contribute to, the combustion of other material;

Oxidizing solid means a solid which, while in itself not necessarily combustible, may, generally by yielding oxygen, cause, or contribute to, the combustion of other material;

QSAR means "quantitative structure-activity relationships";

Pictogram means a graphical composition that may include a symbol plus other graphic elements, such as a border, background pattern or colour that is intended to convey specific information;

Precautionary statement means a phrase (and/or pictogram) that describes recommended measures that should be taken to minimize or prevent adverse effects resulting from exposure to a hazardous product, or improper storage or handling of a hazardous product;

Product identifier means the name or number used for a hazardous product on a label or in the SDS. It provides a unique means by which the product user can identify the substance or mixture within the particular use setting e.g. transport, consumer or workplace;

Pyrophoric liquid means a liquid which, even in small quantities, is liable of igniting within five minutes after coming into contact with air;

Pyrophoric solid means a solid which, even in small quantities, is liable of igniting within five minutes after coming into contact with air;

Pyrotechnic article means an article containing one or more pyrotechnic substances;

Pyrotechnic substance means a substance or mixture of substances designed to produce an effect by heat, light, sound, gas or smoke or a combination of these as the result of non-detonative self-sustaining exothermic chemical reactions;

Readily combustible solid means powdered, granular, or pasty substance or mixture which is dangerous if it can be easily ignited by brief contact with an ignition source, such as a burning match, and if the flame spreads rapidly;

Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria means the latest revised edition of the United Nations publication bearing this title, and any published amendment thereto;

Recommendations on the Transport of Dangerous Goods, Model Regulations means the latest revised edition of the United Nations publication bearing this title, and any published amendment thereto;

Refrigerated liquefied gas means a gas which when packaged is made partially liquid because of its low temperature;

Respiratory sensitizer means a substance that induces hypersensitivity of the airways following inhalation of the substance;

RID means The Regulations concerning the International Carriage of Dangerous Goods by Rail [Annex 1 to Appendix B (Uniform Rules concerning the Contract for International Carriage of Goods by Rail) (CIM) of COTIF (Convention concerning international carriage by rail)], as amended;

SAR means "Structure Activity Relationship";

SDS means "Safety Data Sheet";

Self-Accelerating Decomposition Temperature (SADT) means the lowest temperature at which self-accelerating decomposition may occur with substance as packaged;

Self-heating substance means a solid or liquid substance, other than a pyrophoric substance, which, by reaction with air and without energy supply, is liable to self-heat; this substance differs from a Pyrophoric substance in that it will ignite only when in large amounts (kilograms) and after long periods of time (hours or days);

Self-reactive substance means a thermally unstable liquid or solid substance liable to undergo a strongly exothermic decomposition even without participation of oxygen (air). This definition excludes substances or mixtures classified under the GHS as explosive, organic peroxides or as oxidizing;

Serious eye damage means the production of tissue damage in the eye, or serious physical decay of vision, following application of a test substance to the anterior surface of the eye, which is not fully reversible within 21 days of application;

Signal word means a word used to indicate the relative level of severity of hazard and alert the reader to a potential hazard on the label. The GHS uses 'Danger' and 'Warning' as signal words;

Skin corrosion means the production of irreversible damage to the skin following the application of a test substance for up to 4 hours;

Skin irritation means the production of reversible damage to the skin following the application of a test substance for up to 4 hours;

Skin sensitizer means a substance that will induce an allergic response following skin contact. The definition for "skin sensitizer" is equivalent to "contact sensitizer";

Solid means a substance or mixture which does not meet the definitions of liquid or gas;

SPR means "Structure Property Relationship";

Substance means chemical elements and their compounds in the natural state or obtained by any production process, including any additive necessary to preserve the stability of the product and any impurities deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;

Substance which, in contact with water, emits flammable gases means a solid or liquid substance or mixture which, by interaction with water, is liable to become spontaneously flammable or to give off flammable gases in dangerous quantities;

Supplemental label element means any additional non-harmonized type of information supplied on the container of a hazardous product that is not required or specified under the GHS. In some cases this information may be required by other competent authorities or it may be additional information provided at the discretion of the manufacturer/distributor;

Symbol means a graphical element intended to succinctly convey information;

Technical name means a name that is generally used in commerce, regulations and codes to identify a substance or mixture, other than the IUPAC or CAS name, and that is recognized by the scientific community. Examples of technical names include those used for complex mixtures (e.g., petroleum fractions or natural products), pesticides (e.g., ISO or ANSI systems), dyestuffs (Colour Index system) and minerals;

UNCED means the "United Nations Conference on Environment and Development";

UNCETDG/GHS means the "United Nations Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals";

UN means the "United Nations";

UNEP means the "United Nations Environment Programme";

UNESCO means the "United Nations Educational, Scientific and Cultural Organization";

UNITAR means the "United Nations Institute for Training and Research";

UNSCEGHS means the "United Nations Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals";

UNSCETDG means the "United Nations Sub-Committee of Experts on the Transport of Dangerous Goods";

WHO means the "World Health Organization";

WMO means the "World Meteorological Organization".

CHAPTER 3

GENERAL GUIDANCE FOR COMPILING AN SDS

3.1 GENERAL GUIDANCE

3.1.1 The writer of the SDS needs to keep in mind that a Safety Data Sheet (SDS) must inform its audience of the possible hazards of a substance, and provide information on the safe storage, handling and disposal of the substance. An SDS contains information on the potential health effects of exposure and how to work safely with the substance or mixture. It also contains hazard information on the use, storage, handling and emergency procedures related to that substance or mixture.

3.1.2 When writing the SDS, information should be presented in a consistent and complete form, with the workplace audience firmly in mind. However, it should be considered that all or part of the SDS can be used to inform workers, employers, health and safety professionals, emergency personnel, relevant government agencies, as well as members of the community.

3.1.3 Language used in the SDS should be simple, clear and precise, avoiding jargon, acronyms and abbreviations. Vague and misleading expressions should not be used. Phrases such as 'may be dangerous', 'no health effects', 'safe under most conditions of use', or 'harmless' are also unacceptable. It may be that information on certain properties is of no significance or that it is technically impossible to provide; if so the reasons for this must be clearly stated under each heading. If it is stated that a particular hazard does not exist the safety data sheet should clearly differentiate between cases where no information is available to the classifier, and cases where negative test results are available.

3.1.4 The date of issue of the safety data sheet should be stated and be very apparent.

3.2 CUT-OFF VALUES/CONCENTRATION LIMITS

3.2.1 An SDS should be provided based on the generic cut-off values/concentration limits indicated in Table 1.

Table 1: Cut-off/values concentration limits

Hazard Class	Cut-off value/Concentration Limit
Acute Toxicity	≥ 1.0%
Skin Corrosion/Irritation	≥ 1.0%
Serious damage to eyes/eye irritation	≥ 1.0%
Respiratory/Skin Sensitization	≥ 1.0%
Mutagenicity: Category 1	≥ 0.1%
Mutagenicity: Category 2	≥ 1.0%
Carcinogenicity	≥ 0.1%
Reproductive Toxicity	≥ 0.1%

Target Organ Systemic Toxicity (Single Exposure)	≥ 1.0%
Target Organ Systemic Toxicity (Repeat Exposure)	≥ 1.0%
Hazardous to the Aquatic Environment	≥ 1.0%

3.2.2 As noted in the Classification of Hazardous Substances and Mixtures (See 1.3.3.2 of the GHS document), there may be some cases when the available hazard data may justify classification on the basis of other cut-off values/concentration limits than the generic ones specified in the health and environment hazard class chapters (See Chapters 3.2 to 3.10 of the GHS document). When such specific cut-off values are used for classification, they should also apply to the obligation to compile an SDS.

3.2.3 Some competent authorities (CA) may require SDSs to be compiled for mixtures which are not classified for acute toxicity or aquatic toxicity as a result of application of the additivity formula, but which contain acutely toxic substances or substances toxic to the aquatic environment in concentrations equal to or greater than 1 %².

3.2.4 In accordance with the building block principle, some competent authorities may choose not to regulate certain categories within a hazard class. In such situations, there would be no obligation to compile an SDS.

3.2.5 Once it is clear that an SDS is required for a substance or a mixture then the information required to be included in the SDS should in all cases be provided in accordance with GHS requirements.

3.3 SDS FORMAT

3.3.1 The information in the SDS should be presented using the following 16 headings in the order given below.

1. Identification of the substance/mixture and of the company/undertaking
2. Hazard(s) identification
3. Composition/information on ingredients
4. First-aid measures
5. Fire-fighting measures
6. Accidental release measures
7. Handling and storage
8. Exposure controls/personal protection
9. Physical and chemical properties
10. Stability and reactivity

² The cut-off values for classification of mixtures are normally specified by concentrations expressed as % of the component substance. In some cases, for example acute toxicity (human health), the cut-off values are expressed as acute toxicity values (ATE). The classification of a mixture is determined by additivity calculation based on acute toxicity values (see Chapter 3.1 of the GHS document) and concentrations of component substances. Similarly acute aquatic toxicity classification may be calculated on the basis of acute aquatic toxicity values (See Chapter 3.10 of the GHS document) and where appropriate, corrosion/irritation by adding up concentrations of individual substances (See Chapters 3.2 and 3.3 of the GHS document). Component substances are taken into consideration for application of the formula when the concentration is equal to or greater than 1 %. Some competent authorities (CA) may use this cut-off as a basis of obligation to compile an SDS.

11. Toxicological information
12. Ecological information
13. Disposal considerations
14. Transport information
15. Regulatory information
16. Other information.

3.3.2 An SDS is not a fixed length document. The length of the SDS should be commensurate with the hazard of the material and the information available.

3.3.3 All pages of a printed SDS should be numbered and the total number of pages also given on each page. For example, 'page 1 of 3', 'page 2 of 3', 'page 3 of 3'. An acceptable alternative is to number each page and to indicate on each page whether there is a page following.

3.3.4 There should be some indication of the end of the SDS, such as the words 'End of SDS'.
Not necessary, 3.3.3 is sufficient

3.4 SDS CONTENT

3.4.1 The SDS should provide a clear description of the data used to identify the hazards. The minimum information outlined in Chapter 4 should be included, where applicable and available, on the SDS under the relevant headings³. If specific information is not applicable or not available under a particular subheading, the SDS should clearly state this. Additional information may be required by competent authorities.

3.4.2 Care should be taken when using Abbreviations such as 'N/A' or 'N/R' should not be used, as their usage could lead to confusion. For example, 'N/A' may mean either 'not available' or 'not applicable'. In general, where abbreviations are used, a legend explaining the abbreviations should be included.

This is language dependent, and may be true in English, but not in other languages

3.4.3 Some subheadings relate to information that is national or regional in nature, for example "EC number" and "occupational exposure limits". Suppliers or employers should include information under such SDS subheadings that is appropriate and relevant to the countries or regions for which the SDS is intended and into which the product is being supplied.

3.4.4 This guideline is based on In addition to the guidance on preparation of an SDS developed by the UNSCEGHS, there are a number of internationally recognised standards. These including the ILO Standard under the Recommendation 177 on Safety in the Use of Chemicals at Work, the International Standard 11014 of the International Standard Organization (ISO), the European Union Safety Data Sheet Directive 91/155/EEC as amended by 2001/58/EC and the American National Standard Institute (ANSI) standard Z 400.1.

3.5 INFORMATION REQUIREMENTS

3.5.1 There are information requirements for the preparation of an SDS. The minimum information requirements are outlined in Chapter 4 of this document.

³ Where "applicable" means where the information is applicable to the specific product covered by the SDS. Where "available" means where the information is available to the supplier or other entity that is preparing the SDS.

3.5.2 The SDS may also contain additional information. Where a material has additional relevant and available information about its nature and/or use, that information should be included.

3.6 UNITS

3.6.1 Numbers and quantities should be expressed in units appropriate to International Standards. In general, the International System of Units (SI) should be used, where applicable.

CHAPTER 4

PREPARATION OF THE SDS

General comment : it seems that the guidance has been devised with substances in mind ; a number of provisions are not applicable to mixtures

4.1 SECTION 1 - IDENTIFICATION OF THE SUBSTANCE OR MIXTURE AND OF THE SUPPLIER

Identify the product and provide the name of the supplier, recommended uses and the contact detail information of the supplier including an emergency contact in this section.

4.1.1 Minimum information requirements the word “minimum” is misleading and should be deleted in all the sections

- GHS product identifier.
- Other means of identification.
- Recommended use of the chemical and restrictions on use.
- Supplier’s details (including name, address, phone number etc).
- Emergency phone number.

4.1.2 GHS product identifier

4.1.2.1 The GHS product identifier of the substance or mixture should be exactly as found on the label. If one generic SDS is used to cover several grades or minor variants of a substance or mixture, all grades or names should be listed on the SDS or the SDS should clearly delineate the range of substances included.

4.1.3 Other means of identification

4.1.3.1 The substance or mixture may also be identified by alternative names, numbers, company product codes, or other unique identifiers. Provide other names or synonyms by which the substance or mixture is labelled or commonly known, if applicable. For substances or mixtures that present a physical hazard, the UN Proper Shipping Name, as identified in the UN *Recommendations on the Transport of Dangerous Goods*⁴, should be provided in this subsection if it has not appeared as the GHS product identifier.

4.1.4 Recommended use of the chemical and restrictions on use

⁴ United Nations, *Recommendations on the Transport of Dangerous Good: Model Regulations* (as revised), New York and Geneva.

4.1.4.1 Provide the recommended or intended use of the substance or mixture as far as they are known, including a brief description of what it actually does, e.g. flame retardant, anti-oxidant, etc. and indicate any restrictions on use. Restrictions on use should, as far as possible, be stated including non-statutory recommendations by the supplier.

4.1.5 Supplier's details (including name, address, phone number etc)

4.1.5.1 Provide the name, address and phone number of the supplier, including emergency phone number. Companies should include references to emergency information services on their SDS.

Emergency Phone Number

Indicate if the telephone numbers have any restrictions, such as hours of operation (e.g. Monday - Friday, 8:00 a.m. - 6:00 p.m., or 24 hours) or are limited to a specific type of information (e.g. general information, medical emergencies, transportation emergencies).

4.2 SECTION 2 - HAZARDS IDENTIFICATION

Describe the hazards of the substance or mixture and the appropriate warning information (signal word, hazard statement(s) and precautionary statement(s)) associated with those hazards in this section.

4.2.1 Minimum information requirements

- GHS classification of the substance/mixture and any national or regional information.
- GHS label elements, including precautionary statements. (Hazard symbols may be provided as a graphical reproduction of the symbols in black and white or the name of the symbol e.g. flame, skull and crossbones.)
- Other hazards which do not result in classification (e.g. dust explosion hazard) or are not covered by the GHS.

4.2.2 GHS Classification of the substance or mixture

4.2.2.1 This section indicates the hazardous classification of the substance/mixture.

4.2.2.2 If the substance or mixture is classified in accordance with Parts 2 and/or 3 of the GHS document, provide the appropriate hazard class and category to indicate the hazard. For example, Flammable Liquid Category 1.

4.2.3 GHS label elements, including precautionary statements

4.2.3.1 Based on the classification provide the appropriate signal word, hazard statement and precautionary statement.

4.2.3.2 Hazard symbols may be provided as a graphical reproduction of the symbols in black and white or the name of the symbol e.g. flame, skull and crossbones.

4.2.4 Other hazards which do not result in classification or are not covered by the GHS

4.2.4.1 Provide information on other hazards which do not result in classification or are not covered by the GHS, for example, dust explosion hazards.

Non-Hazardous substances/mixtures

An SDS is a well-accepted and effective method for the provision of workplace information, and may be used to convey information for substances that do not meet the GHS classification criteria.

4.3 SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

Identify the ingredient(s) of the product in this section.

NOTE: For information on ingredients, the competent authority rules for CBI take priority over the rules for product identification.

4.3.1 ~~Minimum~~ information requirements

4.3.1.1 Substance

- Chemical identity.
- Common name, synonyms.
- CAS number, EC number.
- Impurities and stabilizing additives which are themselves classified and which contribute to the classification of the substance.

4.3.1.2 Mixture

- The chemical identity and concentration or concentration ranges of all ingredients which are hazardous within the meaning of the GHS and are present above their cut-off levels.

NOTE: For information on ingredients, the competent authority rules for CBI take priority over the rules for product identification. Moved to the top of 4.3 under identify ...

4.3.2 Chemical identity of the substance

4.3.2.1 The identity of a substance is provided by its common chemical name. The chemical name can be identical to the GHS product identifier.

4.3.3 Common name(s), synonym(s) of the substance

4.3.3.1 Common names and synonyms should be provided where appropriate. Synonyms can include recognised abbreviations, for example, 'TDI' for toluene diisocyanate.

4.3.4 CAS number, EC number for the substance

4.3.4.1 The Chemical Abstract Service (CAS) Registry Number should be provided where available. Chemical Abstract Service Registry Numbers provide a unique identification. The European Communities (EC) Number should also be provided where available.

4.3.5 Impurities and stabilizing additives which are themselves classified and which contribute to the classification of the substance

4.3.5.1 Identify any impurities and/or stabilizing additives which are themselves classified and which contribute to the classification of the substance.

4.3.6 For a mixture, the chemical identity and concentration or concentration ranges of all ingredients which are hazardous within the meaning of the GHS and are present above their cut-off levels

4.3.6.1 Provide the chemical identity and concentration or concentration ranges of all ingredients which are hazardous within the meaning of the GHS and are present above their cut-off levels.

4.3.6.2 For concentration ranges the mixture should have the proportion of ingredients described as:

- (a) exact percentages in descending order by mass or volume; or
- (b) ranges of percentages in descending order by mass or volume.

4.3.6.3 **Indicative** Ranges to be used are:

- (a) $\geq 60\%$
- (b) $\geq 30\%$ and $< 60\%$
- (c) $\geq 10\%$ and $< 30\%$
- (d) $< 10\%$.

4.3.6.4 When using a proportion range, the health **and environmental** hazard effects should describe the upper limit of the range.

4.4 SECTION 4 - FIRST AID MEASURES

Describe the initial care that can be given without the use of sophisticated equipment and without a wide selection of medications available. If medical attention is required, the instructions should state this, including its urgency.

4.4.1 **Minimum information requirements**

- Description of necessary measures, subdivided according to the **relevant different** routes of exposure, i.e. inhalation, skin and eye contact and ingestion, **under different subheadings**.
- Most important symptoms/effects, acute and delayed. **application to mixtures ?**
- Indication of immediate medical attention and special treatment needed, if necessary.

4.4.2 Description of necessary first aid measures

4.4.2.1 Provide first aid instructions by relevant routes of exposure. Use subheadings to indicate the procedure for each route (e.g. inhalation, skin, eye, and ingestion). Describe expected immediate and delayed symptoms.

4.4.2.2 Provide advice, including if:

- (a) immediate medical attention is required and if delayed effects can be expected after exposure;
- (b) movement of exposed individual from area to fresh air is recommended;
- (c) advice on removal and handling of clothing and shoes from individual is recommended;
- (d) any known antidotes may be administered by persons trained in their use as part of the recommended first aid procedure; and
- (e) any information on specific first aid facilities, such as showers or eyewashes, are necessary in a workplace where the particular material is used.

4.4.3 Most important symptoms/effects, acute and delayed.

4.4.3.1 Provide information on the most important symptoms/effects, acute and delayed, from exposure.

4.4.4 Indication of immediate medical attention and special treatment needed, if necessary.

4.4.4.1 As appropriate and legally accepted, provide information on any medical and special treatments. For example, clinical testing and medical monitoring for delayed effects, specific procedures, details on emesis or lavage, antidotes, contraindications. Specific antidotes should be indicated where they are available. Describe the most important symptoms caused by exposure, whether acute or delayed.

4.5 SECTION 5 - FIRE FIGHTING MEASURES

Refer to requirements for fighting a fire caused by the substance or mixture, or arising in its vicinity. Describe the fire and explosive properties of the substance or mixture and provide advice on how to deal with incidents in this section.

4.5.1 ~~Minimum~~ information requirements

- Suitable (and unsuitable) extinguishing media.
- Specific hazards arising from the chemical (e.g. nature of any unusual hazardous combustion products).
- Special protective equipment and precautions for firefighters.

4.5.2 Suitable (and unsuitable) extinguishing media

4.5.2.1 Provide information on the appropriate type of extinguishers or fire fighting agents. In addition, indicate whether any extinguishers are inappropriate for a particular situation involving the material.

4.5.3 Specific hazards arising from the chemical

4.5.3.1 Provide advice on whether specific hazards may arise from the chemical such as when hazardous combustion products occur when the substance burns. For example:

- (a) 'may produce toxic fumes of carbon monoxide if burning'; or
- (b) 'produces oxides of sulfur and nitrogen on combustion'.

4.5.4 Special protective equipment and precautions for firefighters

4.5.4.1 Provide advice on any precaution to be observed in fighting fire. For example, 'keep containers cool with water spray'.

4.5.4.2 Provide information on protective clothing to be worn by fire fighters. For example, boots, overalls, gloves, equipment and breathing apparatus.

4.6 SECTION 6 - ACCIDENTAL RELEASE MEASURES

Recommend the appropriate response to spills, leaks, or releases in order to prevent or minimise the adverse effects on persons, property and the environment in this section.

4.6.1 ~~Minimum~~ information requirements

- Personal precautions, protective equipment and emergency procedures.
- Environmental precautions.
- Methods and materials for containment and cleaning up.

4.6.2 Personal precautions, protective equipment and emergency procedures

4.6.2.1 Provide advice on any personal precautions, protective equipment and emergency procedures related to accidental spills and release of the substance or mixture.

Personal Protective Equipment

If Personal Protective Equipment (PPE) is required for containment/clean up - refer readers to section 8 of the SDS.

4.6.3 Environmental precautions

4.6.3.1 Provide advice on any environmental precautions related to accidental spills and release of the substance or mixture.

4.6.4 Methods and materials for containment and cleaning up

4.6.4.1 Provide appropriate advice on how to contain and clean up a spill. Appropriate containment techniques may include:

- (a) bunding, covering of drains; and
- (b) capping procedures.

4.6.4.2 Appropriate clean up procedures may include:

- (a) neutralisation techniques;
- (b) decontamination techniques;
- (c) adsorbent materials;
- (d) cleaning techniques;
- (e) vacuuming techniques; and
- (f) equipment required for containment/clean up (include the use of non-sparking tools and equipment).

4.6.4.3 Provide any other issues relating to spills and releases. For example, including advice on inappropriate containment or clean up techniques.

Spill Volumes

In 4.6.4, distinguish between responses for large and small spills where spill volume impacts significantly on the hazard; the procedures for containment and recovery may indicate different practices are required.

4.7 SECTION 7 - HANDLING AND STORAGE

Provide guidance on safe handling practices that minimise the potential hazards to people, property and the environment from the substance. Emphasise precautions that are appropriate to the unique properties of the substance, rather than reviewing general storage and handling practices.

4.7.1 Minimum information requirements

- Precautions for safe handling.
- Conditions for safe storage, including any incompatibilities.

4.7.2 Precautions for safe handling

4.7.2.1 Provide advice that:

- (a) minimises contact between the worker and the substance;
- (b) prevents handling of incompatible substances; and
- (c) minimises the release of the substance to the environment.

4.7.2.2 Include general warnings on what practices to avoid or restrict.

Provision of General Hygiene Advice

It is good practice to provide advice on general hygiene. For example:

- prohibiting eating, drinking and smoking in contaminated areas;
- wash hands before eating; and
- remove contaminated clothing and protective equipment before entering eating areas.

4.7.3 Conditions for safe storage, including any incompatibilities

4.7.3.1 Provide advice on specific storage requirements including:

(a) How to avoid:

- i. explosive atmospheres;
- ii. corrosive conditions;
- iii. flammability hazards;
- iv. incompatible substances;
- v. evaporative conditions; and
- vi. potential ignition sources (including electrical equipment).

(b) How to control the effects of:

- i. weather conditions;
- ii. ambient pressure;
- iii. temperature;
- iv. sunlight;

- v. humidity; and
- vi. vibration.

(c) How to maintain the integrity of the substance by the use of:

- i. stabilizers;
- ii. anti-oxidants; and
- iii. phlegmatisers.

(d) Other advice including:

- i. ventilation requirements; and
- ii. packaging compatibilities.

Consistent Advice

Ensure that the advice provided is consistent with the physical and chemical properties in Section 9.

4.8 SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

Detail engineering control measures needed to minimise exposure to and risks associated with the hazards of the substance in this section.

4.8.1 **Minimum information requirements**

- Control parameters e.g. occupational exposure limit values or biological limit values.
- Appropriate engineering controls.
- Individual protection measures, such as personal protective equipment.

4.8.2 **Control parameters**

4.8.2.1 Where available, list the occupational exposure limits, including notations, for a substance and for each of the ingredients of a mixture. Where possible, the occupational exposure limit should be relevant to the countries or regions in which the SDS is being supplied. The source of the occupational exposure limit should be stated on the SDS. When listing occupational exposure limits, use the chemical identity as specified in Section 3 of the SDS. **If there is no occupational exposure limit allocated, then the SDS should state that there is 'no occupational exposure limit allocated'.**

4.8.2.2 Where available, list the biological limit values, including notations, for a substance and for each of the ingredients of a mixture. Where possible, the biological limit value should be relevant to the countries or regions in which the SDS is being supplied. The source of the biological limit value should be stated on the SDS. When listing biological limit values, use the chemical identity as specified in section 3 of the SDS. **If there is no biological limit value allocated, then the SDS should state that there is 'no biological limit value allocated'.**

4.8.4 **Appropriate engineering controls.**

4.8.4.1 The description of appropriate exposure control measures should relate to the intended modes of use of the substance. Indicate whether special engineering controls are necessary, and specify which type. For example:

- (a) 'use only in a well ventilated area';
- (b) 'maintain air concentrations below exposure standards';
- (c) 'use local exhaust ventilation';
- (d) 'use only in an enclosed system';
- (e) 'use only in spray paint booth or enclosure';
- (f) 'use mechanical handling to reduce human contact with materials'; or
- (g) 'use explosive dust handling controls'.

4.8.5 Individual protection measures, such as personal protective equipment (PPE).

4.8.5.1 Identify the personal protective equipment (PPE) needed to minimise the potential for illness or injury due to exposure from the substance.

4.8.5.2 Eye/face protection - specify the type of eye protection (safety glasses, goggles) and/or face shield required, based on the hazard of the substance and potential for contact.

4.8.5.3 Skin protection - specify the protective equipment to be worn (e.g. gloves, boots, bodysuit) based on the hazards associated with the substance and the potential for contact.

4.8.5.4 Respiratory protection – specify appropriate types of respiratory protection based on the exposure, including air-purifying respirators and the proper purifying element (cartridge or canister).

4.8.5.5 Thermal hazards - when specifying protective equipment to be worn for materials that represent a thermal hazard, special consideration should be given to the construction of the PPE.

Special Requirements for PPE

See also Section 5 of the SDS for specific fire/chemical PPE advice.

Special requirements may exist for gloves or other protective clothing to prevent skin, eye or lung exposure. Where relevant, this type of PPE should be clearly stated. For example, 'PVC gloves' or 'nitrile rubber gloves'.

Special requirements may exist for respirators. Vague information such as 'use face mask' is not acceptable whereas 'use half-face filter respirator suitable for organic vapours' would be acceptable.

4.9 SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Describe the empirical data of the substance in this section.

In the case of a mixture, the entries should clearly indicate to which ingredient the data applies, unless it is valid for the whole mixture

4.9.1 Minimum information requirements

4.9.1.1 Clearly identify the following properties and note if specific characteristics do not apply, are not available or are irrelevant.

Provision of Physical/Chemical Information

The data included in this subsection should apply to the substance or mixture as used at work. If the product is a mixture, the physical data should describe the mixture or formulation. If that information is not available the physical/chemical properties of the ingredients should be provided.

4.9.1.2 Specify appropriate units of measure and/or reference conditions where appropriate.

- Appearance (physical state, colour etc).
- Odour if relevant.
- Odour threshold.
- pH.
- Melting point/freezing point.
- Initial boiling point and boiling range.
- Flash point.
- Evaporation rate.
- Flammability (solid, gas).
- Upper/lower flammability or explosive limits.
- Vapour pressure.
- Vapour density.
- Relative density.
- Solubility(ies).
- Partition coefficient: n-octanol/water.
- Auto-ignition temperature.
- Decomposition temperature.

4.10 SECTION 10 - STABILITY AND REACTIVITY

Describe reactivity hazards of the substance in this section. Provide specific test data for the product as a whole, where available. However, the information may also be based on general data for the class or family of chemical if such data adequately represents the anticipated hazard of the substance.

4.10.1 ~~Minimum~~ information requirements

- Chemical stability.
- Possibility of hazardous reactions.
- Conditions to avoid (e.g. static discharge, shock or vibration).
- Incompatible materials.
- Hazardous decomposition products.

4.10.2 Chemical stability

4.10.2.1 Indicate if the substance is stable or dangerously unstable under normal ambient and anticipated storage and handling conditions of temperature and pressure.

4.10.3 Possibility of hazardous reactions

4.10.3.1 If relevant, state if the substance will react or polymerize, releasing excess pressure or heat, or creating other hazardous conditions. Describe under what conditions the hazardous reactions may occur.

4.10.4 Conditions to avoid

4.10.4.1 List conditions such as heat, pressure, shock, static discharge, vibrations or other physical stresses that might result in a hazardous situation.

4.10.5 Incompatible materials

4.10.5.1 List classes of chemicals or specific substances with which the substance could react to produce a hazardous situation (e.g. explosion, release of toxic or flammable materials, liberation of excessive heat).

Availability of Data

If data for mixtures are not available, ingredient data should be provided. In determining incompatibility, consider the substances, containers, and contaminants that the substance might be exposed to during transportation, storage and use.

4.10.6 Hazardous decomposition products

4.10.6.1 List known and reasonably anticipated hazardous substances produced as a result of oxidation, heating, or reaction with another substance, including the production of flammable and toxic materials. **What are the cut-offs ?**

4.11 SECTION 11 - TOXICOLOGICAL INFORMATION

Describe, in lay language, the potential adverse health effects and symptoms associated with exposure to the product and its ingredients or known by-products.

While this section is used primarily by medical professionals, occupational health and safety professionals and toxicologists, the language used in this section should be understandable **to anyone in the workplace.**

4.11.1 **Minimum** information requirements

Concise but complete and comprehensible description of the various toxicological (health) effects and the available data used to identify those effects, including:

- information on the likely routes of exposure (inhalation, ingestion, skin and eye contact);
- Symptoms related to the physical, chemical and toxicological characteristics;
- Delayed and immediate effects and also chronic effects from short- and long-term exposure;
- Numerical measures of toxicity (such as acute toxicity estimates).

The health effects included in the SDS should be consistent with those described in the studies used for the classification of the substance.

This is hardly applicable to mixtures. As this section is presently drafted, the information mentioned will either be not available or not meaningful for mixtures.

4.11.2 Information on the likely routes of exposure

4.11.2.1 Provide information on the likely routes of exposure and the effects of the substance via each possible route of exposure, that is, through ingestion (swallowing), inhalation or skin/eye exposure. A statement should be made if these health effects are not known.

4.11.3 Symptoms related to the physical, chemical and toxicological characteristics

4.11.3.1 Provide information on the symptoms related to the physical, chemical, and toxicological characteristics of the substance following exposure **related to the intended uses**. These should range from the first symptoms at the lowest exposures to the consequences of severe exposure; for example, 'headaches and dizziness may occur, proceeding to fainting or unconsciousness; large doses may result in coma and death'.

4.11.4 Delayed and immediate effects and also chronic effects from short and long term exposure

4.11.4.1 Provide information on whether delayed or immediate effects can be expected after short or long term exposure. Also provide information on acute and chronic health effects relating to human exposure to the substance. Where human data are not available, animal data should be summarised and the species clearly identified.

4.11.5 Numerical measures of toxicity (such as acute toxicity estimates).

4.11.5.1 Provide information on the dose, concentration or conditions of exposure likely to cause injury. Where possible, doses should be linked to symptoms and effects and include the period of exposure likely to cause harm. For example, '10 ppm respiratory irritation, 250-300 ppm difficulty in breathing, 500 ppm unconsciousness leading to death after 30 minutes'.

4.11.5.2 Also provide information on the relevant negative data. For example, the statement 'carcinogenicity studies in the rat have shown no significant increase in the incidence of cancer'.

4.11.6 Further Guidance on Completing Section 11

4.11.6.1 General Versus Specific Statements

4.11.6.1.1 General statements such as 'toxic' with no supporting data or 'safe if properly used' are not acceptable as they may be misleading and do not provide a description of health effects. Phrases such as 'not applicable', 'not relevant', or leaving blank spaces in the health effects section can lead to confusion and misunderstanding and should not be used. For health effects where information is not available, this should be clearly stated. Health effects should be described accurately and relevant distinctions made. For example, allergic contact dermatitis and irritant contact dermatitis should be distinguished from each other.

4.11.6.2 Where Specific Chemical Data are not Available

4.11.6.2.1 It may not always be possible to obtain information on the hazards of a substance as many have never been fully tested. In cases where data on the specific substance are not available, data on the chemical class, if appropriate, may be used. Where generic data are used or where data are not available, this should be stated clearly on the SDS.

4.11.6.3 Mixture VS Ingredient Information

4.11.6.3.1 Most frequently the material requiring an SDS is a mixture. If the mixture has not been tested for its health effects as a whole then information on ingredients should be provided. After collecting data on health effects and dose-response for each ingredient, an estimation of the combined health effects needs to be made. When using ingredient data to estimate the health effects of a mixture the following should be taken into account:

- (a) the concentrations of the ingredients, including airborne concentrations;
- (b) the relevant hazard of the material; and
- (c) any potential interactions in the body between the ingredients.

4.11.6.3.2 Ingredients may interact with each other in the body resulting in different rates of absorption, metabolism and excretion. As a result, the toxic actions may be altered and the overall toxicity of the mixture may be different from its ingredients.

4.11.6.3.3 It is necessary to consider whether the concentration of each ingredient is sufficient to contribute to the overall health effects of the mixture. The information on toxic effects should be presented for each ingredient, except:

- (a) if the information is duplicated, it is not necessary to list this more than once. For example, if two ingredients both cause vomiting and diarrhoea, it is not necessary to list this twice. Overall, the mixture is described as causing vomiting and diarrhoea;
- (b) if it is unlikely that these effects will occur at the concentrations present. For example, when a mild irritant is diluted in a non-irritating solution, there comes a point where the overall mixture would be unlikely to cause irritation.

4.11.6.3.4 Predicting the interactions between ingredients is extremely difficult, and where information on interactions is not available, assumptions should not be made and instead the health effects of each ingredient should be listed separately.

4.11.6.4 *Summary of Toxicity Data*

4.11.6.4.1 Summarise the data available. Where there is a substantial amount of test data on the ingredient or the material, it may be desirable to summarise results by route of exposure or to discuss only selected studies that are representative of the hazards that give rise to the classification reported in Section 2 of the SDS.

4.11.6.5 *Human/Animal Data*

4.11.6.5.1 If there are human data, including exposure information, human case histories or epidemiological studies these should be highlighted. Where there are no human data, report effects based on animal testing. All studies should be adequately referenced including the epidemiological studies.

4.11.6.6 *Carcinogenicity Studies*

4.11.6.6.1 Carcinogenicity studies should include whether the evidence is animal or human, the type of study and the type of cancer and/or organs affected.

4.11.6.6.2 In addition, where possible, an indication of the weight of evidence for carcinogenicity in humans should be included. This can be obtained from government/international agencies, which evaluate the carcinogenic potential of selected substances. A sample statement would be 'has been classified as a probable human carcinogen by the International Agency for Research on Cancer'.

4.11.6.7 *Compounding Effects*

4.11.6.7.1 Information on compounding effects should be included if relevant. For example:

- (a) if symptoms are exacerbated by drinking alcohol, taking medication or smoking;
- (b) if the substance is secreted in breast milk; or

(c) if pre-existing medical conditions such as asthma, high blood pressure or a predisposition to allergic reactions may place an individual at an increased risk.

4.11.6.8 Other Information

4.11.6.8.1 All information on adverse health effects should be included even when not required by the GHS classification criteria.

4.12 SECTION 12 - ECOLOGICAL INFORMATION

Provide information to evaluate the environmental impact of the substance if it is released to the environment. It can assist in handling spills, and evaluating waste treatment practices and should clearly indicate species, media, units, test duration and test conditions. Where information is not available this should be stated.

4.12.1 Minimum information requirements

- Ecotoxicity (aquatic and terrestrial, where available).
- Persistence and degradability.
- Bioaccumulative potential.
- Mobility in soil.
- Other adverse effects.

4.12.2 Ecotoxicity

4.12.2.1 Ecotoxicity information can be provided using aquatic and/or terrestrial toxicity data, where available. The relevant ecotoxicological classification criteria are found in Chapter 3.10 of the GHS document.

4.12.2.2 Acute aquatic toxicity would normally be determined using a fish 96 hour LC₅₀ (OECD Test Guideline 203 or equivalent), a crustacea species 48 hour EC₅₀ (OECD Test Guideline 202 or equivalent) and/or an algal species 72 or 96 hour EC₅₀ (OECD Test Guideline 201 or equivalent). These species are considered as surrogate for all aquatic organisms and data on other species such as Lemna may also be considered if the test methodology is suitable.

4.12.2.3 Chronic toxicity data are less available than acute data and the range of testing procedures less standardised. Data generated according to the OECD Test Guidelines 210 (Fish Early Life Stage), or 211 (Daphnia Reproduction) and 201 (Algal Growth Inhibition) can be accepted (See also Chapter 3.3.2 of Annex 8 of the GHS document). Other validated and internationally accepted tests could also be used. The NOECs or other equivalent L(E)Cx should be used.

4.12.3 Persistence and degradability

4.12.3.1 Environmental degradation may be biotic or abiotic (e.g. hydrolysis) and the criteria used reflect this fact (See 3.10.2.10.3 of the GHS document). Ready biodegradation can most easily be defined using the OECD biodegradability tests OECD Test Guideline 301 (A - F). A pass level in these tests can be considered as indicative of rapid degradation in most environments. These are freshwater tests and thus the use of the results from OECD Test Guideline 306 which is more suitable for marine environments has also been included. Where such data are not available, a BOD(5 days)/COD ratio > 0.5 is considered as indicative of rapid degradation.

4.12.3.2 Abiotic degradation such as hydrolysis, primary degradation, both abiotic and biotic, degradation in non-aquatic media and proven rapid degradation in the environment may all be

considered in defining rapid degradability. Special guidance on data interpretation is provided in Annex 8 of the GHS document.

4.12.4 Bioaccumulative potential

4.12.4.1 The potential for bioaccumulation would normally be determined by using the octanol/water partition coefficient, usually reported as a log K_{ow} determined by OECD Test Guideline 107 or 117. While this represents a potential to bioaccumulate, an experimentally determined Bioconcentration Factor (BCF) provides a better measure and should be used in preference when available. A BCF should be determined according to OECD Test Guideline 305.

4.12.5 Mobility in soil

4.12.5.1 Information on mobility can be determined from relevant mobility data such as adsorption studies or leaching studies. Modeled data are also acceptable. For example, K_{oc} values can be predicted from octanol/water partition co-efficients. Leaching and mobility can be predicted from models.

4.12.6 Other adverse effects

4.12.6.1 Information on other adverse effects to the environment should be included where available, such as environmental fate (exposure).

4.13 SECTION 13 - DISPOSAL CONSIDERATIONS

Provide information on disposal and recycling or reclamation of the substance and/or its container in this section.

4.13.1 Minimum information requirements

- Description of waste residues and information on their safe handling and methods of disposal, including the disposal of any contaminated packaging.

4.13.2 Disposal methods

4.13.2.1 Provide information for proper disposal, recycling or reclamation of the substance and/or its container to assist in the determination of safe and environmentally preferred waste management options.

4.13.2.2 Specify disposal containers and methods.

4.13.2.3 Discuss physical/chemical properties that may affect disposal options.

4.13.2.4 Discourage sewage disposal.

4.13.2.5 Where appropriate, identify any special precautions for incineration or landfill.

4.14 SECTION 14 - TRANSPORT INFORMATION

Provide basic classification information for the preparation of a substance for transporting/shipment. Where information is not available or relevant this should be stated.

4.14.1 Minimum information requirements

- UN number.
- UN Proper shipping name.

- Transport Hazard class(es).
- Packing group, if applicable.
- Marine pollutant (Yes/No).
- 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 their premises.

4.14.2 UN Number

4.14.2.1 Provide the UN Number from the *UN Recommendations on the Transport of Dangerous Goods*. The UN Number is assigned to goods by The UN Committee of Experts on the Transport of Dangerous Goods and is published by the UN in *Recommendations on the Transport of Dangerous Goods*.

4.14.3 UN Proper Shipping Name

4.14.3.1 Provide the UN Proper Shipping Name. The UN Proper Shipping Name is used to identify Dangerous Goods.

4.14.4 Transport hazard class(es)

4.14.4.1 Provide the transport hazard class(es) for those substances that present a physical hazard. The classes are specified in the *UN Recommendations on the Transport of Dangerous Goods*.

4.14.5 Packing Group, if applicable

4.14.5.1 Provide the Packing Group number if applicable. The Packing Group number is a convention used to classify the degree of hazard within a class for most substances which present a physical hazard. ~~Packing Group I is the highest hazard and Packing Group III the lowest. The Packing Group is specified in the UN Recommendations on the Transport of Dangerous Goods.~~ such narrative explanation is not in line with the level of guidance given in the other sections

4.14.6 Marine pollutant (Yes/No) or % of marine pollutant

4.14.6.1 Indicate whether the substance is a known marine pollutant.

4.14.7 Special precautions for user

4.14.7.1 Provide information on 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 their premises.~~

4.15 SECTION 15 - REGULATORY INFORMATION

Describe any other regulatory information on the substance that is not provided elsewhere in the SDS.

4.15.1 Minimum information requirements

- Safety, health and environmental regulations specific for the product in question.

4.15.2 Safety, health and environmental regulations specific for the product in question

4.15.2.1 Provide relevant national and/or regional information on the regulatory status of the product (including its ingredients) under relevant safety, health and environmental regulations.

4.16 SECTION 16 - OTHER INFORMATION

Provide information relevant to the preparation of the SDS in this section.

4.16.1 Minimum information requirements

- Other information including information on preparation and revision of the SDS including:

(a) the date of preparation or last revision of the SDS; (unless this information is given elsewhere, i.e. in the header of each page, or very apparent on the first page).

(b) a key/legend to abbreviations and acronyms used in the SDS;

(c) literature references; and

(d) sources for data.

Preparation and Revisions

When revisions are made to an SDS, unless it has been indicated elsewhere, clearly indicate where the changes have been made to the previous version of the SDS, with, if appropriate, an explanation of the changes.

Comment on the text in the box :