UN/SCEGHS/6/INF.1

Sub-Committee of Experts
on the Globally Harmonized System of Classification
and Labelling of Chemical
(Sixth session, 10-12 December 2003)

Revised draft of the GHS SDS Guidance document

For discussion by the SDS Correspondence Group (on Tuesday 9 December 2003, 13:30-16:30, Room 3, Palais des Nations), and for presentation in plenary at the SCE GHS 6th meeting, 10-12 December 2003

CONTENTS

	Page
Introduction and background	**i**
Draft guidance document on the preparation of SDS	**iii**
Discussion points for the 9th December meeting	**37**

* * * * * *

Introduction and background

As identified at the SCEGHS meeting 5 in July 2003. a number of members provided comments on the first draft of the SDS Guidance document. The document, and the comments, was provided at UN/SCEGHS/5/INF.6, and UN/SCEGHS/5/INF.6/Add1-Add9. In addition, some comments were received from Norway and the UK at a later date. All of these comments have been provided to Correspondence Group members.

Australia notes the contribution of a large number of the Correspondence Group members, both in the comments provided and in the participation in teleconference calls. Without those valuable contributions, no changes would have been possible to the document. I hope that we have captured all comments provided.

Australia, in consultation with a small group of Correspondence Group members, conducted a teleconference on 17 October to discuss further changes to the draft. This approach was agreed by the Correspondence Group in July 2003. Resulting from that teleconference, a revised draft has been prepared. Unfortunately, due to the size of the document, it is not practicable to provide a version of the revised draft in a 'track-change' format. As such, I would encourage all members to look at the new document, paying particular attention to the sections for which they provided comments.

All comments were considered, but as the Chair of the group, there were occasions where comments were not agreed and consequently no changes were made. This was often as a result of different comments on the same sections from different members. The meeting in December 2003 will not be limited to those 'discussion points' provided in the attached papers. I think that sufficient time has been put aside for Members to raise additional discussion points, including reconsideration of their original comments by the entire group.

In summary, the following main changes have been made:

1. Text in boxes has been incorporated into the main body text in the document.
2. Text that is not yet agreed, or that requires further discussion, has been bracketed and highlighted.
3. Superfluous dot-points and paragraph numbering have been removed.
4. The word 'shall' has been replaced with 'should'.
5. The reference to substance and mixture has been made consistent throughout.
6. Additional guidance on how to provide information on mixtures, especially in Section 4, has been provided.

A number of changes, recommended by Correspondence Group members, have not been incorporated. These include:

1. Changes to the definitions. These definitions are consistent with the GHS document, and should remain so.
2. Changes to the minimum information requirements and/or headings, have not been made. Again, these are consistent with the information requirements outlined in the GHS document (from p35 onwards in that document), and should remain so.

If Correspondence Group members require the track-change version of the document, I might be able to provide it directly to you. Please let me know. I would also encourage members to provide comments on this revised draft prior to the SCEGHS prior to our discussions in December, if you have sufficient time to do so.

Drew Wagner
Executive Manager
National Occupational Health and Safety Commission Office
GPO Box 1577
Canberra
ACT 2601
ph: 02 6279 1060
fax: 02 6279 1150
email: drew.wagner@nohsc.gov.au

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

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 document[1], 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

FOREWORD ..... **iv**
PREFACE ..... **vii**
CHAPTER 1 – TITLE, PURPOSE, SCOPE AND APPLICATION **8**
CHAPTER 2 – DEFINITIONS AND ABBREVIATIONS **9**
CHAPTER 3 – GENERAL GUIDANCE FOR COMPILING AN SDS **16**
CHAPTER 4 – PREPARATION OF THE SDS **21**

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 substance or mixture related and, usually, is not able to provide specific information that is relevant for any given workplace where the substance or mixture may finally be used, although where substances or mixtures 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). Use of this guidance document should allow the SDS to be prepared in accordance with the recommended GHS format.

4. The use 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

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

1.2 PURPOSE

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

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 SDS for mixtures not meeting the criteria for classification as hazardous but which contain hazardous substances in certain concentrations (See section 3.2). Manufacturers may choose to communicate information on non-hazardous substances and mixtures in the form of an SDS. An SDS is a well-accepted and effective method for the provision of workplace information, and may be used to convey information for substances or mixtures that do not meet the GHS classification criteria.

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 ≤ -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;

EC_{50} 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";

ErC_{50} means EC_{50} 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;

LC_{50} **(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;

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

$L(E)C_{50}$ means LC_{50} or EC_{50};

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 -0-0- 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 hazards of a substance or mixture, and provide information on the safe storage, handling and disposal of the substance or mixture. An SDS contains information on the potential health effects of exposure and how to work safely with the substance or mixture. It also contains information derived from physico-chemical properties or environmental effects, on the use, storage, handling and emergency response measures 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 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 system toxicity in concentrations exceeding the cut-off limits for SDS specified by the criteria for mixtures (see Table 1). The competent authority may choose also to require SDS for mixtures not meeting the criteria for classification as hazardous but which contain hazardous substances in certain concentrations.

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 SDS to be compiled for mixtures which are not classified for acute or chronic 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
2. Hazard(s) identification
3. Composition/information on ingredients
4. First-aid measures
5. Fire-fighting measures
6. Accidental release measures

[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.

7. Handling and storage

8. Exposure controls/personal protection

9. Physical and chemical properties

10. Stability and reactivity

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'.]

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 of this document should be included, where applicable and available, on the SDS under the relevant headings[3]. 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

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 substance or mixture is being supplied.]

3.4.4. This guideline is based on a number of internationally recognised standards 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

[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.

amended by 2001/58/EEC 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.

3.5.2. 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

4.1. SECTION 1 – IDENTIFICATION: MINIMUM INFORMATION REQUIREMENTS

Identify the substance or mixture 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. GHS product identifier

[The identity of the substance or mixture (GHS product identifier) 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.]

4.1.2. Other means of identification

[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.]

4.1.3. Recommended use of the chemical and restrictions on use

[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.. Restrictions on use should, as far as possible, be stated including. non-statutory recommendations by the supplier.]

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

[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.]

4.1.5. 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: MINIMUM INFORMATION REQUIREMENTS

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

4.2.1. GHS Classification of the substance or mixture

4.2.1.1. This section indicates the hazardous classification of the substance or mixture.

4.2.1.2. 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.

4.2.2. GHS label elements, including precautionary statements

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

4.2.2.2. [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.]

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

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

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. When applicable, indicate that confidential information about the composition was omitted.*

4.3.1. MINIMUM-INFORMATION REQUIREMENTS: Substance

4.3.1.1. Chemical identity of the substance

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

4.3.1.2. Common name(s), synonym(s) of the substance

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

4.3.1.3. CAS number, EC number for the substance

[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.]

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

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

4.3.2. MINIMUM-INFORMATION REQUIREMENTS: Mixture

4.3.2.1. 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

4.3.2.1.1. [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. Manufacturers may choose to list all ingredients, including non-hazardous ingredients.]

4.3.2.1.2. 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 if such ranges are acceptable to the appropriate competent national authority.]

4.3.2.1.3. 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: MINIMUM INFORMATION REQUIREMENTS

Describe the initial care that can be given by an untrained responder 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. It may be useful to provide information on the immediate effects, by route of exposure, and indicate the immediate treatment, followed by possible delayed effects with specific medical surveillance required.

4.4.1. Description of necessary first aid measures

4.4.1.1. 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.

4.4.1.2. 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) advice on personal protective equipment (PPE) for first aid responders is recommended; 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.

4.4.2. Most important symptoms/effects, acute and delayed.

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

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

4.4.3.1. 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 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: MINIMUM-INFORMATION REQUIREMENTS

Refer to requirements for fighting a fire caused by the substance or mixture, or arising in its vicinity.

4.5.1. Suitable (and unsuitable) extinguishing media

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.

4.5.2. Specific hazards arising from the chemical

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

(a) ‘may produce toxic fumes of carbon monoxide if burning’; or

(b) ‘produces oxides of sulfur and nitrogen on combustion’.

4.5.3. Special protective equipment and precautions for fire fighters

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

4.5.3.2. Provide information on appropriate protective equipment for by fire fighters. For example, boots, overalls, gloves, equipment and breathing apparatus.

4.6. SECTION 6 - ACCIDENTAL RELEASE MEASURES: MINIMUM INFORMATION REQUIREMENTS

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. 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.

4.6.1. Personal precautions, protective equipment and emergency procedures

Provide advice related to accidental spills and release of the substance or mixture such as:

(a) any personal precautions such as removal of ignition sources and provision for sufficient ventilation;

(b) protective equipment and emergency procedures such as the necessity to evacuate the danger area or consult an expert. If Personal Protective Equipment (PPE) is required for containment/clean up - refer readers to section 8 of the SDS.

4.6.2. Environmental precautions

Provide advice on any environmental precautions related to accidental spills and release of the substance or mixture, such as keeping away from drains, surface and ground water.

4.6.3. Methods and materials for containment and cleaning up

4.6.3.1. 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.

4.6.3.2. 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).

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

4.6.3.4. The SDS should also contain clear and simple criteria to define a large and a small spill.

4.7. SECTION 7 - HANDLING AND STORAGE: MINIMUM INFORMATION REQUIREMENTS

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

4.7.1. Precautions for safe handling

4.7.1.1. Provide advice that:

(a) [minimises contact between the worker and the substance or mixture];

(b) prevents handling of incompatible substances or mixtures; and

(c) minimises the release of the substance or mixture to the environment.

4.7.1.2. Include general warnings on what practices to avoid or restrict. It is good practice to provide advice on general hygiene. For example:

(a) prohibiting eating, drinking and smoking in contaminated areas;

(b) wash hands before eating; and

(c) remove contaminated clothing and protective equipment before entering eating areas.

4.7.2. Conditions for safe storage, including any incompatibilities

Ensure that the advice provided is consistent with the physical and chemical properties in Section 9. Provide advice on specific storage requirements including:

(a) How to avoid:

i. explosive atmospheres;

ii. corrosive conditions;

iii. flammability hazards;

iv. incompatible substances or mixtures;

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 or mixture by the use of:

i. stabilizers;

ii. anti-oxidants; and

(d) Other advice including:

i. ventilation requirements

ii. specific designs for storage rooms/vessels;

iii. quantity limits under storage conditions (if relevant); and

iv. packaging compatibilities.

4.8. SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION: MINIMUM-INFORMATION REQUIREMENTS

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

4.8.1. Control parameters

4.8.1.1. [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'].

4.8.1.2. [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'].

4.8.2. Appropriate engineering controls.

The description of appropriate exposure control measures should relate to the intended modes of use of the substance or mixture. Sufficient information should be provided on suitable control measures to enable a proper risk assessment to be carried out. Indicate whether special engineering controls are necessary, and specify which type. Examples include:

(a) ['maintain air concentrations below occupational exposure standards', using engineering controls if necessary];

(b) ['use local exhaust ventilation'];

(c) 'use only in an enclosed system';

(d) 'use only in spray paint booth or enclosure';

(e) 'use mechanical handling to reduce human contact with materials'; or

(f) 'use explosive dust handling controls'.

The information provided here should complement that provided under section 7 – Storage and Handling.

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

4.8.3.1. Consistent with good occupational hygiene practices, personal protective equipment should be used in conjunction with other control measures, including engineering controls, ventilation, elimination, substitution and isolation. See also Section 5 of the SDS for specific fire/chemical PPE advice.

4.8.3.2. Identify the personal protective equipment (PPE) needed to minimise the potential for illness or injury due to exposure from the substance or mixture, including:

(a) Eye/face protection - specify the type of eye protection and/or face shield required, based on the hazard of the substance or mixture and potential for contact;

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

(c) Respiratory protection – specify appropriate types of respiratory protection based on the exposure and potential for exposure, including air-purifying respirators and the proper purifying element (cartridge or canister) or breathing apparatus; and

(d) 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.

4.8.3.3. 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.

4.9. SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES: MINIMUM INFORMATION REQUIREMENTS

4.9.1. Describe the empirical data of the substance or mixture (if possible) in this section. Describe the potential adverse health effects and symptoms associated with exposure to the substance or mixture and its ingredients or known by-products.

4.9.2. In the case of a mixture, the entries should clearly indicate to which ingredient the data apply, unless it is valid for the whole mixture. 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 toxicological properties of the ingredients should be provided.

4.9.3. Clearly identify the following properties and note if specific characteristics do not apply, are not available or are irrelevant and specify appropriate units of measure and/or reference conditions where appropriate:

- Appearance (physical state, colour etc).
- Odour.
- [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: MINIMUM-INFORMATION REQUIREMENTS

Describe reactivity hazards of the substance or mixture in this section. Provide specific test data for the substance or mixture 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 or mixture.

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

4.10.1. Chemical stability

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

4.10.2. Possibility of hazardous reactions

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

4.10.3. Conditions to avoid

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

4.10.4. Incompatible materials

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

4.10.6 Hazardous decomposition products

4.10.6.1List known and reasonably anticipated hazardous substances or mixtures produced as a result of use, storage, heating, or reaction with another substance, including the production of flammable and toxic materials. This section should be used for hazardous decomposition products only. Hazardous combustion products should be included in Section 5 – Fire Fighting Measures.

4.11. SECTION 11 - TOXICOLOGICAL INFORMATION: MINIMUM INFORMATION REQUIREMENTS

4.11.1. 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 toxicological properties of the ingredients should be provided.

4.11.2. Describe the potential adverse health effects and symptoms associated with exposure to the substance or mixture and its ingredients or known by-products.

4.11.3. 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. A concise but complete and comprehensible description of the various toxicological (health) effects and the available data used to identify those effects should be provided.

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

4.11.5. If a 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. Information on the likely routes of exposure

Provide information on the likely routes of exposure and the effects of the substance or mixture 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.

4.11.7. Symptoms related to the physical, chemical and toxicological characteristics

[Provide information on the symptoms related to the physical, chemical, and toxicological characteristics of the substance or mixture 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'.]

4.11.8. Delayed and immediate effects and also chronic effects from short and long term exposure

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 or mixture. Where human data are not available, animal data should be summarised and the species clearly identified.

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

4.11.9.1. 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'.

4.11.9.2. 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'.

4.11.10. Further Guidance on Completing Section 11

4.11.10.1. General Versus Specific Statements

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.

4.11.10.2. Where Specific Chemical Data are not Available

[It may not always be possible to obtain information on the hazards of a substance or mixture as many have never been fully tested. In cases where data on the specific substance or mixture 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.]

4.11.10.3. Mixture VS Ingredient Information

4.11.10.3.1. 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.

4.11.10.3.2. 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.

4.11.10.3.3. 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.

4.11.10.4. Summary of Toxicity Data

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.

4.11.10.5. Human/Animal Data

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.]

4.11.10.6. Carcinogenicity Studies

Carcinogenicity studies should include whether the evidence is animal or human, the type of study and the type of cancer and/or organs affected. 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 and mixtures. A sample statement would be 'has been classified as a probable human carcinogen by the International Agency for Research on Cancer'.

4.11.10.7. Compounding Effects

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 or mixture 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.]

4.11.10.8. Other Information

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

4.12. SECTION 12 - ECOLOGICAL INFORMATION: MINIMUM-INFORMATION REQUIREMENTS

Provide information to evaluate the environmental impact of the substance or mixture 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. Ecotoxicity

4.12.1.1. [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.

4.12.1.2. Acute aquatic toxicity would normally be determined using a fish 96 hour LC_{50} (OECD Test Guideline 203 or equivalent), a crustacea species 48 hour EC_{50} (OECD Test Guideline 202 or equivalent) and/or an algal species 72 or 96 hour EC_{50} (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.

4.12.1.3. 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 docuement). Other validated and internationally accepted tests could also be used. The NOECs or other equivalent L(E)Cx should be used.]

4.12.2. Persistence and degradability

4.12.2.1. [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.

4.12.2.2. 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.]

4.12.3. Bioaccumulative potential

[The potential for bioaccumulation would normally be determined by using the octanol/water partition coefficient, usually reported as a log Kow 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.]

4.12.4. Mobility in soil

The potential of a substance or the constituents of a mixture, if released to the environment, to transport to the groundwater or distance from the site of release. Information on mobility can be determined from relevant mobility data such as adsorption studies or leaching studies. Modeled data are also acceptable and reference to the methodologies should be provided. For example, Koc values can be predicted from octanol/water partition co-efficients. Leaching and mobility can be predicted from models.

4.12.5. Other adverse effects

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

4.13. SECTION 13 - DISPOSAL CONSIDERATIONS: MINIMUM INFORMATION REQUIREMENTS

Provide information on disposal and recycling or reclamation of the substance or mixture and/or its container in this section. For the safety of persons conducting such activities, please refer to the information in section 4.8.

4.13.1. Disposal methods

4.13.1.1. Provide information for proper disposal, recycling or reclamation of the substance or mixture and/or its container to assist in the determination of safe and environmentally preferred waste management options, consistent with the requirements of the competent national authority.

4.13.1.2. Specify disposal containers and methods.

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

4.13.1.4. Discourage sewage disposal.

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

4.14. SECTION 14 - TRANSPORT INFORMATION: MINIMUM INFORMATION REQUIREMENTS

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

4.14.1. UN Number

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.

4.14.2. UN Proper Shipping Name

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

4.14.3. Transport hazard class(es)

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

4.14.4. Packing Group, if applicable

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 and mixtures, which present a physical hazard.

4.14.5. Marine pollutant (Yes/No)

Indicate whether the substance or mixture is a known marine pollutant, and if so, whether it is a 'marine pollutant' or a 'severe marine pollutant'.

4.14.6. Special precautions for user

Provide information on any special precautions, which a user needs to be aware of, or needs to comply with in connection with transport.

4.15. SECTION 15 - REGULATORY INFORMATION: MINIMUM INFORMATION REQUIREMENTS

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

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

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

4.16. SECTION 16 - OTHER INFORMATION: MINIMUM INFORMATION REQUIREMENTS

[Provide information relevant to the preparation of the SDS in this section. This should incorporate other information that does not belong in sections 4.1 to 4.15 of this document, including information on preparation and revision of the SDS such as:

(a) the date of preparation or last revision of the SDS. 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 an explanation of the changes, if appropriate;

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

(c) key literature references and sources for data.]

Discussion points

Item	Comment	Comment By
3.2.3 Some competent authorities (CA) may require SDSs to be compiled for mixtures which are not classified for acute or chronic 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 %.	The following be added at the end of the clause: " Writers are advised to check this requirement with their national regulator."	South Africa
3.3.4 There should be some indication of the end of the SDS, such as the words 'End of SDS'	We would suggest also to add on the top of the SDS a phrase like: "Safety Data Sheet in accordance with the recommendations of the GHS."	Belgium
	'End of SDS' not necessary if all pages are numbered and the total number of pages is given. Recommend - Delete section and add language to end of 3.3.3	ACC (Replaces ICCA)
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 of this document should be included, where applicable and available, on the SDS under the relevant headings. 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.	Additional information required by 'Competent Authority' should not undermine the uniformity/standardization that GHS hopes to accomplish Recommend - Present 'country specific' information in Section 15.	ACC (Replaces ICCA)
	The value of entering "not available or "not applicable" is debatable. At worst, it makes the SDS look like a box ticking exercise and simply increases the length of the document. In our opinion, the safety data sheet is more comprehensible if headings for which data is not available or not applicable are not shown on the SDS	Croplife

Item	Comment	Comment By
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.	Perhaps the countries for which the SDS finally contains specific information should also be indicated clearly on top.	Belgium
3.6 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	Since this is an attempt to have global harmonization SI units should be used beyond doubt. If necessary, other units may additionally be used for particular countries.	Belgium
	SI UOMs are not used universally Recommend - Include provision that other UOMs may be included	ACC (Replaces ICCA)
4.1.1 The identity of the substance or mixture (GHS product identifier) 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.	The label cannot be used as the primary source of information; the label must be generated from the SDS . The wording needs to clarify this. It should also be stated that the product name on the SDS must be the same as the one used on the label.	South Africa

Item	Comment	Comment By
4.1.2 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 labeled 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*, should be provided in this subsection if it has not appeared as the GHS product identifier.	Why are only physical hazards required?	South Africa
	Delete "~~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*, should be provided in this subsection if it has not appeared as the GHS product identifier~~". Move this description to 4.14. Otherwise it would cause confusion since concept of dangerous goods transportation could be introduced for identification of the product.	JCIA
4.1.3 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.. Restrictions on use should, as far as possible, be stated including. non-statutory recommendations by the supplier.	Does this refer to regional restrictions that are applied to the substance or preparation in its area of manufacture, or is the supplier required to be aware of any other restrictions on the substance or preparation, which may apply in intended markets worldwide?	UK
4.1.4 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.	We propose that the clause be amended to read: "… of the supplier, manufacturer, importer or distributor…"	South Africa

Item	Comment	Comment By
4.1.5 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).	Website address could be also useful. If the emergency phone number is not permanently available, another phone number of an official center that has all necessary information should also be mentioned (e.g. poison center).	Belgium
4.2.2.2 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.	Instead of giving some examples, we propose to give the complete list of the names of the symbols to avoid a mismatch. We propose the following list: Exploding bomb, Flame, Flame over circle, Gas cylinder, Corrosion, Skull and crossbones, Exclamation mark, New Health hazard, Environment.	Belgium
	Name of hazard symbol '!' (i.e., exclamation point) does not indicate hazard Recommend - Provide description(s) for '!' such as 'toxic' or 'irritant'	ACC (Replaces ICCA)
4.3.1.3 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.	Delete "~~The European Communities (EC) Number should also be provided where available~~." Replace with "National and/or regional registry numbers may also be provided where available". Since this is the UN guidance paper, it should be more appropriate to provide with the number used in the laws of the country/region where the SDS is applied.	JCIA
4.3.2.1.1 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. Manufacturers may choose to list all ingredients, including non-hazardous ingredients.	Producers may also want to include non-hazardous ingredients Recommend - Allow for inclusion of non-hazardous ingredients	ACC (Replaces ICCA)

Item	Comment	Comment By
4.3.2.1.2 For concentration ranges the mixture should have the proportion of ingredients described as: (c) exact percentages in descending order by mass or volume; or (d) ranges of percentages in descending order by mass or volume if such ranges are acceptable to the appropriate competent national authority.	Examples are too prescriptive. The most hazardous ingredients will not necessarily be the in the greatest proportions (e.g., pesticides) Recommend - Allow more flexibility in ingredient disclosure (e.g., descending order, hazardous ingredients first, etc.)	ACC (Replaces ICCA)
4.7.1.1 Provide advice that: (a) minimises contact between the worker and the substance or mixture	Isn't it too vague? The intention is not to repeat here what we will have in 4.8.5 but we suppose that the intention is to propose technical measures when handling the substance such as measures to prevent aerosol and dust generation, local and general ventilation… could we precise it?	Belgium
4.8.1.1 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'	'No occupational exposure limit allocated' is too prescriptive Recommend - Allow use of any indicator that no exposure limit has been established	ACC (Replaces ICCA)
	Not necessary to be prescriptive about the actual words used. We also want to avoid a long table listing all the components without OELs. Recommend – [text to go at end of paragraph] "Where at least one OEL is listed, it is not necessary to list the ingredients for which no OEL is allocated".	Croplife

Item	Comment	Comment By
4.8.1.2 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'	Recommend – [text to go at end of paragraph] "Where at least one biological limit value is listed, it is not necessary to list the ingredients for which no OEL is allocated"	Croplife
4.8.2 The description of appropriate exposure control measures should relate to the intended modes of use of the substance or mixture. Sufficient information should be provided on suitable control measures to enable a proper risk assessment to be carried out. Indicate whether special engineering controls are necessary, and specify which type. Examples include: (g) 'maintain air concentrations below occupational exposure standards', using engineering controls if necessary; (h) 'use local exhaust ventilation';	*(a) ;- this statement by itself is not helpful as the obvious question is – how do we do this? and how do we know if we have achieved it?* (b) again not specific enough to be helpful as LEV can be anything from a simple single point extraction unit to a system costing hundreds of thousands of pounds/euros etc	UK

Item	Comment	Comment By
4.8.3.2 Identify the personal protective equipment (PPE) needed to minimise the potential for illness or injury due to exposure from the substance or mixture, including: **(b)** Skin protection - specify the protective equipment to be worn (e.g. gloves, boots, bodysuit) based on the hazards associated with the substance or mixture and the potential for contact.	(b) The type of material to be used should also be specified. Also if possible the breakthrough time of the material with respect to the amount and duration of exposure. Using PPE after breakthrough has occurred can sometimes be worse than using no PPE.	UK
4.9.3 Clearly identify the following properties and note if specific characteristics do not apply, are not available or are irrelevant and specify appropriate units of measure and/or reference conditions where appropriate: • Odour threshold.	This needs a statement the odour threshold is not a suitable basis to make decisions on the need for control	UK
4.11.7 Provide information on the symptoms related to the physical, chemical, and toxicological characteristics of the substance or mixture 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'.	It may be simpler to list the symptoms from the mildest ones to the most severe. The timing of their occurrence may not always be the same.	Belgium
4.11.10.2 It may not always be possible to obtain information on the hazards of a substance or mixture as many have never been fully tested. In cases where data on the specific substance or mixture 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.	Add to end of the clause: "In general, the use of data from substances in the same chemical class to fill data gaps can provide useful information. However, in some instances the use of non-specific data may be inappropriate. Therefore a short justification for the use of non-specific data should be included in the SDS."	UK

Item	Comment	Comment By
4.11.10.5 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.	'All studies should be adequately referenced…' References will not add value, will decrease comprehension and increase document length Recommend - Remove reference requirement. Require that manufacturers provide references if requested.	ACC (Replaces ICCA)
4.11.10.7 Information on compounding effects should be included if relevant. For example: (d) if symptoms are exacerbated by drinking alcohol, taking medication or smoking; (e) if the substance or mixture is secreted in breast milk; or (f) 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.	Examples are pre-existing conditions which should be given in Section 4 Recommend - Remove or change examples	ACC (Replaces ICCA)
	In principle the provision of information on compounding effects can be very useful. There is potential for any list of compounding effects to be wide-ranging, such as interactions with alcohol and medication. Of course, where there is information indicating that a substance does interact with specific pharmaceuticals this should be clearly stated. The breast milk example is inappropriate, as excretion via this route should be discussed in the toxicology section. Therefore, it is suggested that the specific examples should be limited to an indication that a substance may exacerbate symptoms in pre-existing asthmatics, as this is considered to be an excellent example of the type of information that should be conveyed.	UK
4.12.1	Requirement to provide test method is inconsistent with other sections Recommend - Remove requirement	ACC (Replaces ICCA)

Item	Comment	Comment By
4.12.2	Requirement to provide test method is inconsistent with other sections Recommend - Remove requirement	ACC (Replaces ICCA)
4.12.3 The potential for bioaccumulation would normally be determined by using the octanol/water partition coefficient, usually reported as a log Kow 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.	Requirement to provide test method is inconsistent with other sections Recommend - Remove requirement	ACC (Replaces ICCA)
4.16 Provide information relevant to the preparation of the SDS in this section. This should incorporate other information that does not belong in sections 4.1 to 4.15 of this document, including information on preparation and revision of the SDS such as: (d) the date of preparation or last revision of the SDS. 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 an explanation of the changes, if appropriate; (e) a key/legend to abbreviations and acronyms used in the SDS; (f) key literature references; and (g) sources for data.	Indicate whether the name of the compiler should be given with the date of preparation or last revision. Disclaimers are often included in this section. We feel that the document should give guidance on the inclusion (or not) of disclaimers.	South Africa
	There's no value in quoting long lists of references that the public are not able to access. Also need to consider the value of listing every reference that a compiler has looked at when compiling the SDS. Of course, the compiler should keep a record of these references Recommend – [text to go at end of (d)] "…if publicly available".	Croplife