

# **ANNEX 4**

## **GUIDANCE ON THE PREPARATION OF SAFETY DATA SHEETS (SDS)**



## Annex 4

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#### A4.1 Introduction

A4.1.1 This annex provides guidance on the preparation of an SDS under the requirements of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). SDS's are an important element of hazard communication in the GHS, as explained in Chapter 1.5. Use of this guidance document should support compliance with competent authority (CA) requirements and should allow the SDS to be prepared in accordance with the GHS.

A4.1.2 The use of this guidance document is dependent on importing countries requirements for SDS. It is hoped that the application of the GHS worldwide will eventually lead to a fully harmonized situation.

A4.1.3 Unless otherwise stated, all chapters, sections and tables referred to in this annex can be found in the main text of the GHS.

#### A4.2 General guidance for compiling an SDS

##### A4.2.1 *Scope and application*

Safety Data Sheets (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 Table 1.5.1 in Chapter 1.5). The competent authority (CA) may also require SDS for mixtures not meeting the criteria for classification as hazardous but which contain hazardous substances in certain concentrations (see Chapter 3.2). The CA may also require SDS for substances or mixtures that meet the criteria for classification as hazardous for non-GHS classes/end-points. An SDS is a well-accepted and effective method for the provision of information, and may be used to convey information for substances or mixtures that do not meet or are not included in the GHS classification criteria.

##### A4.2.2 *General guidance*

A4.2.2.1 The writer of the SDS needs to keep in mind that an SDS must inform its audience of the hazards of a substance or a mixture and provide information on the safe storage, handling and disposal of the substance or a 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 hazard information derived from physicochemical properties or environmental effects, on the use, storage, handling and emergency response measures related to that substance or mixture. The purpose of this guidance is to ensure consistency and accuracy in the content of each of the mandatory headings required under GHS, so that the resulting safety data sheets will enable users to take the necessary measures relating to protection of health and safety at the workplace, and the protection of the environment. The information in the SDS shall be written in a clear and concise manner. The SDS shall be prepared by a competent person who shall take into account the specific needs of the user audience, as far as it is known. Persons placing substances and mixtures on the market shall ensure that refresher courses and training on the preparation of SDS be regularly attended by the competent persons.

A4.2.2.2 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.

A4.2.2.3 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 not recommended. 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.

A4.2.2.4 The date of issue of the SDS should be stated and be very apparent. The date of issue is the date the SDS version was made public. This generally occurs shortly after the SDS authoring and publishing process is completed. Revised SDS’s should clearly state the date of issue as well as a version number, revision number, supersedes date or some other indication of what version is replaced.

### **A4.2.3        *SDS format***

A4.2.3.1 The information in the SDS should be presented using the following 16 headings in the order given below (see also 1.5.3.2.1):

1. Identification
2. Hazard 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
11. Toxicological information
12. Ecological information
13. Disposal considerations
14. Transport information
15. Regulatory information
16. Other information

A4.2.3.2 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.

A4.2.3.3 All pages of an SDS should be numbered and some indication of the end of the SDS should be given (for example: “page 1 of 3”). Alternatively, number each page and indicate whether there is a page following (e.g. “Continued on next page” or “End of SDS”).

### **A4.2.4        *SDS content***

A4.2.4.1 General information on SDS content can be found in 1.5.3.3. More practical information is given below.

A4.2.4.2 The minimum information outlined in Section A4.3 of this annex should be included on the SDS, where applicable and available<sup>1</sup>, under the relevant headings. When information is not available or lacking this should be clearly stated. The SDS should not contain any blanks.

A4.2.4.3 In addition, the SDS should contain a brief summary/conclusion of the data given, making it easy even for non-experts in the field to identify all the hazards for the hazardous substance/mixture.

A4.2.4.4 Use of abbreviations is not recommended because they may lead to confusion or decreased understanding.

#### **A4.2.5 *Other information requirements***

A4.2.5.1 There are information requirements for the preparation of an SDS. The minimum information requirements are outlined in A4.3.

A4.2.5.2 In addition to the minimum information requirements (see A4.2.4.2), 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 in the SDS (see A4.3.16 for further advice on additional information requirements).

#### **A4.2.6 *Units***

Numbers and quantities should be expressed in units appropriate to the region into which the product is being supplied. In general, the International System of Units (SI) should be used.

### **A4.3 Information requirements for the preparation of the SDS**

This section describes the GHS information requirements for SDS's. Additional information may be required by competent authorities.

#### **A4.3.1 SECTION 1 – Identification**

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.

##### **A4.3.1.1 *GHS product identifier***

In addition, or as an alternative, to the 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 minor variants of a substance or mixture, all names and variants should be listed on the SDS or the SDS should clearly delineate the range of substances included.

##### **A4.3.1.2 *Other means of identification***

The substance or mixture may 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.

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<sup>1</sup> 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.

#### **A4.3.1.3**      *Recommended use of the chemical and restrictions on use*

Provide the recommended or intended use of the substance or mixture, 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.

#### **A4.3.1.4**      *Supplier's details*

The name, full address and phone number(s) of the supplier should be included on the SDS.

#### **A4.3.1.5**      *Emergency phone number*

References to emergency information services should be included in all SDS. If any restrictions apply, such as hours of operation (e.g. Monday - Friday, 8:00 a.m. - 6:00 p.m., or 24 hours) or limits on specific types of information (e.g., medical emergencies, or transportation emergencies), this should be clearly stated.

### **A4.3.2**            **SECTION 2 – Hazard identification**

This section describes 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. The section should include a brief summary/conclusion of the data given as described in A4.2.4.3.

#### **A4.3.2.1**      *Classification of the substance or mixture*

A4.3.2.1.1      This sub-section indicates the hazard classification of the substance or mixture.

A4.3.2.1.2      If the substance or mixture is classified in accordance with Parts 2, 3 and/or 4 of the GHS, provide the appropriate hazard class and category to indicate the hazard. For example, flammable liquid Category 1.

#### **A4.3.2.2**      *GHS label elements, including precautionary statements*

A4.3.2.2.1      Based on the classification, provide the appropriate labelling elements: signal word(s), hazard statement(s) and precautionary statement(s).

A4.3.2.2.2      Pictograms (or 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.

#### **A4.3.2.3**      *Other hazards which do not result in classification*

Provide information on other hazards which do not result in classification but may contribute to the overall hazards of the material, for example, formation of air contaminants during hardening or processing, dust explosion hazards, suffocation, freezing or environmental effects such as hazards to soil-dwelling organisms.

### **A4.3.3**            **SECTION 3 – Composition/information on ingredients**

Identify the ingredient(s) of the product in this section. This includes identifying impurities and stabilizing additives which are themselves classified and which contribute to the classification of the substance. This section may also be used to provide information on complex substances.

***NOTE:** For information on ingredients, the competent authority rules for Confidential Business Information (CBI) take priority over the rules for product identification. When applicable, indicate that confidential information about the composition was omitted.*

#### **A4.3.3.1 Substances**

##### *A4.3.3.1.1 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.

*NOTE: The “common chemical name” may, for example, be the CAS name or IUPAC name, as applicable.*

##### *A4.3.3.1.2 Common name(s), synonym(s) of the substance*

Common names and synonyms should be provided where appropriate.

##### *A4.3.3.1.3 CAS number and other unique identifiers for the substance*

The Chemical Abstract Service (CAS) Registry Number provides a unique chemical identification and should be provided when available. Other unique identifiers specific to a country or region, such as the European Community (EC) number could be added.

##### *A4.3.3.1.4 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.

#### **A4.3.3.2 Mixtures**

A4.3.3.2.1 For a mixture, provide the chemical identity, identification number (within the meaning of A4.3.3.1.3) and concentration or concentration ranges of all hazardous ingredients, which are hazardous to health or the environment within the meaning of the GHS, and are present above their cut-off levels. Manufacturers or suppliers may choose to list all ingredients, including non-hazardous ingredients.

A4.3.3.2.2 The concentrations of the ingredients of a mixture should be 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.

A4.3.3.2.3 When using a proportion range, the health and environmental hazard effects should describe the effects of the highest concentration of each ingredient, provided that the effects of the mixture as a whole are not available.

*NOTE: The “proportion range” refers to the concentration or percentage range of the ingredient in the mixture.*

#### **A4.3.4 SECTION 4 – First-aid measures**

This section describes 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.

#### **A4.3.4.1**      *Description of necessary first aid measures*

A4.3.4.1.1      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.

A4.3.4.1.2      Provide advice whether:

- (a)    immediate medical attention is required and if delayed effects can be expected after exposure;
- (b)    movement of the exposed individual from the area to fresh air is recommended;
- (c)    removal and handling of clothing and shoes from the individual is recommended; and
- (d)    personal protective equipment (PPE) for first-aid responders is recommended.

#### **A4.3.4.2**      *Most important symptoms/effects, acute and delayed*

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

#### **A4.3.4.3**      *Indication of immediate medical attention and special treatment needed, if necessary*

Where appropriate, provide information on clinical testing and medical monitoring for delayed effects, specific details on antidotes (where they are known) and contraindications.

#### **A4.3.5**          **SECTION 5 – Fire-fighting measures**

This section covers the requirements for fighting a fire caused by the substance or mixture, or arising in its vicinity.

#### **A4.3.5.1**      *Suitable 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 substance or mixture.

#### **A4.3.5.2**      *Specific hazards arising from the chemical*

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

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

#### **A4.3.5.3**      *Special protective equipment and precautions for fire fighters*

A4.3.5.3.1      Provide advice on any precaution to be taken during fire-fighting. For example, “keep containers cool with water spray”.

A4.3.5.3.2      Provide advice on appropriate protective equipment for fire-fighters. For example, boots, overalls, gloves, eye and face protection and breathing apparatus.



#### A4.3.6 SECTION 6 – Accidental release measures

This section recommends the appropriate response to spills, leaks, or releases in order to prevent or minimize the adverse effects on persons, property and the environment in this section. Distinguish between responses for large and small spills where the spill volume has a significant impact on the hazard. The procedures for containment and recovery may indicate that different practices are required.

##### A4.3.6.1 *Personal precautions, protective equipment and emergency procedures*

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

- (a) the wearing of suitable protective equipment (including personal protective equipment, see Section 8 of the SDS) to prevent any contamination of skin, eyes and personal clothing;
- (b) removal of ignition sources and provision of sufficient ventilation; and
- (c) emergency procedures such as the necessity to evacuate the danger area or to consult an expert.

##### A4.3.6.2 *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.

##### A4.3.6.3 *Methods and materials for containment and cleaning up*

A4.3.6.3.1 Provide appropriate advice on how to contain and clean up a spill. Appropriate containment techniques may include:

- (a) bunding<sup>2</sup>, covering of drains; and
- (b) capping procedures<sup>3</sup>.

A4.3.6.3.2 Appropriate clean up procedures may include:

- (a) neutralization 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 where applicable).

A4.3.6.3.3 Provide any other issues relating to spills and releases. For example, including advice on inappropriate containment or clean up techniques.

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<sup>2</sup> A **bund** is a provision of liquid collection facilities which, in the event of any leak or spillage from tanks or pipe work, will capture well in excess of the volume of liquids held, e.g. an embankment. Bunded areas should drain to a capture tank which should have facilities for water/oil separation.

<sup>3</sup> i.e. providing a cover or protection (e.g. to prevent damage or spillage).

#### **A4.3.7 SECTION 7 – Handling and storage**

This section provides guidance on safe handling practices that minimize the potential hazards to people, property and the environment from the substance or mixture. Emphasize precautions that are appropriate to the intended use and to the unique properties of the substance or mixture.

##### **A4.3.7.1 *Precautions for safe handling***

A4.3.7.1.1 Provide advice that:

- (a) allows safe handling of the substance or mixture;
- (b) prevents handling of incompatible substances or mixtures; and
- (c) minimizes the release of the substance or mixture to the environment.

A4.3.7.1.2 It is good practice to provide advice on general hygiene. For example:

- (a) “eating, drinking and smoking in work areas is prohibited”;
- (b) “wash hands after use”; and
- (c) “remove contaminated clothing and protective equipment before entering eating areas”.

##### **A4.3.7.2 *Conditions for safe storage, including any incompatibilities***

Ensure that the advice provided is consistent with the physical and chemical properties in Section 9 – *Physical and chemical properties* of the SDS. If relevant, 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; and
  - (ii) anti-oxidants.
- (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.

#### **A4.3.8 SECTION 8 – Exposure controls/personal protection**

Within this guidance the term “occupational exposure limit(s)” refers to limits in the air of the workplace or biological limit values. In addition, for the purposes of this document “exposure control” means the full range of specific protection and prevention measures to be taken during use in order to minimize worker and environmental exposure. Engineering control measures that are needed to minimize exposure to, and risks associated with the hazards of, the substance or mixture should be included in this section.

##### **A4.3.8.1 *Control parameters***

A4.3.8.1.1 Where available, list the occupational exposure limits (limits in the air of the workplace or biological limit values), including notations, for a substance and for each of the ingredients of a mixture. If air contaminants are formed when using the substance or mixture as intended available occupational exposure limits for these should also be listed. If an occupational exposure limit exists for the country or region in which the SDS is being supplied, this should be listed. 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 – *Composition/Information on ingredients* of the SDS.

A4.3.8.1.2 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.

A4.3.8.1.3 Where a control banding approach is recommended for providing protection in relation to specific uses then sufficient detail should be given to enable effective management of the risk. The context and limitations of the specific control banding recommendation should be made clear.

##### **A4.3.8.2 *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 to enable a proper risk assessment to be carried out. Indicate when 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 when...”;
- (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– *Handling and storage* of the SDS.

#### **A4.3.8.3      *Individual protection measures, such as personal protective equipment (PPE)***

A4.3.8.3.1      Consistent with good occupational hygiene practices, personal protective equipment (PPE) should be used in conjunction with other control measures, including engineering controls, ventilation and isolation. See also Section 5 – *Fire-fighting measures* of the SDS for specific fire/chemical PPE advice.

A4.3.8.3.2      Identify the PPE needed to minimize 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. type of 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 hazard 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.

A4.3.8.3.3      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”, and thickness and breakthrough time of the glove material. Special requirements may exist for respirators.

#### **A4.3.9            SECTION 9 – Physical and chemical properties**

A4.3.9.1          Describe the empirical data of the substance or mixture (if possible) in this section.

A4.3.9.2          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.

A4.9.2.3          Clearly identify the following properties and specify appropriate units of measure and/or reference conditions where appropriate. If relevant for the interpretation of the numeric value, the method of determination should also be provided (e.g. for flash point, open-cup/closed-cup):

- (a) Appearance (physical state, colour etc);
- (b) Odour;
- (c) Odour threshold;
- (d) pH;

- (e) Melting point/freezing point;
- (f) Initial boiling point and boiling range;
- (g) Flash point;
- (h) Evaporation rate;
- (i) Flammability (solid, gas);
- (j) Upper/lower flammability or explosive limits;
- (k) Vapour pressure;
- (l) Vapour density;
- (m) Relative density;
- (n) Solubility(ies);
- (o) Partition coefficient: n-octanol/water;
- (p) Auto-ignition temperature;
- (q) Decomposition temperature;
- (r) Viscosity.

If specific characteristics do not apply or are not available, they should still be listed on the SDS with a statement that they do not apply or not available.

Other physical or chemical parameters in addition to those listed above may also be included in this section of the SDS.

## **A4.3.10 SECTION 10 – Stability and reactivity**

### **A4.3.10.1 *Reactivity***

A4.3.10.1.1 Describe the 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 represent the anticipated hazard of the substance or mixture.

A4.3.10.1.2 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.

### **A4.3.10.2 *Chemical stability***

Indicate if the substance or mixture is stable or unstable under normal ambient and anticipated storage and handling conditions of temperature and pressure. Describe any stabilizers which are, or may need to be, used to maintain the product. Indicate the safety significance of any change in the physical appearance of the product.

#### **A4.3.10.3**      *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.

#### **A4.3.10.4**      *Conditions to avoid*

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

#### **A4.3.10.5**      *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).

#### **A4.3.10.6**      *Hazardous decomposition products*

List known and reasonably anticipated hazardous decomposition products produced as a result of use, storage and heating. Hazardous combustion products should be included in Section 5 – *Fire-fighting measures* of the SDS.

### **A4.3.11**      **SECTION 11 – Toxicological information**

A4.3.11.1      This section is used primarily by medical professionals, occupational health and safety professionals and toxicologists. 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. Under GHS classification, the relevant hazards, for which data should be provided, are:

- (a) acute toxicity;
- (b) skin corrosion/irritation;
- (c) serious eye damage/irritation;
- (d) respiratory or skin sensitization;
- (e) germ cell mutagenicity;
- (f) carcinogenicity;
- (g) reproductive toxicity;
- (h) STOST-single exposure;
- (i) STOST-repeated exposure; and
- (j) aspiration hazard.

If data for any of these hazards is not available, they should still be listed on the SDS with a statement that data is not available.

A4.3.11.2      The data included in this subsection should apply to the substance or mixture as used. The toxicological data should describe the mixture. If that information is not available, the classification under GHS and the toxicological properties of the hazardous ingredients should be provided.

A4.3.11.3 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.

A4.3.11.4 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.

A4.3.11.5 Where there is a substantial amount of test data on the substance or mixture, it may be desirable to summarize results. e.g. by route of exposure (see A4.3.11.1).

A4.3.11.6 Also provide information on the relevant negative data (see A4.1.2.3). Information to support negative test results should be provided (e.g. “carcinogenicity studies in the rat have shown no significant increase in the incidence of cancer”).

#### **A4.3.11.7 *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 health effects are not known.

#### **A4.3.11.8 *Symptoms related to the physical, chemical and toxicological characteristics***

Describe the potential adverse health effects and symptoms associated with exposure to the substance or mixture and its ingredients or known by-products. 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. Describe the first symptoms at the lowest exposures through 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”.

#### **A4.3.11.9 *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. It should be indicated in the SDS whether toxicological data is based on human or animal data.

#### **A4.3.11.10 *Numerical measures of toxicity (such as acute toxicity estimates)***

Provide information on the dose, concentration or conditions of exposure that may cause adverse health effects. Where appropriate, doses should be linked to symptoms and effects, including the period of exposure likely to cause harm.

#### **A4.3.11.11 *Interactive effects***

Information on interactions should be included if relevant and readily available.

#### **A4.3.11.12 *Where specific chemical data are not available***

It may not always be possible to obtain information on the hazards of a substance or mixture. 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 in the SDS.

#### **A4.3.11.13**     ***Mixtures***

If a mixture has not been tested for its health effects as a whole then information on each ingredient listed under A4.3.3.2.1 should be provided and the mixture should be classified using the processes that are described in the GHS (Section 1.3.2.3 and subsequent chapters).

#### **A4.3.11.14**     ***Mixture versus ingredient information***

A4.3.11.14.1    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.

A4.3.11.14.2    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;
- (c) 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.

#### **A4.3.11.15**     ***Other information***

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

### **A4.3.12**        **SECTION 12 – Ecological information**

A4.3.12.1        Provide information to evaluate the environmental impact of the substance or mixture if it were released to the environment. This information 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. Provide also a short summary of the data given under A4.3.12.3 to A4.3.12.7.

A4.3.12.2        Some ecotoxicological properties are substance specific, i.e. bioaccumulation, persistence and degradability. The information should therefore be given, where available and appropriate, for each substance of the mixture.

#### **A4.3.12.3**     ***Toxicity***

Information on toxicity can be provided using data from tests performed on aquatic and/or terrestrial organisms. This should include relevant available data on both acute and chronic aquatic toxicity for fish, crustaceans, algae and other aquatic plants. In addition, toxicity data on other organisms (including soil micro-and macro-organisms) such as birds, bees and plants, should be included when available. Where the substance or preparation has inhibitory effects on the activity of micro-organisms, the possible impact on sewage treatment plants should be mentioned.



#### **A4.3.12.4**      *Persistence and degradability*

Persistence and degradability is the potential for the substance or the appropriate constituents of a mixture to degrade in the environment, either through biodegradation or other processes, such as oxidation or hydrolysis. Test results relevant to assess persistence and degradability should be given where available. If degradation half-lives are quoted it must be indicated whether these half-lives refer to mineralization or to primary degradation. The potential of the substance or certain constituents (see also A4.3.12.6) of a mixture to degrade in sewage treatment plants should also be mentioned.

#### **A4.3.12.5**      *Bioaccumulative potential*

Bioaccumulation is the potential for the substance or certain constituents of a mixture to accumulate in biota and, possibly, pass through the food chain. Test results relevant to assess the bioaccumulative potential should be given. This should include reference to the octanol-water partition coefficient ( $K_{ow}$ ) and bioconcentration factor (BCF), if available.

#### **A4.3.12.6**      *Mobility in soil*

Mobility in soil is the potential of a substance or the constituents of a mixture, if released to the environment, to move under natural forces to the groundwater or to a distance from the site of release. The potential for mobility in soil should be given where available. Information on mobility can be determined from relevant mobility data such as adsorption studies or leaching studies. For example,  $K_{oc}$  values can be predicted from octanol/water partition coefficients ( $K_{ow}$ ). Leaching and mobility can be predicted from models.

**NOTE:**      *Where real data on the substance or mixture is available this data will take precedence over models and predictions.*

#### **A4.3.12.7**      *Other adverse effects*

Information on any other adverse effects to the environment should be included where available, such as environmental fate (exposure), ozone depletion potential, photochemical ozone creation potential, endocrine disrupting potential and/or global warming potential.

### **A4.3.13**      **SECTION 13 – Disposal considerations**

#### **A4.3.13.1**      *Disposal methods*

A4.3.13.1.1      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 national competent authority. For the safety of persons conducting disposal, recycling or reclamation activities, please refer to the information in Section 8 – *Exposure Controls and Personal Protection* of the SDS.

A4.3.13.1.2      Specify disposal containers and methods.

A4.3.13.1.3      Discuss physical/chemical properties that may affect disposal options.

A4.3.13.1.4      Discourage sewage disposal.

A4.3.13.1.5      Where appropriate, identify any special precautions for incineration or landfill.

### **A4.3.14**      **SECTION 14 – Transport information**

This section provides basic classification information for the transporting/shipment of a hazardous substance or mixture by road, rail, sea or air. Where information is not available or relevant this should be stated.

#### **A4.3.14.1**      *UN Number*

Provide the UN Number (i.e. four-figure identification number of the substance or article) from the *UN Model Regulations*<sup>4</sup>.

#### **A4.3.14.2**      *UN Proper Shipping Name*

Provide the UN Proper Shipping Name from the *UN Model Regulations*<sup>4</sup>. For substances or mixtures the UN Proper Shipping Name should be provided in this subsection if it has not appeared as the GHS product identifier or national or regional identifiers.

#### **A4.3.14.3**      *Transport hazard class(es)*

Provide the transport class (and subsidiary risks) assigned to the substances or mixtures according to the most predominant hazard that they present in accordance with the *UN Model Regulations*<sup>4</sup>.

#### **A4.3.14.4**      *Packing Group, if applicable*

Provide the Packing Group number from the *UN Model Regulations*<sup>4</sup>, if applicable. The Packing Group number is assigned to certain substances in accordance with their degree of hazard.

#### **A4.3.14.5**      *Environmental hazards*

Indicate whether the substance or mixture is a known marine pollutant according to the IMDG Code<sup>5</sup>, and if so, whether it is a “marine pollutant” or a “severe marine pollutant”. Also indicate whether the substance or mixture is environmentally hazardous according to the *UN Model Regulations*<sup>4</sup>, ADR<sup>6</sup>, RID<sup>7</sup> and ADN<sup>8</sup>.

#### **A4.3.14.6**      *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.

#### **A4.3.15**      **SECTION 15 – Regulatory information**

Describe any other regulatory information on the substance or mixture that is not provided elsewhere in the SDS (e.g. whether the substance or mixture is subject to the Montreal Protocol<sup>9</sup>, the Stockholm Convention<sup>10</sup> or the Rotterdam Convention<sup>11</sup>).

#### **A4.3.15.1**      *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.

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<sup>4</sup> *UN Model Regulations* means the Model Regulations annexed to the most recently revised edition of the Recommendations on the Transport of Dangerous Goods published by the United Nations.

<sup>5</sup> *IMDG Code* means the International Maritime Dangerous Goods code, as amended.

<sup>6</sup> *ADR* means the European Agreement concerning the International Carriage of Dangerous Goods by Road, as amended.

<sup>7</sup> *RID* means the Regulations concerning the International Carriage of Dangerous Goods by Rail, as amended.

<sup>8</sup> *ADN* means the European Agreement concerning the International Transport of Dangerous Goods by Inland Waterways, as amended.

<sup>9</sup> *Montreal Protocol* means the Montreal Protocol on Substances that Deplete the Ozone Layer, as either adjusted and/or amended.

<sup>10</sup> *Stockholm Convention* means the Stockholm Convention on persistent organic pollutants.

<sup>11</sup> *Rotterdam Convention* means the Rotterdam Convention on the prior informed consent procedure for certain hazardous chemicals and pesticides in international trade.

This should include whether the substance is subject to any prohibitions or restrictions in the country or region into which it is being supplied.

**A4.3.16 SECTION 16 – Other information**

Provide information relevant to the preparation of the SDS in this section. This should incorporate other information that does not belong in sections 1 to 15 of the SDS, including information on preparation and revision of the SDS such as:

- (a) the date of preparation of the latest 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. Suppliers should maintain an explanation of the changes and be willing to provide it upon request;
- (b) a key/legend to abbreviations and acronyms used in the SDS; and
- (c) key literature references and sources for data used to compile the SDS.

*NOTE: While references are not necessary in SDS's, references may be included in this section if desired.*

