UN/GHS-SC/4/INF.14

Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals (Fourth session, 9-11 December 2002, Agenda item 2)

Revision of ISO 11014 Safety data sheet

Submitted by the Secretariat

The UNECE Secretariat has been informed by ISO that they are currently in the process of revising the ISO 11014 Standard about safety data sheets in order to introduce and comply with the requirements laid down in Chapter 1.5 of the GHS regarding the SDS. This project of revision is in its preliminary stage. The task is performed by Technical Committee TC 47 serviced by the Japan Chemical Industry Association (JCIA). JCIA is inviting all the affiliated standardization organizations of ISO to participate in the revision and propose amendments to the draft proposed by the >Secretariat. ISO is inviting the UNECE to give its input if any and, eventually, to actively participate in the project.

The GHS delegates will find reproduced below for their information and consideration a copy of the preliminary draft of the revised standard proposed by JCIA. For easy convenience, JCIA has also provided a table that compares the current ISO edition (1994), the draft GHS Chapter 1.5 on SDS and the new ISO proposal. This comparison table is not reproduced on this paper but is available on our website as INF.14/Add.1.

The GHS Sub-Committee may wish to propose comments to ISO TC 47 on the ISO 11014 revised proposal.

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Secretariat: JISC

Safety data sheet for chemical products — Part 1: Content and order of sections

Fiches de données de sécurité pour les produits chimiquies — Partie 1: Contenu et plan type

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 11014-1 was prepared by Technical Committee ISO/TC 47, Chemistry.

This second edition cancels and replaces the first edition (ISO 11014—1:1994) and annex of which have been technically revised.

Annex A forms an integral part of this part of this International Standard.

Introduction

The safety data sheet for chemical products, SDS, gives information on various aspects of these chemical products (substances or mixtures) concerning safety, health and environmental protection. The SDS supplies for these aspects, basic knowledge of the chemical products and given recommendations on protective measures and emergency actions. In some countries, this sheet is called a material safety data sheet, MSDS. Throughout ISO this International Standard, the term SDS will be used.

The SDS is a means of transferring essential hazard information (including information on transport, handling, storage and emergency actions) from the supplier of a chemical product to the recipient of the product. It may also be used to transfer this information to institutions, services and other bodies that play a role in dealing with the chemical product.

The objective of this International Standard is to create consistency in providing information on safety, health and environmental matters for chemical products.

In order to establish uniformity, certain requirements, have been laid down as to how information on the chemical product shall be given (for instance the wording, numbering and sequence of the headings) This International Standard provides flexibility to accommodate different text- processing/transmission systems

The first edition (ISO 11014-1:1994) had been developed for worldwide application and followed a SDS model as outlined in e.g. EC Commission Directive 91/155/EEC defining and laying down the detailed arrangements for the system of specific information relating to dangerous preparations and Chemical Manufacturing Association (CMA), present American Chemistry Council (ACC), Interim guideline for the preparation of material safety data sheets, with only minor deviations in the text of the section headings. 1992 UN Conference on the Environment and Development (UNCED) adopted Agenda 21 in which UNCED recommended that a globally harmonized hazard classification and compatible labelling system of chemicals (GHS) including safety data sheet and easily understandable symbols should be available, as one of the six areas for action identified in Chapter 19 on environmentally sound management of toxic chemicals. Upon this recommendation, the technical work of harmonization was carried out through three focal points, namely OECD for health and environmental hazard classification criteria, the UN committee of experts on transport of dangerous goods (UN CETDG) for physical classification criteria, and International Labour Office (ILO) for hazard communication. ILO working group comprised of experts from member countries, employers, workers, and observers from inter-governmental and non-governmental-organisations finalized the integrated GHS document. The final GHS document which includes the classification criteria, labeling elements, decision logic for classification and selection of labeling elements, as well as a guidance on safety data sheet and various aspects of the system as it applies to transport, work place or consumers was transmitted to the UN sub-committee of experts on GHS within the UN Committee of experts for the transport of dangerous goods and globally harmonized system of classification and labelling of chemicals, established by the UN Economic and Social Council.

This International Standard has been developed by revising the first edition to introduce the requirements laid down in the GHS document on hazard communication: Safety Data Sheets.

It does not necessarily reflect or represent the different national or local regulatory requirements that may be specific for certain countries/states. It is therefore recommended that reviews outlining the different national or local regulatory requirement relevant to SDSs are made available to those who prepare SDSs. The provision of this knowledge to SDS authors will enhance the establishment and acceptance of only one SDS per chemical product in different countries/states, enabling fully consistent information to be provided.

The obligations of the recipient of an SDS are beyond the scope of this International Standard. Some of them are included, however, to clearly differentiate between the obligations of the SDS and those of the recipient of the SDS.

Safety data sheet for chemical products — Part 1: Content and order of sections

Scope

ISO 11014 presents information for the compilation and completion of an SDS. It defines specifically;

- the general layout of the SDS;
- the 16 standard headings;
- the numbering and the sequence of these 16 standard headings;
- the items necessary to fill in an SDS and the conditions of their applicability or utilization.

This International Standard does not define a fixed format, nor does it include an actual SDS to be filled in.

Normative reference

The following referenced document is indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 31-8:1992, Quantities and units — Part 8: Physical chemistry and molecular physics.

Terms and

definitions

For the purposes of this International Standard, the following terms and definitions apply.

3.1

safety

freedom from unacceptable risk of harm1)

3.2

risk

combination of the probability of occurrence of harm and the severity of that harm 1)

3.3

hazard

a potential source of harm¹⁾

3.4

harm

physical injury and/or damage to health or property 1)

¹⁾ ISO/IEC Guide 51:1999. Guidelines for the inclusion of safety aspects in standards.

3.5

supplier

party responsible for making a chemical product available to a recipient

3.6

recipient

party receiving a chemical product for industrial or professional use, such as storage, handling, processing or packaging, from a supplier

3.7

substance

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

3.8

mixture

mixture or solution composed of two or more substances

3.9

chemical product

substance or preparation

3.10

ingredient

constituent of a chemical product

3.11

exposure control

the full range of precautionary measures to protect the user of the chemical product

3.12

item

any textual information corresponding to a subheading in an SDS

3.13

GHS

Globally Harmonized System for the Classification and Labelling of Chemicals²⁾

General aspects

An SDS applies to a chemical product as a whole.

Information contained in an SDS is non-confidential. Confidential information on ingredients may be given in a different way, provided section 2 of annex A is observed.

Any supplier should provide a complete SDS to the recipient and shall report relevant information on safety, health and environment. The supplier has the obligation to keep the SDSs up to date and to provide the recipient with the latest edition.

The recipient of an SDS is responsible for acting in accordance with a risk assessment in regard of the conditions of product use and for taking necessary precautionary measure in a given work situation, and has the responsibility to keep the users informed about the hazards relevant to their individual workplace.

²⁾ The document is to be published by UN

The recipient of an SDS is responsible for choosing the appropriate way of informing the users. When formulating the specific instructions for the workplace, the recipient should consider the general recommendations of relevant SDSs.

Since an SDS is merely product-related, it cannot take into account all the possible situations which may arise at any given workplace. Therefore an SDS only constitutes part of the information necessary to establish a safety programme.

Contents and general layout of an SDS

An SDS shall provide the chemical product information given under the following 16 standard headings, the wording, numbering and sequence of which shall not be altered:

- 1 Product and company identification
- 2 Hazards 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

Under each of the 16 standard headings, relevant information shall be stated. If this information is not available, then it shall be stated why not. Blanks shall not be left, with one exception under standard heading 16 "Other information", where a blank is allowed. In an SDS, the sources of information do not normally have to be specified.

The 16 sections corresponding to the 16 standard headings shall be completed in accordance with the recommendations and requirements of annex A "Instructions for the compilation and completion of an SDS".

These 16 sections may be subdivided by means of subheadings. However, unlike the 16 standard headings, the subheadings shall not be numbered.

The use of subheadings where appropriate is recommended. When subheadings or items are given, they shall be given in the sequence specified in annex A. If specific information is not applicable or not available under a particular subheading, the SDS should clearly state this. Every page of an SDS shall include the name of the chemical product as used on the label, and shall be dated and numbered. The page numbering system should include the total number of pages or should indicate the last page as such. The date indicated shall be the latest revision date.

The 16 sections shall be separated clearly. The headings and subheadings shall be presented in a conspicuous way.

Texts in an SDS should be written in a clear and concise manner. Commonly used phrases are recommended. An SDS should be in a language acceptable to the recipient.

(normative)

Instruction for the compilation and completion of an SDS

The following instructions are intended as guidance for the compilation and completion of SDSs. Their purpose is to ensure that the content of each of the sections listed will enable recipients to take the necessary measures relating to safety, protection of health at the workplace and protection of the environment.

- The 16 sections of SDSs shall be completed in accordance with the recommendations and requirements of this annex.
- This annex lists the main items which will be used to complete the 16 sections. This annex lists the main items only, because it is impracticable to list all items which may possibly be included in an SDS.
- These main items may be used as subheadings in an SDS. If they are used, the wording given is recommended, not obligatory. The preferred wording is underlined. Other items may be used as subheadings, but are not recommended.
- Information not specifically relevant to one of the items/subheadings mentioned in this annex, but relevant for the SDS, may be stated under an additional subheading, called for instance "Further information" or "Specific data".
- For a given chemical product, not all of the items/subheadings listed have to be used and completed, since some of them are optional.

PRODUCT AND COMPANY IIDENTIFICATION

This section shall state the identification of the substance or mixture and of the supplier. <u>Product name</u> as used on the label shall be stated.

Other means of identification available, e.g. the supplier product code, may also be indicated. Indicate the intended or recommended uses and restrictions on use of the substance or mixture as far as they are known. Where there are many possible uses, only the most important or common uses need be listed. This should include a brief description of what it actually does. The name, address and telephone number of the supplier shall be stated. Telefax number may also be given.

The <u>emergency telephone number</u> used by the company should be given.

HAZARDS IDENTIFICATION

This section shall state the classification and label information of the substance / mixture. If the product is classified in the GHS, this section shall state <u>GHS classification</u> of the substance/mixture and any regional information as well as <u>GHS label elements</u>, including precautionary statements. (Hazard symbols may be provided as a graphical reproduction of the symbols in black and white or the name of the symbol e.g. flame, skull and crossbones.)

Other hazards which do not result in classification (e.g. dust explosion hazard) or are not covered by the GHS should be given.

It may be necessary to summarize clearly and briefly the <u>most important hazards</u> and effects of the product (adverse human health effects, environmental effects, physical and chemical hazards.

Where appropriate, specific hazards should be given.

COMPOSITION/INFORMATION ON INGREDIENTS

This section shall state whether the chemical product is a substance or a mixture. In the case of a substance, the <u>common chemical name</u> or the <u>generic name</u> shall be given. <u>Synonyms</u>, if any, should be given.

The Chemical Abstract Service Registry Number (<u>CAS number</u>), if any, should be given. Any regional information, e.g. EU number, may be given.

Impurities and stabilizing additives which are themselves classified and which contribute to the hazard and/or classification of the substance should also be indicated.

In the case of mixture, if the ingredients which are hazardous within the meaning of the GHS and are present above their cut-off levels, the chemical identity and concentration or concentration ranges of ingredients shall be given. It is not necessary to give the full composition. When defined, <u>components contributing to the hazard</u> or impurities contributing to the hazard of the mixture should be given, with their chemical or generic name and their concentration or concentration range.

FIRST-AID MEASURES

This section shall state the first-aid measures to be taken, if necessary, if appropriate, it shall state which actions have to be avoided at all costs. The information should be readily understandable by the victim and/or the first-aider

The information shall be subdivided according to the different exposure routes, i.e. <u>inhalation</u>, skin contact, eye contact and ingestion.

A brief description of the <u>most important symptoms/effects</u>, acute and delayed, may be given here, but a detailed description of symptoms and effects should be given under heading 11. If appropriate, advice for the <u>protection of first-aiders</u> and/or special <u>notes to a physician</u> should be included here.

Indication of immediate medical attention and special treatment needed, if necessary, should be stated.

FIRE-FIGHTING MEASURES

This section shall state which <u>extinguishing media</u> are suitable and subsequently, if appropriate, which extinguishing media are unsuitable.

<u>Specific hazards</u> arising from the chemical (e.g. nature of any hazardous combustion products) should be indicated here.

Special <u>protective equipment</u> and <u>precautions for fire-fighters</u> should be indicated here.

ACCIDENTAL RELEASE MEASURES

This section shall contain information on:

- Personal precautions, protective equipment and emergency procedures;
- environmental precautions;
- methods and materials for containment and cleaning up (recovery, neutralization and disposal, if different from section 13).

HANDLING AND STORAGE

Handling

This subsection shall describe precautions for safe handling.

Storage

This subsection shall describe conditions for safe storage, including any incompatibilities.

EXPOSURE CONTROLS/PERSONAL PROTECTION

Specific <u>control parameters</u> such as occupational exposure limit values or biological limit values should be given.

If appropriate, <u>engineering controls</u> should be given in this section.

This section shall also contain recommendations on appropriate <u>personal protective</u> <u>equipment</u>, such as for:

- respiratory protection;
- hand protection;
- eye protection;
- skin and body protection.

PHYSICAL AND CHEMICAL PROPERTIES

This section shall include chemical product information on appearance, i.e., <u>physical state</u>, <u>form(option)</u> and <u>colour</u>, and on <u>odour</u>.

Where available, odour threshold may be given.

Where applicable, this section shall state information on:

- <u>pH</u>, with indication of the concentration;
- specific temperatures/temperature ranges at which changes in physical state occur (e.g. melting point/freezing point, boiling point/initial boiling point/boiling range);
- <u>flashpoint</u>;
- autoignition temperature;
- evaporation rate;
- flammability (solid, gas);
- upper/lower flammability or explosive limits;
- vapour pressure;
- vapour density;
- density/relative density;
- solubility(ies), with indication of the solvent(s);
- partition coefficient: octanol/water;.
- decomposition temperature.

Other data relevant to the safe use of the chemical product, such as radioactivity or bulk density, should be indicated as well.

Units shall be expressed in accordance with the SI system, as in ISO 31-8. Other units may also be given, but only in addition to the SI units.

If appropriate, the method used in the determination of a property should be identified.

STABILITY AND REACTIVITY

This section should state the <u>chemical stability</u> and <u>possibility of hazardous reactions</u> occurring under specific conditions.

This heading shall contain information on:

- conditions to avoid (e.g. static discharge, shock or vibration);
- incompatible materials;
- hazardous decomposition products.

TOXICOLOGICAL INFORMATION

This section shall contain the concise but complete and comprehensible description of the various toxicological (health) effects of the chemical product, which can arise if the user comes into contact with the chemical product, and the available data used to identify those effects.

Information should be given according to the different exposure routes (e.g. inhalation, skin contact, eye contact, ingestion).

Symptoms related to the physical, chemical and toxicological characteristics should be stated. If appropriate, distinction shall be made between effects due to single exposure, repeated exposure and continuous exposure. If appropriate, delayed and immediate effects and also chronic effects from short- and long-term exposure shall be mentioned separately.

Numerical measures of toxicity should include, if appropriate:

- acute toxicity:
- skin irritation/corrosion;
- eye irritation/corrosion;
- respiration or skin sensitization;
- mutagenicity;
- carcinogenicity;
- reproductive toxicity;
- specific target organ oriented toxicity/ chronic toxicity or long term toxicity.

Additional results of data from scientific experiments, with a reference to the source of information, may be given.

ECOLOGICAL INFORMATION

This section shall contain information possible environmental effects, behaviour and fate, such as information on:

- ecotoxicity (aquatic and terrestrial, where available)
- persistence and degradability
- bioaccumulative potential
- mobility in soil
- other adverse effects

Additional results or data from scientific experiments, with a reference to the source of information, may be given.

Any ecological limit value may be indicated here.

DISPOSAL CONSIDERATIONS

This section shall contain appropriate information on recommended methods for safe and environmentally preferred disposal.

These methods of disposal apply not only to the chemical product (<u>waste from residues</u>) but also to any <u>contaminated packaging</u>.

Attention of the recipient should be drawn to the possible existence of local disposal regulations.

TRANSPORT INFORMATION

This section should contain information on codes and classifications according to <u>international regulations/regional regulations</u> for transport, differentiated by the mode of transport, such as land, inland waterways, sea and <u>air.</u>

The <u>UN number</u>, <u>UN Proper shipping name</u>, <u>Transport Hazard class(es)</u> and <u>packing group</u>, if applicable, should be stated.

Marine pollutant (Y/N) should be stated.

Special precautions which a user needs to be aware of or needs to comply with in connection with transport or conveyance either within or outside their premises should be mentioned.

REGULATORY INFORMATION

This section should contain information on safety, health and environmental regulations specific for the product in question.

OTHER INFORMATION

This section should provide any further information which may be important from a safety point of view but not specifically relevant to previous headings. Literature references may be specified here.