ECHA
EUROPEAN CHEMICALS AGENCY

GUIDANCE IN A NUTSHELL

# Compilation of safety data sheets

The document aims to explain in simple terms the main principles and obligations relating to the compilation and provision of safety data sheets in accordance with the REACH Regulation

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# 1. Introduction

This Guidance in a Nutshell provides a concise and simple introduction to the obligations related to compilation and provision of a safety data sheet (SDS) as foreseen by Article 31 and Annex II to Regulation (EC) No 1907/2006 (the REACH Regulation), in particular as amended by Commission Regulation (EU) No 453/2010. It describes in brief the main principles related to compilation of SDSs and the requirements which suppliers of substances and mixtures have to fulfil to comply with the obligation of providing an SDS to their customers.

This Guidance in a Nutshell is mainly aimed at managers and decision-makers of companies supplying chemical substances in the European Economic Area[1] (EEA), particularly those belonging to the Small and Medium-sized Enterprises (SME) category. This Guidance will help the reader to understand what is required from those who are in charge of compiling SDSs for substances and mixtures and the important link between information in the SDS and obligations under the legislation on the protection of workers. Eventually the reader can decide whether he needs to read the full *Guidance on the compilation of safety data sheets.* Please note that the information contained in this Guidance in a Nutshell will not suffice for those who are required to compile a safety data sheet – they are strongly advised to read the full guidance.

This document will also be useful to recipients of an SDS to understand what they should expect and how to deal with the information received.

Companies located outside the EEA whose products are exported to the EEA may use this Guidance in a Nutshell to help them to understand the requirements for SDSs and the obligations that their agents and customers in the EEA have to fulfil.

[1] The European Economic Area is composed of Iceland, Liechtenstein, Norway and the 28 European Union Member States.

# 2. Essentials to understand

## 2.1 The safety data sheet (SDS)

SDSs are a well-established and effective mechanism for transmitting appropriate safety information along the supply chain on substances and mixtures which meet specific classification criteria. The requirements for SDSs were already in place before the REACH Regulation entered into force but the Regulation further developed these requirements.

The original requirements introduced by REACH have been further adapted to take into account the rules of the Global Harmonised System (GHS)[2] for safety data sheets and the implementation of the CLP Regulation[3].

The SDS should provide comprehensive information about a substance or mixture that is used in a professional or industrial environment. It is a source of information on both environmental and health hazards and on safety precautions.

The content and format of an SDS within the EEA is defined in Annex II to the REACH Regulation. Basically, the SDS follows a 16-Section format which is internationally agreed and to be provided in the official language of the Member State(s) where the substance or mixture is placed on the market.

It needs to be noted that Annex II to REACH has been amended and special transition periods for the implementation of the specific requirements are in place. In particular, some provisions entered into force on 1 December 2010 and additional new provisions will enter into force on 1 June 2015. The full *Guidance on the compilation of safety data sheets* provides detailed information on the relation between the provisions as outlined in the different versions of Annex II.

## 2.2 Who is required to compile an SDS?

The SDS is normally first compiled by the manufacturer or importer or Only Representative (or by someone on their behalf), but the requirements of REACH in relation to the provision of SDSs apply at each stage of the supply chain. A supplier of a substance or mixture, which fulfills specific conditions, must provide an SDS for it, regardless of his position in the supply chain. When compiling their own SDSs, each of the actors along the supply chain should check the adequacy of the SDS received from his supplier and use all the relevant information to compile his own SDS.

Each actor remains responsible for the accuracy of the information in the SDS they provide.

It should be kept in mind that the compilation of a good SDS requires extensive knowledge in different fields, as the SDS itself covers a wide range of aspects concerning the substance or mixture properties, occupational health and safety, transport safety and environmental protection. REACH indicates that the SDS should be compiled by a “competent” person, but no specific definition of “competent” in this context is given in the Regulation. The responsible person may need to seek input from different internal or external sources, whilst still ensuring consistency of the SDS.

[2] The revised version is available at: unece.org/trans/danger/publi/ghs/ghs_rev04/04files_e.html
[3] Regulation (EU) No 1272/2008.

## 2.3 SDSs and REACH

The REACH Regulation retains, to a large extent, the traditional structure and format of the previous legislation. However, it introduces some important changes with the aim to improve the quality and completeness of the information to be forwarded downstream. The full *Guidance on the compilation of safety data sheets*, chapter 2, provides an introductory overview of the main changes to the different sections and subsections of the SDS. In particular, it highlights where additional requirements or changes arise from the revision of Annex II to REACH, which are to be applied only by specific deadlines.

One of the main new elements to be considered arises from the requirement under REACH to register substances manufactured or imported at a volume above 1 tonne per year. For registered substances, information in the SDS for the substance must be consistent with that provided in the registration dossier. In addition, where registrants and downstream users are required to prepare a Chemical Safety Report (CSR) which results in the generation of an exposure scenario, they must attach the relevant exposure scenario(s) as an annex(es) to the SDS.

Downstream users have to consider relevant exposure scenario information received from suppliers when compiling their SDSs. Suppliers of mixtures may have several options for communicating relevant safe use information on the mixture. These are outlined in chapter 5.1 of this Gudiance in a Nutshell and in more detail in the parent *Guidance on the compilation of safety data sheets*.

# 3. For which products is an SDS required?

## 3.1 SDS to be provided mandatorily without request

REACH establishes specific criteria for when an SDS must be provided for a substance or a mixture. An SDS must be provided for a substance that meets the criteria for classification as hazardous on the basis of the criteria established by the CLP Regulation ((EC) No 1272/2008) (for mixtures, until 1 June 2015, the relevant piece of legislation is Directive 1999/45/EC, the "Dangerous Preparations Directive" (DPD)).

Furthermore, the obligation to provide an SDS also applies to substances which are considered to be Persistent, Bioaccumulative and Toxic (PBT) or very Persistent and very Bioaccumulative (vPvB) according to Annex XIII to REACH or are included in the Candidate List of substances for possible inclusion in the Authorisation List[4]. It should be noted that the Candidate list is regularly updated with the addition of new substances.

## 3.2 SDS to be provided upon request

When the substance or mixture does not meet the criteria[5] for classification as hazardous, the supplier is not obliged to provide an SDS for this substance or mixture. Nevertheless, if a mixture contains classified substances, substances that are PBT or vPvB or a substance included in the Candidate List above a certain threshold specified in the REACH Regulation or substances which have Community workplace exposure limits[6], the customer is entitled to

[4] For more information on the Candidate List and the authorisation process please refer to the dedicated ECHA web page at echa.europa.eu/web/guest/regulations/reach/authorisation/the-candidate-list.
[5] For mixtures, until 1 June 2015 this refers to criteria for classification as dangerous according to the DPD; from 1 June 2015 this refers criteria for classification as hazardous according to the CLP regulation.
[6] A relevant source of information is the web page on OELs on the OSHA website available at osha.europa.eu/en/topics/ds/exposure_limits.

request an SDS and the supplier has the obligation to provide it.

Only a downstream user (industrial or professional user)[7] or a distributor[8] has the right to request an SDS for a mixture meeting the above mentioned criteria.

### 3.3 Information to be provided to the general public

When hazardous substances or dangerous mixtures are also offered or sold to the general public, an SDS does not need to be supplied. To rely on this exemption however, the supplier must provide "*sufficient information to enable the user to take all necessary measures as regards the protection of human health, safety and the environment*". REACH does not specify how this safety information should be provided, hence the supplier can choose the most suitable means according to the case and the recipient (e.g. by labelling or with product inserts).

### 3.4 Products for which an SDS is not required

For some mixtures REACH provides a general exemption from the need to supply information covered by Title IV "Information in the supply chain", including the provision of SDSs. The mixtures which benefit from such an exemption are such that are in the finished state, intended for the final user, and that belong to specific categories for which other pieces of legislation exist and an ovelap with REACH requirements should be avoided (e.g. medicinal products, cosmetic products and food and feedingstuffs).

Certain substances are not in the scope of the REACH Regulation (radioactive substances, substances under customs supervision, non-isolated intermediates, products during carriage by rail, road, inland waterway, sea or air, etc.) and therefore again the SDS-related obligations do not apply.

## 4. When and how the SDS has to be provided

The SDS must be provided free of charge, no later than when the substance or the mixture is first supplied. It can be provided on paper or electronically. In every case, it is a duty of the supplier to actually deliver the SDS to the recipient. This means, for instance, that to only make it available on a web page is not sufficient.

There is no need to supply further copy(ies) of an SDS with subsequent deliveries to the same recipient unless the SDS is revised. An SDS must however be updated without delay when specific new information is available. The REACH Regulation specifies which new information triggers the obligation for an update: information affecting risk management measures, information on hazards, when authorisation has been granted or refused or when a restriction has been imposed. Updates for other reasons can be made voluntarily at any time by the supplier. The update must also be provided to all former recipients to whom the substance or mixture has been supplied within the preceding 12 months.

## 5. Which information has to be included in an SDS

Annex II to REACH specifies the 16 Sections and their subsections which must form the

[7] Defined accroding to REACH (Article3(13)).
[8] Defined according to REACH (Article 3(14)).

structure of the SDS as well as the content of each.

A transitional period has been established to allow a smooth change to information based on the CLP Regulation. Particular provisions concern, for example, the information on classification and labelling and the identification of the constituents of substances or components of a mixture to be indicated on the SDS.

For substances, until 1 June 2015, the hazard classification is to be given according to the CLP Regulation together with that according to Directive 67/548/EEC (the “Dangerous Substances Directive” (DSD)). After that date, only the CLP classification is required.

For mixtures, until the same date 1 June 2015, classification according to Directive 1999/45/EC (DPD) must be indicated. The supplier can nevertheless decide whether he wants to indicate also the classification according to CLP (note: this is mandatory if the mixture is labelled in accordance with CLP). From 1 June 2015, only information on classification according to CLP should be given for both substances and mixtures.

The full *Guidance on the compilation of safety data sheets* provides more guidance as well as an explanatory table on the application of this transitional period.

When compiling the SDS, it needs to be noted that where specific data are not used, or where data are not available, this must be clearly stated in the corresponding Section or subsection of the SDS, as the SDS must not contain blank subsections. The reason for a lack of information must be a valid one. Since the SDS must enable users to take the necessary measures to protect human health, safety at the workplace, and protection of the environment, information which is required to appear in an SDS cannot be claimed as confidential for the purposes of communication of information in the supply chain.

## 5.1 Including exposure scenario information

One of the main concepts introduced by REACH and affecting SDSs is that of the exposure scenario. Any actor required to prepare a CSR including exposure scenarios has to attach the relevant exposure scenario(s) to the SDS. An exposure scenario describes how a substance can be manufactured or used in a safe way (i.e. ensuring protection of human health and environment) and should refer to the uses identified in the SDS itself. In practice, the exposure scenario(s) extend(s) the information given in the main body of the SDS. Thus the exposure scenario and the SDS need to be considered together and be consistent. It is very important that the supplier presents the information in a way that is readily understandable by the immediate downstream user who has to identify, apply and recommend the relevant measures further downstream.

Downstream users and other actors who need to supply an SDS for a substance or mixture, but are not required to prepare a CSR, have to consider and include relevant safe use information sourced from exposure scenario(s) received from their supplier(s) when compiling their SDS(s). They can either attach the relevant exposure scenarios to the SDS, integrate relevant exposure information in the body of the SDS (i.e. Sections 1 – 16 of the SDS) or append safe use information for the mixture derived from the exposure scenarios of the component substances. The most suitable option should be selected based on considerations made on a case by case basis. It should be considered that not all the possible options are equally suitable for the specific recipients who should, furthermore, receive only the information relevant to them. More detailed information on this is provided in chapter 3.23 and Appendix 2 of the parent guidance and also in the ECHA *Guidance for downstream users*.

By contrast with the case for an SDS, the format of the exposure scenario is not fixed by the legal text. One available supporting tool to generate a suitable format is the Chemical Safety

Assessment and Reporting tool, Chesar[9], which generates exposure scenarios ready to be annexed to the SDS.

# 6. Where to find further guidance and other relevant information

This Guidance in a Nutshell should provide you with a summary and short explanation of the main principles concerning the compilation of safety data sheets under Article 31 and Annex II to the REACH Regulation. However, those actually compiling SDSs are strongly recommended to consult the full *Guidance on the compilation of safety data sheets* to meet communication requirements. This is available at

echa.europa.eu/web/guest/guidance-documents/guidance-on-reach.

The full Guidance on the compilation of the safaty data sheets provides more detailed information on the content of each Section of the SDS and on special cases, as well as some examples entries in subsections. Additional insight and relevant information may also be gained by consulting in particular the following documents and web pages:

- The ECHA database on registered substances: echa.europa.eu/web/guest/information-on-chemicals/registered-substances;
- The ECHA classification and labelling inventory: echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database;
- The ECHA *Guidance for downstream users*: echa.europa.eu/web/guest/guidance-documents/guidance-on-reach;
- The European Commission web page on SDSs: ec.europa.eu/enterprise/sectors/chemicals/documents/classification/archives/safety-data-sheet/index_en.htm

[9] Available at chesar.echa.europa.eu.

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