

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

Version 2.0
December 2015



LEGAL NOTICE

This document aims to assist users in complying with their obligations under the REACH Regulation. However, users are reminded that the text of the REACH Regulation is the only authentic legal reference and that the information in this document does not constitute legal advice. Usage of the information remains under the sole responsibility of the user. The European Chemicals Agency does not accept any liability with regard to the use that may be made of the information contained in this document.

Reference: ECHA-15-G-08-EN

ISBN: 978-92-9247-585-7

Publ.date: December 2015

Language: EN

The European Chemicals Agency (ECHA) is producing a series of “simplified” versions of the REACH guidance documents in order to make the corresponding REACH guidance documents published by the Agency more accessible for industry. As short summaries, these documents cannot contain all details included in the full guidance documents. Thus, in case of doubt, it is recommended to consult the full guidance documents for further information.

© European Chemicals Agency, 2015

If you have questions or comments in relation to this document please send them (indicating the document reference, issue date, chapter and/or page of the document which your comment refers to) using the Guidance feedback form. The Guidance feedback form can be accessed via the “Support” section of the ECHA website at:

comments.echa.europa.eu/comments_cms/FeedbackGuidance.aspx.

European Chemicals Agency

Mailing address: P.O. Box 400, FI-00121 Helsinki, Finland

Visiting address: Annankatu 18, Helsinki, Finland

Version	Changes	Date
Version 1.0	First edition.	December 2013
Version 2.0	Update following the update of the parent guidance to version 3.0. The update is limited to the following: (1) Addition in chapter 1 of reference to Commission Regulation (EU) 2015/830. (2) Update in chapter 2.1 and 5 of information about transitional period according to Commission Regulation (EU) 2015/830. (3) Deletion in chapter 2.3 of reference to the overview of changes brought by REACH which was deleted from parent guidance. (4) Deletion in chapter 3.1 of reference to Dangerous Preparation Directive in relation to mixtures. (5) Update in chapter 6 of sources for further guidance.	December 2015

Table of Contents

1. INTRODUCTION	5
2. ESSENTIALS TO UNDERSTAND.....	6
2.1 The safety data sheet (SDS)	6
2.2 Who is required to compile an SDS?.....	6
2.3 SDSs and REACH.....	7
3. FOR WHICH PRODUCTS IS AN SDS REQUIRED?	7
3.1 SDS to be provided mandatorily without request	7
3.2 SDS to be provided upon request	7
3.3 Information to be provided to the general public	8
3.4 Products for which an SDS is not required	8
4. WHEN AND HOW THE SDS HAS TO BE PROVIDED	8
5. WHICH INFORMATION HAS TO BE INCLUDED IN AN SDS	8
5.1 Including exposure scenario information.....	9
6. WHERE TO FIND FURTHER GUIDANCE AND OTHER RELEVANT INFORMATION.....	9

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) 2015/830. 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 Area¹ (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 Regulation³.

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 a special transition period for the implementation of the specific requirements is in place. In particular, under certain conditions SDSs provided to any recipient before 1 June 2015 may continue to be used until 31 May 2017 without bringing them into line with the version in the Annex to Regulation (EU) 2015/830. The full *Guidance on the compilation of safety data sheets* provides more information on this.

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: http://www.unece.org/trans/danger/publi/ghs/ghs_welcome_e.html

³ Regulation (EU) No 1272/2008.

2.3 SDSs and REACH

The REACH Regulation retained, to a large extent, the traditional structure and format of the previous legislation. However, it introduced some important changes with the aim to improve the quality and completeness of the information to be forwarded downstream.

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 Guidance 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 or mixture that meets the criteria for classification as hazardous on the basis of the criteria established by the CLP Regulation ((EC) No 1272/2008).

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 List⁴. 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 criteria⁵ 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 limits⁶, the customer is entitled to request an SDS and the supplier has the obligation to provide it.

Only a downstream user (industrial or professional user)⁷ or a distributor⁸ has the right to request an SDS for a mixture meeting the above mentioned criteria.

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 Note that from 1 June 2015 this refers to criteria for classification as hazardous according to the CLP regulation also for mixtures.

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.

⁷ Defined according to REACH (Article 3(13)).

⁸ Defined according to REACH (Article 3(14)).

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 overlap 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 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.

From 1 June 2015, only information on classification according to CLP should be given for both substances and mixtures in the SDS (as well as on labels). There are transitional provisions for

SDSs (and for labelling) for substances and mixtures already on the market before 1 June 2015. However the information in the SDS has always to correspond to that on the label.

The full *Guidance on the compilation of safety data sheets* provides more guidance 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 2.23 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, Chesar⁹, 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

⁹ Available at chesar.echa.europa.eu.

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

The full Guidance on the compilation of the safety 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 Safety data sheet eGuide: <http://view.pagetiger.com/ECHAeGuide1-1/Issue1>
- 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;

EUROPEAN CHEMICALS AGENCY
ANNANKATU 18, P.O. BOX 400,
FI-00121 HELSINKI, FINLAND
ECHA.EUROPA.EU