CIA | Chemical Industries Association

Working for chemical and pharmaceutical businesses

Compiling Extended-Safety Data Sheets – March 2018

Tips and recommendations for substances

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This document is aimed at providing basic tips and recommendations to writers of extended-Safety Data Sheet on how to improve the readability of the annex for substances. It reflects the feedback provided by CIA members based on their practical experience in writing extended-Safety Data Sheet and also includes a number of suggestions extracted from existing ECHA guidance documents and supporting industry material.

This document is part of a series of guidance documents on Extended-Safety Data Sheets produced by the CIA. Titles in this series include:

Compiling Extended-Safety Data Sheets: Tips and recommendations for substances

Compiling Extended-Safety Data Sheets: Tips and recommendations for mixtures

Receiving Extended-Safety Data Sheets: 5 steps for assessing and extracting information

Background – legal requirements

The provision of extended-Safety Data Sheet (ext-SDS) is a legal requirement under REACH and applies to hazardous substances and PBTs/vPvBs manufactured and imported above 10 tonnes per year. Manufacturers and importers have the duty to communicate the information contained in the Chemical Safety Report (CSR) of relevance to downstream users through the transmission of the ext-SDS in order to ensure safe use of the substance.

By law, exposure scenarios must be included for identified uses in the annex of the ext-SDS with the view to provide 'use-related' advice on the safe conditions of use for the substance concerned throughout its life cycle. This includes the communication of risk management measures in relation to workers, environment and consumers exposure.

REACH introduces also clear legal obligations to recipients of ext-SDS, as they must check if their own uses are covered by the exposure scenarios supplied, comply with the operational conditions and risk management measures provided by the supplier of the ext-SDS or demonstrate that equivalent level of control is in place at site level. They have also to enable further communication down the supply chain.

REACH has therefore introduced new challenges for both suppliers and downstream users in terms of communication.

Efforts should be made to consolidate the information provided, in order to improve the readability of the documents whilst making them as clear and concise as possible. This will help ensure that the information is transmitted in a useable and understandable format down the supply chain.

Basics

As a starting point, companies involved in the preparation of ext-SDS should bear the following in mind:

- **Think about your audience**

Companies should always consider and remember who their audience is. Efforts should be made to produce ext-SDS in a format as practical and understandable as possible for customers. Two-way communication with DUs is essential to determine customers' needs and to avoid gold plated recommendations in terms of engineering control measures. It is also important to highlight that the companies writing ext-SDS could be faced with audiences with different needs and expectations in terms of exposure scenarios communication (for instance end-users and formulators).

- **Extended SDSs are a communication tool**

The main aim of the SDS is to communicate risk management effectively and improve SHE management practices up and down the supply chains. It is important to check whether the information provided is fit-for-purpose and accessible and to guide customers to the information relevant to their company.

- **Who to involve at company level**

The new annex focuses on both health & safety and environmental risk management requirements. It is important for companies to involve both their occupational hygienist and environmental managers in the writing up of the document to ensure that the information is useful and in an understandable format for those two audiences. It is likely that both companies producing and receiving ext-SDSs need the practical support of an occupational hygienist and environment expert to check exposure scenarios and compare these with risk management measures already in place. Close communication and interaction between Regulatory Affairs and SHE departments at company level is therefore essential.

- **Human input is fundamental**

IT softwares are important tools that drive and support companies' day-to-day work in relation to the generation of SDS. Writing up exposure scenarios in a format understandable to the supply chain cannot be left to software only however. Human input is always required to ensure the information provided is understandable and of good quality.

- **Effective navigation is key**

Although the new safety data sheets are a lot longer that they were in the recent past, the actual length of the document may not be the biggest issue for readers. Most people only need to concentrate on a specific exposure scenarios that may run to a couple of pages. Finding the relevant information is the key and a good navigation system through the safety datasheet, such as a table of content, is a key aspect that SDS writers should consider to improve access to the different ext-SDS sections. In addition, good pagination with individual exposure scenarios starting at the top of a page is a good mean to make finding them easier.

- **Translating new terminology for the uninitiated**

REACH is full of new acronyms and codes that most people could be not familiar with. It could prove good practice to add a glossary of the key codes used in the document for easy reference or to provide a glossary as a standard part of the package of information provided as part of a company Product Stewardship communication programme.

Tips on improving the annex's content

Reducing the length

Some of the difficulties for readers are related to the fact that the inclusion of exposure scenarios in SDS leads to the production in some instances of very large documents for substances with multiple uses. This can be overwhelming at first. Writers of ext-SDS should endeavour to reduce the length of the document wherever possible. There are already some concise examples available.

Having extremely long and detailed documents could prove counter-productive with companies failing to find the relevant information to their circumstances leading to a reduction in SHE protection. Below is an outline of the elements to be considered to try to reduce the length of the document:

- **Be concise:** Try to limit each exposure scenario to 2 sides of A4 wherever possible. The exposure scenario information could be structured and presented in form of tables.

- **Provide an appropriate level of information:** The information in ext-SDS needs to be sufficient and balanced in terms of amount of details provided, whilst still being understandable and complying with REACH requirements. The exposure scenarios for communication in the supply chain need to contain all the information on operational conditions of use and risk management measures relevant to the downstream users in order to ensure that the product can be handled safely.

    Not all the information provided in the CSR needs to be included in the extended SDS. Nevertheless, do not forget that consistency with the information available in the CSR is required by law.

    Additional information could be made available for example through links to companies' website. For instance, information on exposure estimation does not necessarily need to be reported directly in the annex in form of numerical data (e.g. estimation of exposure and risk characterisation ratios). A link to a website could be used to address the recipient to this information.

- **Speak to your customers to understand their needs.** You might be faced with audiences with different needs in terms of exposure scenarios communication. Some customers could look for concise SDS (e.g. end users of chemicals); others (e.g. formulators) are likely to request additional or more detail information that needs to be processed further by them for incorporation into SDS for mixtures.

- **Use maps** have been developed to improve the quality of information on both uses and the conditions of use of substances that is being communicated up the supply chain. The use maps are normally completed by downstream user sector organisations. Information is collected on uses and the conditions of use within that sector in a harmonised and structured way. Registrants can also benefit from these use maps as they provide comprehensive information directly from the downstream users which will aid in the development of the chemical safety assessment.

- **Assess whether tailored exposure scenarios are a feasible option or not.** A way to reduce the length of the extended-SDS would be to produce tailored exposure scenarios for customers to cover only their relevant uses. The decision to produce tailored exposure scenarios or to send all exposure scenarios included in the registration should be taken on a case-by-case basis depending on the specific supply chain characteristics. However, sending tailored exposure scenarios to customers could be very difficult to put in practice especially in the case of commodity chemicals that can be used in many applications. It is also an unlikely option when your chemical is supplied by a distributor.

    Not all downstream users need to receive all the exposure scenarios that have been generated for a substance, especially where the supplier knows that a particular use is confidential or is very specialised and thus irrelevant to most customers.

    Suppliers should also consider whether some exposure scenarios are relevant for their own company's activities but not for their customers e.g. exposure scenarios for 'manufacturing activities' may only be relevant for a supplier's own activities.

    Whilst tailoring exposure scenarios may be desirable, it might not, however, be practical in some situations depending on the IT systems used to author and dispatch safety data sheets.

    In the long term, a function allowing companies to select which exposure scenarios should be included for a specific customer may be added to the software used to pull the ext-SDS together.

Improving comprehension

Some of the difficulties for readers are related to the fact that the inclusion of exposure scenarios in SDS leads to the production in some instances of very large documents for substances with multiple uses. This can be overwhelming at first. Writers of ext-SDS should endeavour to reduce the length of the document wherever possible. There are already some concise examples available.

Some tips that could help companies in the providing more accessible documents include:

- **Include a good navigation tool:** Although the ext-SDSs are on average longer than the traditional SDSs, the length of the document may not be the biggest issue for readers. Navigation through the safety data sheet is a key aspect that SDS writers should consider to improve the readability and accessibility of the information provided in the different sections of the ext-SDS. Means to improve navigation through the ext-SDS could include for instance:
  — A table of contents with reference to page numbers and short titles of the exposure scenarios, located in between the end of the main body of the SDS and the beginning of the annex;
  — Assigning a number/code for each exposure scenario and one for each contributing scenario (CS);
  — Group or arrange the exposure scenarios in a logical order according to life cycle stages or market sector;
  — The version number of the extended SDS should be referenced in the exposure scenarios.

- **Use simple language:** The exposure scenarios need to be readable and understandable to the intended user. The text used should be as clear and easy to follow as possible. The title of each exposure scenario needs to be clear and understandable so that the reader can identify which scenario applies to his/her company readily. For example, the use descriptors section can be followed by a description of the scope of process, which details the activities covered. The Use descriptor system developed by ECHA aims to standardise the way uses are described in the supply chain. Each contributing activity should be linked to a standardised use descriptor category (Process category [PROC], environmental release category [ERC], Product category [PC] and article category [AC]). This ensures that the contributing activities within the exposure scenario are being described the same along the supply chain. However, it cannot be assumed that all readers of exposure scenarios will be able to interpret the use descriptors. Therefore, it could be useful to include a glossary for the terminology used within the annex to aid the reader. The use descriptors can be also used as input parameters to derive exposure estimates in modelling tools such as ECETOC –TRA.

  ESCom standard phrase catalogue is part of the ESCom package produced by Cefic and DUCC and consists of standard phrases for exposure scenario communication. This enables information in the exposure scenarios to be communicated along the supply chain in a harmonised way while ensuring that the quality, consistency and clarity in the information exchanged between suppliers of substances and their customers is at a high level. Therefore, it is advisable to use these standard phrases where possible when constructing an exposure scenario.

- **Avoid copy-pasting:** As a supplier, it is your duty to ensure that the information provided enable readers to handle your product safely. Companies should not extract and simply append the full section 9 of the CSR of their registration dossier to the SDS. This approach may have been taken as an interim measure to meet legal requirements within the very tight deadline imposed by REACH deadlines in some cases. However, this is not an acceptable long-term practice and efforts should be made to improve and shorten the SDS, as it is very difficult for a non-expert to understand the information presented in a CSR.

- **Interact with SHE colleagues:** Work on the content of the annex with your company's SHE team to ensure that it is understandable and useable by environment and occupational experts.

- **Supply good practice advice separately:** Where suppliers like to provide good practice advice that goes beyond the REACH Chemical Safety Report, this information should be provided separately from the annex section on operational conditions and risk management measures. In particular, according to the ECHA guidance on exposure scenario format, a separate information field outside the exposure scenario should be used in the CSR and in the ext-SDS in case the registrant wishes to provide additional advice on how to practically control and prevent risks. It is important to note that these measures are not needed to demonstrate control of risks as defined by REACH. There is no obligation in fact for the downstream user to carry out a Chemical Safety Assessment [1] if the additional advice is not implemented.

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[1]   The Chemical Safety Assessment (CSA) is the process that identifies and describes the conditions under which the manufacturing and use of a substance is considered to be safe. The CSA is documented in the Chemical Safety Report (CSR). Downstream users should not forget that they could be requested in some circumstances to carry out their own Chemical Safety Assessment and Chemical Safety Report if their use/conditions of use are not covered by the suppliers' exposure scenarios. More information is available in the ECHA factsheet on SDS and exposure scenarios at http://echa.europa.eu/documents/10162/17246/du_fact_sheet_en.pdf

Formatting Exposure Scenarios

The format for exposure scenarios communication has changed several times in the guidance, which has led to some variations in the format found in ext-SDSs today. No prescribed format is required by the legal text at the moment however, ECHA has produced illustrative examples of exposure scenarios to highlight what is required in each of the four sections. Overall, unstructured documents should be avoided as they could prove challenging for the reader.

The latest version of exposure scenarios for communication is based on a '4 section format', as described in the *An Illustrative example of exposure scenarios to be annexed to the safety data sheet,* published in July 2014. The 4 section format is designed to help standardisation and reflects the formats included in IT integrated systems. The 4 section format replaces the '9 section format', which is described in the *ECHA guidance on info requirements and CSA-part D* (May 2008).

Section 1: Title section

This section should include both a short title and a title. The short title provides a brief description of the scope of the exposure scenario and is composed using the life cycle stage (formulation/industrial use) and the market sector information (product category/sector of use/article category). The title incorporates the exposure scenario name and all applicable tasks/activities, using the use descriptor system (PROC/ERC) where necessary.

Section 2: Conditions of use affecting exposure

This section describes the operational conditions and risk management measures for each contributing scenario that are required to ensure the safe use of the substance. Only conditions of use that are relevant for the downstream user to ensure safe use should be included. Therefore, it is advisable not to transfer all conditions of use from the chemical safety report.

Section 3: Exposure estimation

This section is for the communication of the methodology and calculation tools used to determine the exposure estimates for example ECETOC –TRA. You are able to just report the RCRs, as the exposure estimates can be calculated from the DNELs/PNECs in section 8 of the SDS.

Section 4: Guidance to downstream user

This final section is not mandatory but can be used to include advice to the downstream user on how they can confirm that their use(s) are covered. If scaling can be applied then all details, such as scaling tools, scaling algorithms and scalable parameters should be indicated within this section. If the data is too extensive then it is acceptable to include a hyperlink to a website where all the data can be accessed.

The use of the 4 section format is recommended as it supports the establishment of a standardised format for ext-SDS annexes ensuring the exchange of information up and down the supply chain is improved. Formulators of mixtures can process the information more easily in this way. The ECHA CHESAR tool is also based on the '4 section format'.

Useful links:

4 Section format: *The ECHA guidance on Exposure Scenario Format* (published in May 2010) is available at:

http://echa.europa.eu/documents/10162/17224/information_requirements_esformat_en.pdf

An Illustrative example of exposure scenarios to be annexed to the safety data sheet (published July 2014) is available at:

https://echa.europa.eu/support/practical-examples-of-exposure-scenarios

Consistency with SDS main body

The information provided in annex should be consistent with the content of the relevant sections in the main body.

The information on worker exposure provided in the annex needs to be consistent with section 7 and 8 in the SDS main body. ECHA has produced guidelines and recommendations that should aid the writer of both the SDS and the exposure scenario. The key points are mentioned below.

- Where information on risk management measures are stated in the exposure scenario it is also recommended to provide a reference to that exposure scenario within section 8.2 of the SDS

- It is recommended to provide a clear summary of all risk management measures in section 8.2

- Measures stated in section 7.1 of the SDS describing how to control risk during handling of both substances and mixtures do not need to be repeated within each exposure scenario as these are not geared towards an individual use.

- For each exposure scenario it is recommended that the type and technical specification of personal protective equipment (PPE) should be stated along with the tasks it is needed for and the required effectiveness.

- In section 8.2 of the SDS the PPE that is required to guarantee protection from substance specific hazards should be stated.

- Section 8 of the SDS should follow the hierarchy of control and specific recommendations on the type of equipment needed

NB: Personal protective equipment (PPE) should be the last resort for companies should use to control risks in line with the risk mitigation approach outline in COSHH.

A table to check consistency is available in the ECHA guidance on safety datasheets, (Appendix 1 Including relevant exposure scenario information into safety data sheets), to link the different sections of the exposure scenarios to the corresponding sections of the SDS.

Further information is available at the following link:

https://echa.europa.eu/documents/10162/13643/sds_en.pdf

Supporting material and tools: Use what is available

Reducing the length

A number of documents and tools are available to help companies with the development and transmission of exposure scenarios for communication in the supply chain and the preparation of the new safety data sheets.

Here is an overview of the documents and tools that companies can access, namely:

ECHA guidance documents and tools

- **ECHA guidance on information requirements and CSA – part D:** Framework for exposure assessment (August 2016). This document provides guidance on how to carry out an exposure assessment to determine the conditions of safe use for all the uses of a substance registered under REACH.

https://echa.europa.eu/documents/10162/13632/information_requirements_part_d_en.pdf

- **Practical examples of exposure scenarios** (July 2014). This three part guidance document shows a registrant how to extract the relevant information from their chemical safety report and communicate them effectively as exposure scenarios for the downstream user.

    — Part 1: an Introductory note

    — Part 2: An example of exposure scenarios

    — Part 3: Chesar 2.3 substance file

Examples have been developed in collaboration with European Industry Associations and can support the productions of good quality exposure scenarios and communication of safe use in the supply chain (August 2011).

    — Exposure scenarios for the semiconductor industry

    — Professional use of a substance in floor coatings

    — Consumer user of a substance in cleaning products

These examples, developed in collaboration with European Industry Associations, can support the production of good quality exposure scenarios for CSR and for communication in the supply chain. Please note that they are not necessarily representative for substances with other properties/uses.

The guidance documents and practical examples can be found at the following link:

https://echa.europa.eu/support/practical-examples-of-exposure-scenarios

- **Annotated templates for an Exposure Scenario**

    — Annotated ES template – Industrial

    — Annotated ES template – professional

    — Annotated ES template – consumer

These templates provide registrants with the structure that has been recommended for exposure scenario communication. Please note that the format is not specified in the legal text, although the examples show the recommended structure based on practical experience and helps industry move towards a more harmonised format.

All the templates can be found at the following link:

https://echa.europa.eu/support/guidance-on-reach-and-clp-implementation/formats

- **ECHA guidance on the compilation of safety datasheets** (November 2015). This guidance document aims to assist companies to ensure they fulfil their obligations under Article 31 of REACH and Annex II of REACH.

https://echa.europa.eu/documents/10162/13643/sds_en.pdf

- **Use maps templates and use map library** (February 2016). The use map concept has been designed to improve the quality of information on use and conditions of use communicated in the supply chain.

https://echa.europa.eu/csr-es-roadmap/use-maps/concept

- **Chesar 3.1.1** (December 2016): Chesar helps registrants in carrying out the CSA and preparing the CSR. Among other functionalities, it enables the users **to generate the exposure scenarios for communication to downstream users**. These exposure scenarios can then be annexed to the extended Safety Data Sheet. The tool can be downloaded free of charge at:

https://chesar.echa.europa.eu/home

Cefic guidance documents and tools

- **ESCom package version 2.3:** Cefic and DUCC have produced the ESCom package, a standard for electronic exchange of exposure scenarios information in the supply chain via IT systems using a phrase library and a XML format. The package is available for download at

www.cefic.org/Industry-support/Implementing-reach/escom/

- **ESCom phrases:** A catalogue with standard phrases for Exposure Scenario communication has been prepared by different industry sectors, associations and companies in order to provide a basis for standardising the exchange of text information. They have a unique phrase identifier, based on EuPhraC codes. The ESCom phrases are available in English. The use of standard phrases is expected to facilitate translation and automation.

- ESCom XML 2.0: ESCom XML rel. 2.0 is an xml format that has been developed to avoid manual retyping of this information and to facilitate partly automated processing of the information in the supply chain. ESCom XML 2.0 and ESCom phrases are designed to work together. The supplier is requested to enter the exposure scenarios information into his EHS system. In addition, an IT interface needs to be built between EHS systems at companies' level and the ESCom XML. Exposure scenarios information may be communicated on a voluntary basis electronically for instance through the ESCom XML 2.0. This is in addition to the mandatory transmission of the extended- SDS down the supply chain.

'Messages to communicate in the supply chain on extended SDS for substances II'. This document, jointly prepared by Cefic, Concawe, FECC and DUCC, explains which actions companies should take once they receive an extended SDS. It includes a check-list for recipients of extended SDS. This document is currently under review for 2018 registration. The document can be accessed at the following link:

www.cefic.org/Documents/IndustrySupport/REACH-Implementation/Guidance-and-Tools/Cefic%20communication%20on%20extSDS_130711.pdf

Overview of association activities last updated 1st February 2016. Cefic regularly updates its library listing the work done by European associations to support companies in the preparation of exposure scenarios. The library includes the contact details of these associations. For info, visit

www.cefic.org/Industry-support/Implementing-reach/Guidances-and-Tools1/

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Disclaimer: This guidance document is intended as a starting point only and should not be used in isolation. It is not designed to inform the reader of what is an extended-safety data sheet, exposure scenario etc. A selection of additional sources of information is provided in a separate document to help the reader further.