

An illustrative example of the exposure scenarios to be annexed to the safety data sheet

Part 1: Introductory Note

June 2017

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List of acronyms

AC	Article category
Chesar	Chemical Safety Assessment and Reporting tool
CSA	Chemical Safety Assessment
CSR	Chemical Safety Report
DNEL	Derived no effect level
DUs	Downstream Users
ECHA	European Chemicals Agency
ERC	Environmental release category
ES	Exposure Scenario
ESCom	IT project on Exposure Scenario for communication
ESD	Emission Scenario Document
EUSES	European Union System for the Evaluation of Substances
IUCLID	International Uniform Chemical Information Database
LEV	Local Exhaust Ventilation
OC	Operational Conditions
PC	Chemical product category
PNEC	Predicted no effect concentration
PROC	Process category
RCR	Risk characterisation ratio
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RMM	Risk management measure
SDS	Safety Data Sheet
SPERC	Specific Environmental Release Category
SU	Sector of Use
TRA	Targeted Risk Assessment

1. INTRODUCTION

Exposure scenarios (ESs) are prepared for hazardous substances and reported in a chemical safety report (CSR) under the REACH Regulation. They document such conditions of use for a substance, that the risks to human health and/or the environment are controlled. When a substance for which a CSR has been prepared is supplied to downstream users, the relevant exposure scenarios have to be included as an annex to the safety data sheet (SDS). This is commonly referred to as 'the extended safety data sheet'.

The exposure scenarios in the CSR contain information on all the identified uses of a substance that have been assessed by the registrant. The CSR (and its exposure scenarios) needs to be kept up to date by the registrant and made available; for instance, to provide information to the authorities.

The exposure scenario that is communicated down the supply chain needs to be relevant for the receiving downstream users (DUs) and useful in ensuring that they can use the substance (either a substance as such or in a mixture) safely, thus support them in fulfilling their obligations under REACH and other legislation (e.g. worker health and safety, control of environmental emissions, consumer product safety). For that purpose, it is necessary to modify the ES included in the registration CSR before communicating it downstream. The key information that an exposure scenario for communication should contain is:

- The uses and types of activities that the exposure scenario covers.
- The operational conditions (OC) and Risk Management Measures (RMM) that were assumed by the registrant when assessing the risk.
- Advice for safe use of the substance, addressing the different activities during a use.

This information should preferably be provided in a harmonised format, with harmonised phrases, to facilitate use of receiving ESs for communication prepared by different registrants.

This publication has been prepared as one of the activities under CSR/ES Roadmap¹ and is intended to support registrants in preparing their exposure scenarios for communication. The two main challenges are i) to identify the information to be extracted from the CSR and forwarded to the supply chain and ii) to select the suitable standard phrases for communication: the illustrative example has been developed in order to provide solutions and advice to these challenges.

1.1 Structure of this publication

The publication consists of three parts:

Part 1: is this Introductory Note, which gives an overview of the format for the ESs to be annexed to the safety data sheet (SDS), provides advice regarding the selection of standard phrases and how this was done in the illustrative example. It also includes

¹ See the "CSR/ES Roadmap" action 1.2, <http://echa.europa.eu/csr-es-roadmap>

general points to consider when preparing such exposure scenarios.

Part 2: is an illustrative example of exposure scenarios to be annexed to the SDS. It exemplifies how the information contained in the exposure scenarios developed for a CSR can be extracted effectively and communicated in the ES annexed to SDS. The exposure scenarios are presented in two printing formats. The example is derived from the "Illustrative example of a CSR"² for a hypothetical substance (the so-called "ECHA Substance"). Due to the nature of this substance³, and the status of some discussions, this example has some limitations:

- The human health toxicity of the substance is comparably low. The environmental toxicity is also low, and for the purposes of this example it is not regarded to have long-term adverse effects. Thus, the example does not illustrate cases where more stringent occupational and environmental risk management measures (RMMs) are needed.
- The example does not include exposure scenarios for the service life stage and waste life stage of the substance. The experience on how and when to communicate specific advice on waste collection and treatment is still being built.
- The example includes contributing scenarios for contained (closed) paint application processes. The possibilities of the ECETOC TRA and the ECom phrase catalogue are limited in this respect. At present, the ECETOC TRA does not support the description and assessment of containment conditions in a process/task-specific way, except for synthesis and formulation. Therefore, the example suggests a work-around to deal with this limitation. Similarly, while the latest version of Guidance R12 includes PROC specific for maintenance (28), it is not included in the ECETOC TRA: the example describes an approach to address this issue too.

These limitations will be addressed over time, with development of experience and knowledge.

This illustrative example serves to provide solutions and advice on how to extract information from a chemical safety report and how to report it in the exposure scenario; it thereby responds to the industry's demands for more clarity and harmonisation in the way information is communicated in the supply chain.

Part 3: is the Chesar 3.2⁴ file, containing the CSR and the exposure scenarios for communication. Chesar is ECHA's tool for developing chemical safety assessments and was used to prepare the illustrative example CSR and the exposure scenarios for communication.

You can find further information and illustration on exposure scenarios for communication on the ECHA website⁵.

² <https://echa.europa.eu/support/practical-examples-of-chemical-safety-reports>

³ The hazard profile of the ECHA substance can be found in the *Illustrative example of a CSR*, section 4.3. Overview of Substance Properties and Hazard Classification

⁴ <http://chesar.echa.europa.eu/>

⁵ <https://echa.europa.eu/support/practical-examples-of-exposure-scenarios>

2. GENERAL ADVICE WHEN PREPARING AN EXPOSURE SCENARIO TO BE ANNEXED TO THE SAFETY DATA SHEET

Some general tips to consider when generating the ES for communication are as follows:

- Include a table of contents (ToC) in front of the actual ESs for communication that are annexed to the safety data sheet. This table of contents provides an overview of the exposure scenarios contained in the extended safety data sheet. It should consist of ES short titles (see section 3.1.1 below). Rules on how to generate the short titles are available at the CSR/ES roadmap web page on the ECHA website⁶.
- Group or arrange the ESs in a logical order, e.g. according to life cycle stages including the main user groups, or to the market sector.
- Prepare only those ESs and contributing scenarios⁷ within an exposure scenario for communication that are really needed. For example, there is no need to communicate the ESs for the registrant's manufacturing or own use.
- Limit the information in the ES to that which is practically relevant to the addressees (DUs). It is generally not necessary to include conditions which do not constrain the use of the substance or cannot be controlled by the DUs.
- The ES should be neither excessively descriptive nor too general or vague. Seek a dialogue with downstream user organisations to strike the right balance. Risk management measures should be meaningful and appropriate. If available, utilize use-maps⁸ information compiled by downstream sector organisation for your assessment. This will help you to address the needs of your customers.
- Clearly differentiate in the ES between the conditions of use that the downstream user is required to implement (and on which the assessment was based) and those conditions that are additional good practice advice.
- Ensure that the information is consistent within the different parts of the ES itself and between the ES and the main body of the safety data sheet, particularly Sections 7 and 8 of the safety data sheet.
- Use a harmonised format (such as the ES format published by ECHA) and ECom standard phrases (see section 3) as much as possible. Translation of the ES for communication will be easier, and could be automated, if you are using ECom standard phrases.

⁶ <http://echa.europa.eu/csr-es-roadmap>

⁷ See also Part D and Chapter R12 of the Guidance on Information Requirements and Chemical Safety Assessment (<https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment>)

⁸ <https://echa.europa.eu/csr-es-roadmap/use-maps/concept>

3. HARMONISED COMMUNICATION FOR EXPOSURE SCENARIOS

Industry sector organisations, IT providers and ECHA are working together under the CSR/ES Roadmap⁹ to standardise the communication of exposure scenarios. The cooperation relates to the format of the exposure scenario, the use of standard phrases in the exposure scenario and the electronic communication of the information. The aim is to facilitate the communication in the supply chain required under REACH.

Standardisation relating to exposure scenarios brings several advantages:

- It enables automation of the generation of the extended safety data sheets.
- It facilitates the process of translating the information into different languages.
- It minimises the potential for misunderstandings or conveying incorrect information.
- It provides consistency for the recipients.

This illustrative example is based on the harmonised format agreed between industry sector organisations and ECHA. The format is described in section 3.1 below, together with some considerations on how to identify the information to communicate. Due to the advantages described above, ECHA strongly recommends the use of the harmonized formats.

The standard phrases used in the illustrative example are based on the ECom Standard Phrase Catalogue¹⁰ wherever possible. Further considerations related to the selection and development of standard phrases are discussed in section 3.2.

An IT standard (termed the ECom XML) has been developed to enable the electronic communication of exposure scenario information and the standard phrases contained in the ECom standard phrase catalogue. Chesar is able to generate the exposure scenarios for communication in this xml format.

This example illustrates the layout of the ES for communication when generated by Chesar (see section 4).

3.1 Format and content of exposure scenarios

The agreed format of the exposure scenario consists of 4 sections:

- 1. Title section**
- 2. Conditions of use affecting exposure**
- 3. Exposure estimation and reference to its source**
- 4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES**

⁹ See the “CSR/ES Roadmap” action 4.2, <http://echa.europa.eu/csr-es-roadmap>

¹⁰ <http://www.cefic.org/Industry-support/Implementing-reach/escom/>

An outline of the content of each section, with reference to the illustrative example, is presented below.

3.1.1 Title section

The title section includes a "short title" and a "title".

The "short title" gives a brief description of the scope of the ES and can be used to build the table of contents for the exposure scenarios that are annexed to the safety data sheet. It is composed of at least two identifiers:

- Life cycle stage: such as formulation, use at industrial site, professional use
- Market sector information: such as Product category (PC) Sector of Use (SU) or the Article Category (AC).

It may include an optional additional third identifier such as i) the level of containment (open process, closed process) or ii) the technical process (dry for solids, solvent based, water based, other organic liquids).

Principles on how to build structured short titles have been agreed at ENES 6¹¹ and guidelines are available on the ECHA website¹².

The "title" includes the Exposure Scenario name. It also presents a list of all applicable tasks/activities (termed 'contributing scenarios' (CS)) covered by the ES. The names and assigned use descriptors¹³ (Environmental release category ERC, Process category PROC, PC, AC) of each contributing scenario are reported here.

The "short title" and "title" should be consistent. In most cases, the "short title" will be a structured summary of the information provided in the title section.

3.1.2 Conditions of use affecting exposure

This section is the core of the ES as it presents the Operational Conditions (OCs) and Risk Management Measures (RMMs) recommended for each contributing activity.

Only those conditions of use that are practically relevant for a DU to ensure safe use are reported. This means that not all of the conditions of use that are reported in the ES in the CSR are transferred to the ES for communication. Factors that affect the relevance for the ES for communication include:

1. Whether the condition constrains the use of the substance. However, it has to be taken into account that, in some cases, even though conditions do not constrain the use, it is still useful to communicate them e.g. assumptions by the registrant during the assessment, or even making explicit that no limitation applies.
2. Whether DUs have control over the conditions of use; this is particularly important

¹¹ http://echa.europa.eu/view-article/-/journal_content/title/sixth-meeting-of-the-echa-stakeholder-exchange-network-on-exposure-scenarios-enes-6-

¹² <https://echa.europa.eu/csr-es-roadmap/action-area-4>

¹³ For definition of Contributing Activity, Contributing Scenario and Use descriptors refer to Part D and Chapter R12 of the of the Guidance on Information Requirements and Chemical Safety Assessment (<https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment>)

for ES addressed to end-users.

3. Whether the condition is important to enable the DUs understand the assumptions that the registrant has made on how the substance is used.

Illustrations of how the above-mentioned factors are applied in the example (Part 2) are:

- Re. 1. Information that constrain the use, such as "the substance cannot be used for more than 1 hour/day" is always reported in the ES.

Information on conditions that are "absent" is generally not included. For example, if the use of local exhaust ventilation (LEV) is not required in the chemical safety assessment, "no LEV" is not included in the ES for communication.

- Re: 2 The exposure scenarios ES3 and ES4 in the illustrative example are intended for professional and consumer uses of the substance respectively. End-users have no control over the environmental conditions of use that are specified for the abovementioned uses since their uses are considered as wide dispersive uses (except for using specific routes in the locally available waste management scheme). Consequently, the environmental conditions of use related to a Sewage Treatment Plant (STP), such as flow rates, application of sludge to agricultural soil, etc., are not reported in the environmental contributing scenarios in the ES for communication.

- Re 3: The exposure scenario ES 4 describes the consumers' use of a coating. Consumers do not receive SDS or ES. The ES for consumer uses are addressed to formulators so that they can use the information in the design of the products for consumers. For example, in these cases, the information on the concentration, amount per use event, number of expected use-events per day, release area, room size and ventilation rate are included. A formulator can check and compare these conditions of use with the design of his product and the related technical instructions.

3.1.3 Exposure estimation

Section 3 of the exposure scenario for communication reports the methodology that has been applied to develop the emission estimation, the estimated level of exposure and the risk characterisation ratio for all the relevant protection targets (environment) and route/type of effects (human health). Alternative ways of completing section 3 are also possible, such as reporting the risk characterisation ratio only; in such case, the expected exposure can be calculated by the recipient of the SDS by means of the DNEL/PNEC reported in section 8.1.4 of the SDS.

This section is relevant to formulators and end-users of substances, if they are undertaking a more detailed review of the ES, or when they wish to use the exposure estimates as an information for their own local risk assessment for work places.

3.1.4 Guidance to Downstream Users to evaluate whether they work inside the boundaries set by the ES

Section 4 includes advice to the downstream users on how they can verify that their use is covered by an ES. One typical situation when such advice may be needed relates to the variability in the conditions of use ensuring control of risk. Various combinations of, for example, concentration and exposure time can lead to the same risk characterisation ratio. The same applies for the combination of daily use amount on site and environmental risk management measures. Usually the registrant will communicate one

of such combination in his ES (in particular those that he has retrieved from use map information) but the DU may work with a combination different from that in the ES. In such a situation a method termed "scaling" can be applied. This section is not mandatory; it can be used by the registrant if he wishes to provide information on scaling; if so, the section must include, as a minimum:

- Scaling method and suggested scaling tool
- Scalable parameters and boundaries of scaling
- Guidance/instruction

This section is helpful for recipients, when they are checking if their use is covered and it would typically direct them to a website calculator provided by the supplier.

Section 4 has not been completed in this illustrative example as the corresponding Cefic tool and guidance are still under development.

More information on how to verify, if you are working in the boundaries set by the exposure scenario and details on scaling is provided in the Guidance for downstream users¹⁴ and the Practical Guide 13.¹⁵

3.2 Standard phrases in the ECom Catalogue

The ECom Standard Phrase Catalogue was used extensively in developing the example. Version 2.3 was used, the version available at the time of publication.

Existing standard phrases were selected as much as possible, whenever they were consistent with the information in the illustrative example CSR. Suitable standard phrases were typically available for the use names and for the phrases that relate to the conditions of use based on the exposure estimation tools such as ECETOC TRA.

Nevertheless, it was not always possible to identify a suitable standard phrase in the catalogue. Situations where this occurred in the illustrative example include:

- For the environment, the conditions of use linked to the specific exposure assessment (such as related to Specific Environmental Release Categories, SPERCs) are often expressed using phrases that are not currently available in the ECom Standard Phrase Catalogue (see for example ES 2 in the example). Therefore phrases were used which are currently not in the ECom catalogue.

In general, when a suitable phrase could not be identified in the ECom Standard Phrase Catalogue, a phrase which is currently not in the ECom catalogue has been used for exemplification purposes for the relevant identified use. Where this occurs, the phrase was made as general as possible, so that it can be used in other contexts. Such phrases may become standard phrases in the future. In the illustrative example, any phrase that does not come from the ECom Standard Phrase Catalogue has been written in *Italic* in the ES for communication (see Part 2).

The ECom Standard Phrase Catalogue will be regularly updated, taking into account

¹⁴ https://echa.europa.eu/documents/10162/23036412/du_en.pdf/9ac65ab5-e86c-405f-a44a-190ff4c36489

¹⁵ https://echa.europa.eu/documents/10162/13655/du_practical_guide_13_en.pdf/2c3bc624-fb3c-4515-a581-87b79d460d38

new proposals from sectors and/or tools owners, so that its usability will further improve in the future.

If you generate “new phrases” that are not already included in the ECom Standard Phrase Catalogue, first check whether a similar phrase is already available in the catalogue; if not, try to be as generic as possible so that the phrase can be applicable to similar cases. Involve sector organisations or co-registrants when generating new phrases; finally, follow the rules for building phrases as set in the phrase guidance document, and consider to submit them as new phrase proposal to the eSDScom website.¹⁶

At the moment, the ECom phrases are only provided in the English language. Translations are currently part of the commercial activities of the IT providers.

¹⁶ <http://www.esdscom.eu>

4. GENERATION OF EXPOSURE SCENARIOS USING CHESAR

The ES for communication has been generated using ECHA's Chesar 3.2¹⁷ tool from the Illustrative Example of a CSR.¹⁸

The benefits of using Chesar include:

- It ensures consistency between the ES for CSR (submitted to ECHA as part of the registration dossier), the ES for communication (supplied to downstream users as an annex to the safety data sheet), and the use description in the IUCLID dossier.
- It enables the upload of the ESCom Standard Phrase Catalogue and the search for suitable phrases using key words or metadata.
- It contains standard phrases associated with the Tier I determinants (conditions of use associated with Tier I models such as ECETOC TRA and EUSES), so that they will be automatically included in the ES for communication.
- It makes a pre-selection (see paragraph 2.1.2) of those conditions that merit reporting in the ES for communication, while permitting the user to deviate from the proposed pre-selection.
- It facilitates the printing out of the ES in two standardised formats in paper form. Note: ECHA would like to receive feedback on which of the two formats would be preferred.¹⁹ The aim is to define in the end one single standard format for printing.
- It enables the generation of the exposure scenarios in xml exchange format to be fed directly into suppliers' and downstream users' safety data sheet systems.
- It also enables the upload of sector use maps, in which downstream sector organisations can already assign the phrases in which their membership wishes to receive the risk management advice from the registrants.

¹⁷ <https://chesar.echa.europa.eu/>

¹⁸ <https://echa.europa.eu/support/practical-examples-of-chemical-safety-reports>

¹⁹ To provide feedback, use the information request form which can be accessed via the Contact ECHA page at: <http://echa.europa.eu/contact> (quote the document reference and issue date).

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