

Guide on Safety data sheets and Exposure scenarios





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Guide on Safety data sheets and Exposure scenarios

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Safety Data Sheets (SDS)

Introduction

THE KEY POINTS

Safety data sheets are intended to provide the users of chemicals with the necessary information to help them protect human health and the environment.

Users of chemicals are are companies or individuals within the European Union/European Economic Area who use a substance, either on its own or in a mixture, in their industrial or professional activities.

Safety data sheets are intended both for the workers who handle the chemicals and for those responsible for safety.

The format of the safety data sheet is defined in the REACH Regulation. It is divided into 16 sections, and each section is described in the following part of this Guide.

When should a safety data sheet be provided?

A safety data sheet should be provided when:

• A substance or a mixture is classified as hazardous;

• A substance is persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB); or

• A substance is included in the Candidate List for Authorisation according to REACH for other reasons than the above.

Mixtures which are not classified as hazardous, but which contain specified concentrations of certain hazardous substances, also require a safety data sheet to be provided on request.

If a supplier updates a safety data sheet, he must provide updated versions to all recipients to whom the substance or mixture has been supplied within the preceding 12 months.

More tips on what a supplier or recipient should look out for (e.g. when to update, checking the contents etc.) are provided in the "closer look" sections.

You can find the definition of technical terms (such as "CAS" or "registration number") in the ECHA-term (https://echa-term.echa.europa.eu/).

Note that this Guide focuses on the obligations related to REACH. Your company may have additional obligations under other legislation that are not dealt with here.

A R d

As with any other obligation under REACH, remember to document your decisions and actions.

A CLOSER LOOK FOR **RECIPIENTS**

What should you do when you receive a safety data sheet?

When you receive a safety data sheet, you need to identify and apply appropriate measures to properly control the risks at your site.

You should also perform a consistency and plausibility check of the safety data sheet contents at a level appropriate to your circumstances. This is to avoid using inaccurate SDS information as a basis for workplace and environmental safety assessments. In particular, you should compare all sections related to chemical identification, composition, classification, and safe use against your own information on the substance or mixture. Assess any discrepancies and take appropriate corrective actions.

If you have new information on the hazardous properties of substances and mixtures, or consider that the advice provided in the SDS or in other information supplied is not appropriate, you have to communicate it up the supply chain to suppliers (see Table 13 in the ECHA *Guidance for downstream users* for more details).

If exposure scenarios are attached to the SDS, look at the "Exposure Scenario" section of this Guide for additional obligations that apply.

Formulators of mixtures may have integrated the information from exposure scenarios for constituent substances into the main body of the SDS, or provided them in a consolidated annex instead of attaching them individually. Such information must then be treated like information from an exposure scenario, with the ensuing obligations for downstream users. More information can be found in section 7.2.3. of the **Guidance for downstream users** (https://echa.europa.eu/ documents/10162/23036412/du_en.pdf). Please refer to the "Exposure Scenario" section of this Guide on how to check that your use of the mixture is covered.

If a safety data sheet is not required but is provided voluntarily, you do not have specific obligations under REACH. However, you have a general obligation to use chemicals safely.

A CLOSER LOOK FOR **SUPPLIERS**

The contents of the different sections of the safety data sheet are prescribed in the legal text of Annex II to the REACH Regulation, and elaborated in the **Guidance on the compilation of safety data sheets** (https://echa.europa.eu/documents/10162/13643/ sds_en.pdf). These are the main references that suppliers should use when compiling their safety data sheets. This Guide provides tips for suppliers on issues to watch out for within each section.

When should you update a safety data sheet?

You should provide an update of the safety data sheet when:

- new information on the risk management measures, or new information on hazards becomes available;
- once an authorisation has been granted or refused, or a restriction has been imposed.

It is, in any case, recommended to review the contents of a safety data sheet at regular intervals.



"New information" also includes the substance being placed on the Candidate List for Authorisation.

Identification of the substance/mixture and of the company/undertaking

THE KEY POINTS

Section 1 gives information on:

- The name of the substance, or for a mixture the trade name or designation of the mixture;
- Other relevant identifiers such as trade names, alternative names, and EC, CAS or Index numbers according to Annex VI to the CLP Regulation;
- The uses the chemical is intended for, and uses advised against;
- Details about the supplier of the safety data sheet;
- Emergency telephone number.

If the substance has been registered under REACH, **Section 1.1** will include a REACH registration number. This number nearly always starts with '01' (e.g. 01-nnnnnnnnnnnnnn). If the product is a mixture, the registration numbers of the substances present in the mixture will be in **Section 3.2**.

Registration number

You can use registration numbers to access more information on the registrants and on the substance.

On the ECHA website in the **"Information on Chemicals**" section (https://echa.europa.eu/ information-on-chemicals, you can search using the registration number. This shows who has registered the substance, either as individuals or as members of a joint registration.

If the registration number ends with "-0000", this is the lead registrant. If the last four digits are -XXXX, then the registrant is kept confidential; typically when a supplier supplies substances from a number of registrants. An example of this can be seen here **REACH registration number** (https://echa.europa. eu/documents/10162/22787005/sds_section1_ registration numberXXXX_en.jpg). The search also shows if the registration number provided is still active, as well as other information.

The supplier has to communicate the registration number down the supply chain. If no registration number is given in the safety data sheet, this indicates that the substance is exempt from the registration requirements, or is not yet registered.

If you suspect that your supplier should have registered the substance already, we recommend that you contact them immediately to check. Substances which have not been registered should be checked thoroughly to confirm that they are permitted for use in Europe. You may also consider contacting the enforcement authority.

Substances may be pre-registered, that is, the manufacturer or importer intends to register them but they are not yet registered. A pre-registration number begins with "05-". There are no downstream user obligations associated with pre-registered substances. After the 2018 registration deadline, there is no reason for the supplier to include a pre-registration number in the SDS.

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We recommend you to keep a record of the date of receipt for all safety data sheets that contain a registration number.

Identified uses

When you receive a safety data sheet with exposure scenarios, you should check that your use is identified by your supplier in **Section 1.2**. If it is not, you can contact your supplier and ask for your use to be included. See **Q&A 136** (https://echa.europa.eu/support/qas-support/qas) for what information to communicate to your supplier, and how best to do it.



If your supplier identifies some uses that are "advised against" it means that they do not support them.

If **Section 1.2** of the safety data sheet specifies that your use is advised against, you should consider the following options:

• Stop this use of the substance (as such or in a mixture);

• Switch to a supplier who has covered your use with the necessary risk management measures;

• Undertake a downstream user chemical safety report to verify that the use is safe. Read more about this in section 5 of the **Guidance** for downstream users (https://echa.europa.eu/documents/10162/23036412/du en.pdf).

The uses identified in **Section 1.2** may be described with text (for example "Coatings and paints") or codes. The codes used are often from the Standard Use Descriptor System (for example "SU21, PC18"). Find out more about the use descriptor system in the **Guidance on use description** (https://echa. europa.eu/documents/10162/13632/information_ requirements_r12_en.pdf). Use descriptors may also be given for the identified uses in **Section 16** and in the exposure scenario.

A CLOSER LOOK FOR SUPPLIERS

Product identifier

The product identifier of a substance or mixture is provided as specified in Article 18 of the CLP Regulation. The rules are described in detail in the **Guidance on the compilation of safety data sheets** (chapter 3.1) (https://echa.europa.eu/ documents/10162/23036412/sds_en.pdf), and are quite different when dealing with a substance or a mixture.

For a **substance**, the following diagram can be useful for finding the product identifier.

For **mixtures** the trade name or desgination must be provided in **Section 1.1**, while further information on its components must be provided in **Section 3.2**. For more information see the **Guidance on the compilation of safety data sheets** (https://echa. europa.eu/documents/10162/23036412/sds_ en.pdf).

If you are a registrant, note that providing an SDS with a registration number mayinitiate obligations for your customers (downstream users). You should make sure to attach the relevant exposure scenarios, if the substance is hazardous according to CLP and you have carried out an exposure assessment as part of your registration.

If you are preparing an SDS for a mixture, you must communicate the registration numbers for all registered substances in the mixture (in Section 3), as well as other relevant information, such as the classification, risk management advice etc.



Registration number

If you have registered the substance, then you must provide the registration number in the SDS. Absence of a registration number indicates that the substance is exempt from the registration requirements or is not yet registered. You may want to indicate this, to avoid questioning the reason for its absence, by using one of the following phrases:

- The substance does not require registration according to Regulation (EC) No 1907/2006 [REACH].
- The transition period according to Article 23 of the REACH Regulationhas not yet expired.
- Biocides are regarded as registered substances according to Regulation (EC) No. 1907/2006 [REACH], Article 15 (1 and 2).
- This substance is exempted from registration according to the provisions of Article 2(7)a and Annex IV of REACH
- This substance is exempted according to REACH Article 2(7) and Annex V.

Pre-registration numbers beginning with "05-" are not required to be included in the SDS.

Identified uses

If you are a registrant, your customers, through their sector organisations, may have communicated information about their uses to you through the **use maps** (https://echa.europa.eu/csr-es-roadmap/ use-maps/concept). When providing the safety data sheet, you should include these uses as identified uses in **Section 1.2**. Your customers will appreciate information tailored to their needs.

For registered substances for which a chemical safety report is required, the identified uses must be consistent with those identified in the CSR and exposure scenarios (basically where you have assessed the risk to be adequately controlled).

If you are a formulator, you should indicate the uses of the formulation based upon the relevant information received for the constituent substances.

If you are a registrant, information on uses advised against is also required, and must be consistent with the information in Section 3.6 of IUCLID ("Uses Advised Against") for substances for which a registration is required. Do not forget that where a use is advised against, the reason

Example of Safety Data Section 1

Click on the image to zoom in (+) or zoom out (-)

Hazard identification

THE KEY POINTS

Section 2 gives information on:

- The hazard classification of the chemical;
- How the chemical should be labelled (hazard pictograms, hazard statements and safety advice). Examples of labels can be found at the "CLP label" page (https://echa.europa. eu/documents/10162/22787005/clp_label_examples_en.jpg);
- Any additional hazard information not resulting in classification and, if relevant, why the substance is a PBT or vPvB.

The information on classification and labelling given here must be consistent with that on the actual labels for the chemical in question. If not, contact your supplier to inform and confirm which information applies.

Classification and labelling of chemicals is undergoing global changes. In the EU, the Classification, Labelling and Packaging (CLP) Regulation is in force and implements the United Nations' Globally Harmonised System (GHS).

Classification of the substance or mixture

Section 2.1 shows the hazard classification of the substance or mixture. This information is essential when assessing the risk to the workers and the environment. Additional information, such as the full text of hazard statements, can be found in Section 16. If the criteria for classification in accordance with Regulation (EC) No 1272/2008 are not met, this should be clearly stated.

You should check whether the classification is consistent with the information provided in **Sections 9** to **12**.

For substances, you should check whether M-factors are provided. For more information on when M-factors (or cut-off values or concentration limits) should be provided, please refer to the **Guidance on the compilation of safety data sheets** (https://echa. europa.eu/documents/10162/13643/sds_en.pdf).

You are not obliged to verify the classification of your supplier(s). However, if you choose to do so (using the **Guidance on the Application of the CLP Criteria** (https://echa.europa.eu/ documents/10162/23036412/clp_en.pdf)), and you reach a different conclusion to your supplier(s), you should contact them to discuss whether an agreed classification could be found between you. If agreement cannot be found, then you must report your classification to ECHA (for substances that you use in quantities of one tonne per year or more). Differences in classification from different suppliers may arise for a justified reason e.g. impurities, concentrations etc. See the **Tips for users of Chemicals in the workplace** (https:// echa.europa.eu/documents/10162/966058/ tips_users_chemicals_workplace_en.pdf). If there is any doubt, recipients shouldtheir suppliers.

You can check the classification of substances on ECHA's website in the Infocard/Brief Profile, in particular to see if there is a harmonised classification.

Label elements

Section 2.2 shows the elements the substance or mixture should be labelled with.

For both substances and mixtures the label elements are to be indicated according to the CLP Regulation.

If a substance on its own or in a mixture is subject to REACH authorisation, the authorisation number (see the **ECHA-term** (https://echa-term.echa.europa.eu/) for a definition) must be included here. You can find more information on authorisation in **Section 15** of this Guide .

You should inform your supplier without delay of any new information on hazards, including classification and labelling.



A CLOSER LOOK FOR SUPPLIERS

Classification of the substance or mixture

From 1 June 2015, classification of substances and mixtures has to be carried out in accordance with the CLP Regulation.

Substance: If you have notified the information on the substance to the Classification and Labelling Inventory, the classification given in the SDS must

be the same as that provided in your notification, and provided in accordance with the rules in the CLP Regulation.



Mixtures: The classification is given in accordance with the CLP Regulation. However, for mixtures already on the market before 1 June 2015, a transitional period allows such mixtures complying

with the Dangerous Preparations Directive to remain on the market without the need to be re-labelled and re-packaged before 1 June 2017. The procedure used to derive the mixture classification could alternatively be placed in this section (instead of Section 16).

Label elements

The label elements indicated must be consistent with the corresponding label affixed to the product.

If you have received a REACH authorisation for your substance, on its own or in a mixture, you must include the authorisation number (see the ECHAterm (https://echa-term.echa.europa.eu/)for a definition) here, and provide further information on the authorisation in Section 15.

Other hazards

You should provide any additional hazard information not resulting in classification here, including, if relevant, if the substance is a PBT or vPvB.

Such information may be in the form of statements such as: "May form explosible dust-air mixture if dispersed", "Risk of blindness after swallowing the product" or "According to the results of its assessment, this substance is not a PBT or a vPvB".

The PBT or vPvB status must match the results of any PBT or vPvB assessment indicated in **Section 12.5** (only required when there is a chemical safety report).

Example of Safety Data Sheets Section 2

Click on the image to zoom in (+) or zoom out (-)

SDS Section 3: Composition/information on ingredients

THE KEY POINTS

Section 3 provides information on the composition of the chemical product. If it is a substance, the information is provided in **Section 3.1**. If the chemical is a mixture, the information is in **Section 3.2**.

The information is usually provided in a table. It includes the name and/or trade name, and other identifiers (such as CAS number, registration number etc.) of the substances, ingredients or impurities which:

- Contribute to the overall hazard classification; or
- Are present at concentrations above certain levels of concern; or
- Have occupational exposure limits.

For mixtures, the concentration or concentration range at which the constituent is present is provided.

A supplier can include non-hazardous constituents or components here, if choosing to list the full composition of the substance or mixture.

Substances and mixtures

If the substance or mixture is classified as hazardous – as defined by the Classification, Labelling and Packaging (CLP) Regulation – the hazardous ingredients or impurities will be presented in a table showing the chemical name, the EC and/or CAS number. If available, the registration number will also be included.

If the use of an alternative chemical name has been allowed in accordance with the Classification, Labelling and Packaging (CLP) Regulation (or the Dangerous Preparations Directive before 1 June 2015), it can be used for a substance in a mixture.

For mixtures, the classification of constituent substances or the reason for indicating them in **Section 3.2** should be described (for example "nonclassified vPvB substance" or "substance with a Community workplace exposure limit").





Click on the image to zoom in (+) or zoom out (-)

Example of Safety Data Sheets Section 3_a	Example of Safety Data Sheets Section 3_b

A CLOSER LOOK FOR SUPPLIERS

Substances

Examples of how to present the information are described in the Guidance on the compilation of safety data sheets (https://echa.europa.eu/ documents/10162/23036412/sds en.pdf) Note that although only impurities that contribute to the classification have to be listed, it may be helpful to your customers if you include information on all impurities (even if they do not contribute to the classification) and their concentration (or range).

Mixtures



Examples are provided in the Guidance on the compilation of safety data sheets (https://echa.europa.eu/ documents/10162/23036412/sds en.pdf). For mixtures, you must provide the concentration (or concentration range) and classification for all the substances meeting the criteria for classification, and for those not meeting the criteria but presenting certain hazards and above certain concentrations (as described in the legal text). In addition, you may choose to list all substances in the mixture, to help your customers.



Alternative chemical names

Where an alternative chemical name is being used (because it is permitted according to the provisions of Article 24 of CLP), you should indicate so in this subsection (or in Sections 15 or 16).



Weight/concentration ranges

Weight ranges may be given instead of actual weight percentages. The classification derived for a particular concentration range should be based on the highest concentration in the range quoted.



The generic cut-off values and M-factors are mentioned in the legal text only in the context of deciding which substances need to be listed in the SDS. However, where the information is available it would be potentially useful and therefore recommended to provide it.

First aid measures

THE KEY POINTS

Section 4 gives information on:

- The first aid measures to be applied in case of accidental exposure to the chemical;
- The symptoms and effects of exposure;
- Indications on whether urgent or special medical attention (antidote, medical monitoring) or other measures (personal protective equipment for first-aiders) are needed.

The first aid measures must be described in such a way that they can be understood and carried out by an untrained person, and should be consistent with the precautionary statements in **Section 2.2**.



It is useful to take the safety data sheet with you when seeking medical care after accidental exposure to the chemical. Additional information provided specifically to medical personnel may be given under a heading such as "Notes for

the doctor". This information may contain special medical terms which may be difficult to understand for non-medical personnel.



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Example of Safety Data Sheets Section 4



Firefighting measures

THE KEY POINTS

Section 5 gives information on:

- The firefighting measures to be applied in case of a fire involving the chemical;
- The possible hazards arising from the chemical in case of fire (such as hazardous combustion products or vapour cloud explosion risks).

This section may also contain specific information for firefighters, including special protective equipment to be used.



Pay special attention to the unsuitable extinguishing media described in **Section 5.1**. Their use may cause chemical or physical reactions resulting in an additional potential hazard. For example, some substances emit flammable or toxic gases

when in contact with water.

Example of Safety Data Sheets Section 5

Click on the image to zoom in (+) or zoom out (-)

Accidental release measures

THE KEY POINTS

Section 6 gives recommendations on how to deal with accidental spills or leaks of the chemical to prevent or minimise further adverse effects. Recommendations include:

- Containment, recovery and cleaning methods;
- Personal precautions to be used during these actions.

This section may refer to **Sections 8** and **13**, to avoid repeating information which is relevant to potential accidental release. If references are made to other sections, those sections should be adequately completed.

Example of Safety Data Sheets Section 6

Click on the image to zoom in (+) or zoom out (-)

Handling and storage

THE KEY POINTS

Section 7 gives information on how to handle and store chemicals

safely, to avoid potentially dangerous incidents. The information is appropriate for the uses identified in **Section 1.2**, and to the properties of the chemical (as given in particular in **Sections 9** and **10**). It should be consistent with any exposure scenario provided.

Advice on safe handling practices includes:

- Containment and measures to prevent fire as well as aerosol and dust generation;
- Avoiding hazards due to incompatibility of substances or mixtures;
- Reducing the release of the substance or mixture to the environment, such as avoiding spills or keeping away from drains;
- Implementing good occupational hygiene practices.

Advice on safe storage practices includes:

- Managing risks associated with explosive atmospheres, corrosive conditions, flammability hazards etc.;
- Controlling the effects of the surroundings, such as the weather, humidity, vibration etc.;
- Maintaining the integrity of the substance or mixture;
- Other advice, such as ventilation requirements, quantity limits etc.

In addition to information given in this section, relevant information may also be found in **Section 8**.

Check that the uses indicated in **Section 7.3** match the uses indicated in **Section 1.2**.

A CLOSER LOOK FOR SUPPLIERS

Ensure that any advice on avoidance of certain container material (e.g. metal) matches the hazard information provided in other sections.

This section may also be useful if you need to communicate information about using a substance that is classified as hazardous due to its physicochemical properties (e.g. flammability).

For a substance registered above 10 tonnes/year and classified for its physicochemical properties (notably flammability, explosive properties and oxidising properties), the registrant has to assess the uses in a chemical safety report. As part of this assessment, the registrant has to recommend risk management measures to control or reduce the risk (see Guidance on IR&CSA Part E (https://echa. europa.eu/documents/10162/13632/information requirements part e en.pdf)). These measures are then communicated through the exposure scenarios. When the same measures apply to several uses, it may be more practical to communicate the measures in this section of the safety data sheet, with a reference in each exposure scenario indicating where to find the relevant information.

Example of Safety Data Sheets Section 7



Exposure controls/personal protection

THE KEY POINTS

Section 8 gives important information on exposure limit values (Section 8.1) and the measures to control exposure (Section 8.2). The information is appropriate for the properties of the chemical and all intended uses (as described in Section 1.2 or in the exposure scenarios that may be annexed to the safety data sheet).

Section 8.1 Control parameters

Exposure limits for workers, consumers and the environment are provided, as relevant. These include applicable occupational exposure limits (OELs), derived no effect levels (DNELs), predicted no effect concentrations (PNECs) etc. In addition to the OELs applicable in your country, limits valid in other countries may also be indicated, depending on the market of your supplier. You can find the definition of technical terms such as OEL or DNEL in ECHA-term (https://echa-term.echa.europa.eu/).

For more information on OELs and DNELs, read this **guidance document** (http://ec.europa.eu/social/ BlobServlet?docId=15614&langId=en) by the Senior Labour Inspector's Committee (SLIC).

Section 8.2 Exposure controls

Measures to manage the risks and to ensure the safe use of the chemical are described, covering both engineering controls and personal protection measures. The measures are designed to reduce worker and environmental exposure to a safe level. More detailed information on exposure controls may also be found in any exposure scenarios attached to the safety data sheet.

Exposure controls described in **Section 8.2** are the protective measures to be taken during use of the substance or mixture to reduce worker and environmental exposure to a safe level. They include:

- Appropriate engineering controls;
- Personal protective equipment (including detailed specification such as break through time or references to appropriate CEN standards);
- Environmental exposure controls.

This subsection may refer to the exposure scenarios or to **Section 7** of the safety data sheet (Handling and storage), if the measures are described in more detail there. Summaries in **Section 8.2** must be consistent with the information in the exposure scenario.

A CLOSER LOOK FOR **RECIPIENTS**

Section 8 contains important information related to occupational health.

The control parameters contained in **Section 8.1** are limit values, below which the risks are considered to be controlled.

Downstream users can use these parameters as criteria for measurements they conduct onsite or if they decide to conduct their own chemical safety assessment. Refer to the **Guidance for downstream users** (https://echa.europa.eu/documents/10162/23036412/du_en.pdf).

The currently recommended monitoring or observation methods may be included here. These monitoring methods can be, for example, personal air monitoring, room air monitoring, or biological monitoring, according to agreed standards. Section 8 is very important for downstream users when identifying and applying appropriate measures to adequately control the risk of the chemical at their site (see the introduction to the safety data sheet page). If the information is derived from an exposure scenario, see the "Exposure Scenario" section of this Guide.

A CLOSER LOOK FOR SUPPLIERS

Section 8.1 Control parameters

The derived no effect levels (DNELs) and predicted no effect concentrations (PNECs) applicable to the exposure scenarios in any required annexes to the SDS for a specific substance or mixture must be listed in this section.

Only the relevant DNELs and PNECs should be listed. An example of how the required information on DNELs and PNECs in this section could be structured is given in the **Guidance on the compilation of safety data sheets** (https://echa.europa.eu/ documents/10162/23036412/sds en.pdf). Where applicable specific control parameters, such as occupational exposure limit values (OELVs) and/ or biological limit values, are provided in this section, they must be given for the Member State where the substance or mixture is placed on the market.



Example of Safety Data Sheets Section 8.1	Example of Safety Data Sheets Section 8.2

Physical and chemical properties

THE KEY POINTS

Section 9 gives information on:

- The basic physical and chemical properties of the chemical substance or mixture (such as appearance, odour, pH, boiling point etc.) which are relevant to the classification and the hazards;
- Physical and chemical properties which are not relevant or where no information is available, and the reason why.

Check that the information in this section is consistent with the classification and labelling information in **Section 2** and any transport classification given in **Section 14**. If not, contact your supplier.

A CLOSER LOOK FOR SUPPLIERS

You have to give the reference for the test methods used and specify the appropriate units of measurement and/or reference conditions.

If the SDS covers a nanomaterial form, then this should be described under appearance e.g. physical state: solid (nanomaterial). This should be consistent with any other mention about nanomaterials, forms or ranges in other sections.

Example of Safety Data Sheets Section 9

Click on the image to zoom in (+) or zoom out (-)

Stability and reactivity

THE KEY POINTS

Section 10 gives information on:

- The stability of the substance or mixture;
- Hazardous reactions that could occur under certain conditions of use or if released into the environment;
- Conditions to avoid;
- Incompatible materials;
- Hazardous decomposition products.

The hazards associated with stability and reactivity are related to the physical and chemical properties provided in **Section 9**. The normal practice is to use **Section 9** to indicate measurable properties derived from test procedures, whereas **Section 10** gives (qualitative) descriptions of possible consequences.

Check that the information is consistent between the different subsections, and with the information provided in other sections of the safety data sheet, particularly **Sections 5**, **7** and **9**. If not, contact your supplier to inform him, and confirm which information applies.

A CLOSER LOOK FOR **SUPPLIERS**

Information relevant to **Section 10** may already be given in other sections. Repetition can be avoided by cross-references, while making sure that the information is correctly provided in the other sections.

Example of Safety Data Sheets Section 10

Click on the image to zoom in (+) or zoom out (-)

Toxicological information

THE KEY POINTS

Section 11 is intended primarily for medical professionals, occupational health and safety professionals, and toxicologists, and gives detailed information on:

- The likely routes of exposure;
- The symptoms caused by the physical, chemical, and toxicological characteristics of the substance, mixture and/or known by-products;
- The immediate and delayed adverse effects, including chronic effects, from short and long-term exposure.

You should also find a description of how the chemical was tested for health hazards and the test results.

The content of this section provides the basis for the classification and risk management measures given in the safety data sheet. The information in **Sections 2, 3, 4, 6, 7, 8, 9, 13, 14 and 15** should be consistent with the toxicological information provided here.

A large quantity of information may be provided under this section, particularly in an SDS for a mixture. Ideally, it will be laid out with a clear separation between the data that apply to a mixture as a whole (where applicable) and that for individual (component) substances. Click here for an example of Section 11 for a mixture (https://echa.europa.eu/documents/10162/22786913/sds_section11_mixture_en.pdf).

Check that the information in this section supports the classification and is consistent with other sections of the safety data sheet as indicated in the key points.

You can also check the information in this section against the information on ECHA's website, such as the registration information (if applicable).

If you have any doubts then contact your supplier.

A CLOSER LOOK FOR **SUPPLIERS**

Information concerning the different hazard classes should be clearly and separately reported. The absence of data, and its justification, should also be indicated.

Example of Safety Data Sheet Section 11_a	Example of Safety Data Sheet Section 11_b
	Example of Safety Data Sheet Section 11_c
	Example of Safety Data Sheet Section 11_c
	Example of Safety Data Sheet Section 11_c
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Click on the image to zoom in (+) or zoom out (-)	Example of Safety Data Sheet Section 11_c

Ecological information

THE KEY POINTS

Section 12 gives summarised information on:

- The effects of the chemical on the environment if released;
- What happens to the chemical after its release into the environment (its environmental fate);
- How the chemical was tested for toxicity, persistence and degradability, bioaccumulative potential, and mobility in soil, together with the test results;
- The results of a PBT and vPvB assessment, if one has been carried out as part of a chemical safety assessment. You can find the definition of PBT and vPvB in the ECHA-term.

The content of this section provides the basis for the classification and risk management measures given in the safety data sheet. The information in **Sections 2, 3, 4, 6, 7, 8, 9, 13, 14, and 15** should be consistent with the ecological information provided here.

This information may assist in handling spills, and evaluating waste treatment practices, control of release, accidental release measures and transport.

Check that the information in this section supports the classification and is consistent with various other sections of the safety data sheet as indicated in the key points.

You can also check the information in this section against the information on ECHA's website, such as the registration information (if applicable).

If you have any doubts then contact your supplier.

A CLOSER LOOK FOR **SUPPLIERS**

Information should be clearly reported. When referring to a mixture, it should be clear whether the information applies to the component substances or to the mixture as a whole. **Click here** for an example of Section 12 for a mixture (https://echa. europa.eu/documents/10162/22787005 /sds_ section12_mixture_en). The absence of data, and its justification, must also be indicated.

The results of the PBT or vPvB assessment indicated in Section 12.5 (for those substances/substances in mixtures for which a chemical safety report is required) must match the PBT or vPvB status indicated in Section 2.3.



Example of Safety Data Sheet Section 12_a	Example of Safety Data Sheet Section 12_b

Disposal considerations

THE KEY POINTS

Section 13 gives information on:

- The proper waste management of the substance or mixture;
- The appropriate treatment methods for both the substance or mixture waste.

If the waste is likely to include any contaminated packaging waste, advice on treatment methods for contaminated packaging should also be provided as appropriate.



Waste disposal should be in accordance with local, national and European legislation.

Check that the information in this section is consistent with the classification in **Section 2** and with the exposure controls in **Section 8**.

Bear in mind that if the substance becomes a waste, REACH ceases to apply and waste legislation becomes the correct legal framework within which to operate.

The legal responsibility for disposal rests with the disposer. When confronted with limited information e.g. "Dispose of in accordance with all applicable local and national regulations", it may be diserable to obtain advice from reputable waste contractors.

A CLOSER LOOK FOR **SUPPLIERS**

It may be helpful for your customers to separate the information in this section while considering the following:

- before intended use versus after intended use (to indicate, if possible, when the substance becomes a hazardous waste);
- this substance/mixture itself versus any contaminated packaging (different waste codes may be applied).

It is considered desirable to specify the relevant List of Wastes (LoW) codes, where possible, and provide specific, practical advice (not simply refer to following local regulations).

Example of Safety Data Section 13

Click on the image to zoom in (+) or zoom out (-)

Transport information

THE KEY POINTS

Section 14 gives information on:

- Classification for transportation of the substance or mixture by road, rail, sea, inland waterways or air (UN number and associated detail);
- Additional information where relevant, such as tunnel restriction codes or indication of a marine pollutant;
- Special precautions for the user (this may refer to **Section 8** (Exposure Controls/Personal Protection of the SDS));
- Information on transport in bulk by sea or inland waterways, when cargoes are intended to be carried in bulk according to the following IMO instruments: Annex II of Marpol and the IBC Code.

This section provides information on the transport classification applicable for each of the **UN Model Regulations** governing transport in Europe.

Check that information is consistent with the classification and composition in Sections 2 and 3.

A CLOSER LOOK FOR **SUPPLIERS**

Providing information in all subsections should ensure that your customers have the relevant transport information without having to refer back to you. Where information is not available or relevant, this must be stated.

Example of Safety Data Sheets Section 14

Click on the image to zoom in (+) or zoom out (-)

Regulatory information

THE KEY POINTS

Section 15 gives information on:

- The safety, health, and environmental legislation specific for the chemical, which is not already indicated elsewhere in the SDS;
- Whether a chemical safety assessment (CSA) has been carried out.

The relevant legislation may include any national and/or regional regulatory information on the chemical, where it is being placed on the market, as well as European legislation, such as the young workers or pregnant workers, plant protection and biocides, water framework etc.

When a CSA has been carried out, for hazardous substances registered at 10 tonnes or more per year, the registrant must also prepare exposure scenarios as part of their assessment.



If a substance is subject to any restrictions or to authorisation, it should be indicated in this section.

Relevant national legislation

Check whether your relevant national legislation is indicated, and consistent with the substance/ mixture composition and classification.

Authorisation and restriction

Specific obligations apply to the use of authorised substances. See Q&A 151 for more information. (https://echa.europa.eu/support/qas-support/qas)

If a restriction applies, it has to be complied with.

Chemical safety assessment

A chemical safety assessment (CSA) must be carried out for substances registered at a manufacture or import quantity of 10 tonnes or more per year per registrant. A registration number in **Section 1** (for a substance as such) or **Section 3** (for a substance in a mixture) indicates that a substance is registered.

When a CSA has been undertaken for a hazardous substance, relevant exposure scenarios should be attached to the safety data sheet for the substance. The information should also be included in the information provided for any mixture containing the substance. For a mixture containing such a substance, the supplier may choose to integrate the information into the main body of the SDS, append safe use information for the mixture (SUMI) or attach relevant exposure scenarios.

When risk management measures from an exposure scenario are integrated in the SDS or a consolidated annex, you still have to fulfil the obligations described in the "Exposure Scenario" section to check that your use of the mixture is covered.

Section 15.2 indicates whether a chemical safety report has been carried out for the substance as such or in a mixture. If the SDS is for a substance, exposure scenarios should be attached to the SDS.

A CLOSER LOOK FOR SUPPLIERS

Relevant national legislation

Suppliers need to check the relevant national legislation in the Member States in which they intend to place the substance on the market.

Authorisation and restriction

Suppliers need to indicate if they have been granted an authorisation or if a restriction applies.

Chemical safety assessment

When formulators consolidate or integrate information on risk management measures, from ingredient substance exposure scenarios, into their mixture information, they would help their customers by identifying that information as such.

Click on the image to zoom in (+) or zoom out (-) Example of Safety Data Sheets Section 15

Other information

THE KEY POINTS

Relevant information that has not been included in the previous sections is provided in **Section 16**. This might include:

- Changes from the previous SDS version. If you need an explanation of the changes then contact your supplier;
- A legend to any abbreviations and acronyms used;
- Key literature references and sources for data;
- For mixtures, the procedure used to derive the classification;
- Relevant risk phrases, hazard statements, safety phrases and/or precautionary statements (number and full text);
- Advice on training, for those handling the chemical;
- An index table or table of contents for any attached exposure scenarios.

Many SDS will include a disclaimer or notice to the reader. Such statements do not absolve the legal obligations of the supplier to provide accurate and useful information.



In practice, information in this section will vary considerably. Some other examples of how **Section 16** could look are here:

Example 1 (https://echa.europa.eu/documents/10162/22786913/sds_section16_example1_en.pdf)
Example 2 (https://echa.europa.eu/documents/10162/22786913/sds_section16_example2_en.pdf)

Example of Safety Data Sheets Section 16

Click on the image to zoom in (+) or zoom out (-)



Exposure Scenarios (ES)

Introduction

THE KEY POINTS

An extended safety data sheet, with exposure scenarios attached, has to be supplied if a hazardous substance is registered in a quantity above 10 tonnes per year per registrant.

An exposure scenario describes how the exposure of humans and the environment to the substance can be controlled to ensure its safe use.

An exposure scenario refers to an identified use, or group of similar identified uses, such as formulation, processing or production of an article. It describes the operational conditions and risk management measures that ensure safe use of the substance for that use.

Exposure scenarios may include a number of "contributing scenarios". A contributing scenario describes each contributing activity within the identified use (e.g. mixing, transferring into small containers, applying a substance by spraying etc.).

For every exposure scenario, one or more contributing scenarios refer to the conditions that determine the release to the environment. Depending on the identified use, the releases will be from an industrial site or widespread sources, as with professional or consumer uses. One or more contributing scenarios refer to human exposure. Depending on the identified use, they will relate to workers' exposure or to consumers', associated with a particular task or activity.

Format of the exposure scenario

Unlike the main body of the safety data sheet, the format of the exposure scenario is not defined in REACH. This means the supplier may present the information in different ways. Although this gives flexibility to suppliers it also means that recipients receive information in different formats which leads to difficulties in identifying information relevant to them.

ECHA and stakeholders have worked to harmonise the layout and the phrases used, and recommend a format for the exposure scenario which includes the following four sections:

- Title section;
- Conditions of use affecting exposure;
- Exposure estimation;
- Guidance to downstream users to evaluate if their use is within the boundaries of the exposure scenario.

More information on each section is provided in the following four sections of this Guide. Exposure scenario templates, with a brief description and examples of what is contained in each section, are provided here **ES for workers industrial** (https:// echa.europa.eu/documents/10162/22786913/ annotated_es_template_industrial_en.pdf), **ES for workers professional** (https://echa. europa.eu/documents/10162/22786913/ annotated_es_template_professional_en.pdf) **ES for consumers** (https://echa.europa.eu/ documents/10162/22786913/ annotated_es_ template_consumer_en.pdf). You can also find practical examples of exposure scenarios on ECHA's website.

Exposure scenarios are for substances, many of which will eventually be formulated into mixtures. For hazardous mixtures, formulators should communicate the relevant information from the exposure scenarios of the ingredient substances with the safety data sheet for the mixture. Formulators can:

- Provide consolidated safe use information for the mixture as an annex to the safety data sheet; or
- Incorporate consolidated safe use information for the mixture in the main body of the safety data sheet, mainly in Section 8; or

• Attach relevant exposure scenarios for the ingredient substances as an annex to the safety data sheet.

A methodology is available to help formulators identify the relevant risk management measures to communicate (Lead Component Identification (LCID) Methodology).

Some sector organisations are developing safe use of mixture information for common product types using an agreed format, called SUMIs. The formulators can select the appropriate SUMIs for their products and uses, and provide them as an annex to the safety data sheet.

For more information on LCID and SUMI see the to Extended safety data sheet section of the ECHA website (https://echa.europa.eu/safety-data-sheets)

What should you do when you receive an extended safety data sheet?

If you receive an extended safety data sheet this means that there are exposure scenarios attached. In this case, you must first identify the exposure scenario(s) that describes your, and your customers' identified use(s).

A table of contents may be provided that is compiled from the short titles. These short titles, together with the ES number, are meant to help you browse through the annex and identify potentially relevant ESs, when more than one is attached. An example of the table of contents can be found here (https:// echa.europa.eu /documents/10162/22786913/ es_Table_of_contents_en.pdf).

Once a relevant exposure scenario has been identified, you have to check if the identified use and the conditions of use described are in line with the use and conditions of use in practice e.g. conditions at your site or the way the products you supply are used by your customers. If you are a formulator or re-packer, you also have to consider the foreseeable use by your customers. **Click here** for more details (https://echa.europa. eu/documents/10162/22786913/es_receiving_ whattodo_en.pdf).

Look at **ES Sections 1** and **2** of this Guide for advice on how to do this check. A workflow diagram that illustrates what to do when you receive exposure scenarios from suppliers is **here** (https:// echa.europa.eu/documents/10162/22786913/ es_receiving_flowchart_en.pdf). The obligations are summarised in **Q&A 149** (https://echa.europa.eu/ support/qas-support/qas).

Sometimes your use is described in an exposure scenario, but there are differences in the conditions of use. This could be the concentration of the substance, duration of exposure, the quantity of substance used etc. You may be able to show that your actual conditions are still within the boundaries of the exposure scenario received using an approach called "scaling". This is described in **ES Section 4**.

The outcome of the check you perform may lead to either of the following conclusions:

1. Your uses/conditions of use are covered by the

conditions of the exposure scenario, possibly by applying scaling; or

2. Your uses/conditions of use are not covered by the exposure scenario.

If your use is covered, document your findings, and if it is not covered you can find information on what to do in Section 2 of the Practical Guide 13 - How **downstream users can handle exposure scenarios** (https://echa.europa.eu/documents/10162/13655/ du_practical_guide_13_en.pdf/) and in Q&A 150 (https://echa.europa.eu/support/qas-support/qas).

When you receive a safety data sheet, check if a registration number is provided in Section 1.1 (for substances) or 3.2 (for mixtures). If so, you have **12 months** to implement the conditions of use included in any exposure scenarios received for your use or to take appropriate actions. Find out more about what to do under "a closer look". If you expect exposure scenarios but haven't received them, see **Q&A 476** (https://echa.europa.eu/support/qas-support/qas) for possible reasons why. Contact your supplier immediately if you should have received exposure scenarios but have not.

For a hazardous mixture SDS, you first need to identify any exposure scenario information which may be appended, integrated or attached. Look for an indication in the SDS Section 1.2 or for any attachments after Section 16.

A CLOSER LOOK FOR **SUPPLIERS**

Manufacturers and importers of substances preparing a chemical safety assessment (CSA) and supplying exposure scenarios (ESs) for communication, or downstream users preparing their own assessment (DU CSA) and related ESs should:

- Use the harmonised templates provided;
- Make ESs which are representative of the actual conditions of use, and not prepare an ES with unrealistic conditions of use. Basing your assessment on the conditions of use described by sectors in use maps ensures that the ESs remain realistic;
- Be clear (and use standard phrases) in the identification of uses and description of conditions of use. The exposure scenario communications package (ESCom) standard for exchanging exposure scenario data between IT systems has been developed to help you. Use the information provided by downstream users in the sector organisation use maps;
- Provide detailed scaling instructions when applicable (these are described in the Guidance for downstream users (https://echa.europa.eu/ documents/10162/23036412/du_en.pdf) and in the ES templates).

Formulators of mixtures providing safe use information to their customers should:

- Decide which is the best way to pass on any exposure scenario information from their component substances (appending, integrating or attaching the information). The same standard phrases etc. should be passed on.
- Check if the sectors they supply mixtures to have SUMIs available and use them, if applicable.

When you receive a safety data sheet, check if a registration number is provided in Section 1.1 (for substances) or 3.2 (for mixtures). If so, you have 12 months to implement the conditions of use included in any exposure scenarios received for your use or to take appropriate actions. Find out more about what to do under "a closer look". If you expect exposure scenarios but haven't received them, see Q&A 476 for possible reasons why. Contact your supplier immediately if you should have received exposure scenarios but have not.

For a hazardous mixture SDS, you first need to identify any exposure scenario information which may be appended, integrated or attached. Look for an indication in the SDS Section 1.2 or for any attachments after Section 16. ES Section 1

Title Section

THE KEY POINTS

The **Title Section** of the exposure scenario typically includes the following:

- Uses covered by the exposure scenario: This information gives a brief description of the scope of the exposure scenario in the ES name. It may provide information on the life cycle stage (e.g. use at industrial site, widespread use by professional workers) and market information (e.g. use in paints, use in manufacturing of electric appliances). The short title (http://www.cefic.org) may also include additional elements such as technical process and level of containment.
- List of applicable tasks/activities covered by contributing scenarios within the exposure scenario: This information includes the name of the contributing scenario and the assigned use descriptors. The name is meant to contain more specific information where appropriate, not just paraphrase the use descriptor name.
- The reference number of the exposure scenario, assigned by the supplier.
- The information in the Title Section usually includes use descriptors which aim to describe the uses in a highly standardised way.

They include information on:

- Life cycle stage: such as formulation or re-packing, use at industrial sites, widespread use by professional workers;
- Market sector: such as Product Category (PC) Sector of Use (SU) or the Article Category (AC);
- Application or process type: Process Category (PROC);
- The type of release to the environment: Environmental Release Category (ERC).

The way to describe uses including the standard use description system is described in the Guidance on IR&CSA, Chapter R.12

You should compare your use with the information in the Title Section by considering aspects such as:

- Are all your uses identified in the Title Section of one or more of the exposure scenarios?
- Does(do) the exposure scenario(s) cover all tasks or processes relevant to the uses?

Examples of how to check the ES title can be found in **ES Section 1 - Case examples** (https://echa.europa. eu/documents/10162/22786913/es_section1_ check_example_en.pdf).

A CLOSER LOOK FOR SUPPLIERS

If you are a registrant, make sure that your ES title is the same as the use name in your chemical safety report and IUCLID dossier, and is in line with your identified uses in **SDS Section 1.2**. Basing your assessment on use maps will also ensure that the ES names are meaningful and standardised. Include a reference to the appropriate SWED/SUMI if it has been based on use maps.

 ${\sf Example of Exposure Scenarios Section 1}$



ES Section 2

Conditions of use affecting exposure

THE KEY POINTS

This section is the core of the ES. It presents the recommended operational conditions (OCs) and risk management measures (RMMs) for each contributing scenario. These define the "conditions of use" of the substance that have been assessed as being safe.

The "operational conditions" (OCs) are a set of information on the use of a substance. They describe the types of activities to which the exposure scenario relates: how much, how often and for how long a substance is used and in which types of process, at which temperatures it is used etc. The parameters that influence the exposure level are included in the exposure scenario you receive.

The term "risk management measure" (RMM) means an activity or device that reduces or avoids the exposure of humans and the environment to a substance during its use. Risk management measures applied in industrial uses include local exhaust ventilation (LEV), personal protective equipment (PPE), waste gas incinerators or onsite and municipal waste (water) treatment. For more information, see Guidance on IR&CSA Part D.

If the exposure scenario contains several contributing scenarios, section 2 will include the operational conditions and risk management measures related to each contributing scenario. Usually an exposure scenario contains at least one contributing scenario relating to releases to the environment and multiple contributing scenarios relating to exposure of workers or consumers.

An example of an exposure scenario is available here (https://echa.europa.eu/documents/10162/22786913/es_all_sections_en.pdf).

How to check the operational conditions and risk management measures

You need to verify that the conditions of use at your site and/or the foreseeable conditions of use of your products by your customers are in line with the information in the supplier exposure scenario. Here are points to consider and links to some examples:



ENVIRONMENT ES Section 2 (Environment)

- Is the daily and annual amount of the substance used within the amount assumed in the ES?
- Is the type of risk management measure (RMM) indicated in the exposure scenario in line with the technologies used (such as waste water treatment processes, filters, air abatement systems)?
- Does the effectiveness of the RMM in place match or exceed the effectiveness of the RMM indicated in the exposure scenarios?

https://echa.europa.eu/ documents/10162/22786913/es_section2_ environment check example en.pdf



WORKERS ES Section 2 (Worker)

- Do product characteristics (such as concentration of substance in a mixture, viscosity, etc.) match those specified in the ES?
- Are general ventilation conditions (such as room volume, indoor/outdoor) met?
- Are conditions which control the release of the substance (such as transfer systems, containment, temperature, application method) consistent with those specified in the ES?
- Are the specified risk management measures in use at the effectiveness required?
- Are any organisational measures (training, maintenance) complied with?

https://echa.europa.eu/ documents/10162/22786913/es_section2_workers_ check_exampl_en.pdf



- Do product characteristics (such as concentration, application, form, etc.) match those specified in the ES?
- Does the amount used per event, frequency and duration of use match the assumptions in the ES?
- Do conditions such as room and ventilation conditions match with the ES?
- Are specific personal protective equipment or hygiene practice recommendations included in the consumer product's directions/label/instructions?

The Use comparison table (https://echa.europa. eu/documents/10162/22786913/es_use_ comparison_table_en.docx) may help you to compare the exposure scenario from your supplier with the conditions on your site. If your use is covered document your findings, and if it is not covered, you can find information on what to do in Section 2 of the Practical Guide 13 - How downstream users can handle exposure scenarios (https://echa.europa.eu/ documents/10162/13655/du_practical_guide_13_ en.pdf/) and in Q&A 150 (https://echa.europa.eu/ support/qas-support/browse/-/qa/70Qx/view/ ids/150).

https://echa.europa.eu/ documents/10162/22786913/es_section2_ consumers_check_example_en.pdf

A CLOSER LOOK FOR **SUPPLIERS**

If you are a registrant make sure that the information you provide here is consistent with information in your chemical safety report and in **Sections 7** and **8** of the SDS.

If you are a formulator providing a mixture safety data sheet then you need to pass on any exposure scenario information from your component substances. You may find helpful the approaches (LCID and SUMI) developed through the CSR/ES Roadmap.

Example of Exposure Scenarios Section 2

Click on the image to zoom in (+) or zoom out (-)

ES Section 3

Exposure estimation

THE KEY POINTS

Section 3 of the exposure scenario gives the registrant an opportunity to provide information on:

- The estimated level of exposure when the exposure scenario is applied;
- The "risk characterisation ratio" (this has to be less than 1 to indicate that risks are properly controlled, and the use is considered safe);
- The methodology used to develop exposure estimation (for example, the modelling software applied, measured values etc.).

This information is normally provided for each contributing scenario.

The levels of exposure provided in section 3 of the exposure scenario were estimated by the registrants of the substance, in their chemical safety assessment of the substance. They may have used actual measured data (e.g. measurements performed in the workplace) or exposure estimation software.

Exposure estimation software is used to predict exposures to workers, consumers or the environment for a given set of conditions of use. ECETOC TRA and EUSES (for the environment) are among the most frequently used software programs used in exposure estimation.

The risk characterisation ratio is obtained by dividing the exposure estimates by corresponding threshold levels (i.e. DNEL for human health or PNEC for the environment). More information on DNEL and PNEC is available in **SDS Section 8** of this Guide.

The exposure estimation and risk characterisation is not always present, and in many cases recipients do not need them.

The information in this section is relevant if you want to apply scaling, as described in **ES Section 4** of this Guide. It may also be relevant if you are preparing a downstream user chemical safety report, as described in **Section 5** of the **Guidance for downstream users** (https://echa.europa.eu/documents/10162/23036412/du_en.pdf).

A CLOSER LOOK FOR SUPPLIERS

If you are a registrant and you provide exposure estimates then make sure you provide information on the methods/tools you have used, including the version. Exposure estimates may also be useful for your customers who use the exposure scenario as an input to their onsite risk assessment.



Example of Exopsure Scenarios Section 3_a	Example of Exposure Scenarios Section 3_b

ES Section 4

Guidance for downstream users to evaluate if their use is within the boundaries of the ES

THE KEY POINTS

Section 4 includes advice to the downstream users on how they can verify that their use is covered by the exposure scenario if their conditions of use do not match the supplier's ES exactly. One of the verification methods is known as 'scaling'.

The information provided by the supplier should include:

- Scaling method: this could be a mathematical formula, a link to a website with a scaling tool or a reference to the exposure estimation tool used by the supplier for the assessment;
- Scalable parameters: these are the operational parameters which can be scaled;
- Boundaries of scaling: this indicates to what extent the parameters could be changed.

Scaling can only be applied if the supplier has used a modelling tool to estimate the exposure to humans and the environment (see **ES Section 3** for more details). The scaling tool provided by the supplier is usually a simplified and user friendly software based on the exposure estimation tool the supplier has used for the assessment.

When your conditions of use differ from those indicated in the exposure scenario, the estimated exposure levels and the risk characterisation ratio may also differ. To apply scaling you should:

- Check your use against the exposure scenario and/or contributing scenario received from your supplier;
- Identify the conditions (parameters) that differ;
- Check if differing parameters are identified as scalable parameters by the supplier;
- Input your parameters in the scaling tool received from the supplier;
- Check the resulting level of exposure (or RCR) and compare it with the level of exposure (or RCR) in the corresponding contributing scenario, given in **Section 3** of the ES.

To conclude that the use is covered by the ES, the resulting level of exposure after scaling is applied has to be the same or lower than the level of exposure indicated in **Section 3** of the ES (for the corresponding contributing scenario).

If the supplier does not support scaling, or scaling shows that the exposure level has increased from that in the supplier exposure scenario, you have the following options:

1. Implement the conditions in the exposure scenario; or

2. Ask your supplier to cover your use; or

3. Perform a downstream user chemical safety assessment.

Details on scaling are provided in section 4.2.4 of the Guidance for downstream users (https://echa. europa.eu/documents/10162/23036412/du_en.pdf) and examples will be available in Practical Guide 13 (https://echa.europa.eu/documents/10162/13655/ du_practical_guide_13_en.pdf).

You must be able to show that the exposure levels under your conditions of use are equivalent or lower than under the conditions described by the supplier. If you want to perform scaling but the information is not provided or is incomplete, contact your supplier.

Scaling cannot be applied if the registrant has based the assessment on measured exposure data.

If as a registrant, you have used a modelling tool to estimate the exposure to humans and the environment then provide details of the tool here, or a simplified mathematical method that could be applied by the downstream user if you deem scaling appropriate. Include information on the parameters that can be scaled, and any boundaries that are applicable. For more information see ECHA **Practical Guide 17** (https://echa.europa. eu/documents/10162/13655/pg17_du_csr_final_ en.pdf), and in particular Appendix 1 Example 3 on the Cefic ES Conformity tool.

Example of Exposure Scenarios Section 4

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