

Factsheet

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KEY INFORMATION FOR DOWNSTREAM USERS

Safety data sheets and exposure scenarios

This fact sheet is an introduction for downstream users to safety data sheets and exposure scenarios. It describes what they are, when they should be provided and what a downstream user needs to do when they receive them.

If you use hazardous chemicals in industrial or professional activities, your suppliers usually have to provide you with a safety data sheet.

Additional information may be provided from exposure scenarios attached to the safety data sheet. Exposure scenarios describe how human and environmental exposure to a substance can be controlled to ensure its safe use.

WHY IS THIS IMPORTANT?

The information in the safety data sheet and exposure scenarios helps to protect workers and the environment.

As a user of chemicals, you are required to identify and apply the appropriate measures communicated to you from your suppliers to adequately control the risks.

If you supply substances or mixtures downstream, you have to communicate the relevant information and appropriate risk management advice to your customers.



Downstream users are companies or individuals who use a chemical in their industrial or professional activities.

WHAT ARE SAFETY DATA SHEETS?

Safety data sheets provide users of chemicals with the necessary information to help them protect human health and the environment. The safety data sheet includes:

- Details on the supplier;
- Identification and required composition details of the chemical, including a REACH registration number (if registered) and its main technical functions and uses;
- Information on the hazard classification and labelling and the exposure threshold values for human health and the environment;
- Advice for handling and storage, and exposure controls;
- Measures for first aid, firefighting, safe transportation; disposal and emergencies;
- The basic physical and chemical properties of the substance or mixture (e.g. water solubility, vapour pressure, biodegradability) including information on stability and reactivity. Also, detailed toxicological and ecological information; and
- Relevant regulatory information. This includes whether a chemical safety assessment was prepared as part of the REACH registration and if the substance is subject to authorisation or restriction under REACH.

The format and content of safety data sheets are specified in REACH.

WHAT ARE EXPOSURE SCENARIOS?

A REACH registrant prepares a chemical safety assessment with an exposure assessment as part of the registration process, for substances registered in quantities above 10 tonnes per year and with certain hazardous properties.

As part of this assessment, registrants develop exposure scenarios for the uses of the substance that are identified. When they supply the substance, they provide relevant exposure scenarios to downstream users.

Exposure scenarios describe the operational conditions and risk management measures to adequately control the risks to human health and the environment.

Exposure scenarios cover the entire life cycle of

the substance, including formulation, industrial and professional end-use, consumer use and use in articles.

The format and content for an exposure scenario is not specified in REACH but stakeholders have agreed a common format and content. This includes the following sections:

- Title section;
- Conditions of use affecting exposure;
- Exposure estimation (this may include the risk characterisation ratio); and
- Guidance to downstream users to evaluate if their use is within the boundaries of the exposure scenario.

WHEN SHOULD I RECEIVE SAFETY DATA SHEETS AND EXPOSURE SCENARIOS?

You should receive a safety data sheet for:

- A substance or mixture that is classified as hazardous according to CLP; or
- A substance that is persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB); or
- A substance that is included in the Candidate List of substances of very high concern (SVHCs)¹.

However, when the substance or mixture meets the criteria above but is also sold to the general public, a safety data sheet does not need to be provided unless requested by a downstream user or distributor.

For mixtures which are not classified as hazardous but which contain certain hazardous substances above specified limits, a safety data sheet should be provided if requested by downstream users or distributors. You should receive relevant exposure scenarios as an annex to the safety data sheet of a substance when a company in the supply chain has carried out a chemical safety assessment with exposure assessment in accordance with REACH requirements.

WHAT ABOUT MIXTURES?

Suppliers of hazardous mixtures should communicate the relevant information from the exposure scenarios of the ingredient substances with the safety data sheet for the mixture.

This information can be provided in a number of ways:

¹ <https://echa.europa.eu/candidate-list-table>

- 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 communicate².

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 sheet³.

WHAT DO I NEED TO DO?

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

You should also compare information related to chemical identification, composition, classification, and safe use against your own information on the substance or mixture. Assess any discrepancies and take corrective actions if necessary.

When you receive exposure scenarios with the safety data sheet, you first need to establish whether your use is covered in the exposure scenarios you receive. The exposure scenarios should include uses within your own company and foreseeable uses by your customers, including both workers and consumers.

You then verify that the conditions of use are also covered by comparing the supplier's exposure scenarios with the way you and your customers use the substance.

If your use and/or conditions of use are not covered in the exposure scenarios you receive, you must take action!

WHAT ACTION TO TAKE IF MY USE OR MY CONDITIONS OF USE ARE NOT COVERED?

If your use or conditions of use, or those of your customers, are not covered in the exposure scenario you receive, you have the following options:

² LCID

³ DUCC guidelines

- Ask your supplier to provide you with a suitable exposure scenario. You may need to describe your uses and the conditions of use to your supplier⁴;
- As a minimum, implement the conditions of use described in the exposure scenario you have received;
- Substitute the substance or process with an alternative where your use is covered, if applicable;
- Find another supplier who can provide an exposure scenario covering your use;
- Carry out a chemical safety assessment and prepare your own downstream user chemical safety report for your uses and conditions of safe use; or
- Report information to ECHA if required.

Communicate with your suppliers

- If you have doubts or questions on the information you receive from your suppliers, ask them for more information.
- The safety data sheet should be updated without delay if new information becomes available on the hazards or the need for more appropriate risk management measures arises.
- Safety data sheets and exposure scenarios should be provided in an official language of the country where the chemical is supplied within the EEA.
- If you have new information on the hazardous properties of substances and mixtures, or consider that the risk management measures described are not appropriate, you are obliged to communicate this information to your suppliers.

DO I HAVE TO REPORT TO ECHA?

You have to report to ECHA if your use or conditions of use are not covered in an exposure scenario you receive and if:

- You prepare a downstream user chemical safety report and the particular use is more than one tonne per year of the substance; or

⁴ Check first if sector organisations already provide this information in a use map. Use maps are an agreed format for communicating the necessary information on use and conditions of use and are available on [ECHA's website](https://echa.europa.eu)

- You are exempt from preparing a downstream user chemical safety report because you use the substance in a total of less than one tonne per year; or
- You are exempt from preparing a downstream user chemical safety report because you use the substance for product and process-oriented research (PPORD).

Downstream users chemical safety report

A downstream user chemical safety assessment addresses the risks for the uses that are not covered in the received exposure scenarios. They are usually based on the hazard information in the safety data sheet.

You do not have to prepare a downstream user chemical safety report if:

- You use less than one tonne of the substance per year in total; or
- You use the substance in product and process-orientated research and development (PPORD) and adequately control the risks.

You can submit a downstream user report from the downstream user pages of ECHA's website.

WHAT ARE MY DEADLINES?

REACH contains clear timelines (Figure 1) for implementing downstream user obligations. You need to act without delay.

Make sure that you document what you have done and what you are planning to do to achieve good quality implementation.

WHERE CAN I FIND FURTHER INFORMATION AND SUPPORT?

National REACH helpdesks offer practical advice in local languages:

» <http://echa.europa.eu/nationalhelp/>

Industry associations, such as the Downstream Users of Chemicals Co-ordination Group (DUCC) and Cefic, provide information and support.

ECHA provides a wide range of support and guidance for downstream users:

» <http://echa.europa.eu/downstream>

For more information on this topic, consult the interactive eGuide 01 on "Safety data sheets and exposure scenarios" and Practical Guide 13 "How downstream users can handle exposure scenarios":

» <https://echa.europa.eu/practical-guides>

Figure 1: REACH timelines for implementing downstream user obligations



**DOWNSTREAM
USERS**

