

REACH *Fact Sheet*

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Safety Data Sheets and Exposure Scenarios

Key information for Downstream Users

If you use hazardous substances registered under REACH, your suppliers now have to provide you in most cases with a new, extended safety data sheet that includes exposure scenarios. This is one of the main innovations of the REACH Regulation to enable you and your employees and customers to use these substances safely.

Many of the 3500 substances which have been registered with ECHA by the 2010 REACH deadline meet the criteria to be classified as hazardous. ECHA is publishing information on all of them on its website. If you use any of these substances, you can expect your suppliers to send you an extended safety data sheet.

WHY IS THIS IMPORTANT?

The extended safety data sheet summarises the key information from the chemical safety assessment that a company in your supply chain has carried out under REACH. In an exposure scenario you can find which uses are covered. If your uses/ your customers' uses, (as explained overleaf), are covered, the exposure scenarios should give you information about the conditions of safe use relevant to you and your customers.

Every time a safety data sheet is required, you in turn have to provide your customers with information on the hazards, conditions of safe use and appropriate risk management advice.

This fact sheet introduces you to your new duties step-by-step.

WHAT IS NEW IN THE SAFETY DATA SHEET?

Exposure scenarios are the new element. They include conditions of safe use, in other words, the operational conditions and necessary risk management measures.

Ideally, the extended safety data sheet should cover all **your uses** in the life cycle of the substance, from manufacture through to waste, including:

- Uses **within your own company**
- Uses **by your customers** in their processes or products, i.e. mixtures or articles.
- Uses **by companies supplied with chemicals by your customers.**

The extended safety data sheet provided by your supplier should include:

- **The main technical function** of the substance (e.g. flame retardant, pigment, stabilizer) and the uses covered in the exposure scenarios.
- **Threshold values of the exposure levels** for human health and the environment that should not be exceeded¹, according to the assessment made by your supplier.
- **Physicochemical data** needed to carry out exposure assessments (e.g. water solubility, vapour pressure, biodegradability).
- **One or more exposure scenarios** containing **practical advice on the conditions of safe use**, including risk management measures and waste management measures.

WHAT DO I NEED TO DO?

When you receive an extended safety data sheet and a registration number for a substance, you should take the following steps.

Step 1: *Gather information on how the substance is used by you and your customers (if not already done)*

Step 2a: *Check to see whether **your uses** are covered in section 1.2 of the safety data sheet and in the exposure scenarios*

Step 2b: *Assess if there is a clear mismatch between **your uses** and what is covered in the exposure scenarios*

For example: you sell your products to consumer markets, but your supplier does not cover consumer uses in the exposure scenarios.

Step 3a: *If your uses are covered, compare the **conditions of safe use** described in the exposure scenarios with the actual conditions of use in your company and those you know about in your customers' companies.*

Step 3b: *Assess if there is a clear mismatch between your **conditions of use** and what is described in the exposure scenarios*

For example: the substance is contained in your product up to 20%, but the exposure scenario of your supplier only covers a concentration of up to 5%.

If you identify a clear mismatch in step 2 or step 3 you must take action!

¹ DNELs = Derived No Effects Levels and
PNECs = Predicted No Effects Concentrations

WHAT IF MY USE OR MY CONDITIONS OF USE ARE NOT COVERED?

In this situation you may either:

- **Ask your supplier to include *your uses* in his chemical safety report** and to provide you with a revised exposure scenario for it. You need to make sufficient information on your uses and the conditions of use available to your suppliers to enable them to make such an assessment. Usually this will require a dialogue with your suppliers. The time they have to assess your formal request is a maximum of **one month** or one month before the next supply, whichever is later.

- **Adapt your activity** to the conditions of use described in the exposure scenarios, namely:

- Implement as a minimum the conditions of safe use in relation to your own processes
- Adapt the composition/design of your product and
- Recommend as a minimum the relevant conditions of safe use to your customers

- **Look for another supplier** who provides an exposure scenario covering your use or one who is ready to do so.

- **Carry out your own chemical safety assessment** (if none of the exemptions in the blue box apply) and prepare your own chemical safety report for your uses and conditions of safe use. You do not have to submit your chemical safety report to the authorities, but you have to keep it up-to-date and make it available for any inspection or upon request. You also need to attach corresponding exposure scenarios to your own safety data sheets.

WHEN IS A CHEMICAL SAFETY REPORT NOT REQUIRED FROM ME?

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

- A safety data sheet is not required in relation to the substance (e.g. because it is not classified as hazardous); or
- A chemical safety report is not required for the substance at all (e.g. because the registered tonnage is below 10 tonnes); or
- You use less than 1 tonne of the substance per year in total. In this case you still need to identify and apply appropriate risk management measures and include, where necessary, this information in the safety data sheets that you provide to your customers; or
- The concentration of the substance in a mixture you produce is lower than the lowest thresholds specified in REACH Article 14(2); or
- You use the substance exclusively in product and process orientated research and development and the risks to human health and the environment are adequately controlled.

WHEN DO I HAVE TO INFORM ECHA?

You have to report to ECHA when you:

- Need to prepare a downstream user chemical safety report; or
- Wish to benefit from the exemption to prepare a chemical safety report either because:
 - you use the substance in total less than 1 tonne per year; or
 - you use the substance for product and process oriented research.

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If reporting to ECHA is required, specific uses of less than 1 tonne per year do not need to be included in the report, except for the following situation: if the reason you do not need to prepare a chemical safety report is that the total quantity you use is below one 1 tonne, then all uses are to be reported.

You have **6 months to report to ECHA** from the moment you receive an extended safety data sheet with a registration number.

WHAT INFORMATION DO I HAVE TO PROVIDE TO ECHA?

- **Administrative information**, including your identity and that of your supplier's, the substance identity and the registration number of the substance.
- **Brief description of the use** not covered in the exposure scenario and of the conditions of this use.
- If you consider that **testing on vertebrate animals** is necessary to complete the downstream user chemical safety assessment, a proposal for the tests.

HOW DO I COMMUNICATE DOWNSTREAM?

You should include relevant exposure scenarios supplied to you into the safety data sheets for your customers.

You may either:

- Include this information in the main body of the safety data sheet or in the form of an attached exposure scenario; or
- Forward the exposure scenarios supplied to you to your customers, after you have checked their consistency with your safety data sheet.

If you receive an extended safety data sheet identifying additional or more severe hazards than previously known, you have to inform your customers of this without delay.

WHAT ARE MY DEADLINES?

REACH contains challenging timelines for implementing downstream user obligations. You need to act without delay, document what you have done and what you are planning to do to achieve good quality implementation.

Your deadlines start from the day you receive an extended safety data sheet with a registration number.

- **If your uses are covered** and you do not have to prepare your own chemical safety report, you have:

12 months to implement the measures communicated to you in the extended safety data sheet and to update the safety data sheets of mixtures you supply further downstream

- **If your uses are not covered** you have:

12 months to carry out your own chemical safety assessment and to implement the related exposure scenarios.

WHERE CAN I FIND FURTHER INFORMATION AND SUPPORT?

National REACH helpdesks offer practical advice in local languages:
<http://www.echa.europa.eu/nationalhelp/>

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

ECHA provides guidance, IT tools and manuals:
<http://echa.europa.eu/downstream>

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