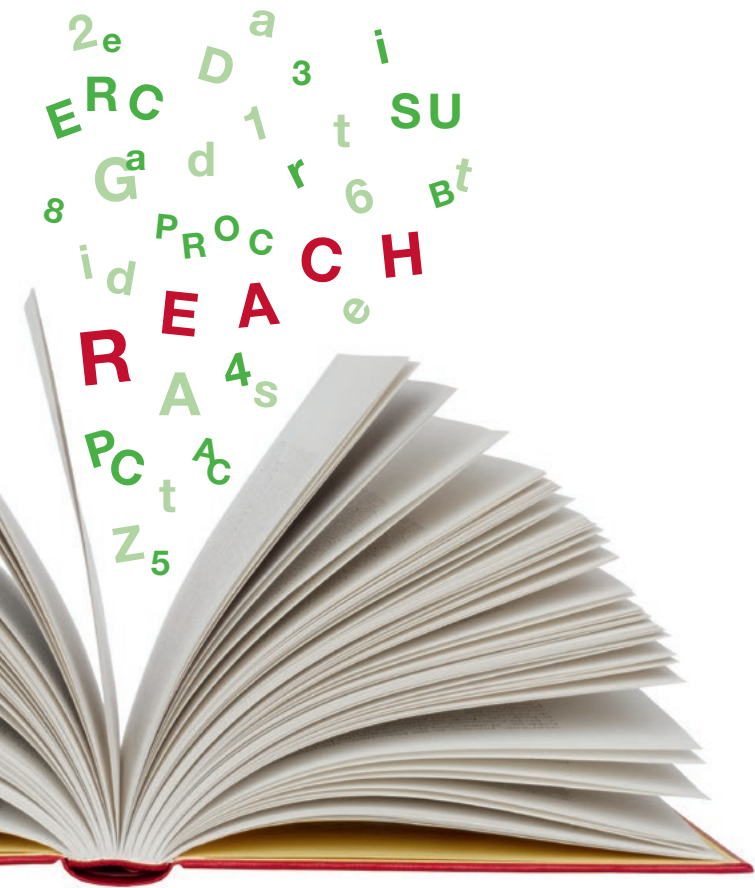


The Safety Data Sheet under REACH – a closed book?

Tips for a better understanding of the Safety Data Sheets



 **BASF**

We create chemistry

Which changes have been made to the Safety Data Sheet due to REACH?

Dear Customers,

The requirements of the REACH regulation have an impact on the structure and contents of Safety Data Sheets. These have become significantly more complex. In providing you with this information, we would like to support you with the task of filtering out the key data for you.

We are making the BASF Safety Data Sheets easier to read by assigning a structure to the annexes of extended Safety Data Sheets (eSDS) that corresponds to the standards of the European Chemicals Agency (ECHA). It consists of modules and features an index for the annex. As usual, we will send every new version of the Safety Data Sheet to you and highlight important changes.

We have compiled the following explanations for you:

- Which changes have been made to the Safety Data Sheet due to REACH.
- What “extended” Safety Data Sheet (eSDS) means and when you will receive one.
- Meaning of exposure scenarios.
- What the recipient of an extended Safety Data Sheet must do.
- What obligations do downstream users have according to REACH.
- Glossary and contact persons.

If you have any questions, please let us know.

Your BASF REACH Team

Major changes have been made in a number of sections of the new Safety Data Sheet:

Section 1: Identification of the substance/mixture and of the company/undertaking

If the chemical has been registered under REACH, the registration number(s) must be indicated in this chapter. Further information on registration can be found on ECHA's web page (1). Please be aware that REACH registration numbers are only applicable within the respective supply chain. In some cases, a Safety Data Sheet will not feature a registration number. There are various valid reasons for this, for instance due to a chemical being exempt from REACH; or the chemical is a polymer.

Apart from the registration number, this section also lists the relevant uses of the chemical substance or mixture and, if applicable, uses advised against. In this regard, BASF restricts itself to a brief description of the use, the use descriptors are specified in the annex of the Safety Data Sheet.

Section 2: Hazards identification

Since December 1, 2010, Safety Data Sheets for chemicals must feature the classification and labeling according to GHS (Globally Harmonized System for Classification and Labelling).

Section 3: Composition/Information on ingredients

This section specifies the chemical identity of the ingredient(s) of the chemical substance or mixture. If the substances in the mixture have been registered at the European Chemicals Agency, for the hazardous ingredients, this section also specifies all the BASF registration numbers relevant for these.

Section 8: Exposure controls/personal protection

If national or EU-wide valid limit values exist for a chemical, these will be listed in this section. If ‘DNEL’ (derived no effect level) – and /or ‘PNEC’ (predicted no effect concentration) values have been calculated within the scope of a chemical safety assessment, the values relevant for the exposure scenarios will be specified in this section. In addition, the protective measures to be heeded are also specified here.

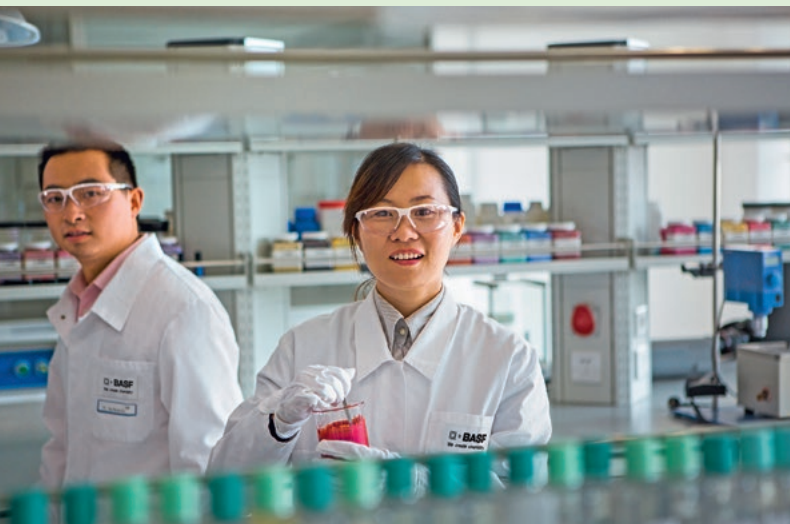
Section 15: Regulatory information

Amongst other things, this section contains information about whether the chemical has been subjected to restrictions or requires authorisation. In individual cases, you have to check resulting obligations for downstream users.

This section also contains information whether or not a chemical safety assessment has been carried out under REACH.

Annex

The new Safety Data Sheet may be available in the form of an “extended Safety Data Sheet”. In this case, it will have an annex.



What does “extended” Safety Data Sheet (eSDS) mean and when will I receive one?

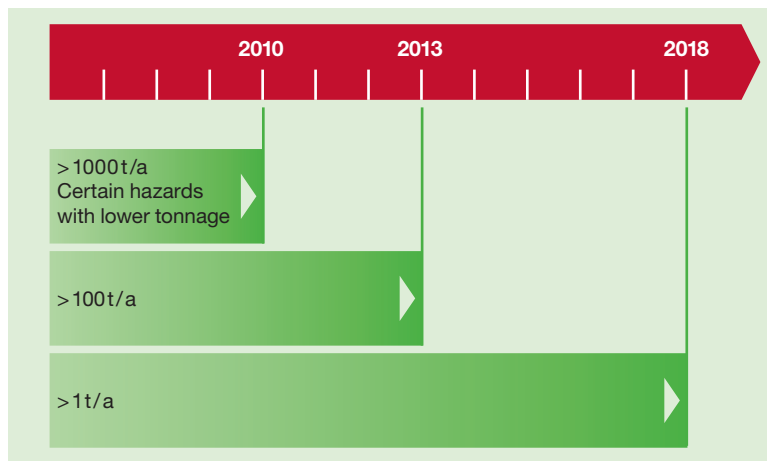
Under certain conditions, the Safety Data Sheet will contain an annex with exposure scenarios. In these cases, the term “extended Safety Data Sheet” is used. Exposure scenarios describe the conditions under which the chemical can be used safely. The exposure scenarios can, above all, be very extensive if they refer to all applications of an industrial association of downstream users (for example AISE, CEPE, and so on).

An extended Safety Data Sheet is required under the following conditions:

- The SDS is for a chemical that has been registered according REACH with the European Chemicals Agency (ECHA).
- The chemical is manufactured or imported in quantities > 10 t / a.
- The chemical is hazardous.

Which chemicals have already been registered?

The registration requirement applies to all chemicals manufactured by a legal entity in the EU in a quantity of 1 ton or more per annum or which are imported in this quantity into the EU by a legal entity.



Click on the following link to display a list of all the substances that have already been registered with the agency by at least one legal entity in the EU: <https://www.echa.europa.eu/information-on-chemicals/registered-substances>



What are exposure scenarios?

Exposure scenarios describe the conditions under which a chemical substance can be manufactured, used and handled safely. They are the outcome of a detailed risk assessment by the registrant. Exposure scenarios are made available to customers as an annex to the Safety Data Sheet.

The exposure scenarios of BASF always follow the same structure:

A short title for the scenario, highlighting the uses assessed. This is followed by a table that lists the detailed conditions (conditions of use such as temperature, duration and risk management measures such as local exhaust ventilation, chemical protective gloves) for safe use. The basic structure follows the recommendations of the European Chemicals Agency (ECHA).

The index of the BASF eSDS

At BASF, the annex to the eSDS features an index of the exposure scenarios to better guide our customers through the BASF eSDS. The index contains all the short titles of the exposure scenarios along with the corresponding use descriptors.

Example:

- 1) Formulation in preparations, (re-) packaging and distribution**
ERC 2; PROC 1, PROC 2, PROC 3, PROC 4, PROC 5, PROC 8a, PROC 8b, PROC 9, PROC 14, PROC 15
- 2) Use as a monomer**
ERC 6c; PROC 1, PROC 2, PROC 3, PROC 4, PROC 5, PROC 8a, PROC 8b, PROC 9
- 3) Formulation of coatings and inks**
ERC 2; PROC 1, PROC 2, PROC 3, PROC 5, PROC 8a, PROC 8b, PROC 9

A list comprising the precise descriptions of the use descriptors (e. g. ERC 2 or PROC 5 in the above example) can be found in the guidance document „Use description (Chapter R.12)“ of the European Chemicals Agency (ECHA)¹.

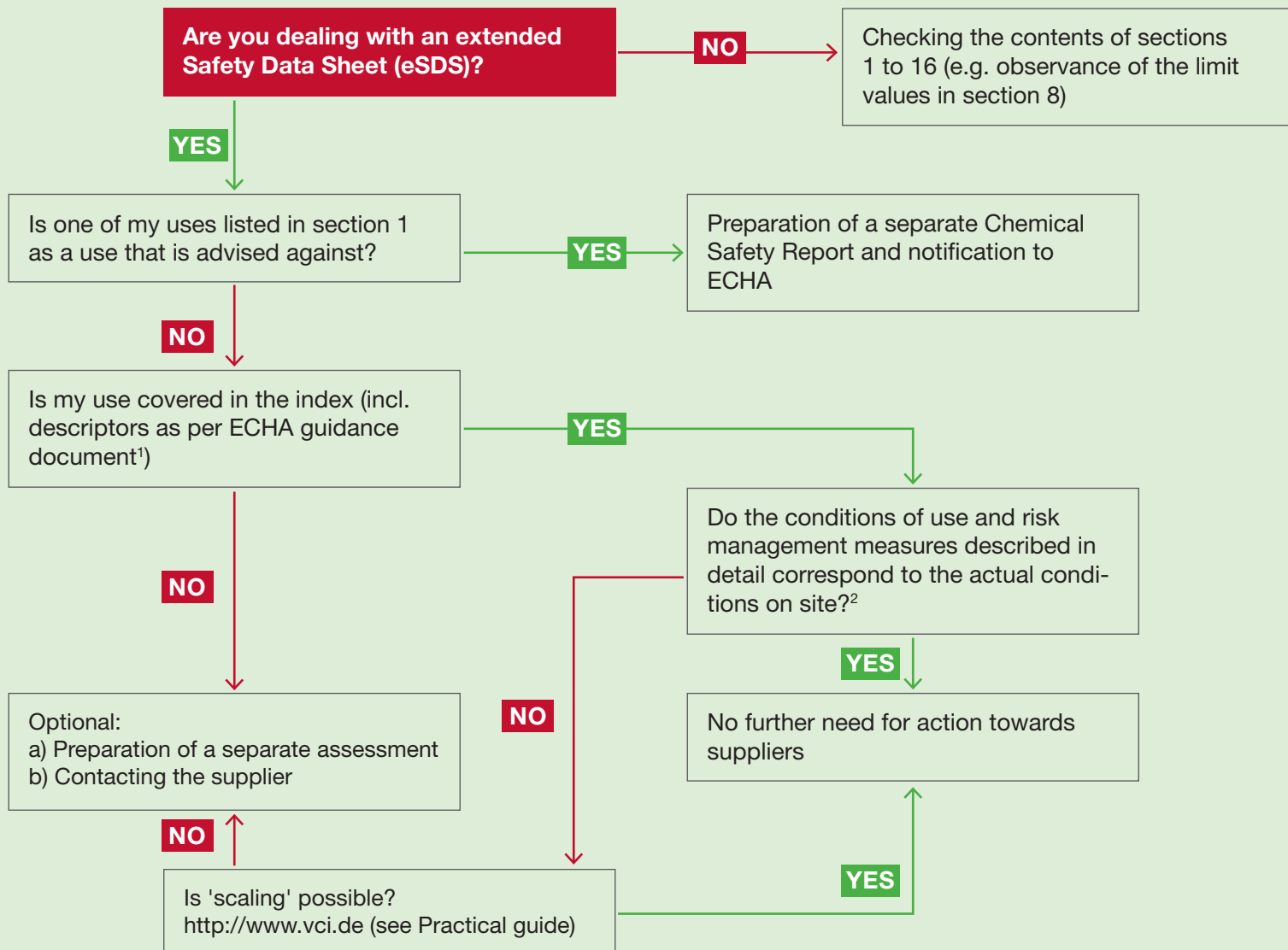
¹ <https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment>



What do I need to do as the recipient of an eSDS?

In addition to the checks performed thus far in sections 1 to 16 of the SDS, in the case of an eSDS, the annex also has to be incorporated into the checking procedure.

According to REACH the following procedure is recommended:



¹http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r12_en.pdf

² If working place limit values are kept the use can be seen as safe for occupational health & safety.

Glossary of the most important terms used in the eSDS

Use descriptors:

Harmonized description of uses with the aid of descriptors subdivided into:

- **LCS (life cycle stages):**
Describes where the use takes place.
- **SU (sector of use):**
Describes the industry (sector) in which the chemical is used.
- **PROC (process category):**
Describes the application techniques and types of processes during the manufacture and use of the chemical, which impact directly on the exposure and, as such, on the necessary risk management measures.
- **ERC (environmental release category):**
Describes the features of a use that are relevant from an environmental protection viewpoint. Various industry sectors have developed more specific descriptions of the environment-related conditions of use. These are referred to as spERCs.
- **PC (chemical product category):**
Describes the use of a chemical substance by the type of the consumer products in which it is used.
- **AC (article category):**
Relates to the use of chemicals in articles.
- **TF (technical functions):**
Describes the role that the product fulfils when it is used.

Emission factors:

The emission factors specify which proportion of the chemical quantity used is taken into account as emission into the corresponding media (air, ground, water) within the scope of the exposure estimation.

Receiving surface water:

In the receiving surface water, the emission from a sewage treatment plant is diluted. Generally, a 10-fold dilution is assumed in fresh water; for the marine environment, a 100-fold dilution is assumed. These standard assumptions can be adapted to the actual situation on site.

RMM (risk management measures):

Measures for a chemical, which reduce both the emission and exposure and, accordingly, the risk during use for workers and the environment.

LEV (local exhaust ventilation):

A value for LEV describes the effectiveness with which an exhaust ventilation system has to be operated from the manufacturer's viewpoint in order to ensure the safe use of the chemical product.

RCR (risk characterization ratio):

The risk that emanates from a use is represented by the comparison of exposure and possible hazard. If the RCR is less than 1, the safe use of the chemical is ensured under the conditions given.

M-Safe (maximum allowable site tonnage):

M-Safe describes the maximum amount of substance that can still be used safely under the specified conditions of use and assumptions (for example for dilution). In other words, M-Safe corresponds to the amount of substance with which the PEC/PNEC ratio (RCR) would still just be less than 1. A complete exposure scenario (ES) consists of one contributing ES relating to the environment (ERCs) and one or more contributing ES relating to human exposure (PROCs). This form of representation permits the description of different activities with various conditions in one ES.

PNEC (predicted no effect concentration):

This relates to the calculated maximum concentration of a chemical in the environment for which no change to the ecosystem is assumed. A PNEC can be calculated for various scenarios (marine water or fresh water, air or soil or water body or sediment, sewage treatment plant or open water) and is specific to the defined basic conditions.

DNEL (derived no effect level):

This refers to the dose derived by taking account of safety factors and which is evaluated as safe for humans. A DNEL can be derived for different groups of persons (workers or consumers), exposure periods (long term or short term), type of effects (local or after distribution in the body) and routes of exposure (oral, dermal, inhalative) and is specific to the defined basic conditions.



Where can I get more help?

Questions about the Safety Data Sheet:

An e-mail address is provided on every BASF Safety Data Sheet. Please send any questions about the Safety Data Sheet to this address.

Further information is available via the following links:

ECHA web site

<https://echa.europa.eu/>

REACH Regulation

<https://echa.europa.eu/regulations/reach/legislation>

ECHA Guidance Documents

http://guidance.echa.europa.eu/guidance_en.htm

ECHA Information on extended Safety Data Sheet

<https://echa.europa.eu/safety-data-sheets>

Cefic Guidance on Safety Data Sheet

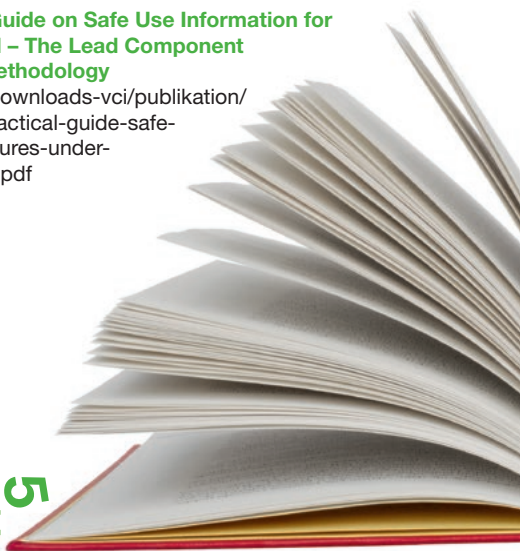
http://www.cefic.org/Documents/IndustrySupport/REACH-Implementation/Guidance-and-Tools/Guidance_on_processes_in_companies_after_receiving_an_extended_SDSI.pdf

VCI Information on Safety Data Sheets and Exposure Scenarios (German)

<https://www.vci.de/reach/lieferkettesdb/uebersichtsseite.jsp>

VCI REACH Practical Guide on Safe Use Information for Mixtures under REACH – The Lead Component Identification (LCID) Methodology

<https://www.vci.de/vci/downloads-vci/publikation/2016-03-14-vci-cefic-practical-guide-safe-use-information-for-mixtures-under-reach-lcid-methodology.pdf>



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