

Factsheet

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Key information for recipients of substances covered by Article 2(7) of the REACH Regulation Communication obligations for certain substances exempted from registration under REACH

The aim of this fact sheet is to familiarize the reader with the fact that some substances can be legally placed on the market without a registration number and with the information he can expect from his supplier concerning in particular those substances which benefit from the exemption from registration according to Article 2(7) of REACH.

Manufacturers or importers that can rely on Article 2(7) of the REACH Regulation regarding the exemption of a substance from the registration provisions can legally place on the market such a substance without submitting a registration dossier. In such a situation, the manufacturer or importer will not obtain a registration number and consequently will not be able to communicate such a registration number in the supply chain.

Companies that wish to benefit from such an exemption must assess whether their substances qualify for the exemption. They also have to provide the authorities (on request) with appropriate information to prove that their substances fulfil the exemption conditions.

Once it has been established that a substance can be legally placed on the market although a registration number may not be available, a further obligation applies. The supplier of such substances has a duty to communicate information down the supply chain to his recipients to enable them to use the substance safely.

SUBSTANCES EXEMPTED FROM REGISTRATION UNDER ARTICLE 2(7)

The following substances are exempted from the registration obligations:

- **Substances included in Annex IV to the REACH Regulation** as they present minimum risk because of their intrinsic properties (e.g. water, nitrogen);
- **Substances covered by Annex V to the REACH Regulation** as for these substances (substances occurring in nature, e.g. minerals, ores and ore concentrates if they are not chemically modified) registration is deemed inappropriate or unnecessary;
- **Substances already registered and recovered through a recovery process in the EU;**
- **Substances already registered and exported from and re-imported into the EU.**

The specific conditions under which the above-mentioned exemptions from registration under REACH apply are described in detail in the ECHA [Guidance on registration](#) (section 2.2.3).

ACTORS CONCERNED

Information included in this document may be relevant for any actor involved in the supply chain of a substance exempted under any of the provisions of Article 2(7). Since exempted substances may be placed on the market without indicating a registration number, this factsheet is addressed in particular to:

- recipients (including downstream users using the substances in their professional and/or industrial activity) who are not certain if the substances they receive are legally placed on the market;
- suppliers who have to provide their customers with a safety data sheet (an SDS) or other sufficient information on the safe use of a substance they supply in case no SDS is required.

In some cases distributors (including retailers) may find this information useful, since they also contribute to the flow of information in the supply chain.

WHAT INFORMATION CAN I GENERALLY EXPECT FROM MY SUPPLIER?

Safety data sheet

A supplier has to provide an SDS, **whenever** the substance (on its own or in a mixture) falls within one of the following categories:

- it meets the criteria for **classification as hazardous** in accordance with the Regulation on classification, labelling and packaging of substances and mixtures (CLP Regulation) or the mixture containing the substance is classified as dangerous in accordance with the Dangerous Preparation Directive (DPD);
- it is persistent, bioaccumulative and toxic (**PBT**) or very persistent and very bioaccumulative (**vPvB**) in accordance with Annex XIII of the REACH Regulation;
- it is included in [the candidate list of substances](#) which may be subjected to authorisation.

A supplier has also to provide on request an SDS for any mixture which does not meet the criteria for classification as dangerous but which contains:

- $\geq 1\%$ (by weight) for non-gaseous mixtures (or $\geq 0.2\%$ by volume for a gaseous mixture) of a substance posing human health or environmental hazards; or
- $\geq 0.1\%$ (by weight) for non-gaseous mixtures of a PBT or a vPvB substance in accordance with Annex XIII; or
- a substance for which there are Community workplace exposure limits.

Please note that the SDS does not have to be supplied if a hazardous substance or dangerous mixture is offered or sold to the general public and provided with sufficient information to use the substance safely unless specifically requested by a downstream user or distributor. It follows that SDSs are only for professional users.

For more information on which substances and mixtures SDSs needs to be provided for and by whom, please consult the [Guidance on the compilation of safety data sheets](#).

Extended SDS

In some cases actors in the supply chain will be provided with one or more exposure scenario(s) (ES) attached to the SDS for a substance or mixture. This may happen if a substance is subject to registration for quantities of 10 tonnes or more per year. In this situation the registrant is required to perform a chemical safety assessment (CSA) to ensure that the risks arising from the manufacture and use of a substance are under control. The results of a CSA are then documented in a chemical safety report (CSR). The final ES is an integral part of CSR and it is developed for all identified uses. Once a relevant ES is completed it has to be communicated to you and other downstream users of the registrant as an annex to the SDS – thus creating a so-called “extended SDS”. The ES will provide appropriate instructions on risk management measures (RMM) that you should apply in order to ensure control of risks.

However, actors should be aware that not all registrants who are required to carry out a CSA and prepare a CSR are necessarily required to prepare an ES. For example,

although a CSA and a CSR is generally required for all substances subject to registration in quantities of 10 tonnes or more, an ES is only required for those which fulfill the criteria for any of the hazard classes or categories set out in Article 14(4) of the REACH Regulation or are assessed to be a PBT or vPvB.

Furthermore, the CSA and CSR would normally be carried out as part of the preparations for a registration by the relevant deadline. The ES for a particular substance on its own or in mixture will therefore normally only be attached to SDS after the relevant substance has been registered.

To learn more about the information content of the ES please see the [Guidance on information requirements and chemical safety assessment. Part D: Exposure Scenario Building](#).

You may also find useful to consult [Practical examples of exposure scenarios](#) available on the ECHA website.

Other information

According to Article 32(1) of the REACH Regulation when supplying a substance or a mixture for which an SDS is not required suppliers still have to communicate the following information:

- if the substance is subject to [authorisation](#) and the details of the granted or denied authorisation or appropriate information if authorisation has been denied;
- the details of any [restriction](#) imposed;
- any available and relevant information about the substance that is necessary to enable appropriate risk management;
- the **registration number** if available for any substances for which information is communicated as outlined above.

WHAT CHANGES IN CASE ARTICLE 2(7) APPLIES?

There are however substances for which your supplier is **not** required to provide you with all information listed above. These are discussed further below.

Substances covered by Annex IV and V of the REACH Regulation

If the conditions of Article 2(7)(a) or Article 2(7)(b) of the REACH Regulation (concerning substances listed in Annexes IV or V of the Regulation because either sufficient information is already known about them or registration is deemed inappropriate or unnecessary, respectively) are met for a substance, it is exempted from the registration provisions and can be legally placed on the market without a registration number. Please note that the registration number refers to the submission of a specific registration dossier for a substance by each manufacturer or importer. Therefore, recipients of substances that have not been registered by their manufacturer or importer because the exemptions according to Article 2(7)(a) or 2(7)(b) apply will not receive a registration number from the manufacturer or importer of these substances.

As mentioned before, a CSR documenting the CSA is only needed for substances subject to registration in quantities of 10 tonnes or more per year per registrant. As a consequence for substances that are exempted from registration the CSA and CSR are not needed at all. Therefore, if you are the recipient of such a substance you will not receive an ES as part of the safety data sheet.

For more explanations and background information on applying the different exemptions and clarifications as to when an exemption could or cannot be applied, please consult the [Guidance on Annex V](#).

Recovered substances

A recovery operator who establishes the sameness of a substance with one already registered and who possesses the required information according to Articles 31 or 32 of REACH is exempted from registration of that substance and consequently does not have to perform a CSA or complete a CSR for the substance. Therefore, even if the registration of the same "original" substance does not cover its use as a recovered substance, the recovery operator is not required to prepare an ES for the use of the recovered substance. It should be recalled, however, that the recovery operator must in any case provide relevant and adequate safety information to allow safe use of the recovered substance.

When placing a recovered substance on the market, a recovery operator does not have to indicate a registration number, as he is exempted from the provisions of Title II of REACH. Therefore, if you are recipient of a recovered substance that has not been registered by the recovery operator because the exemption of Article 2(7)(d) of the REACH Regulation applies, you will generally not receive:

- a registration number;
- an ES for the subsequent downstream uses within the new life cycle chain after the recovery has taken place;

from the manufacturer of the recovered substance as part of the SDS or as an attachment to it.

However, please be aware that according to the provisions of Article 32(1) of REACH it may be required, to provide a registration number free of charge if this is available to the recovery operator.

To learn more about the conditions under which legal entities recovering substances from waste can benefit from the exemption laid down in Article 2(7)(d) and their obligations to share information in the supply chain please consult the [Guidance on waste and recovered substances](#).

Re-imported substances

In cases where a substance is first manufactured in the EU, then exported and then brought back into the EU again this could lead to a double registration obligation if it happens within the same supply chain. Therefore, substances which have been registered according to Title II of REACH, exported and then re-imported are exempted from registration under the following conditions:

- the substance must have been registered before it was exported from the EU;
- the substance already registered and exported must be the same as the substance being re-imported;
- the substance must not only be the same but it must actually proceed from the same supply chain in which the substance was registered;

- the re-importer must have been provided with information on the exported substance, and that information must comply with the requirements established under REACH for the provision of information down the supply chain.

The re-importer will need to have documentation showing that the substance is identical to that registered in the EU by him or someone in his supply chain. The sameness of the substance must be assessed according to the criteria defined in the [Guidance on identification and naming of substances under REACH and CLP](#).

Furthermore, in order to avoid a double registration obligation, the re-importer needs to have available an SDS, or other information required by Article 32 relating to the exported substance. The re-importer can show this by tracing and documenting the supply chain and identifying the original registrant of the substance.

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 often also provide information and support to their members.

LINKS TO RELATED MATERIAL

[REACH Regulation](#) EC No 1907/2006

[REACH Guidance](#): this section of the ECHA website is a single point of access to general and detailed technical guidance on REACH.

[Guidance Fact Sheets](#) and [Frequently Asked Questions](#) can be found in the "support" section of the ECHA website.

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