

## Questions & Answers on REACH

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### Where to find the REACH Registration Number (RRN)?

The RRN is shown in section 1 of SDS for substances, while in SDS for mixtures the RRNs are mentioned under section 3 for classified components.

Note: The RRN is a simple evidence that a certain registrant has registered the substance. The number is uniquely linked to the substance and the registrant, in other words: the RRN allows identifying the registrant and the corresponding registration dossier upon an inspection by the enforcement body.

By agreement with ECHA distributors can omit the last four digits (or replace them by "xxxx"). In case of an inspection the authorities will ask the Downstream User (i.e. our customer or our customer's customer) to provide the name of its supplier and the enquiry goes up the supply chain until it reaches the registrant who shall be the European manufacturer or importer.

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### What is the reason that Univar does not provide a REACH Registration Number (RRN) on the Safety Data Sheet (SDS)?

For **substances** (either mono-constituent substance, multi-constituent substance or a UVCB substance):

If a substance is supplied without RRN it does not necessarily mean that the substance is not in compliance with REACH.

In most cases, the substance is exempt from registration because the manufacturer or importer relies on one or more sub-paragraphs of Art. 2 of REACH.

Exemptions according to Art. 2(7) apply to

- substances included in Annex IV
- substances covered by Annex V
- substances already registered and recovered in a recovery process in the EU/EEA
- substances already registered and exported and later re-imported into the EU/EEA

Exemptions according to Art. 2(5) apply to

- pharmaceutical products (human and veterinary)
- food and feeding stuff

Volume exemption according to Art. 6

- If the volume of a substance manufactured or imported is below 1 ton per year (so 999kg max) a registration is not needed

Further, for UVCB substances (Substances of Unknown or Variable composition, Complex reaction products or Biological materials) their corresponding RRN is mentioned in section 1. However, in section 3 key ingredients and typical impurities of this complex substances are listed because of their classification or because of an OEL. As the substance has a RRN listed in section 1, these ingredients will not necessarily show a registration number.

### Mixtures

Since the registration applies to substances only, a mixture cannot be registered as such. A mixture under REACH is obtained by blending two or more substances without a chemical reaction (as otherwise it would be the synthesis of a new chemical). Substances within a mixture should be registered separately if the substances are subject to registration.

In some cases the SDS does not show a RRN for one or several components. This does not necessarily mean these components are not compliant.

- the component is an impurity contained in a registered substance and therefore it has no RRN

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- the component is a registered Biocide and therefore has no RRN – see below
- the component is exempted (as described above)

Further, the SDS only shows hazardous components (classified for at least one endpoint under CLP Regulation), usually above 0.1/1% or components having an EU workplace threshold limit. Non-hazardous components are not to be listed.

### **Biocides**

Active substances and co-formulants for use in plant protection products only and active substances for use in biocidal products only, if registered & listed to their respective regulations, are regarded as being registered and therefore RNNs are not available.

Other ingredients which are not “active” (often called “inert”) have to comply with REACH, so must be registered unless exempt (see above).

### **Polymers**

Polymers are exempted from the provisions on registration of Title II of REACH (Art. 2(9)). The manufacturer or importer is therefore not required to provide to the ECHA any information on intrinsic properties of the polymer itself.

The monomers however must be registered either by the manufacturer or the importer of the polymer or must be registered by an actor up in the supply chain, unless the monomer(s) are exempt.

An assessment of safe use needs to be carried out. If the conclusion is that the polymer meets the criteria for classification a SDS according to Art. 31 must be provided.

- a SDS is not required for most polymers as they are not classified
- a SDS is however to establish if the polymer meets the criteria for classification as hazardous, as PBT, as vPvB or is listed on the candidate list.

As polymers are exempt from registration, there is no RRN and no registered use. And the only use of the monomers is the synthesis of polymers.

For polymers Univar imports directly, we check that all monomers are registered (or exempt) before we declare the product as “polymer exempt”. For polymers supplied from EU manufacturers, we do not provide additional statements for the monomers used; these monomers are either registered or exempt. The manufacturers in the EU are working under the same obligations as we and our customers do. There is no need and no use to report on the monomers and/or their registration numbers.

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### **What is the reason, that Univar doesn't provide a SDS?**

From a legal point of view there are some cases where the supply of a SDS is not mandatory, these are:

- (1) a substance is not classified, not PBT and not vPvB and is not part of the candidate list and no request according to Art. 31(3) is pending, and there is no community threshold limit applied
- (2) the product is a mixture and all contained substances are covered by (1)

Certain general exemptions from the need to supply information according to Title IV (i.e. no need to include SDS) are given in Art 2(6).

No need to provide information in a SDS applies for mixtures in the finished state intended for the final user (public/consumer):

- Medicinal products (human and veterinary)
- Cosmetic products
- Medical devices (invasive or used in direct physical contact)
- Food and feeding stuff

In general, for articles (i.e. consumables) no SDS has to be provided. Which is the only case where separate SVHC confirmations are required.

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### **Why do I sometimes get a SDS with Exposure Scenario (ES) while on other occasions there is no ES?**

Under certain conditions the SDS needs more detailed information about how to manage risks under various operational conditions so that the exposure to the substance of humans and the environment can be controlled and risks can be managed. This information is called "Exposure Scenario" (short "ES"). The SDS is extended by these ESs addressing the uses and their exposure of humans (i.e. industrial users (workers), professional users and consumers) and the environment to the substance and provides instructions for appropriate control of the exposure. The final use of the product needs to be covered by at least one of the ESs.

An Exposure Scenario is required for registered substances that are classified as hazardous and manufactured or imported at an annual quantity of 10 tons and more.

Upon receipt of an extended SDS you as a Downstream User (DU) have obligations as set out under Title V of REACH.

ES are neither available nor required for mixtures. ES are available for hazardous substances only.

There is also no registered use available for mixtures. Uses are registered for substances only and consequently the manufacturer of a blend needs to proof the substances contained are suitable for the intended application by the customers. Customers would need to check the manufacturers' recommendation for the usage of formulated products (blends/mixtures).

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### **What are my obligations if I receive a SDS with Exposure Scenario (so called extended Safety Data Sheet (eSDS))?**

Upon receipt of an eSDS for a substance, you have 12 months to implement the conditions of use included in the Exposure Scenario for your use.

If one of your uses is not covered, you should inform your supplier (Univar), who informs next supplier in the supply chain to take the use up in his registration if he is the registrant or to communicate the request to his next supplier, or conduct own DU CSR and notify ECHA.

Should the registrant decide not to take into consideration the additional use or you do not want to disclose certain use(s) for reasons of protection of intellectual property you would have to perform a Downstream User Chemical Safety Assessment (DU CSA).

Univar will assist you in either the use notification or the search of an alternate supplier or product to substitute.

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### **Restriction according to Article 67 (1)**

The REACH Regulation lists substances, groups of substances and mixtures with restricted use in Annex XVII. Customers should note that the substance-specific restriction conditions mentioned there must be observed when using the material. A reference to a list of substances in Annex XVII is given in Chapter 15 of our SDSs.