

The Easy HANDBOOK

of European SDSs

SECTION 15:

regulatory information



What information do I need to provide in section 15 of the SDS?



15.1

Safety, health and environmental regulations/legislation specific for the substance or mixture



15.2

Chemical safety assessment

This section of the safety data sheet shall describe other regulatory information on the substance or mixture that is not already provided in the SDS. In addition, if the product is a substance, it must indicate if the substance was the subject of a chemical safety assessment as part of the REACH registration. If the product is a mixture, this information must be given relatively to the substances that compose it.

15.1

subsection

FIRST STEP

Safety, health and environmental regulations/legislation specific for the substance or mixture



Information shall be provided regarding relevant Union safety, health and environmental provisions or regarding the national regulatory status of the substance or mixture (including the substances in the mixture), including advice on action that should be taken by the recipient as a result of these provisions.

For example, it must be indicated if the substance or mixture is subject to an authorization under Title VII of the REACH Regulation or to a restriction under Title VIII of the same regulation. Additionally, where an authorisation imposes conditions or monitoring arrangements to a downstream user of the substance or mixture, they shall be provided. At a Union level it is also appropriate to indicate if there are any applicable procedures for export or import of substances from the EU or to the EU (Regulation EU 2012/649).

In addition, the following type of information may be included in this subsection (this is a non-exhaustive list):



- national laws of the relevant Member States which implement provisions such as the young worker directive and directive on pregnant workers, since these may require that young workers or **pregnant workers** do not work with certain substances and mixtures;

- information from the plant protection and **biocides** legislation, such as approval/authorisation status/numbers, additional labelling information from the specific legislation;



- information on applicable elements of the **Water** Framework Directive;

- information relative to the classification of the product in accordance with **directive 2012/18/EU** (Seveso directive);



- for paint and varnish products, if applicable, a reference to Directive 2004/42/EC on the limitation of emissions of **volatile organic compounds** may be included;

- for **detergents**, the ingredient declaration according to the Detergent Regulation 648/2004/EC, if not already given in section 2.2;

- national information on the regulatory status of the substance or mixture (including the substances in the mixture), including advice regarding action that should be taken by the **recipient** as a result of these provisions.

It is advisable to clearly specify if the abovementioned legislation applies to the product.

15.2

subsection

SECOND STEP Chemical safety assessment



This subsection of the safety data sheet shall indicate whether a chemical safety assessment was carried out for the substance or mixture.

For **substances** produced or imported from **outside the EU**, and registered according to REACH, a **chemical safety assessment is mandatory if** they are produced (or imported) in quantities **above 10 tons/year** and are **hazardous**. There are very few exceptions, that relate to substances exclusively classified for the following hazards:

- gases under pressure;
- self-reactive substances type C, D, E, F, or G;
- self-heating substances;
- oxidising liquids or solids category 3;
- organic peroxides type G;
- substances that are corrosive to metals;
- desensitised explosives;
- toxic with effects on or via lactation;
- specific target organ toxicity – narcotic effects (H336).

If you buy the substance from a European supplier, the presence of a chemical safety evaluation is indicated by an extended safety data sheet.

For mixtures, there is no obligation to carry out a chemical safety evaluation: the obligation **only** applies **to substances**. However, it should at least be mentioned if the substances in the mixture have been evaluated.

This indication must be given at least for the substances listed in section 3.2 and must be coherent with the received exposure scenarios. To verify if there are any substances have a chemical safety evaluation, check section 15 of the products used.

Keep in mind that, if there are exposure scenarios for the substances in the mixture listed in section 3, it is almost always mandatory to also supply the recipients of the SDS with information on safe use of the product. This includes any operating conditions and risk management measures necessary to ensure the use of the product falls into the scenarios evaluated and “guaranteed” as safe.

The communication options include:

- inserting the information in the SDS body (for example in sections 1, 7, 8, 9, 12, 15 and/or 16);
- attaching the relevant parts of the exposure scenarios received by the suppliers;
- attaching one or more scenarios created for the product.

In all these cases, the SDS becomes an extended SDS.

Even when you do not receive any exposure scenarios or information related to the presence of a chemical safety assessment, you must still communicate this information.



For example, you can write:

“The supplier did not conduct any chemical safety assessment for this substance/mixture.”