The Easy HANDBOOK
of European SDSs

SECTION 11:
toxicological information

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What information do I need to provide in section 11 of the SDS?

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

11.2 Information on other hazards

Section 11 of the SDS is primarily directed at **medical personnel, occupational health and safety professionals and toxicologists**.

A brief but complete and comprehensible description of the following shall be provided:

- probable routes of exposure;
- symptoms caused by the physical, chemical and toxicological characteristics of the substance, mixture and/or known derivatives;
- immediate and delayed adverse effects, including chronic effects, caused by short- and long-term exposure.

Firstly

Firstly, we must emphasize the importance of section 11 in the process of compiling an SDS.
The information in this section is the result of all the information relating to the substance or mixture collected so far, which has made it possible to determine the hazards and the consequent classification and labelling.
In addition, given that it may be necessary to provide a large amount of information in this section, especially for a mixture SDS, it is advisable to organise its arrangement in such a way that a clear distinction is made between the data that apply to the product as a whole (if applicable) and those relating to the individual substances that comprise it.

11.1 subsection

FIRST STEP

Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information must be provided for each health hazard class or differentiation (e.g. sensibilization: respiratory/cutaneous).

The relevant hazard classes, for which information must always be provided in the SDS, are all the health hazard classes established in the CLP Regulation:

a) acute toxicity;
b) skin corrosion/irritation;
c) serious eye damage/irritation;
d) respiratory or skin sensitisation;
e) germ cell mutagenicity;
f) carcinogenicity;
g) reproductive toxicity;
h) specific target organ toxicity (STOT) — single exposure;
i) specific target organ toxicity (STOT) — repeated exposure;
j) aspiration hazard.

What data to provide

The data contained in this subsection relate to the substance or mixture at the time of placing on the market. For mixtures, the data shall describe the toxicological properties of the mixture as such, except for hazard classes carcinogenicity, reproductive toxicity and mutagenesis.
Where available, the relevant toxicological properties of hazardous substances in a mixture, such as LD50, LC50 and acute toxicity estimates, shall also be reported.

Please note that there is **an obligation** to include **any other available and relevant information** on adverse health effects, even when not prescribed by the classification criteria.

Absence of specific data

It is not always possible to obtain information on the hazards of a particular substance or mixture. Where data on a specific substance or mixture are not available, data on similar substances or mixtures may be used, where appropriate, provided that the similar substance or mixture is identified. It shall be clearly indicated if no specific data have been used or are not available.

Format to use

Information on the different hazard classes must be reported separately and clearly.
Within each of the hazard classes you can organize the information as in the example below, where the item "Acute toxicity" is considered.

- *Acute toxicity*:
- *Method*:
- *Species*:
- *Routes of exposure*:
- *Dose effect*:
- *Duration of exposure*:
- *Results*:

If a significant amount of **data from substance or mixture tests** is available, it may be necessary to create a summary with the results of the critical studies used, e.g., by route of exposure.

If the product is not classified for a hazard class

If the classification criteria for a given hazard class are not met, information shall be provided to support this conclusion.
If the substance or mixture is not classified in a particular hazard class or differentiation, it shall be clear in the SDS whether this is due to lack of data, technical impossibility of obtaining data, inconclusive data or conclusive data not requiring classification; in the latter case you should specify that "on the basis of the available data, the classification criteria are not met".

Information on likely routes of exposure

Information must be provided on likely routes of exposure and the effects of the substance or mixture for each possible route of exposure, i.e., ingestion (swallowing), inhalation or skin/eye exposure. **It should also be indicated if the health effects are not known**.

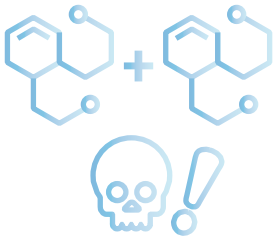
Symptoms related to physical, chemical and toxicological characteristics

Potential adverse health effects and symptoms associated with exposure to the substance or mixture and its ingredients or known by-products shall be described. Available information must be provided on symptoms related to the physical, chemical and toxicological characteristics of the substance or mixture following exposure. The full range of symptoms should be described, from the first at low exposures through to the consequences of severe exposures, e.g., "headaches and dizziness may occur, proceeding to fainting or unconsciousness; large doses may result in coma and death."

Immediate and delayed effects as well as chronic effects from short and long-term exposure

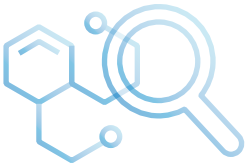
Information shall be provided on whether delayed or immediate effects can be expected after short or long-term exposure. Information on acute and chronic health effects relating to human exposure to the substance or mixture shall also be provided.
If human data are not available, information on experimental data shall be summarised, clearly indicating whether the toxicological data are based on animal data or in vitro tests. You shall clearly identify the species for animal data and cell types for in vitro tests.

Interactive effects



The substances in a mixture can interact with each other in the body, resulting in different rates of absorption, metabolism and excretion. As a result, the toxic action may be altered and the overall toxicity of the mixture may differ from that of the substances in it.
Information on possible interactions shall be included in this section if relevant and available.
Note that, in the context of interactive effects information, the phrase "if relevant and available" means that the person responsible for compiling the SDS is required to make a reasonable search for such information, if it is not already available to them.

Focus on ... substances



Information (such as key findings) shall be provided for relevant hazard classes and differentiations, as indicated above.
This information should be distinguished according to the route of exposure, species (rat, guinea pig, man, etc.), duration and method of the study. If no data are available for a specific substance and the read-across method or QSAR model are applied, this must be clearly mentioned. In the case of specific target organ toxicity (STOT), the information shall include indications of the specific target organ.

For substances subject to registration, brief summaries shall be provided of information derived from the application of Annexes VII to XI to REACH (i.e., test results, including non-animal testing, or other alternative means of generating the information required for registration). Where appropriate, include a brief reference to the test method used.

Focus on ... mixtures

If a mixture has not been tested as such for a given health effect, useful information on the relevant substances listed in Section 3 shall be provided.
For mixtures containing substances subject to registration, the information provided in this section for those substances shall correspond to that provided in the respective individual registrations.

It is necessary to consider whether the concentration of each substance is sufficient to contribute to the overall health effects of the mixture. Information on toxic effects shall be presented for each substance, except for the following cases:

a) if the information is repeated, it shall be listed only once, for example if two substances both cause vomiting and diarrhoea;

b) if the effects are unlikely to occur because of the concentration, for example if a mild irritant is diluted below a certain concentration in a non-irritant solution;

c) if no information is available on interactions between substances in a mixture, assumptions shall not be made, Instead, the health effects of each substance shall be listed separately.

In the case of mixtures for which relevant information on the substances is available (e.g., LD50, LC50, acute toxicity estimates), these shall be provided in addition to the information that applies to the mixture.

When a mixture has been classified according to CLP using an acute toxicity estimate (ATE), the calculated ATEmix value shall be included in this subsection, for example using a structure such as:

ATE_{mix} (oral) = 130 mg/kg
ATE_{mix} (dermal) = 20 mg/kg
ATE_{mix} (inhalation) = 10 mg/l/4h (vapour)

If information on the mixture as such is not available for a given hazard class or differentiation, but several of its constituent substances have the same health effect, this effect may be mentioned in relation to the mixture and not in relation to individual substances.

Focus on ... where to find toxicological information

If the product is a substance subject to registration, the main source of data is the chemical safety report when available. Other information from bibliographic searches shall be added where appropriate.

In other cases, the main source is always the safety data sheet and other documentation given by the supplier for the product, or for the raw materials used in the product that is being placed on the market.
Further information can be searched in the following public databases:

- **ECHA database on registered substances**:
https://echa.europa.eu/en/information-on-chemicals/registered-substances
- **GESTIS**
https://gestis-database.dguv.de/search
- **IPCS INCHEM**
http://www.inchem.org
- **TOXNET**
https://pubchem.ncbi.nlm.nih.gov

Remember that in all cases (even when information on substances has been obtained from the SDS of the relative suppliers) the supplier of an SDS is responsible for the accuracy of its contents; therefore, if you have any doubts about the correctness of the data of an SDS you receive, always discuss and collaborate with your supplier.

11.2 subsection

SECOND STEP
Information on other hazards

Information on adverse health effects caused by substances identified as having endocrine disrupting properties in subsection 2.3 shall be provided in this subsection.
This information must consist of brief summaries of the information derived from the application of the assessment criteria laid down in the REACH Regulation and Regulations 2017/2100 and 2018/605.

Guidance on endocrine disruptors and their identification is available at:
https://echa.europa.eu/hot-topics/endocrine-disruptors

Focus on ... Consistency with other sections of the safety data sheet

An assessment of the consistency of Section 11 with the following sections is necessary:

- **SECTION 2:** hazards identification ;
- **SECTION 4:** first aid measures;
- **SECTION 6:** accidental release measures ;
- **SECTION 7:** handling and storage ;
- **SECTION 8:** exposure controls/personal protection ;
- **SECTION 9:** physical and chemical properties ;
- **SECTION 13:** disposal considerations;
- **SECTION 14:** transport information;
- **SECTION 15:** regulatory information.