The Easy HANDBOOK
of European SDSs

SECTION 3:

composition/
information on
ingredients

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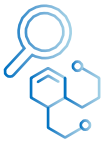
What information do I need to provide in section 3 of the SDS?

This is the only section of the SDS with a variable structure. Depending on whether the product is a substance or a mixture, subsection 3.1 or subsection 3.2 will be compiled respectively.



3.1 Substances

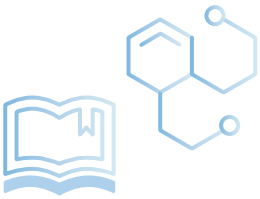
3.2 Mixtures

If the subsection that does not apply is printed, the field must be filled in with the indication **"not applicable"**. It is not sufficient to use only the main title "Section 3: Composition/Information on Ingredients".

3.1 subsection

FIRST CASE
Substances

What is a substance?



According to the REACH Reg. Article 3, **a substance is a chemical element and its compounds**, in their natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.

However, there are:
- **'Well-defined' substances**, with a defined qualitative and quantitative composition;
- **'UVCB substances',** with unknown or variable composition, products of complex reactions or biological materials.

The **variability** in composition of **well-defined substances** is specified by the upper and lower limit of the concentration range(s) of the main constituent(s). For **UVCB** substances, the variability is relatively wide and/or unpredictable. For this reason, the concept of **impurity does not apply to these substances.**

How to identify the substance

a. **The identity of the main substance shall be provided using the first available identifier among the following:**

1. if the substance is included in Annex VI to CLP, the name and identification number (**INDEX** number) as given therein;
2. if the substance is not included in Annex VI to CLP but appears in the classification and labelling inventory (C&L), the name and identification number as given therein;
3. if the substance is not included in Part 3 of Annex VI nor in the classification and labelling inventory, the number provided by the CAS ('**CAS** number') together with the name set out in the nomenclature provided by the IUPAC ('**IUPAC** nomenclature') or the CAS number together with another international chemical name(s);
4. if the CAS number is not available, the name set out in the IUPAC nomenclature or **another international chemical name(s)**.

When the name of the IUPAC nomenclature exceeds 100 characters, one of the other names (usual name, trade name, abbreviation) may be used, provided that it has been notified, together with the IUPAC name, in the notification submitted to ECHA for the purpose of establishing the C&L Inventory (Art. 40 to CLP).

b. **In addition to the identity of the main substance, the identities of any impurities, stabilising additives, or individual constituents** other than the main constituent shall be listed, **if they are classified** as dangerous and contribute to the classification of the substance as a whole.

It is also necessary to list:

- any specific concentration limits;
- the M factor if the substance is classified in Category 1 of hazard to the aquatic environment, acute or chronic;
- the acute toxicity estimates set out in Annex VI to the CLP Regulation (if the substance is included) or determined in accordance with Annex I to the CLP Regulation.

The **classification of the substance is not mandatory in this section,** as it is already given in section 2.

If known, quantities and classification of components may be indicated for substances with hazardous impurities or **UVCB** or multi-component substances, to allow downstream users to fill out their SDS without necessarily having to request further information. Pay attention to the **consistency between section 2 and section 3**. Also, formulate the information in a way that makes it clear that the classification of the constituents has already been considered for the classification of the substance.

If the substance does not meet the classification criteria, the reason why it is listed in point 3.1 shall be described, for example in the following way "Unclassified vPvB substance" or "Substance with a Union workplace exposure limit".

If the substance is registered and concerns a nanoform, **the particle characteristics that describe the nanoform shall be indicated**, as described in Annex VI to the REACH Regulation. On the other hand, if the substance is not registered, but the safety data sheet concerns nanoforms whose particle characteristics affect the safety of the substance, these characteristics must be indicated.

The additional information for nanoforms is mainly that set out in the ECHA Guide **"Guidance on the compilation of safety data sheets"**.

- Name of the nanoform(s);
- Particle size distribution (report the main percentiles, e.g. D10, D50, D90);
- Particle shape and aspect ratio (for elongated particles);
- Crystallinity (Indicate the ratio of crystal structures);
- Surface treatment or functionalisation (list of treatment agents and brief process description);
- Specific surface area;
- Additional information specific to the type of nanoform.

3.2 subsection

SECOND CASE mixtures

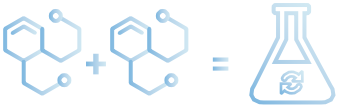
What is a mixture?

It consists of **two or more substances, mixed to form a product.**

The components of a mixture that must be listed are different depending on whether the mixture itself is **hazardous** or not according to the CLP regulation.

Components to be listed for non-hazardous mixtures

For mixtures that are not classified as hazardous according to the criteria of the CLP Regulation, the substances to be listed in section 3.2 are the following:



	Type of substances
1.	Substances which present a health or environmental hazard, in quantities greater than or equal to 1% (or 0.2% by volume if the mixture is gaseous).
2.	Substances for which Union workplace exposure limits have been assigned, in quantities greater than or equal to 1% (or 0.2% by volume if the mixture is gaseous).
3.	Persistent, bioaccumulative and toxic (PBT) or very persistent and very accumulative (vPvB) substances, in quantities greater than or equal to 0.1%.
4.	Substances in the Candidate list, in quantities greater than or equal to 0.1%.

5.	Substances with endocrine-disrupting properties, in quantities greater than or equal to 0.1%.
6.	Substances classified as toxic for reproduction category 1A, 1B or 2 or with effects on or via lactation, in quantities greater than or equal to 0.1%.
7.	Substances classified as skin or respiratory sensitisers, in quantities greater than or equal to one tenth of the applicable classification limit (generic or specific).

Components to be listed for hazardous mixtures

For mixtures that are classified as hazardous according to the criteria of the CLP Regulation, the substances to be listed in section 3.2 are the following:

	Type of substances
1.	Substances presenting a health or environmental hazard, if greater than the lowest of the cut-off values set out in the table below for the Classes/Categories with which the individual substance is classified. If they have individual specific limits below the cut-off value, the specific limits apply. If they have an M-factor greater than 1, the cut-off value should be divided by 10, 100, 1000, etc., depending on the value of the M-factor.
2.	Substances for which Union workplace exposure limits have been set, independently from their quantity.
3.	Persistent, bioaccumulative and toxic substances (PBT) or very persistent and very accumulative substances (vPvB), in quantities greater than or equal to 0.1%.
4.	Substances listed in the Candidate list, in quantities greater than or equal to 0.1%.
5.	Substances with endocrine-disrupting properties, in quantities greater than or equal to 0.1%.

The cut-off values for substances to be listed in section 3.2 (for hazardous mixtures) according to the classification (point 1 of the previous table) are the following:

Classification	Related hazard statements	Cut-off values
Acute toxicity, Category 1, 2 or 3	H300, H301,H310, H311, H330, H331	0,1%
Acute toxicity, Category 4	H302, H312, H332	1%
Skin corrosion/irritation	H314, H315	1%
Serious eye damage/eye irritation	H318, H319	1%
Respiratory or skin sensitization, Category 1 or Category 1B	H317, H334	0,1% If the substance has a specific classification limit, the cut-off value shall be one tenth of the specific limit.
Respiratory or skin sensitization, Category 1A	H317, H334	0,01% If the substance has a specific classification limit, the cut-off value shall be one tenth of the specific limit.
Mutagenicity, Category 1A or 1B	H340	0,1%
Mutagenicity, Category 2	H341	1%
Carcinogenicity, Category 1A, 1B or 2	H350, H351	0,1%
Reproductive toxicity, Category 1A, 1B, or 2 and effects on or via lactation	H360, H361, H362	0,1%
Specific target organ toxicity, single exposure, Category 1, 2 or 3	H370, H371,H335, H336	1%
Specific target organ toxicity, repeated exposure, Category 1 and 2	H372, H373	1%
Aspiration hazard	H304	1%
Acute toxicity to the aquatic environment, Category 1	H400	0,1% (divided by the M-factor, if applicable)
Chronic toxicity to the aquatic environment, Category 1	H410	0,1% (divided by the M-factor, if applicable)
Chronic toxicity to the aquatic environment, Categories 2, 3 or 4	H411, H412, H413	1%
Hazardous to the ozone layer	H420	0,1%

The lowest applicable cut-off value shall be considered. Additionally, if there is a specific limit for a classification, set in Annex VI of the CLP or based on supplier data, this shall prevail if it is lower than the lowest cut-off value.

What information is required for the substances listed in Section 3?

1. Substance identification

For the substances listed in subsection 3.2, the name, EC number and/or CAS shall be provided; the CAS number and the IUPAC name, if available, may also be indicated. In addition, if available, you should indicate the REACH registration number (the one communicated by the supplier of the substance, pure or in a raw material). Sometimes you may receive several registration numbers for the same substance, if it comes from several supply chains.

The supplier may omit the part of the registration number that identifies the single registrant (the last 4 digits) if they commit to providing the full registration number upon request, for enforcement reasons, or to request it from their supplier within seven days. If you need to request the full number from your supplier, you must also notify the Authority from which the request was made.

2. Substance concentration

The concentrations of the substances in the mixture shall be described in one of the following ways:

- exact % in descending order by mass or by volume, if technically possible;
- ranges of % in descending order by mass or volume, if technically possible.

If percentage ranges are indicated (instead of the precise percentage), the classification of the mixture shall describe the effects of the highest concentration of each ingredient listed.

3. Substance classification

For the substances listed in subsection 3.2, the classification of the substance according to Reg. No. 1272/2008 (CLP) shall be indicated, including:

- hazard classes;
- category codes;
- hazard statements corresponding to the physical, human health and environmental hazards;
- Any additional hazard statements (EUH statements).

If the substance does not meet the classification criteria, the reason why it is indicated in point 3.2 shall be explained, for example in the following way "Non-classified vPvB substance" or "Substance with a Union workplace exposure limit".
In this section the substance classifications are often indicated in a concise way, listing only the codes for space reasons. In this case, the full text corresponding to each code must be listed in section 16.

Note that the codes related to the classifications do not need translation, as they are, in fact, codes: for example, Acute tox 2 indicates a classification of acute toxicity of Category 2 and is an indication valid in every country of the European Union, regardless of the language of the country.

4. Other substance data

Where available, the following shall be indicated for the substances listed in subsection 3.2:

- any specific concentration limits;
- the M-factor if the substance is classified in Category 1 of toxicity to the environment, acute or chronic;
- The acute toxicity estimate as set out in Annex VI to the CLP Regulation (if the substance is included) or determined in accordance with Annex I to the CLP Regulation.

If the substance used in the mixture is a nanoform and is registered, the characteristics of the particles specifying the nanoform as described in Annex VI to the REACH Regulation shall be indicated. If, on the other hand, the substance used in the mixture is a nanoform but is not registered, the characteristics of the particles affecting the safety of the mixture shall be indicated. The main information to be reported is that indicated for nanoforms in section 3.1 of this document.