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Safety data sheets (SDS): Guidelines for synthetic nanomaterials

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What is the purpose of the guidelines for the nano SDS?

The guidelines for writing an SDS for nanoparticles deal with the responsible and safe handling of synthetic nanomaterials to protect human health and the environment. As things stand today, the risk to human health and the environment by products which contain nanomaterials cannot be excluded. It is therefore necessary to embed nanospecific information (and the term “nano") in the SDS.

For whom are the nano SDS and the nano SDS guidelines intended?

The SDS guidelines are primarily aimed at producers / importers of products containing nanomaterials. Use of these nano SDS guidelines is not compulsory. Nevertheless, producers implementing the recommendations therein can assume that they are fulfilling their duty to inform users of the latest developments in accordance with current legislation.

They should however also serve as an aid for all people who use safety data sheets, be they involved in industry, trade, commerce, the authorities, insurance or research laboratories. All of those people have a responsibility regarding the safety of their employees and consumers as well as the environment.

What are the functions of the SDS guidelines?

- **They help to identify relevant information** regarding synthetic nanomaterials and set out in what form and in which chapter they are to be listed in the SDS. Each section of the SDS is looked at specifically and a hierarchy is worked out for the importance of the nanospecific information to be included.
- **They provide textual examples** for integrating nanospecific information and also show how to deal with a lack of target and limit values.
- **They indicate where complementary information** can be found as well as existing assistance (such as the “Precautionary matrix for synthetic nanomaterials” and “Self-regulation for synthetic nanomaterials” guide, for example).
- **They supplement the general guidelines on producing SDSs**, safety data sheets “The Safety Data Sheet in Switzerland“. The legal framework conditions are applicable to all materials, whether or not they contain nanomaterials. An SDS must therefore primarily be aimed at the specific properties and potential hazards of a particular material.

How are nanomaterials defined in these guidelines?

The validity of these guidelines covers **nanomaterials** and preparations which include them.

With the exception of **nanomaterials** as defined in ChemO, this guide also applies to intentionally produced materials which contain particles in an unbound state or as an aggregate or as an agglomerate, where one or more external dimensions is in the size range 1-500 nm.

For clarification

- There are currently several different definitions of "nanomaterial" in use worldwide. The size of the primary particles is an essential component of most of these definitions. The generally accepted criterion is that nanomaterials must have at least one external dimension measuring less than 100 nm. However, no scientific justification exists for this 100 nm threshold as organisms can also internalise particles larger than this. Such materials are absorbed not just by specialised, phagocytic cells; materials up to 500 nm are also internalised by non-phagocytic cells[1] [2] [3]. As a result, nanospecific effects can occur even with particles whose external dimensions exceed 100 nm. The information in this guide therefore also applies to such particles. Adopting an upper threshold of 500 nm ensures that all particles and particle distributions presenting possible nanospecific effects are taken into account. Depending on their composition, nanomaterials fall under the definition of either "substance", as given in ChemO, or "preparation", as given in ChemA.

- **Surface structures** and coatings with only **one nanoscale dimension**, which are firmly connected with a carrier material, do not need to be specified in the SDS, provided the carrier material does not contain nanomaterials.
- These guidelines limit to **specifically manufactured** (i.e. synthetic) particles. Particles of this size, which arise as unwanted by-products, such as welding fumes and diesel soot or unintentionally produced or naturally occurring ultrafine particles are not relevant for an SDS.
- As an example of a preparation for which an SDS should also be written, we can cite **liquids and gases** for which the release of nanomaterials cannot be ruled out. This relates in particular to **nanodispersions** (liquid-particulate mixtures) which contain nanomaterials and which require an SDS due to potential spray applications. Another example would be a **nanopolymer in a plastic granulate** which is designed for **further processing**.

What is the legal basis for the SDS?

According to Article 6 of the Swiss Employment Act (EmpA, SR 822.11), the employer is required to take all measures for the general health protection of the employees which experience has shown are necessary, which can be implemented technically and which are adapted to the circumstances of the enterprise. This duty also applies to the handling of nanomaterials. It is established by the legal requirement that the producer/vendor provide information (Art. 5 ChemO, SR 813.11) in particular the SDS. The SDS is a document which is

[1] Rejman et al.; Size-dependent internalization of particles via the pathways of clathrin- and caveolae-mediated endocytosis; Biochem. J. (2004)377, 159-169.

[2] SCENIHR: Risk Assessment of Products of Nanotechnologies, 2009, p. 26.

[3] A. Bruinink, J. Wang, P. Wick. Arch Toxicol (2015) 89:659–675

a support for this self-regulation and contains the necessary information to ensure health protection and safety in the workplace as well as protection of the environment (Art. 18, ChemO, SR 813.11). Nanomaterials have new and different characteristics, which means that direct contact with them may expose humans and the environment to additional risks that are not present when the same material is in non-nanoscale form.
Various institutions and organisations around the world are working on the scientific basis that can be used for specific future regulations regarding nanomaterials. As long as there are no specific legal regulations for nanomaterials, the general legal employee-protection framework applies.

Prioritisation of nanospecific information in the SDS sections

No.	SDS chapter description	Priorities for the declaration of nanospecific information / data
1	Identification of the substance/mixture and of the company/undertaking	**Necessary**
2	Hazard identification	**Necessary**
3	Composition/information on ingredients	**Necessary** (also for the use of the precautionary matrix)
4	Description of first aid measures	**Preferable**
5	Firefighting measures	**Important**
6	Accidental release measures	**Preferable**
7	Handling and storage	**Important**
8	Exposure controls/personal protection	**Necessary**
9	Physical and chemical properties	**Necessary** (also for the use of the precautionary matrix)
10	Stability and reactivity	**Preferable**
11	Toxicological information	**Preferable**
12	Ecological information	**Preferable**
13	Disposal considerations	**Important**
14	Transport information	**Preferable**
15	Regulatory information	**Preferable**
16	Other information	**Preferable**

For a more detailed definition of **necessary** **important** **preferable***: see the SDS guidelines for nanomaterials.*

Further sources of information

The Swiss Federal government spoke out in favour of good governance in the development of synthetic nanomaterials in April 2008 with its synthetic nanomaterials action plan. Both, the various economic interests and health and environmental protection are taken into account.

You can obtain general information and documents about the "Action plan for synthetic nanomaterials" here: (www.bafu.admin.ch/publikationen/publikation/00574)

You can obtain general information and documents about nanotechnology here: (www.infonano.ch)

You can obtain general information and documents about SDSs here: (www.seco.admin.ch/seco/de/home/Arbeit/Arbeitsbedingungen/Chemikalien-und-Arbeit/Sicherheitsdatenblatt.html)

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