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Safety data sheet (SDS):
Guidelines for synthetic nanomaterials

November 2016

(Version 3.0)

The present guidelines represent a consolidated version containing additions, suggestions and corrections from various people representing associations, companies and the field of science. Feedback of any kind is very much welcome and can be submitted (see contact address below). A document can also be requested which shows the modifications from the most recent version as corrections. **The legal requirements regarding the content and the structure of the safety data sheet are the same in Switzerland as in the EU.**

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Cover image: various nanoproducts (photo: L. Bergamin Strotz/ SECO)

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Alongside these guidelines for the safety data sheet (SDS) for synthetic nanomaterials two further documents, a summary leaflet and an annex with two hypothetical SDS for products with synthetic nanomaterials have been produced. For these two examples the required nanospecific information was included in the relevant SDS-section. The two examples are for clarification purposes only and should not be used independently of these guidelines.

1 Introduction

Synthetic nanomaterials are taking on increasing importance in our daily lives. Information about their properties are of great importance in establishing the necessary hazard and protection phrases as well as the resulting protective measures.

The safety data sheet (SDS) plays a key role in this respect. On the one hand, it has to enable the processing industry and business in general to recognise potential hazards during the production and manufacturing processes. At the same time, it has to provide the necessary basis on which to evaluate potential health and environmental hazards in the finished products. For nanoparticles with their specific properties, current knowledge suggests that there are other potential risks for humans and for the environment, and the SDS should be aligned to reflect this.

1.1 Aims

The guidelines should

- demonstrate which information is necessary to ensure the safe handling of nanomaterials and of products which contain nanomaterials,
- offer assistance on how the relevant information can be identified and in which form and which place they are to be listed in the SDS,
- raise awareness among employees of companies which produce or process synthetic nanomaterials regarding the particular properties of these materials. Where necessary, companies should request the relevant information from their suppliers,
- supplement the FOPH Internet document: "Safety data sheet in Switzerland".

It is therefore recommended that:

- existing SDSs should be supplemented with nanospecific data as set out in the information in the present document, or
- a separate SDS should be drawn up for the nanomaterials in question,
- an SDS based on the recommendations in the present document should also be drawn up for nanoparticles for which no there is no requirement as set out in the Swiss Chemicals Ordinance (ChemO, SR 813.11 Article 19).

In any case, the applicable legal and regulatory texts shall be considered as authoritative.

1.2 Legal framework

"The safety data sheet (SDS) is there to enable people who handle substances or preparations / mixtures either professionally or commercially to establish the adequate measures regarding health protection and safety in the workplace as well as environmental protection" (ChemO, SR 813.11, Article 18). Dangerous substances and preparations and also prepara-

tions which contain dangerous substances in a defined concentration therefore also need to have a safety data sheet drawn up (ChemO, Article 19). Since there are not yet any specific legal provisions for nanomaterials other than the definition (ChemO, SR 813.11 Article 2) and the obligation to report physical and chemical properties during the registration process (ChemO, SR 813.11 Articles 48 and 49) in the technical dossier (ChemO, SR 813.11 Annex 4), the legal base for general health and environmental protection apply to these substances.
Nanomaterials that are already regulated for employee protection purposes include carbon nanotubes (CNT).
SUVA has formulated standard values in the 2011 threshold value list, recommending the value 0.01 fibres/ml for carbon nanotubes / CNT. This value, which corresponds to the threshold value for asbestos fibres is also cited in the most current SUVA threshold value list "Grenzwerte am Arbeitsplatz", updated annually. However, according to SUVA there are currently no standard measuring protocols with standardized metrics for carbon nanotubes or suitable counting rules for tangles.
The requirements of the SDS are set out in Annex 2 of ChemO SR 813.11. As a rule, the SDS protection objective mentioned in Article 18 also applies to nanomaterials. The producer is required to assess whether new hazards may arise from the material since it occurs on a nanoscale, and whether specific protective measures are to be taken. According to Article 6 of Swiss Employment Act (SR 822.11), the employer is required to take all measures which experience has shown to be necessary for the general protection of their employees' health and the prevention of industrial accidents and illnesses; these measures must be able to be implemented technically and adapted to the given circumstances. This duty also applies to nanomaterials.
According to Article 30 of the Swiss Environmental Protection Act (EPA, SR 814.01), waste products are to be avoided wherever possible and should be disposed of within the country in an environmentally-friendly manner wherever it is possible and reasonable to do so. Particular attention should be paid to the recycling of waste. These principles also apply to waste with nanospecific properties. Should waste of this kind be classified as hazardous, then the rules set out in the Ordinance of 22 June 2005 on the Movements of Waste (OMW, SR 814.610) also apply.

Details of how to draw up SDSs are described in detail in the "Safety data sheet in Switzerland" guide; additions regarding nanospecific information are contained in the present guidelines.

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2 Definition, terms and applicability

2.1 Definition and terms

The word "nanomaterial" is a relatively non-specific collective term which covers all materials which contain nanosized components, regardless of their composition.
Article 2, Letter q of the ChemO (SR 813.11) defines nanomaterials as follows: *"Nanomaterial* means a material containing particles in an unbound state or as an aggregate or as an agglomerate, where one or more external dimensions is in the size range 1-100nm, or a material where the specific surface area by volume is greater than $60m^2/cm^3$. A material is only considered to be a nanomaterial if it is deliberately produced to utilise the properties arising from the defined external dimensions of the particles it contains, or from the defined surface area by volume of the material. Fullerenes, graphene flakes and single-wall carbon nanotubes with one or more external dimensions below 1 nm are considered to be nanomaterials."

2.2 Applicability of the guidelines and own definition of nanomaterials

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

[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

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 plastic granulate** which is designed for **further processing**.

The use of these SDS guidelines on nanomaterials is not compulsory. However, companies which implement the recommendations therein can assume that they are fulfilling their obligation to inform as required by ChemA and ChemO.

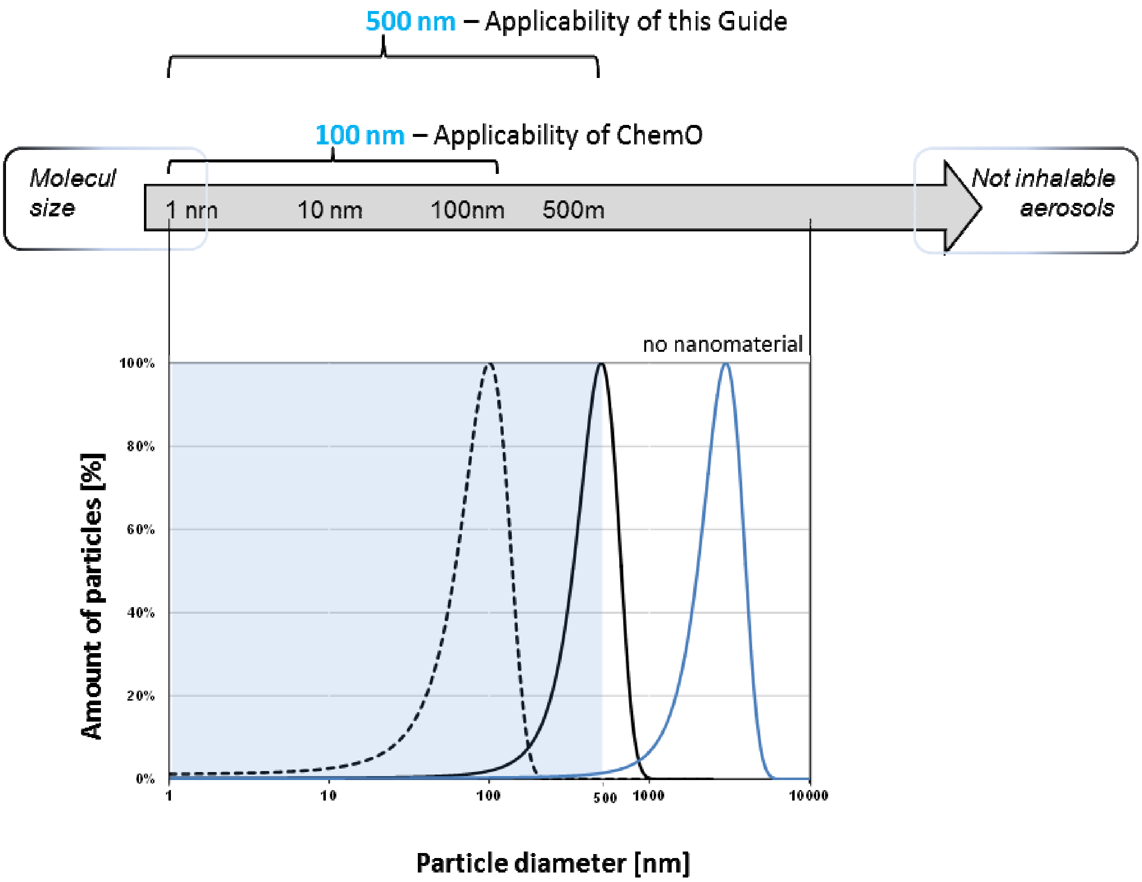

Chart: Applicability of this guide and of ChemO

3 Properties and possible risks of nanomaterials

3.1 Specific properties of nanomaterials

Nano sized often demonstrate **"altered" physical and chemical properties** when compared to the analogous non nano-sized substances.

An important feature of nanomaterials is their large surface relative to the volume (=**large surface-volume ratio**). Increased **responsiveness** and an improved **binding capacity** can often be a by-product of this.

Many nanomaterials have a very high tendency to **agglomerate** or to **aggregate**, which may lead to a change in their properties. The large surface relative to the volume can however also remain.

As well as their outer structural characteristics, nanomaterials can also be distinguished in chemical terms. While some nanomaterials are made of chemically homogenous substances or compounds, others are deliberately **modified** or **functionalised**[4] (e.g. by means of surface **coatings**).

As a result of the manufacturing process, remnants of auxiliary materials can occur as **impurities** on the surface of nanoparticles and have an influence on their properties.

Nanospecific risks occur primarily when nanomaterials are released and are picked up by living organisms or the environment.

Possible health and environmental risks particularly occur from freely occurring particulate nanomaterials (fibrous and particulate). These can occur as dust, powder or in dispersions and in the form of aerosol droplets, or they can be released in bundled form. The possibility of the release of nanomaterials must therefore be monitored at every stage of a nanomaterial's or nanoproduct's life cycle.

3.2 Possible health and environmental risks

So far, no conclusive tests have been carried out on the majority of nanomaterials, as it is currently only possible to carry out non-standardised spot assessments, and data from the same materials with larger particles does not necessarily apply to the corresponding nanoparticles. According to the OECD, the toxicological test processes which are carried out nowadays can be applied to the majority of nanosized materials with just a few adjustments and developments (Guidance Manual for the Testing of Manufactured Nanomaterials: OECD Sponsorship Programme: First Revision).

Based on human data, the results of experimental studies on animals and the results of *in vitro* studies, potential damage to health cannot currently be ruled out in general terms for certain nanosized materials. Nanosized materials of certain materials (e.g. flammable or cat-

[4] See Section 6 Glossary for a definition

alytic substances) also have a potential risk due to fire, explosions or unexpected chemical reactions.

It should be noted that expertise in the field of nanotoxicology is growing all the time, i.e. new knowledge regarding specific nanomaterials is becoming available. The growing use of synthetic nanomaterials means that in the future, we will have to expect increased human exposure and higher emissions into the environment (soil, water and air). The results of research that are available on the behaviour and effect of ultra-particulate matter (nanosized dust fractions) can only be applied in a limited way to artificially produced nanoparticles, since environmental particles are often fundamentally different from industrial ones. There are currently still very few studies covering the behaviour of nanomaterials in the environment. The ecotoxicological tests which up until now have primarily been carried out on aquatic organisms show that toxic effects can be expected for some nanomaterials.

4 Nanomaterials in production chains

Production chains nowadays are often complex and constantly being optimised. As a result, safety information must be managed as flexibly and transparently as possible. To guarantee the safe handling of nanomaterials in the production chain, it is necessary for safety information to be passed on. The need for this approach should be demonstrated using two examples.

- **Example 1:** the life cycle of ***one*** nanomaterial in a ***given product*** (see 4.1). Spray application with amorphous silica.
- **Example 2:** taking ***various*** life cycles of ***one*** nanomaterials as base material for a ***variety of different*** products (see 4.2). Sol-gel application with dispersion of nanosized titanium dioxide particles.

Since the health and environmental risks of products which contain nanomaterials cannot be excluded, it is necessary to embed nanospecific information (and the term “nano") in the SDS.

Information on the characterisation and on the nanospecific properties of nanomaterials should be included in the SDS, which will enable the necessary care and attention to be taken during the usage and further processing of nanomaterials.

4.1 Example 1: Simple production chain (end-user product)

- **Company 1 / Production of raw materials:** for the production of the spray, nanosized amorphous silica (SiO_2) in the form of agglomerated powder is required as the basic material from the supplier. Amorphous silica has a SUVA threshold limit value / TLV[5] (SUVA threshold value list, "Grenzwerte am Arbeitsplatz") of 3mg/m^3 (e) = dust threshold value (respirable) and must therefore be delivered with a safety data sheet.
- **Company 2 / Formulation of the product:** The basic material is processed by a company and introduced into liquid. The powder is then first deagglomerated by the company and the free nanoparticles which occurred are chemically modified (or functionalised) on the surface. After that, a stable dispersion is produced with the nanoparticles in a flammable solvent (ethanol). According to current legislation (ChemO, SR 813.11, Article 19), only the flammable ethanol has to be declared as a dangerous ingredient on the safety data sheet. As the (nano) silica is now dispersed and < 1%, the company no longer has to include the (nano) silica and its dust threshold value on the SDS.

[5] See Section 6 Glossary for a definition

- **Company 3 / Filling:** The filling of the pump sprays is carried out by another company which can only take information on the hazardous properties of ethanol from the SDS that is included. The formulated spray will be declared as highly inflammable due to the high proportion of ethanol.
- **Company 4 / Usage:** When the spray is used at the end of the production chain in significant amounts, aerosols which contain nanosized silica particles are created. A possible hazard due to inhaling these nanoparticle-containing aerosols is not (or no longer) discernible for users based on the product information provided.
- **Company 5 / Disposal:** Disposal companies also only receive very little, if any, information regarding the existence of nanomaterials, in this case nanosized silica particles, in production waste.

4.2 Example 2: Complex production chain (further processing)

Note: titanium dioxide nanoparticles are used in a wide variety of production chains in difference sectors. In order to keep an overview, not every chain will be dealt with below (as was the case in the previous example).

Material production

- **Raw material production:** The titanium tetra-ethanolate liquid is hydrolysed into fine titanium dioxide particles using a sol-gel process, which enables colloids with both higher and lower photocatalytic reactivity to be produced, depending on what type of subsequent use will be made of it at a later stage. The average primary particle size is around 30nm. During the machining processes which follow – separating, drying and filling – inhalable dust may be produced, and this must be pointed out in a safety data sheet for the protection of employees (ChemO, SR 813.11 Article 19 f). The data required to evaluate the hazard potential caused by the fact that the various different titanium dioxide particles are nanosized is not available in the safety data sheet.

Sector-specific processing

(E.g. in production chains in the "paints and varnishes", "plastics" and "paper" sectors)

- **Functionalising / coating:** The titanium dioxide which has been bought as a raw material for lacquers will now be functionalised according to the desired properties and usage, to increase the various properties e.g. light, weather and heat resistance of the materials (e.g. varnishes, paints, plastics, paper) to be coated. For example, the particles for printer toner are coated with silanes, car varnish is coated with aluminium and zircon oxide and those for cosmetic use are coated with silicon. New functionalisation may change the original substance properties completely. Therefore it can become necessary to draw up a new safety data sheet for every new developed functionalised material.

- **Dispersing:** In a further step, the functionalised titanium dioxide nanoparticles are dispersed with binders, additives and solvents and then put into varnishes, paints, plastics, paper, etc. Since the functionalised raw material is in the form of agglomerates, it is then functionalised further by means of a special chemo-mechanical process under pre-defined conditions and transferred into a stable nanodispersion at the same time. New safety data sheets can also become necessary here for these preparations, depending upon whether they contain dangerous ingredients. The danger of dust is no longer relevant for these materials, but the details about the nanosized contents are still important to provide since the usage with high-pressure sprays is possible or to be expected. Therefore it should be explicitly stated that aerosolisation of the nanomaterials is to avoid.
- **Industrial use of the formulation:** Formulations containing titanium dioxide particles are implemented in a wide variety of areas, for example as photo catalysts in solar cells, as an additive for toners and plastics, in indoor and outdoor paint as well as in resin and paper. The particularities of nanosized titanium dioxide particles are no longer featured in the safety data sheets for all of these usages. Exposure scenarios of the extended SDS must be reviewed to determine if there is any chance of particles being released. The possibility of a release of particles must be mentioned, if necessary.
- **Disposal:** Disposal companies also only receive very little, if any, information regarding the existence of nanomaterials in production waste or in products for disposal. Exposure scenarios must be reviewed to determine if there is any chance of particles being released. The possibility of a release of particles must be mentioned, if necessary.

5 Explanations about the SDS sections

Hereafter you will find explanations and concrete recommendations on the integration of nanospecific information into the various sections of the SDS. It should be remembered here that these data refer solely to nanomaterials. Any declaration of **non-nanospecific data** on the product in question and its handling must always be given in accordance with the guidelines in the Swiss Chemicals Ordinance (ChemO, SR 813.11) which are set out in the FOPH Internet document: "Safety data sheet in Switzerland".

It bears special mention that the requirement to declare nanospecific properties in SDSs applies also to certain substance groups which have been used for a long time and in large quantities. The following substances and substance groups regularly appear in nanosized amounts:

- carbon black
- paints, pigments, fillers
- metal oxides (e.g. zinc, titanium, aluminium and iron, semi-metal oxides such as silicon and also rare earth metals such as cerium)

At any company working with these substance groups, the individuals in charge should take particular care to nanospecific information provided in the safety data sheet. In addition, they should always remember the main aim of the SDS, which is to provide important information and handling recommendations to ensure the safe usage of chemical products. First and foremost, this means training the staff properly to do so.

Hereafter concrete recommendations are formulated concerning those SDS sections listed in the following table as **necessary** or **important** for the risk evaluation and safe handling of nanomaterials. For those which are **preferable**, no examples are given, since currently for these sections there is rarely any nanospecific information available.

The text examples showing how to embed nanospecific information in the various sections of the SDS are marked as nanospecific and written in blue.

Current prioritisation of nanospecific information in the SDS sections

No	SDS section 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 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 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

Captions: Data for the risk evaluation and the safe handling of nanomaterials:

necessary	**Necessary data for evaluation and safe handling** In the corresponding five sections, minimal data on nanomaterials is necessary. Test methods are to be provided and in particular whether tests with nanosized or with bulk material (homologous macroscopic substances) have been carried out. **Implementation of the precautionary matrix** = data is also necessary for filling in the precautionary matrix. Notes on how to use and where to implement the precautionary matrix can be found in section 7 of these guidelines.
important	**Important data for evaluation and safe handling** Nanospecific information should be provided and recommendations for safe handling made wherever possible in these three SDS sections.
preferable	**Preferable data for evaluation and safe handling** Data on these sections is currently available for very few nanomaterials. Should however any data be available from scientific research or from literature, it should be included. It should also be noted that new information is constantly becoming available, primarily since data in the supply chain is starting to be forwarded on as part of REACH[6], and also thanks to the work carried out by the OECD[7] and the rapidly increasing findings emanating from research carried out by the scientific community (publications).

[6] See Section 6 Glossary for a definition

[7] See Section 6 Glossary for a definition

5.1 Necessary data for the evaluation and safe handling of nanomaterials

The following minimum information requirements about the nanomaterial contained in the product are considered as essential for the five SDS sections marked **necessary**.

5.1.1 SDS section 1 "Identification of the substance/mixture and of the company/undertaking"

Under "purpose" (insofar as it is known), a declaration of the specific properties of the nanosized components should be made.

Text examples SDS section 1: (Identification of the substance/mixture and of the company):

1. The nanomaterials contained increase the antibacterial properties of the coat of paint.
2. The nanomaterials alter the surface structure and make cleaning easier.
3. Contains nanomaterials; these increase the protection (of the house facade / surface) against damage by UV rays.

5.1.2 SDS section 2 "Hazard identification"

As well as providing opportunities for new applications and products, the specific properties of nanomaterials can also harbour possible risks to human health and to the environment. Human data, experimental studies on animals and in vitro studies with nanomaterials have revealed indications of possible health and environmental hazards. No general consequences can however be drawn from this regarding the potential risks of nanomaterials. Potential dangers should be set out in this section for the purposes of a general assessment of possible sources of risk, since, at the moment, specific data on damage to health and the environment are only available for individual cases. When these are available, they should be cited. Where such dangers are known, they should be included. The precautionary matrix (see section 7) can for example be used as an aid for evaluation.

The following questions are designed to help formulate possible risk / risk and safety phrases:

1. Can dust formation or release of nanoparticles or nanofibres be expected when handled properly?
2. Are persistent nanofibres or fibrous structures contained or could they appear (due to agglomeration or aggregation)?
3. What are the most important routes of exposure (product-specific)?
4. Which processes can be expected to have an effect on the environment (water, soil, air)?

5. What is the possible reaction of the substance in the organism (absorption, stability, etc.)?
6. Are different or more marked properties possible compared with a non-nanosized product (e.g. via the formation of free radicals)?

Text examples SDS section 2 (Hazard identification):

More than one relevant description of possible dangers can be given. The data to which these statements relate should be substantiated where possible in section 8, 11 or 12 of the SDS (e.g. with quotes from studies).

1. Nanomaterials may be released during dust-generating work with the product.
2. Aerosols containing nanoparticles occur when the product is sprayed with blowing agents.
3. Nanoparticles in this product may encourage the formation of radicals in organisms.
4. The nanomaterials used may penetrate cell membranes and the blood-brain barrier.
5. The nanomaterials used may accumulate in organisms and / or the environment.

5.1.3 SDS section 3 "Composition/information on ingredients"

It is strongly recommended that the nanospecific information in this section indicate the type and amount of nanomaterials present in the product (as well as the necessary data regarding composition). Information on any coating or any functionalisation of the nanoparticles is also important.

The most accurate data possible regarding the composition should be provided in this section, in particular regarding the following nanospecific properties:

- Chemical name and elemental composition (e.g. nano TiO_2)
- Chemical structure and crystal structure of the nanoparticles (e.g. rutile or anatase-shaped)
- Form of the nanoparticles (e.g. particulate or fibrous)
- Mass of the nanoparticles (e.g. 1% nanoparticles, by weight)
- Nanosized impurities (e.g. metal oxides)
- Functionalisation and / or coating (yes, which ones? / no)

Text examples SDS section 3 (Composition/information on ingredients):

1. This ready-to-use solution contains ceroxide nanoparticles; spraying with blowing agents will produce aerosols with a droplet size of less than 10 micrometres (<10µm).
2. Silica-coated titanium dioxide (rutile) nanoparticles
3. Contains (elementary) silver in the form of nanoparticles.
4. Contains dispersed nanosized components made of (elementary) silver.
5. Contains carbon (graphite) in the form of MWCNT[8].

[8] See Section 6 Glossary for a definition

5.1.4 SDS section 8 "Exposure controls/personal protection"

To date, no occupational exposure threshold values[9] (TLV, short-term limits) have been issued for synthetic nanomaterials. As the effects of nanomaterials on human health have yet to be ascertained, exposure should, as a rule, be kept to a minimum.

Text examples SDS section 8 (general):

1. There are currently no specific exposure threshold values that can (as yet) be justified on toxicological or occupational health grounds for the nanoparticles contained.
2. For bio-resistant granular nanomaterials with a density of less than 6,000kg/m^3, the concentration of particles measuring 1-100nm should not exceed 40,000 particles/cm^3 as recommended by the nanoportal of the German BGIA-DGUV (Institute for Occupational Health and Safety – Social Accident Insurance) on 30 June 2009).

Exposure limits

As a general rule, the TOP principle set out in section 5.2.2 of these guidelines should be followed to limit exposure. It is important that work be carried out in a specially protected area (e.g. vacuum) or in a small, enclosed chamber (e.g. glove box).

Text **examples SDS section 8 (Exposure controls):**

1. Minimise exposure to aerosols containing nanoparticles by extracting them at the source.
2. Isolate danger areas (through partitioned rooms, working in glove box).
3. Restrict access to rooms in which nanomaterials are being used to authorised, trained personnel.
4. Minimise the frequency and length of exposure as well as the number of people exposed.
5. Use particle filters (HEPA H14) when extracting at the source.
6. Feed removed air back into working areas only after it has been adequately cleaned.
7. Remove dust deposits through damp/wet methods, using suitable vacuum cleaners only as a backup method (never blow away dust with compressed air).
8. Do not keep cleaning rags dirtied with nanoproducts in pockets/garment bags.

Personal protective equipment/PPE

By now it is well known which types and systems of protective equipment offer effective protection from synthetic nanomaterials (see “NanoSafe”: Safe production and use of nano-

[9] See Section 6 Glossary for a definition

materials and „Nano to go!“: Safe handling of nano materials and other advanced materials at workplaces). This information is to be taken into account when writing the SDS. In particular, the SDS should explain that wearing two layers of gloves protects against dermal exposure to dried and possibly dusty product residue.

Text examples SDS section 8 (Personal protective equipment/PPE)

1. **Respiratory protection**

   If it is not possible to prevent the release of nanoparticles (as dust or aerosol) during work, a particle-filtering form of respiratory protection (filter class P-3) should be worn in addition to the technical protective measures.

2. **Gloves**

   If it is not possible to avoid direct contact with nanoparticles (in liquid, solid or dust form), at least two layers of gloves should be worn. Depending on the situation, this may be latex gloves combined with chemical-resistant gloves, or two pairs of disposal gloves worn one over the other, etc. It is essential to put on and take off gloves carefully and to ensure that they overlap with the protective suit in order to provide adequate protection. Glove material must be chosen based on the chemicals handled – when it comes to particle-containing substances, proper PPE is more important than penetration time. Two pairs of gloves worn one over the other offer better protection when removing them.

3. **Protective suit**

   A long-sleeved protective suit made of membrane material (non-woven or fleece) shall be worn. Woven materials should be avoided.

4. **Protective eyewear**

   At the very least, a pair of sealing goggles should be worn to protect the eyes. However, a full mask offers better protection.

5.1.5 SDS section 9 “Physical and chemical properties”

Pursuant to ChemO Article 49, the following information must be provided when registering nanomaterials and preparations: composition, particle form and mean particle size and, where available, the specific surface area by volume, crystal structure, aggregation status, surface coating and surface functionalization. This information should also be listed in the SDS, regardless of whether the nanomaterial is to be registered. In addition, it is preferable to include information about the following properties as well:

a) Data regarding **size distribution**[10] of the particles contained in the product. This data is also recommended whenever the existence of such particles has been identified in the product. Should the size distribution not be known, a declaration of the known

[10] See Section 6 Glossary for a definition

particle sizes is useful (e.g. "contains nanoparticles of around 10nm"). It should be remembered that for a size distribution with a maximum of 200nm for example, a significant proportion of the particles could be nanosized (particles smaller than 100nm, definition of nanomaterials). For larger product quantities, a proportion of a few per cent can be important or relevant for health reasons.

b) Data regarding the water **solubility** of the nanomaterial as an indication of its stability. It should be remembered that when nanomaterials are introduced into a solvent, there are two possible effects: dissolving of the material into its molecular or ionic components or suspension of the nanoparticles as complete units. Data on water solubility should distinguish between these two effects.

c) Data regarding the **stability of agglomerates and aggregates**: Agglomerates/aggregates can deagglomerate/deaggregate under certain conditions (in the body or in the environment). In certain circumstances, large agglomerates/aggregates which are supposedly safe can nevertheless harbour a potential hazard if they decompose again into the primary particles.

d) Data regarding the **reduction and oxidation capability**[11] of the nanomaterials. Reduction and oxidation capability can be determined quantitatively by the redox potential. Measuring the redox potential of nanomaterials is useful if they are involved in electron transfer processes. It should be noted here that nanoparticle coatings can alter their redox potential.

e) Information on the **potential to form radicals**[12] is an important criterion for the risk analysis of nanomaterials. All data which can contribute to the evaluation of the probability and type of radical formation is considered useful, e.g. data regarding the **photocatalytic activity**[13] of nanomaterials. Photocatalytically active materials are semiconductors which can form highly reactive free radicals under the influence of light. Photocatalytic activity is to a large extent dependent on the type of material, the size of the nanoparticles, the surface modifications or the targeted doping of the material. Photocatalytic activity must be determined on a case-by-case basis.

[11] See Section 6 Glossary for a definition

[12] See Section 6 Glossary for a definition

[13] See Section 6 Glossary for a definition

Precautionary matrix:

The above information provided for SDS section 9 is also necessary for filling in a precautionary matrix form[14]. The more details are provided in SDS sections, the more informative the precautionary matrix will be based on this data.

Text examples SDS section 9 (Physical and chemical properties):

1. Proportion of nanosized CeO_2 in the product: 90%. It has a specific surface (specific surface area, SSA_{BET}) of 20 – 85m^2 per gramme of substance, as measured by the BET method. The diameter of the nanoparticles contained (d_{BET}) is 10 - 40nm.
2. The product contains uncoated nanoparticles in a size range from 50 – 200nm.
3. Maximal frequency in the particle size distribution: 50nm. Coating of nanoparticles prevents the formation of agglomerates.
4. Agglomerate (200nm) can deagglomerate in the body / in the environment.
5. The photocatalytic effect of the titanium dioxide nanoparticles contained is reduced by means of functionalisation (coating) in comparison with the non-coated form.
6. Significantly increased reactivity compared to non-nano forms of the same material.
7. Encourages the formation of oxygen radicals.
8. The product is catalytic or redox active.
9. The titanium dioxide nanoparticles contained are stable (not degradable or soluble in the body / in the environment).
10. The MWCNT contained have a diameter of 20-40nm and a length of at least 500nm. The length-to-diameter ratio is around 10:1.

5.2 Important data for the evaluation and the safe handling of nanomaterials

In three additional sections of the SDS, specific information on the nanomaterials contained in the product should be provided (where available and/or if it requires no more than reasonable effort to ascertain them).

5.2.1 SDS section 5 "Firefighting measures"

Nanomaterials may be more reactive than the same substances in non-nanosized form. Metallic iron nanoparticles oxidise for example in the blink of an eye when flames are present in the air. In certain circumstances a new firefighting approach is therefore required for nanomaterials. Data on the increased risk of fire or explosion should always be provided in a substance-specific way and – wherever possible – include data.

Text examples SDS section 5 (Firefighting measures):

[14] See Section 6 Glossary for a definition

1. The iron nanoparticles contained are highly flammable / combustible.
2. The iron nanoparticles contained are pyrophoric.

5.2.2 SDS section 7 "Handling and storage"

General procedure

When handling and storing nanomaterials (including those in preparations) with unknown potential effects, exposure is to be avoided as a rule or at the very least kept to a minimum as a precaution. In order to systematically minimise exposure, there are various measures which are suitable and which should be prioritised based on the "**TOP Procedure Principle**". Establishing the priority of the protective measures should also be set out in the SDS:

1.	**T = Technical protective measures** Use locked facilities Avoid creation of dust or aerosols (glove-box etc.) Extract dust or aerosols directly at the source Exhaust air treatment should be provided for extracted air (filter) Partitioning of working space and adaptation of ventilation (slight vacuum) Damp or wet cleaning. Only use a vacuum cleaner as an alternative option. Never blowe away the dust.
2.	**O = Organisational protective measures** Minimise exposure time Minimise the number of persons exposed Impose access restrictions Instruct personnel on the dangers and the protective measures (operating instructions)
3.	**P = Personal protective measures (use of PPE)** Use of suitable personal protective equipment (PPE) is only to be indicated if the above-mentioned technical and organisational measures provide insufficient protection. The specific demands of this PPE are to be included in SDS section 8.

Handling

When handling inflammable nanoparticles, additional **explosion protection measures** need to be taken if a hazardous amount of dust is capable of developing. → Establish explosion protective zones.

When handling reactive or catalytic nanoparticles, contact with incompatible substances should also be avoided where possible.

Text examples SDS section 7 (Handling):

1. Use a particle filter (HEPA H14 filter) when extracting air at the source.
2. Damp or wet clean. Only use a vacuum cleaner as an alternative option, and in this case use a particle filter (e.g. HEPA H14). Be careful to avoid potential exposure during maintenance and disposal.
3. Avoid aerosol build-up and eliminate sources of ignition.
4. When unloading and loading containers which contain nanoparticles in powder form, a protective mask (with P-3 filter), protective suit (non-woven) and Nitrile gloves (two pairs, one over the other) should be worn, and work should be carried out in a specially protected area (e.g. vacuum) or in a small chamber (e.g. glove box).

Storage

As a rule, the regulations for substances in non-nano form apply to the storage of nanomaterials. If there are nanoparticles in powder form, people should primarily be made aware of the inhalation potential and of the dangers of any dust explosions; sources of ignition should also be eliminated where necessary.

Text examples SDS section 7 (Storage):

1. Nanomaterials in powder form should be stored in anti-static bags (either filled with argon or nitrogen or air-tight and vacuum-packed).
2. Metallic nanopowder should be welded in the anti-static bag under air-free conditions and stored in metal containers.

5.2.3 SDS section 13 "Disposal considerations"

Section 13 should contain information on possible nanospecific properties which during the disposal process of nanomaterials could lead to the release of nanomaterials, to the exposure of the employees and to emissions into the environment. The proprietor of the waste should be able to evaluate whether nanospecific disposal of the nanowaste should be arranged. Waste which contains synthetic nanomaterials which are free or can be released should be disposed of as hazardous waste if effects on health, safety or the environment cannot be ruled out due to their nanospecific properties. To help evaluate possible handling requirements, the "Precautionary matrix for synthetic nanomaterials"[15] and the document "Environmentally sound and safe disposal of waste from manufacturing, and industrial and commercial processing of synthetic nanomaterials" (available under *Aids to enforcement*) can be used, for example.

[15] See Section 6 Glossary for a definition

The requirements regarding disposal are particularly dependent on whether the waste to be disposed of is hazardous waste or not. Hazardous waste is defined according to the Ordinance on Movements of Waste (OMW Article 2 Paragraph 2 Letter a, SR 814.610), as waste which, due to its composition, chemical-physical or biological properties, requires comprehensive, special technical and organisational measures for it to be disposed of in an environmentally friendly manner, even when transported within the country. What constitutes hazardous waste is set out in the list of wastes (Annex 1 of the Ordinance of the Swiss Federal Department of Environment, Transport, Energy and Communications (DETEC)[16] regarding lists on dealing with waste, SR 814.610.1). All hazardous waste has a specific waste code. For hazardous nanowaste which cannot have a specific waste code attributed to it due to its material properties, the corresponding collective code for hazardous wastes is to be used:

16 03 03 S Inorganic waste containing dangerous substances

16 03 05 S Organic waste containing dangerous substances

Text examples SDS section 13 (Disposal considerations):

1. Hazardous waste 16 03 05 S; contains releasable silver nanoparticles (max. 0.05%) integrated into the plastic.
2. Powdery production waste containing nanoparticles stabilised in anti-static bags.
3. Production waste containing CNT. Disposal by high-temperature combustion recommended.

[16] See Section 6 Glossary for a definition

6 Glossary and abbreviations

Term	Explanation / Definition	Note
Agglomerate	An accumulation of loosely-bound particles or aggregates, or mixtures of the two, in which the resulting surface is similar to the sum of the surfaces of the individual components. The forces which keep an agglomerate together are weak forces, for example Van der Waal's forces or simple physical hooking.	Unlike ultra-fine particles in the environment, synthetic nanoparticles are often functionalised or chemically coated to reduce their tendency to agglomerate.
Aggregate	Particles from tightly-bound or fused particles in which the resulting surface can be significantly smaller than the sum of the calculated surfaces of the individual components. The forces which keep an aggregate together are strong forces, for example covalent bindings or ones which are based on sintering or complex physical hooking.	
BET surface (BET = Brunnauer-Emmett-Teller)	Description of the specific surface of a material which has been measured using the BET method. The specific surface of solids or powders is determined by gas adsorption.	Example: One gramme of TiO_2 (Rutile) with a particle diameter of 50nm has a specific surface of 30m^2.
Bulk	In this document: a homologous substance in macro or microscopic form	As distinct from the nanosized form of the substance
CNT Carbon nanotubes	These can be either MWCNT= multi-walled CNT or SWCNT= single-walled CNT	Example of MWCNT (available over the counter): Diameter = 20-40nm Length = 500-40,000nm
Coating	Modifications to the surfaces of nanoparticles via coatings (e.g. with polymers or with positive / negative groups / molecules).This is also called functionalisation.	Nanoparticles are often coated to prevent agglomerates and aggregates from forming and to minimise the reactivity of the individual particles.
DETEC	Swiss Federal Department of the Environment, Transport, Energy and Communications	www.uvek.admin.ch
Doping	Targeted addition of foreign atoms to a material (usually crystalline) to alter its (primarily electrical) properties.	The photocatalytic activity of a material can be significantly strengthened by doping and requires special attention.
Fibres (respirable)	Fibres which have a length of more than 5µm, a diameter of less than 3µm and have a length-diameter ratio of more than 3:1 (WHO definition). Fibres such as these are defined as respirable fibres.	Some fibre dust is considered as posing a risk of cancer (e.g. asbestos). It is suspected that CNTs behave in a similar way to asbestos fibres.

Term	Explanation / Definition	Note
Functionalisation	See Coating	
HEPA	High Efficiency Particulate Air. Particulate air filters which filter 99.9% of all dust particles larger than 0.1–0.3µm from the air. The EN 1822 European standard defines filter classes H10–H14 (HEPA) and U15–U17 (ULPA).	HEPA Vacuum filter cassettes do not necessarily correspond to the EN 1822 standard.
MAK value	Maximum workplace concentration (MAK value). The maximal workplace concentration value is an 8 hour average.	Maximum workplace concentration values (MAK values), biological agent tolerance values (BAT values) and limit values for physical effects are published periodically by SUVA ("Grenzwerte am Arbeitsplatz").
Nanofibres	Object with two nanosized external dimensions	See ISO terminology (section 2.1).
Nanomaterial	In the present guidelines, this term is used to refer to synthetic nanomaterials.	The term "nanomaterial" is a relatively unspecific collective name under which all materials which contain nanosized components can be subsumed.
Nano-objects	Objects which are nanosized in one, two or three external dimensions (see ISO Terms (section 2.1)	Only nano-objects which are nanosized in two or three external dimensions are dealt with in these guidelines.
Nanoparticle	Object with three nanosized external dimensions.	See ISO terminology (section 2.1).
NanoSafe	EU development project for the safe handling of nanomaterials	Dissemination reports, available on the Internet
Nanosized	Covers the size range from 1-100nm, as set out in the ISO definition. The latest findings indicate that a nano-specific interaction with the biological environment is also possible with particles measuring up to c. 300nm.	It is therefore recommended as part of the precautionary matrix that systems smaller than 500nm should be mentioned as nanosized separately from bulk materials.
Particle size distribution	Nanomaterials typically comprise particle of different sizes. While a pure product often has a clearly-defined most frequent size in the distribution, a mixture can however deviate significantly from this.	Different measuring processes for size and particle size distribution in nanomaterials are not necessary comparable, depending on the circumstances.
Photocatalysis	A chemical reaction set off by light and which can lead to the creation of highly-creative free radicals.	Photocatalytic activity needs to be dealt with on a case-by-case basis.
P-3 (Filter class P-3)	The EN149 European standard defines three classes (1-3) of particulate air filters for masks for work at	Unlike with HEPA, the total leakage of a mask, comprising the areas of leakage on the

Term	Explanation / Definition	Note
	locations with occupational exposure limit values which are exceed by 4, 10 and 30-times respectively. P-3 is an abbreviation for FFP3, which is a type of filtering face piece.	face, the leakage from the exhalation valve (where available) as well as from the actual filter outlet, is what is used for evaluation.
Redox activity	Interaction with the environment via an exchange of electrons (reduction or oxidation). Redox activity is expressed by redox potential.	Measuring the redox potential of nanomaterials makes sense if they are involved in electron transfer processes. Coatings can alter the redox activity of nanoparticles.
Short-term limit	Maximum short-term exposure concentration value (see MAK value). This value is a 15 minute average.	More information can be found in the SUVA Brochure on occupational exposure limits "Grenzwerte am Arbeitsplatz".
Synthetic nanoparticles or nano-objects, see ISO terminology (section 2.1)	Specifically produced nanoparticles (e.g. nanotubes, fullerenes, metal oxides, quantum dots etc.).	Naturally-occurring nanoparticles and work-related by-products (e.g. welding fumes) are not included.
Waste code	The CH-Waste list attributes numbers (codes) to problematic waste so that it can be disposed of in a targeted way.	Discussions are on-going as to whether waste containing nanomaterials should be given a new code to give them a special designation for safety reasons.
Zeta potential	Electrical potential on the shear layer of a moved particle in a suspension. It describes the ability to exercise force on an adjacent charge.	Zeta potential is a measure of interparticulate repulsive forces and is thus of interest in terms of the agglomeration.

For further explanations and definitions of terms, please consult the glossary of the Swiss Federation's central information platform on the subject of nanotechnology at www.infonano.ch

7 Further links

InfoNano: The Swiss federal central information centre on nanotechnology, based on the "synthetic nanomaterials" action plan, summarises current discussions about the uses and risks of nanotechnology. www.infonano.ch

Guide to self-regulation of synthetic nanomaterials: This guide, published by the FOEN, FOPH, SECO and FOAG, is aimed at producers and importers of synthetic nanomaterials and preparations and objects containing nanomaterials. This self-regulation guide concretely sets out the requirements stipulated by Swiss acts and ordinances, thereby promoting consistent self-regulation. Producers and importers following this guide can expect to be in compliance with Swiss law. Contact: Federal Office for the Environment FOEN, Air Pollution Control and Chemicals division, 3003 Bern. www.infonano.ch

Precautionary matrix for synthetic nanomaterials: The safe handling of synthetic nanomaterials while protecting health and the environment is the responsibility of industry and business. The precautionary matrix is an aid to establish to what extent it is appropriate to carry out safety measures when developing and handling nanomaterials. A risk assessment in the literal sense cannot and should not be carried out using this tool, which in no way replaces a risk analysis. It can be found on the FOPH information page www.infonano.ch.

SUVA: This article provides information about nanoparticles and demonstrates concrete protective measures which are to be observed when dealing with nanoparticles at the workplace.
www.suva.ch/startseite-suva/praevention-suva/arbeit-suva/branchen-und-themen-filter-suva/nanopartikel-arbeitsplaetzen-suva.htm

BAuA: Support to handle nanomaterials. This German Federal Institute for Occupational Safety and Health (BAuA) website summarizes recommendations to handle nanomaterials from all over the world.
www.baua.de/de/Themen-von-A-Z/Gefahrstoffe/Nanotechnologie/Links-Beispiele.html

BAuA/VCI: Guidelines from the German Federal Institute for Occupational Safety and Health (BAuA) and from the German Chemical Industry Association (VCI) provide orientation regarding measures to be taken when producing/using nanomaterials at the workplace (2012).
www.baua.de/de/Publikationen/Fachbeitraege/Gd4.html

DGUV: This German Statutory Accident Insurance Association (DGUV) website supplements the recommendations made by SUVA and BAuA and contains concrete recommendations on work and PPE (personal protective equipment). There is also information on the findings of the NanoSafe projects.
http://www.dguv.de/fb-rci/sachgebiete/gefahrstoffe/nanotechnologie/index-2.jsp

NanoSafe: The "Dissemination reports" of this EU project demonstrate in a simple and easy-to-understand way how it is possible to work safely in various nano sectors. These reports (which are only available in English) cover the following subjects:

1. Are conventional protective devices such as fibrous filter media, respirator cartridges, protective clothing and gloves also efficient for nanoaerosols? (Jan 2008)
2. What about explosivity and flammability of nanopowders? (Feb 2008)
3. Is it possible to easily measure engineered nanoparticles at workplaces? (June 2008)
4. How to estimate nanoaerosol explosion risk (Oct 2008)
5. What is nanotoxicology? (Oct 2008)
6. First results for safe procedures for handling nanoparticles (Oct 2008)
7. Do current regulations apply to engineered nanomaterials? Standards – Why standardisation and standards are important? (Feb 2009)

www.nanosafe.org/scripts/home/publigen/content/templates/show.asp?P=63&L=EN&ITEMID=13

NanoValid (www.nanovalid.eu/)
“Nano to go!” (www.nanovalid.eu/index.php/nanovalid-publications/306-nanotogo) and “Safe handling of nanomaterials and other advanced materials at workplaces” **(**Guideline of the German Federal Institute for Occupational Safety and Health (BAuA)**)**

ENRHES: The concluding report of the "Engineered Nanoparticles - Review of Health and Environmental Safety" EU project is a comprehensive and critical scientific examination of the health and environmental safety of fullerenes, carbon nanotubes (CNT) and metallic and oxidic nanomaterials. It was used as the basis for prioritised recommendations to be developed and then set in the context of the development of adequate regulations.
http://cordis.europa.eu/result/rcn/45841_en.html

OECD: Safety of manufactured nanomaterials: the OECD has tested 11 nanomaterials. Monographs are available at:
www.oecd.org/env/ehs/nanosafety/publications-series-safety-manufactured-nanomaterials.htm