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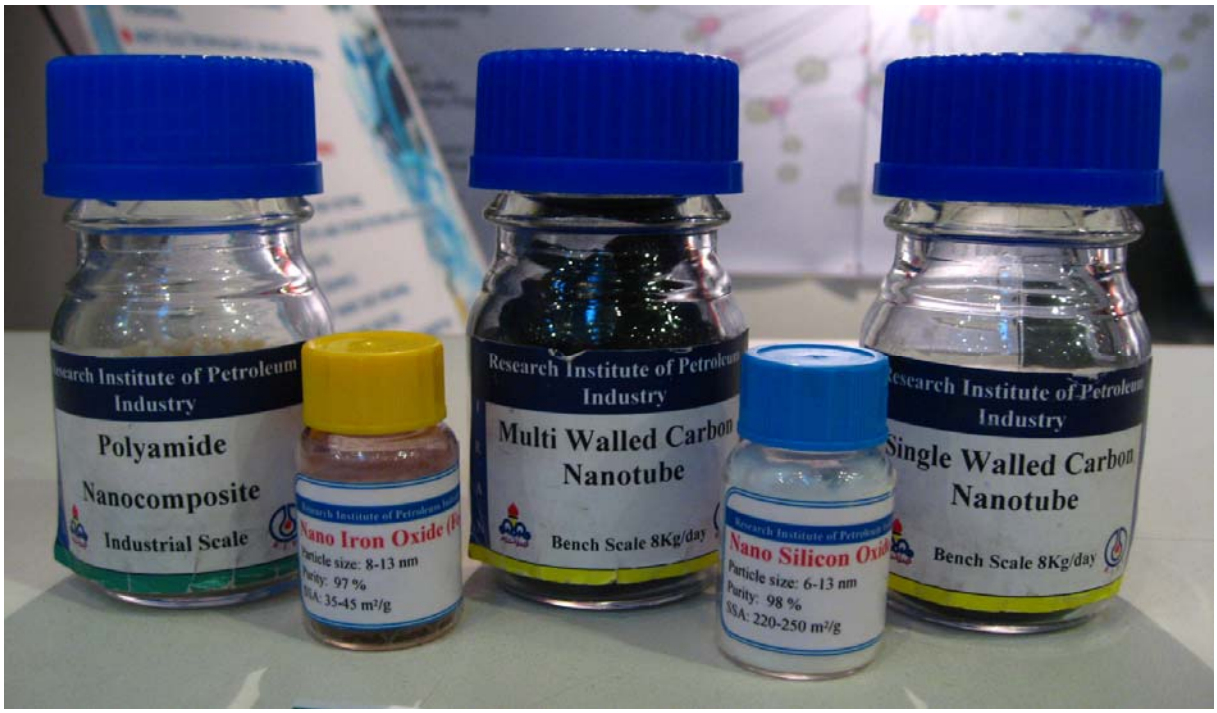
Safety data sheet (SDS):
Guidelines for synthetic nanomaterials



21 december 2010

The present guidelines represent an initial 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 to the above-mentioned e-mail address. The document will be further revised throughout next year and is scheduled to be replaced by an updated version at the end of 2011.

The legal requirements in Switzerland on the content and structure of the safety data sheet are the same as in the EU.

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Cover picture: different nanoproducts (Foto: L. Bergamin / SECO)

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1 Introduction

Synthetic nanomaterials are taking on increasing importance in our daily lives. Information about their properties within production and processing chains are of great importance in establishing the necessary risk and safety phrases and 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 to evaluate potential dangers to health and the environment in the finished products. Based on current knowledge, possible risks from what are known as nano-objects can arise when they are free or when they are released from products.

1.1 Aims

The guidelines should

- demonstrate which information is necessary to ensure the safe handling of nano-objects and of products which contain nano-objects.
- 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.
- contribute to making employees of companies which produce or process synthetic nano-objects aware of 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" (http://www.bag.admin.ch/anmeldestelle).

It is recommended that:

- existing SDSs should be supplemented by nano-specific data as set out in the information in the present document or
- a separate SDS be drawn up for the nano-objects in question.
- an SDS based on the recommendations in the present documents also be drawn up for nano-objects for which no there is no requirement as set out in the Swiss Chemicals Ordinance (ChemV, SR 813.11 section 52).
- Whatever the case, the legal texts are decisive.

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 comply with the measures regarding health protection and safety in the workplace as well as environmental protection”

(Chemikalienverordnung / ChemV, SR 813.11, Section 51). Dangerous substances and preparations and also preparations which contain dangerous substances in a defined concentration therefore also need to have a safety data sheet drawn up (ChemV, Section 52). Since there are not yet any specific legal provisions for nanomaterials, the existing guidelines also apply to these substances.

The requirements of the SDS are set out in annexe 2 of the ChemV SR 813.11. The SDS protection objective mentioned in Section 51 basically also applies to nanomaterials. The person placing the corresponding materials on the market is required to assess whether new hazards may arise from it since it occurs on a nano-scale, and whether specific protective measures are to be taken.

According to section 6 of Swiss Employment Law (ArG, SR 822.11), the employer is required to take all measures for the general health protection of the employees and to prevent industrial accidents and illnesses which experience has shown are necessary, which can be implemented technically and which are adapted to the given circumstances. This duty also applies to nanomaterials.

According to section 30 of the Swiss Environmental Protection Law (USG, SR 814.01), waste products are to be avoided wherever possible and be disposed of within the country in a way which is environmentally friendly and is as reasonable as possible. The exploitation of the waste should be the focus here. These principles also apply to waste with nano-specific properties. Should waste of this kind be classified as hazardous, then the rules set out in the Ordinance of 22 June 2005 on the Movement of Waste (VeVA, SR 814.610) also apply.

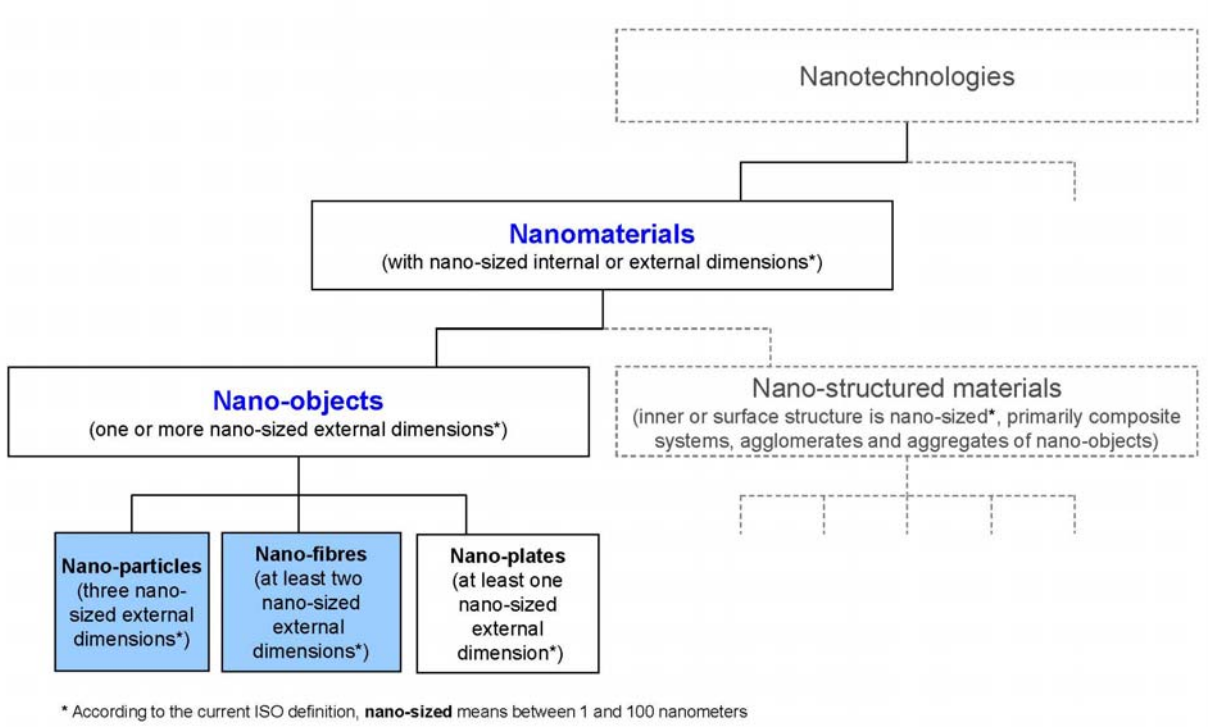
Details on how to draw up SDSs are described in detail in the FOPH Internet document: "Safety data sheet in Switzerland"; additions regarding nano-specific information are contained in the present guidelines.

2 Definitions of terms and applicability

2.1 Definitions and terms

According to the current ISO definition[1], **nano-sized** means between 1 – 100 nanometres.
Nanomaterials are materials with structural components which are nano-sized in at least one outer or inner dimension (nanometre-thin coatings, nano-porous structures, nano-sized surface structures, particulate material in the broadest sense and also as part of composite materials).
The term "nanomaterial“ is therefore a relatively unspecific collective name under which all materials which contain nano-sized components can be subsumed.

Hierarchy of terms linked to nanomaterials and nano-objects
(based on FprCEN ISO/TS 27687):



According to the chart above, there are three different types of (particular) nano-objects:

- **Nano-particles** (with three outer nano-sized dimensions)
- **Nano-fibres** (with two outer nano-sized dimensions)
- **Nano-plates** (with one outer nano-sized dimension)

[1] Ref: ISO **FprCEN ISO/TS 27687**

2.2 Applicability

These guidelines are limited hereafter to **specifically manufactured** (i.e. **synthetic)** nano-objects which are nano-sized in two or three dimensions (i.e. nano-fibres or nano-particles). This is because scientific results suggest that dangers to health and the environment are most likely to be expected from such released nano-objects.
Nano-dispersions (primarily fluid-particulate composites which often occur as colloids) contain nano-objects and are therefore under consideration here. Nano-emulsions (liquid- liquid composites) are however not included in the present guidelines.
Naturally occurring nano-objects (e.g. welding fumes, fine dust etc.) are also not considered here.

It should furthermore be noted that nano-objects up to a size of c. 300nm can have specific interactions with biological systems which cannot be identified among larger versions of the same materials. It is therefore recommended in the precautionary matrix for synthetic nano-materials to include the area up to 500nm when considering possible dangers and risks (see Precautionary matrix chapter 4.3 and chapter 7 of the present guidelines) http://www.bag.admin.ch/themen/chemikalien/00228/00510/05626/index.html?lang=en.

3 Properties and possible risks of nano-objects

3.1 Specific properties of nano-objects

Substances which are nano-sized are subject to the laws of quantum mechanics, which is why nanomaterials often demonstrate **"altered" physical and chemical properties**.
An important feature of nano-objects 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 nano-objects have a very high tendency to **agglomerate** or to **aggregate**, which leads to their losing much of their nano-characteristics. The large surface relative to the volume can however also remain.
As well as their outer structural characteristics, nano-objects can also be distinguished in chemical terms. While some nano-objects are made of chemically homogenous substances or compounds, others are deliberately **modified** or **functionalised** (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 nano-objects and have an influence on their properties.

Nano-specific risks occur primarily when nano-objects are released and are picked up by living organisms or the environment.
Health and environmental risks particularly occur from particulate nano-objects (nano-fibres and nano-particles). These can be occur freely (dust, powder or in dispersions and in the form of aerosol droplets) or be released in bundled form. The release of nano-objects occurs primarily in production and disposal centres.

3.2 Health and environmental risks

A conclusive assessment of the risks caused by nano-sized materials is not currently possible, for two reasons. On the one hand, no conclusive tests have been carried out on a wide variety of nano-objects and micro-sized particles can rarely be transferred onto corresponding nano-objects. On the other hand, the toxicological test processes which are carried out nowadays can only be applied in a limited scope to nano-sized materials.
Based on the results of animal experiments, potential damage to health cannot currently be ruled out for certain nano-sized materials. Nano-particles in certain materials (e.g. flammable or catalytic substances) also conceivably represent 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 nano-objects is becoming available.

The growing use of synthetic nano-objects means that in the future, we will have to expect increased emissions into the environment (soil, water and air). The results of research that are available on the behaviour and effect of ultra-particulate matter (nano-sized dust fractions) can only be applied in a limited way to artificially produced nano-objects, since the systems are often fundamentally different. There are currently still very few studies covering the effects of nano-objects on organisms and on their behaviour in the environment. The ecotoxological tests which up until now have primarily been carried out on aquatic organisms show that toxic effects can be expected for some nano-objects. There is also the possibility of toxic effects, based on the results of experimental studies with cell cultures.

4 Nano-objects in production chains

Production chains nowadays are complex in many cases and constantly being optimised. This creates a need for flexible processing of safety information that is as transparent as possible.

To guarantee the safe handling of nano-objects 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. In the first example, the life cycle of a nano-object in a given product is demonstrated, while in the second, various life cycles of a given nano-object are regarded as base material for a variety of other products.

These are just two examples for the multi-level processing and the implementation of nano-objects.

Since the risk to health and the environment by products which contain nano-objects cannot be excluded, it is necessary to embed the specific information (and the term “nano") in the SDS.

4.1 Example 1: Life-cycle of a surface treatment spray

- **Company 1 / Production of raw materials:** for the production of the spray, nano-sized 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 of 4mg/m^3(e) = dust threshold value (respirable) (http://www.sapros.ch/images/supplier/220/pdf/01903_d.pdf) 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 nano-particles which occurred are chemically modified (or functionalised) on the surface. After that, a stable dispersion is produced with the nano-particles in a flammable solvent (ethanol). According to current legislation (ChemV, SR 813.11 section 52), only the flammable ethanol has to be declared as a dangerous ingredient on the safety data sheet. The (nano) silica is now dispersed in the solvent and the company no longer has to include the dust threshold value on the SDS.
- **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 the solvent from the SDS that is included. The formulated spray will be declared as highly inflammable due to the high solvent proportion.

- **Company 4 / Usage:** When the spray is used at the end of the production chain in significant amounts, aerosols which contain nano-particles are created. A possible hazard due to inhaling these nano-particle-containing aerosols is not (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 nano-particles in production waste.

4.2 Example 2: Titanium dioxide nanoparticles in various production chains

Note: there are a wide variety of production chains in the different sectors into which titanium dioxide nanoparticles are fed. 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 particle size is around 30nm. During the machining processes which follow – separating, drying and filling – respirable dusts may be produced, and this must be pointed out to employees in a safety data sheet for their protection (ChemV, SR 813.11 section 52 f). The necessary data is not available in the safety data sheet to evaluate the hazard potential caused by the fact that the various different titanium dioxide particles are nano-sized.

Branch-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. Under certain circumstances, a new substance can be created with every functionalisation, and one which in its properties is essentially different from the original material. It can therefore become necessary to draw up new safety data sheets for the various functionalised particles.

- **Dispersing:** In a further step, the functionalised nano-titanium dioxide particles are dispersed with binders, additives and solvent 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 chemomechanical process under pre-defined conditions and transferred into a stable nano-dispersion at the same time. New safety data sheets can also become necessary here for these preparations, depending upon whether they contain dangerous ingredients. Data on the nano-sized ingredients are however no longer necessary, since there is no longer a dust hazard.
- **Industrial use of the formulation:** The formulations are implemented in a wide variety of areas which contain titanium dioxide particles, 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 nano-sized particularities of titanium dioxide particles are no longer featured in the safety data sheets for all of these usages.
- **Disposal:** Disposal companies also only receive very little, if any, information regarding the existence of nano-particles in production waste.

5 Explanations on the SBD chapters

Hereafter you will find explanations and concrete recommendations on the integration of nano-specific information into the various chapters of the SDS. It should be remembered here that these data refer solely to nano-objects.

Any declaration of **non-nano-specific data** on the product in question and its handling must always be given in accordance with the guidelines in the Ordnance on Chemical Substances (ChemV SR 813.11) which are set out in the FOPH Internet document: "Safety data sheet in Switzerland (http://www.bag.admin.ch/anmeldestelle/00933/03971/index.html?lang=en)".

The following substances and substance groups regularly appear in nano-sized amounts:

- carbon black
- paints, pigments, fillers
- metal oxides (e.g. zinc, titanium, aluminium, iron, cerium)
- various forms of silicon dioxide

At any company working with these substance groups, the relevant people in charge should make particularly sure that nano-specific information is provided in the safety data sheet.

Overview: Prioritisation of nano-specific information in the SDS chapters

Nr.	SDS chapter description	Priorities for the declaration of nano-specific information / data
1	Identification of the substance/mixture and of the company/undertaking	**necessary**
2	Hazards identification	**necessary**
3	Composition / information on ingredients	**necessary** **(also for the usage 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	**important**
9	Physical and chemical properties	**necessary** **(also for the usage 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**

Caption:

Necessary	**Necessary data for evaluation and safe handling of nano-objects** The necessary minimum data on the nano-objects contained in the product are to be shown in these four chapters of the SDS. Without this data, the necessity of protective measures for employees, consumers and the environment cannot be fully evaluated. The test methods are to be provided where possible and it should be indicated in each case whether tests with nano-sized or with bulk material (homologous macroscopic substances) have been carried out. **Implementation of the precautionary matrix** = this data is also necessary for work with the precautionary matrix. Notes on how to use and where to implement the precautionary matrix can be found in chapter 8 of these guidelines.

Important	**Important data for the evaluation and safe handling** Nano-specific information should be provided and recommendations for safe handling made wherever possible in these four SDS chapters.
Preferable	Data on these chapters is currently available for very few nano-objects. Should however any data be generated in-house, from scientific research or from literature available, 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 and also thanks to the work carried out by the OECD and the rapidly increasing findings emanating from research carried out by the scientific community (publications).

Hereafter you will find concrete recommendations on those SDS chapters which are included in the above table listed as **necessary** or **important** for the evaluation and safe handling of nano-objects.

Although nano-specific information on synthetic nanomaterials is still not widely available these days, it is important that any data available should be listed in the SDS. Where there are grounds for suspicion about possible dangers, precautionary information is necessary.

Text examples relating to nano-objects are marked in blue

5.1 Necessary data for the evaluation and safe handling of nano-objects

For the following four chapters of the SDS, the most specific information possible about the nano-objects contained in the product is considered to be necessary (minimum requirement).

5.1.1. Chapter 1 SDS "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 nano-sized components should be made.

Text examples Chapter 1 SDS:

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

5.1.2. Chapter 2 SDS: "Hazards identification"

As well as providing opportunities for new applications and products, the specific properties of nano-objects can also harbour possible risks to human health and to the environment. Animal and cell experiments with nano-objects have revealed indications of a possible danger to health. No general consequences can however be drawn from this regarding the potential risks of nano-objects.

Data regarding the assessment of potential sources of risk should however be formulated in this chapter for the purposes of a general assessment, since specific data on damage to health and the environment are only available at the moment from individual cases. When these are available, they should be cited. Where no specific dangers are known, general information will be recommended. The precautionary matrix (see ANNEXE 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 the release of nano-particles or nano-fibres be expected when handled properly?

2. Are persistent nano-fibres 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-nano-sized product (e.g. via the formation of free radicals)?

Text examples Chapter 2 SDS:

More than one relevant description of possible dangers can be given.

1. Nano-particles may be released during dusty work with the product.
2. Aerosols containing nano-particles occur when the product is sprayed with blowing agents.
3. Nano-sized particles may encourage the formation of radicals in the organism.
4. The nano-particles used can possibly break down cell membranes and the blood-brain barrier.
5. The nano-particles used may possibly accumulate in humans and / or in organisms.

5.1.3. Chapter 3 SDS "Composition / information on ingredients"

It is strongly recommended that the type and amount of the nano-objects present in the product also be provided in this chapter (as well as the necessary data regarding composition) in the section where it says "nano". Information on any coating or any functionalisation of the nano-objects is also important.

The most accurate data possible regarding the composition should be provided in this chapter, in particular:

- chemical name
- chemical structure and crystal structure of the nano-objects
- form of the nano-objects
- mass of the nano-objects
- nano-sized impurities
- functionalisation and / or coating

Text examples Chapter 3 SDS:

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

5.1.4. Chapter 9 SDS "Physical and chemical properties"

Compared with larger particles of the same chemical composition, nano-sized particles often have differing mechanical, electrical, optical, chemical, magnetic or biological properties. Specialised international committees are currently discussing the relevance of various physical and chemical properties for nano-objects. A temporary suggestion was a minimum data set[2] which would be taken into account in the reports which followed. More detailed information on this can be found at the following links:

http://characterizationmatters.org/

http://www3.interscience.wiley.com/cgi-bin/fulltext/122615141/HTMLSTART?CRETRY=1&SRETRY=0

Data should be provided regarding the following properties of the nano-sized components:

a) Data regarding **size distribution** of the particles contained in the product. This data is also recommended when the existence of such particles has been identified in the product. – Should the size distribution not be known, a declaration of the known particle sizes is useful (e.g. "contains nano-objects of around 100nm"). It should be remembered that for a size distribution with a maximum of 200nm for example, a significant proportion of the particles could be nano-size (particles smaller than 100nm). 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 nano-object as an indication of its stability. It should be remembered that when nano-objects are introduced into a solvent, there are two possible effects: dissolving of the material into its molecular or ionic components or dispersion of the nano-objects as complete units. For data on water solubility, efforts should be made to distinguish between these two effects.

c) Data regarding **agglomeration and aggregation**: do the nano-objects used tend towards the formation of agglomerates or aggregates (which occurs in a number of cases)? What is the size range of the agglomerates or aggregates which are forming? Nano-objects have a strong tendency to mass together (agglomerate and ag-

[2] Journal of Food Science JFS, Letters, Vol. 74, Number 8, 2009, vi-vii

gregate), which means that the number of free particles decreases and the available particles grow. The basic structure of the individual particles is often maintained however. Agglomerates and also aggregates have been known to demonstrate different hazard potentials compared with the nano-objects under review. Agglomerates and aggregates of nanomaterials are handled in biological systems such as larger particles. They can also lose part or all of their particular nano-properties.

d) Data regarding **the stability of agglomerates**: Are these agglomerates stable in the body or in environmental conditions (do the agglomerates that have formed deagglomerate into their nano-sized components)? In certain circumstances, large agglomerates which are supposedly safe can nevertheless harbour a potential hazard if they decompose again into the primary particles.

e) Data regarding the **redox activity** of the nano-objects. The redox activity can be expressed by the redox potential. Measuring the redox potential of nanomaterials is then useful if they can then be involved in electron transfer processes. It should be noted here that coatings of nano-objects for example can alter their redox activity.

f) Data regarding the **catalytic** or **photocatalytic activity** of nano-objects. Photocatalytically active materials are semi-conductors 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 nano-objects, the surface modifications or the targeted doping of the material. Photocatalytic activity has to be clarified on a case-by-case basis.

g) Known information on the **potential to form radicals**. The potential to form radicals is an important criterion for the risk analysis of nanomaterials. All data which can contribute to the evaluation of the probability and the type of radical formation are to be seen as an advantage.

Precautionary matrix:

The information provided above is necessary for filling in a precautionary matrix form; the more details that can be added to this part (and in other SDS chapters), the more significant the precautionary matrix will be based on this data. Further information on how to use and implement the precautionary matrix can be found in chapter 8 of these guidelines.

Text examples Chapter 9 SDS:

1. Proportion of nano-sized 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 nano-particles contained (d_{BET}) is 10 - 40nm.
2. The product contains uncoated nano-particles in a size range from 50 – 200nm.
3. Maximum particle size: 50nm. The coating of the nano-particles prevents the formation of agglomerates.

4. The nano-particles appear as agglomerates (200nm); they de-agglomerate 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 with the non-nano form.
7. Encourages the formation of oxygen radicals.
8. The product is catalytic or redox active.
9. The titanium dioxide nano-objects 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.

5.2 Important data for the evaluation and the safe handling of nano-objects

In four further chapters of the SDS, specific information on the nano-objects 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. Chapter 5 SDS "Firefighting measures"

Nano-objects can demonstrate higher than analogue, non-nano-sized substances. Metallic nano-iron particles oxidise for example in the blink of an eye when flames build up in the air. In certain circumstances a new approach is therefore required for fire-fighting for nano-objects. 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 Chapter 5 SDS:

1. The iron-nano-particles contained are highly flammable / combustible.
2. The iron-nano-particles contained are pyrophoric.

5.2.2. Chapter 7 SDS "Handling and storage"

General procedure

When handling and storing nano-objects (including those in preparations) with unknown potential effects, exposure is basically to be avoided or at least kept to a minimum out of precautionary considerations.

In order to systematically minimise exposure, there are various measures which are suitable and which should be prioritised based on the "**TOP Procedure Principal**". 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 dusts or aerosols
   Suck dusts or aerosols directly out at source
   Exhaust air treatment should be provided for sucked out air (filter)
   Partitioning of working space and adaptation of ventilation (slight vacuum)
   Clean only by absorption or by damp wiping, no blowing away

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 chapter 8.

Handling

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

When handling reactive or catalytic nano-particles, additional contact with incompatible substances should also be avoided where possible.

Text examples Chapter 7 (handling):

1. Perform suction of the sources with a particle filter (HEPA H14 filter)
2. Use a vacuum cleaner with a particle filter (e.g. HEPA H14) for cleaning
3. Avoid aerosol build-up and eliminate sources of ignition
4. When unloading and loading containers which contain nano-particles in powder form, a protective mask (with P3 filter), protective suite (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

The regulations for substances in non-nano-form basically apply to the storage of nano-objects. If there are nano-particles in powder form, people should primarily be made aware of the possibility of inhaling them and of the dangers of any dust explosions; sources of ignition should also be eliminated where necessary.

Text examples Chapter 7 (Storage):

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

5.2.3. Chapter 8 SDS "Exposure controls/personal protection"

To date, no occupational exposure limit values have been issued for synthetic nano-objects. Since the effects of nano-objects on human health have yet to be ascertained, exposure should basically be kept to a minimum.

Text examples Chapter 8 (general):

1. There are currently no exposure limits (threshold limit value / TLV) that can (as yet) be justified on toxicological or occupational health grounds for the nano-particles contained.
2. For bio-resistant granular nano-objects with a density of less than 6,000 kg/m³, the concentration of particles should not exceed 40,000 particles/cm³ in the measuring range of 1 – 100nm (as recommended by the nano-portal of the German BGIA-DGUV (Institute for Occupational Health and Safety at Work – Social Accident Insurance on 30.6.2009).

Exposure limits

As a general rule, the TOP principal set out in SDS chapter 7 should be carried out to limit exposure. It is important that work should be carried out in a specially protected area (e.g. vacuum) or in a small chamber (e.g. glove box).

Text examples Chapter 8 (exposure limits):

1. Exposure to aerosols containing nano-particles should be minimised by sucking them out at source.
2. Danger areas are to be defined (partitioned rooms, carry out work in a glove box).
3. Access to the rooms where work with nano-objects is being carried out should be restricted to authorised personnel who have been briefed.

4. Minimise and restrict the frequency, length and number of exposures of those involved.
5. Suck out at source with a particle filter (H 14).
6. Only feed the removed air back into working areas after it has been sufficiently processed.
7. Eliminate dust deposits with damp or wet methods with suitable vacuum cleaners (never blow off dust containing nano-particles with compressed air).
8. Do not keep any material that has become dirty due to contact with nano-products in clothes bags.

➔ The phrase "avoid exposure " is not sufficiently specific and should not be used here.

Personal protective equipment / PPE

Regarding protective equipment, there are some initial findings regarding which types and which systems are best suited to protection from synthetic nano-objects (NanoSafe: safe production and use of nanomaterials). These findings are to be taken into consideration when drawing up the SDS.

Text examples Chapter 8 (PPE)

1. **Respiratory protection**
   If it is not possible to prevent the release of nano-particles (as dust or aerosol) during work, a particle-filtering form of respiratory protection (filter class P3) should be worn in addition to the technical protective measures.
2. **Gloves**
   If it is not possible to avoid direct contact with nano-particles (in liquid, solid or dust form), at least two layers of gloves should be worn one over the other (depending on the situation, e.g. latex combined with chemical gloves or two pairs of disposal gloves worn one over the other etc.).
3. It is very important to put on and take off the gloves carefully and to make sure that they overlap the protective suit in order to provide good protection. The material of the gloves must be chosen based on the chemicals involved; correct handling is as important in this respect as the penetration time.
4. **Protective suit**
   Wear a long-sleeved protective suit made out of membrane material (non-woven or fleece); woven substances are to be avoided.
5. **Eye protection**
   Wear at least sealing goggles to protect the eyes, although a full mask will offer better protection.

5.2.4. Chapter 13 SDS "Disposal considerations"

Chapter 13 should contain information on possible nano-specific properties which during the disposal process of nanomaterials could lead to the release of nano-objects, to the exposure of the employees and to emissions into the environment. The proprietor of the waste should be able to evaluate whether nano-specific disposal of the nano-waste should be arranged. Waste which contains synthetic nano-objects 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 nano-specific properties.
The precautionary matrix (see ANNEXE 7) can for example be used as an aid for evaluation.

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 the movement of hazardous wastes: **VeVA**, section 2 paragraph 2 part a (SR 814.610 / http://www.admin.ch/ch/d/sr/c814_610.html) as waste which due to its composition, chemical-physical or biologic properties requires comprehensive and particularly technical and organisational measures for it to be disposed of in an environmentally friendly way be means of inland transport. What constitutes hazardous waste is set out in the list of wastes (Annexe 1 of the Ordinance of the Swiss Federal Department of Environment, Transport, Energy and Communications (DETEC) regarding lists on dealing with waste, **LVA**, (SR 814.610.1 / http://www.admin.ch/ch/d/sr/c814_610_1.html). Any hazardous waste has a specific waste code.

For hazardous nano-waste 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 Chapter 13 SDS:

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

6 ANNEXE Two examples of safety data sheets

In annexe 6, two (fictitious) product examples of nano-specific data in various SDS chapters are set out (see also chapter 4 of these guidelines).

This nano-specific information can be identified by the fact that it is written in blue and will be added to the individual chapters of the usual SDS information.

6.1 NANO-BLOGGO surface finisher

Product: "NANO-BLOGGO"
Safety data sheet as per ChemV Annexe 2
Printed: 1 November 2010 Revised: 31 October 2010

Chapter 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product data: Trade name: NANO-BLOGGO

1.2 Intended use:

Surface finishing to produce a water and soil-resistant beading-off layer.

The nano-particles contained alter the surface structure.

1.3 Producer / supplier data:

Producer / supplier: BLOGGO AG / Milchstrasse / 8000 Zürich

Information on safety data sheet: Health protection and the environment department (044 111 11 11, auskunft@bloggo.gsu.com)

Emergency number (company): 044 000 00 00

Emergency information: Swiss Toxicological Information Centre (STIC) Tel 145

Chapter 2: Hazards identification

2.1 Indication of danger:

As per Directive 67/548/EEC

F Highly inflammable, **Xi** Irritant

2.2 Particular dangers for humans and the environment

R-phrases:

R11 Highly inflammable,

R**36** Irritates the eyes,

R**67** Vapours can provoke drowsiness and dizziness.

S-phrases:

S7 Keep container tightly shut.

S16 Keep away from sources of ignition. Do not smoke.

S24/25 Avoid contact with the eyes and the skin.

S26 In case of contact with the eyes, immediately rinse well with water and consult a doctor.

The product contains functionalised nano-particles. Aerosols containing nano-particles are created when the products are sprayed. It cannot currently be fully assessed as to whether this entails specific hazards. Avoid inhaling aerosols.

Chapter 3: Composition / information on ingredients

3.1 Chemical characterisation (preparation):

Aqueous dispersion of alcohol and functionalised nano-particles

3.2 Dangerous ingredients:

Substance	**Ethanol**	**Isopropanol**
Content	40 - 60%	25 - 30%
CAS no.	64-17-5	67-63-0
Danger symbol	F	F, Xi
R-phrase	R11	R11, 36, 67

The product contains < 1% functionalised (or: silanised) nano-particles based on technical pyrogenic silica (CAS no. 7631-86-9).

Chapter 4: Description of first aid measures

In case of inhaling: Breathe in fresh air

In case of contact with the skin: Wash immediately with soap and water. Remove affected clothing.

In case of contact with the eyes: Immediately rinse with lots of running water for at least 15 minutes, with the eyelids wide open (protect uninjured eyes, removed contact lenses). Notify an eye doctor where necessary.

In case of swallowing: drink water immediately. Notify a doctor in the event of discomfort.

Chapter 5: Firefighting measures

5.1 Suitable extinguishing agent:

Carbon dioxide, foam, extinguishing powder

5.2 Particular dangers with fire-fighting:

Combustible substance; vapours are heavier than air and spread over the ground. In case of fire, dangerous gases and vapours may be produced. Explosive mixtures with air are already possible at normal temperature. Do not extinguish with a direct water jet. When fighting the fire, only approach the danger area when equipped with breathing apparatus which is not dependent on circulating air.

5.3 Further information: Cool the closed containers which are near the fire with spray and empty them where necessary. Do not allow the extinguishing water to pour into the surface or groundwater.

No increased flammability is to be expected of the nano-particles which are contained.

Chapter 6: Accidental release measures

6.1 Personal protection measures:

Avoid contact with the substance. Make sure that there is enough fresh air. Do not inhale vapours / aerosols.

6.2 Environmental protection measures:

Do not empty into sewers.

6.3 Cleaning procedures:

Use liquid-absorbent material (e.g. Chemizorb®). Carry out the disposal and clean afterwards.

Chapter 7: Handling and storage

7.1 Handling:

Hints on safe handling: Do not inhale vapours unnecessarily.

Note on fire and explosion protection: Keep away from open flames, hot surfaces and sources of ignition.

7.2 Storage:

Further data on storage conditions: Keep container away from sources of ignition and heat, tightly closed and in a cool, well ventilated place between 5° and 30°C.

Chapter 8: Exposure controls/personal protection

8.1 Components with occupational exposure limits

(TLV values of the ingredients from SDS chapter 2**)**

Description of substance: **Ethanol**

CAS no.: 64-17-5

ml/m³ (ppm) 500

mg/m³ 960

TLV (Suva – Swiss Accident Insurance Fund) 500ml/m^3 or 960 mg/m^3

Description of substance: **Isopropanol**

CAS no.: 67-63-0

ml/m³ (ppm) 200

mg/m³ 500

TLV (Suva – Swiss Accident Insurance Fund) 200ml/m^3 or 500 mg/m^3

There are currently no established limits for the functionalised nano-particles contained in terms of toxicology or occupational health.

Aerosols containing nano-particles occur when spraying the product with propellants. Exposure to aerosols of this kind is to be avoided and to be kept to an absolute minimum by means of technical measures (ventilation – use in separate areas such as a chapel or cabins).

8.2 Personal protective measures

Protective clothing (PPE): PPE is to be selected based on the concentration and amount of hazardous substances. The chemical resistance of the preservative should be clarified with the suppliers.

Respiratory protection: Filter type A (necessary when vapours / aerosols occur); EN143, EN14387.

If technical protective measures are unable to prevent the release of vapours / aerosols and nano-particles, wearing personal respiratory protection (filter class FFP3) is recommended.

Gloves: If there is likely to be contact with the skin over a prolonged period of time, protective gloves should be worn; EN374. In the event of full contact, butyl rubber gloves with a thickness of 0.7mm and a penetration time of at least 480 min. should be worn. In the event of contact with spray, nitrile rubber gloves with a thickness of 0.4mm and a penetration time of at least 120 min. should be worn.

If direct contact with the solution containing nano-particles cannot be avoided, two layers of gloves one over the other are to be worn where possible.

Protective suit: Flame-proof clothing or flame-retardant anti-static protective clothing; EN14605, EN13982, EN345.

Use a protective suit made of membrane material (non-woven, fleece); avoid woven substances.

eye protection: recommended; EN166

Protective glasses should be fully enclosed; full masks are preferable.

Hygiene measures: Do not smoke, eat or drink when working. Avoid prolonged or repeated contact with the skin (wear protective cream and gloves). Do not inhale vapours / spray. Do not keep any material that has become dirty due to contact with the product in clothes bags. Keep away from food products, drinks and animal feed. Wash hands during breaks and once work is finished.

Chapter 9: Physical and chemical properties

Form: liquid

Colour: transparent

Smell: characteristically alcoholic

pH value of the substance: c. 5.0 at 20°C

Melting point: -120°C

Boiling point: 78°C

Ignition temperature: 425°C

Flash point (closed cup): 15°C

Oxidising properties: no data available

Flammability: highly inflammable

Explosion limits: Lower 3.5 Vol%

Explosion limits: Upper 15 Vol%

Vapour pressure: c. 59 hPa (at 20°C)

Relative vapour density: not specified

Rate of vaporisation: not specified

Self-ignition: not specified

Density: 092g/cm^3 (at 20°C)

Water solubility: 20°C soluble

Solubility in organic solvents: Not soluble in non-polar organic solvents (at 20°C).

Maximum size distribution of the nano-particles contained: 45nm (as per BET method)

Solubility of the nano-particles contained in water: 1.8mmol/L (pH 7.3; 37°C), ECE-TOC/JACC report, 51/2006

Redox activity and catalytic / photocatalytic activity of the nano-particles contained: not known

Agglomeration and aggregation behaviour of the nano-particles contained: pyrogenic silica forms agglomerates which are stable under usual process conditions; ECETOC/JACC report, 51/2006.

Zeta potential of the nano-particles contained: not known

Chapter 10: Stability and reactivity

Conditions to be avoided: heating

Substances to be avoided: Danger of explosion with strong oxidising agents.

Dangerous decomposition products: None known

Further information: None

The basic material of the nano-particles contained (pyrogenic silica) is not stable

Chapter 11: Toxicological information

The toxicological classification of the preparation was carried out based on the results of the calculation procedure of the General Dangerous Preparations Directive (1999/45/EC).

The following data apply to ethanol:

Acute tox: LD50 of ethanol orally: 6,200mg/Kg (oral / rat) IUCLID

Acute tox: LD50 of ethanol after inhalation: 95.6mg/L, 4h RTECS

Acute toxicity of ethanol when in contact with the skin: dermatitis symptoms

Skin irritation due to ethanol (rabbit): no irritation (OECD-RL 404)

Eye irritation due to ethanol (rabbit): no irritation (OECD-RL 405)

Sensitisation test of ethanol: negative (Magnusson and Kligman / IUCLID)

No other known data on the preparation in question is known.

Due to the pyrogenic silica contained, the production of oxygen radicals and of inflammatory cytokines is possible.

Chapter 12: Ecological information

General information: The eco-toxicological classification of the preparation was carried out based on the results of the calculation procedure of the General Dangerous Preparations Directive (1999/45/EC).

Fish toxicity (golden orfe): LC50 of ethanol: 8140mg/L (48h)

Daphnia toxicity (Daphnia magna): EC50 of ethanol: 1-14g/L (48h)

Algae toxicity (Scenedesmus quadricauda): EC5 of ethanol: 5,000mg/L (7d)

No data is available regarding the eco-toxicology of the pyrogenic silica contained. The production of oxygen radicals and cytokines is possible.

Other ecologic information: No disturbance in the water treatment plant is to be expected when used correctly. Harmful effects on water organisms in high concentrations.
Pyrogenic silica is inert in the environment and will not be transformed except by dissolving; (ECETOC/JACC report, 51/2006).

Chapter 13: Disposal considerations

Product: Hazardous waste with code 07 01 04 "Other organic solvent, washing liquids, mother liquors"

Further data: Emptied containers can be eliminated as municipal waste.

Waste code (Switzerland):

15 01 01, 15 01 02, 15 01 04, 15 01 05, 15 01 06, 15 01 07 or 15 01 09.

The waste contains < 1% functionalised (silanised) nano-particles comprising technical pyrogenic silica (CAS-no. 7631-86-9).

Chapter 14: Transport information

Land transport ADR (European Agreement on the International Land Transport of Merchandising and Dangerous goods) / COTIF (Convention concerning International Carriage by Rail): UN number: 1263 Paint, Class 3, VG II

UN number: 1170 Ethanol, / Kemler number: 33

Technical postage description: 33/1263 Paint, Solution

Chapter 15: Regulatory information

Chapter 16 SDS: Other information

The above data is based on our current levels of knowledge at the time of printing and does not constitute a warranty of the characteristics in a legal sense. Regulations are to be observed at the user's own responsibility. Please obtain further information regarding the properties of the products from the technical product data sheet.

F/highly inflammable and **Xi**/irritant

R-phrases regarding the contents:

- **R11** Highly inflammable
- **R36** Irritates the eyes

- **R67** Vapours can provoke drowsiness and dizziness

Information on safety data sheet: Health protection and the environment department (044 111 11 11, auskunft@bloggo.gsu.com)

This SDS has been recently revised and replaces all previous editions. It contains nano-specific information.

6.2 SECOKAT, photocatalyst in wall colours

Product: "SECOKAT"
Safety data sheet as per ChemV Annexe 2
Printed: 1 December 2010 Revised: 30 November 2010

Chapter 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product data: Trade name: SECOKAT

1.2 Intended use:

Photocatalyst in wall colours for the destroying of VOC

1.3 Producer / supplier data:

Producer / supplier: Sonne AG

Information on safety data sheet: Health protection and the environment department (044 111 11 11, auskunft@sonne.gsu.com)

Emergency number (company): 044 000 00 00

Emergency information: Swiss Toxicological Information Centre (STIC) Tel 145

Chapter 2: Hazards identification

2.1 Indication of danger:

As per Directive 67/548/EEC

Xi Irritant

2.2 Particular dangers for humans and the environment

R-phrases:

R37 irritates the airways, **R 52/53** harmful for water organisms, can have long-term harmful effects in water.

S-phrases:

S24/25 Avoid contact with the eyes and the skin.

S61 Avoid releasing into the environment. Refer to special instructions / safety data sheet.

Chapter 3: Composition / information on ingredients

3.1 Chemical characterisation (preparation):

Aqueous dispersion of particulate nano titanium dioxide (anatase)

3.2 Dangerous ingredients:

None

Contains 10% TiO_2 nano-particles

Chapter 4: Description of first aid measures

In case of inhaling: Breathe in fresh air

In case of contact with the skin: Wash immediately with soap and water. Remove any adhesive material immediately. Notify a doctor in the event of persistent skin irritation.

In case of contact with the eyes: Immediately rinse with lots of water for at least 15 minutes, including below the eyelids.

In case of ingestion: Rinse mouth with water and consume lots of water. Do not make the patient vomit. Consult a doctor immediately.

General advice: In case of continued discomfort, consult a doctor.

Chapter 5: Firefighting measures

5.1 Suitable extinguishing agent:

Foam, carbon dioxide, dry extinguishing agent, water spray jet

Unsuitable extinguishing agent: full **water** jet

5.2 Particular dangers with fire-fighting:

Carbon monoxide may be released in the event of fire

5.3 Further information: none

Chapter 6: Accidental release measures

6.1 Personal protection measures:

Ensure good ventilation, use personal protective equipment.

6.2 Environmental protection measures:

Do not empty into surface water or sewers. Make sure it does not spread over a surface.

6.3 Cleaning procedures:

Use liquid-absorbent material (e.g. sand, silica gel, universal binder, sawdust). Rinse traces away after cleaning with water.

Chapter 7: Handling and storage

7.1 Handling:

Advice on safe handling:

Ensure good ventilation, suction of air at the workplace.

Note on fire and explosion protection:

The product is not combustible or inflammable.

7.2 Storage:

Further data on storage conditions:

Arrange for a floor without drainage. Close any opened containers carefully and store upright. Keep containers tightly shut and store in a cool well ventilated place.

Chapter 8: Exposure controls/personal protection

8.1 Components with occupational exposure limits

There are currently no established limits for the nano-particles contained in terms of toxicology or occupational health. The general threshold value for respirable dust (1.5mg/m3) is to be respected.

8.2 Personal protective measures

Protective clothing (PPE): PPE is to be selected based on the concentration and amount of hazardous substances. The chemical resistance of the preservative should be clarified with the suppliers.

Respiratory protection: Not required, but vapours should not be inhaled. Exception: aerosol usage; EN143, EN14387, for which a fine dust mask should also be worn (to protect the nose and mouth)

Gloves: If there is likely to be contact with the skin over a prolonged period of time, protective gloves should be worn; EN374. In the event of full contact, butyl rubber gloves with a thickness of 0.7mm and a penetration time of at least 480 min. should be worn. In the event of contact with spray, nitrile rubber gloves with a thickness of 0.4mm and a penetration time of at least 120 min. should be worn.

Wear double-layered protective gloves (water impermeable)

Protective suit: Clothing suitable to the workplace and handling chemicals; EN 14605, EN13982, EN 345

Use a protective suit made of membrane material, avoid woven substances

Eye protection: EN 166

Protective glasses should be fully enclosed; full masks are preferable.

Hygiene measures: The usual protective measures when handling chemicals are to be observed. Wash hands and face before breaks and immediately after handling the product. Do not eat, smoke or drink during use.

Chapter 9: Physical and chemical properties

Form: liquid

Colour: whitish

Smell: characteristic

Flash point: >100°C

Ignition temperature: Not specified

Boiling point / boiling range: 100°C

Density: ca. 1.1g/cm^3

pH value (in water): 7.5

Vapour pressure: Not specified

Viscosity (20°C): c. 200 mPa.s.

Water solubility: mixable

Solids content: 10%

Particle size distribution: Maximum size of the nano-particles contained: 20 nm (BET method)

Water solubility of the nano-particles contained: insoluble

Redox activity and catalytic / photo catalytic activity of the nano-particles contained:

- Redox: barely active
- Photo-catalytic: active

Agglomeration and aggregation behaviour of the nano-particles contained: strong tendency to agglomerate when uncoated.

Zeta potential of the nano-particles contained: 17 at pH 7, isoelectric point: 7.8

Chapter 10: Stability and reactivity

Stability: Stable under normal conditions.

Conditions to be avoided: None when used in accordance with instructions.

Substances to be avoided: No dangerous reactions when stored and handled in accordance with instructions

Dangerous decomposition products: No known dangerous decomposition products.

Further information: None

Chapter 11: Toxicological information

Acute toxicity: Not specified

Local effects: None known

In high dosage, the nano-particles contained do have toxic effects in various cell systems (ROS-activity, based on the ENRHES review 2009)

Long-term toxicity:

NOEC of the nano-particles contained (inhalation, 13 weeks): 0.5 mg m3 (based on the ENRHES review 2009)

Sensitisation: Not specified

Specific effects: Not specified

Effects on humans: Frequent and persistent contact with the skin can lead to skin irritations

Further information: Product-specific toxicological data not known.

Chapter 12: Ecological information

General information: Based on the ENRHES review, 2009:

Acute eco-toxicology of the nano-particles contained:

- Daphnia magna LC50 (96h) 20mg/L
- Pseudokirchneriella sub., EC_{50} (72h): 5.8mg/L

Chronic eco-toxicology of the nano-particles contained:

- Oncorhynchus mykiss, sublethal effects (14d): 0.1mg/L

Other ecological tips: Make sure that it does not penetrate into the soil, water or sewers.

Chapter 13: Disposal considerations

Product: Waste code 06 13 16 [S] metal oxides with the exception of those which come under 06'03'15.

Aqueous dispersion of particulate nano-titanium dioxide (anatase).

Fully emptied containers can be eliminated as municipal waste.

Chapter 14 SDS: Transport information

Land transport ADR (European Agreement on the International Land Transport of Merchandising and Dangerous goods) / COTIF (Convention concerning International Carriage by Rail)

The product is not subject to the transport regulations for land and rail transport.

Sea transport:

The product is not subject to the transport regulations for sea transport.

IMDG (International Maritime Code for Dangerous Goods) / GGVSee (German Carriage of Dangerous Goods by Sea ordinance)

Air transport ICAO/IATA:

The product is not subject to transport regulations for air transport.

Chapter 15: Regulatory information

Chapter 16 SDS: Other information

The information is based on our level of knowledge at the time of printing and in no way represents a guarantee of the properties in terms of legal warranty provisions. Further information on the properties of the product can be found on the technical product information sheet.

R phrases for the contents:
R37 irritates the airways

R52/53 harmful for water organisms, can have long-term harmful effects in water.

Contains 10% titanium dioxide nano-particles.
This SDS has recently been updated and replaces all previous versions. It contains nano-specific information.

7 ANNEXE

Precautionary matrix for synthetic nanomaterials

7.1 Preliminary remark

The precautionary matrix (http://www.bag.admin.ch/themen/chemikalien/00228/00510/05626/index.html?lang=en) for synthetic nanomaterials described hereafter is to be used as a resource to explain to what extent the implementation of preventative measures are workable when developing and handling nanomaterials. Risk assessment per se cannot and should not be carried out using this tool and the precautionary matrix in no way replaces a risk analysis.

7.2 Background

The safe handling of synthetic nanomaterials while protecting health and the environment is the responsibility of industry and business. Special rules for synthetic nanomaterials do not yet exist in either Swiss or European legislation. There is currently insufficient scientific and methodical basis to develop such rules, and this situation is leading to considerable uncertainties in terms of action and investment from businesses and is complicating open debate about the opportunities and risks of nanomaterials.

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 (http://www.bag.admin.ch/themen/chemikalien/00228/00510/index.html?lang=en) which takes into account both the various economic interests and health and environmental protection.

The precautionary matrix, which was developed on behalf of the Federal Ministries for Health and for the Environment is part of this action plan. It is an optional resource which is designed to give all stakeholders (industry, trade, commerce, authorities, insurance companies etc.) who have responsibility for the safety of employees, consumers or the environment, support with the preliminary review of a possible need for action.

7.3 Structured method to assess the nanospecific precautionary need when dealing with synthetic nanomaterials

The present precautionary matrix is a means of assessing the "nano-specific precautionary need" of synthetic nanomaterials and their application for employees, consumers and the environment based on selected parameters. This pragmatic approach can in no way be compared with a risk assessment.

The precautionary matrix helps businesses to evaluate the need for nano-specific measures (hence "precautionary need"). It also helps them to identify possible sources of risk in the development, production, use and disposal of synthetic nanomaterials.
Should they wish to obtain further clarification, users of the precautionary matrix can carry out their own investigations into exposure to humans, the effect on the environment or the effects of nanomaterials or, where applicable, call in experts or consult literature data.

7.4 Parameters to assess potential risks

Only nano-objects which have at least two nano-sized dimensions (or products which contain them) are considered relevant in the precautionary matrix. This type of nano-object is referred to in the precautionary matrix as NPR (nano-particles and rods).
The precautionary matrix is based on a limited number of valuation metrics, including

- particle size
- their reactivity and resistance
- their release potential
- amount of particles.

Based on these parameters, the precautionary need for employees, consumers and the environment is estimated for each defined step in the lifecycle of a product.

If the nano-specific information is integrated into the SDS as recommended in the present guidelines, a precautionary matrix can then also be applied and the potential need for action for the nanomaterials in question can be estimated.

7.5 Further information

For further information on precautionary matrices, the following documents can be consulted (http://www.bag.admin.ch/themen/chemikalien/00228/00510/05626/index.html?lang=en)

- Precautionary matrix for synthetic nanomaterials
- Electronic precautionary matrix for synthetic nanomaterials
- Introduction to the precautionary matrix for synthetic nanomaterials
- Precautionary matrix fact sheet
- FAQs
- Leaflet – all the facts in brief

8 ANNEXE Additional links to information on dealing with nano-objects and on data sources

SUVA: nano-particles at the workplace
This article provides information about nano-particles and demonstrates concrete protective measures which are to be observed when dealing with nano-particles at the workplace (2009).

BAuA (German Federal Institute for Occupational Safety and Health): guidelines for activities involving nanomaterials at the workplace
These guidelines offer orientation regarding measures to be taken when producing and using nanomaterials at the workplace (2007).

DGUV/BGIA: Schutzmassnahmen bei ultrafeinen Aerosolen und Nanopartikeln am Arbeits-platz
This 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 (June 2009 / see also NanoSafe link below).

NanoSafe: safe production and use of nanomaterials
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 the 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 stan-dardisation and standards are important? (Feb 2009)
8.

ENRHES final report
The ENRHES project carried out a comprehensive and critical scientific examination of the health and environmental safety of fullerenes, carbon nano-tubes (CNT) and metallic and oxidic nanomaterials. On the basis of this examination, prioritised recommendations were developed and put into the context of the development of suitable regulations. The final re-port of the project provides a summary of the results.

OECD research database
The OECD research database for the safety of nanomaterials is a global data source on re-search projects which feature the environmental, health and safety aspects of synthetic nanomaterials. This database is based on the Woodrow Wilson International Center for Scholars database: "Nanotechnology Health and Environmental Implications: An Inventory of Current Research" and supports the projects of the OECD's Working Party on Manufactured Nanomaterials (WPMN) as a source for information on current research.

9 ANNEXE 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, synthetic nano-particles 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 nano-sized form of the substance
CNT MWCNT	Carbon-nanotube, multi-walled carbo-nanotube These can comprise either one or several layers	Example for MWCNT (available over the counter): Diameter = 20-40nm Length = 500-40'000nm
Coating	Modifications to the surfaces of nano-particles via coatings (e.g. with polymers or with positive / negative groups / molecules).This is also called functionalisation.	Nano-particles are often coated to prevent agglomerates and aggregates from forming and to minimise the reactivity of the individual particles.
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.
Functionalisation	See Coating	
Nano-fibres	Object with two nano-sized external dimensions	ISO Terms (Chapter 2.1)
Nanomaterial	In the present guidelines, this term is used to refer to synthetic nano-objects.	The term "nanomaterial" is a relatively unspecific collective name under which all materials which contain nano-sized components can be subsumed.

Term	Explanation / Definition	Note
Nano-object	Objects which are nano-sized in one, two or three external dimensions (see ISO Terms (Chapter 2.1)	Only nano-objects which are nano-sized in two or three external dimensions are dealt with in these guidelines.
Nano-particle	Object with three nano-sized external dimensions. Nano-particles are defined according to the International Organisation for Standardisation (ISO) as particles with a diameter smaller than 100 nanometres (=0.1µm) in three dimensions	ISO Terms (Chapter 2.1)
NanoSafe	EU development project for the safe handling of nanomaterials	Dissemination reports, available on the Internet
Nano-sized	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 nano-sized separately from bulk materials.
Synthetic nano-particles (or nano-objects)	Specifically produced nano-particles (e.g. nano-tubes, fullerenes, metal oxides, quantum dots etc.)	Naturally occurring nano-particles (e.g. fine dust i.a.) 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, not because nanomaterials pose a risk a priori, but to give them a special designation for safety reasons.