TECHNICAL REPORT

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Nanomaterials — Preparation of Material Safety Data Sheet (MSDS)

Nanomatériaux — Préparation des feuilles de données de sécurité des matériaux (MSDS)

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Foreword

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The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

In exceptional circumstances, when a technical committee has collected data of a different kind from that which is normally published as an International Standard ("state of the art", for example), it may decide by a simple majority vote of its participating members to publish a Technical Report. A Technical Report is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO/TR 13329 was prepared by Technical Committee ISO/TC 229, *Nanotechnologies*.

Introduction

This Technical Report provides guidance on the development of safety data sheets (SDSs) for manufactured nanomaterials (and materials or products that contain manufactured nanomaterials), and provides additional information on safety issues associated with manufactured nanomaterials. It is not a stand-alone document and should be used in conjunction with ISO 11014:2009[1]. This Technical Report takes into account the *Globally harmonized system of classification and labelling of chemicals (GHS)* document on hazard communication: safety data sheets. The GHS was developed by the United Nations and is being incorporated into the laws of various regions and nations, many of which already have laws that govern the preparation of SDSs. However, implementing the guidance provided in this Technical Report is not a substitute for complying with the law. Organizations should consult with relevant national authorities to address questions about interpreting or complying with national law.

Currently, there is limited information on the hazards of most nanomaterials. In many cases the degree of risk to workers or others who might be exposed to nanomaterials is partly unknown as the toxicological effects of nanomaterials are not yet well known and exposure is difficult to measure. Most hazard information and communication systems require preparation of an SDS for hazardous chemicals, including those containing nanomaterials, for use in manufacture, storage, transport or other occupational handling activities. Yet, only a few SDSs contain specific information about nanomaterials or are specific to nanomaterials. Those that exist generally provide insufficient hazard information (see Reference [2]). There is evidence that some nanomaterials might be more hazardous, e.g. more bio-reactive or active, leading to higher toxicity, than the same material in bulk (non-nanoscale) form. Characteristics predictive of potential safety or toxicity for manufactured nanomaterials need to be determined and included in the preparation of an SDS. Although, currently, no competent authority has a legal requirement to demand an SDS for a nanomaterial that is not already classified as a hazardous chemical, it is good practice to do so since an SDS is a well-accepted and effective method for the provision of workplace health and safety information.

This Technical Report considers the precautionary approach in terms of toxicity and other risks associated with nanomaterials and thus recommends providing an SDS for nanomaterials and nanomaterial-containing products regardless of whether or not the material is classified as hazardous, unless there is existing data for the nanomaterial which demonstrates that it is non-hazardous, or if it is not envisaged that they can be released as nano-objects, or their agglomerates and aggregates greater than 100 nm (NOAA), during handling or use.

Nanomaterials — Preparation of Material Safety Data Sheet (MSDS)

1 Scope

This Technical Report provides guidance on the development of content for, and consistency in, the communication of information on safety, health and environmental matters in safety data sheets (SDS) for substances classified as manufactured nanomaterials and for chemical products containing manufactured nanomaterials. It provides supplemental guidance to ISO 11014:2009[1] on the preparation of SDSs generally, addressing the preparation of an SDS for both manufactured nanomaterials with materials and mixtures containing manufactured nanomaterials.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/TS 27687:2008, *Nanotechnologies — Terminology and definitions for nano-objects: Nanoparticle, nanofibre and nanoplate*

ISO/TS 80004-1:2010, *Nanotechnologies — Vocabulary — Part 1: Core terms*

Globally harmonized system of classification and labelling of chemicals (GHS). United Nations Economic Commission for Europe, Fourth Edition, 2011

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/TS 27687:2008, ISO 80004-1:2010, GHS:2011 and the following apply.

3.1
agglomerate
collection of weakly bound particles or aggregates or mixtures of the two where the resulting external surface area is similar to the sum of the surface areas of the individual components

[ISO/TS 27687:2008, definition 3.2]

Note 1 to entry: The forces holding an agglomerate together are weak forces, for example van der Waals forces, or simple physical entanglement.

Note 2 to entry: Agglomerates are also termed secondary particles and the original source particles are termed primary particles.

3.2
aggregate
particle comprising strongly bonded or fused particles where the resulting external surface area may be significantly smaller than the sum of calculated surface areas of the individual components

[ISO/TS 27687:2008, definition 3.3]

Note 1 to entry: The forces holding an aggregate together are strong forces, for example covalent bonds, or those resulting from sintering or complex physical entanglement.

Note 2 to entry: Aggregates are also termed secondary particles and the original source particles are termed primary particles.

3.3

bioaccumulation

process of accumulation of a substance in organisms or parts thereof

[ISO 6107-6:2004, definition 10]

3.4

biodegradation

degradation due to the biological environment

[ISO 10993-9:2009, definition 3.2]

Note 1 to entry: Biodegradation might be modelled by *in vitro* tests.

3.5

biodurability

physicochemical property which depends on dissolution and leaching as well as mechanical breaking and splitting of a material in a physiological solution such as a Gamble solution

Note 1 to entry: The biodurability test is usually performed *in vitro.*

3.6

biopersistence

ability of a material to persist in a tissue in spite of the tissue's physiological clearance mechanisms and environmental conditions

[EU R 18748:1999]

3.7

chemical product

substance or mixture

[ISO 11014:2009, definition 3.1]

3.8

crystallinity

presence of three-dimensional order at the level of molecular dimensions

[ISO 472:1999]

3.9

dispersibility

level of dispersion when it has become constant under the defined conditions

Note 1 to entry: Dispersion is defined as a suspension of discrete particles.

Note 2 to entry: Adapted from ISO 8780-1 and ISO 1213-1.

3.10

dustiness

propensity of a material to generate airborne dust during their handling

[EN 15051:2006]

3.11

engineered nanomaterial

nanomaterial designed for a specific purpose or function

[ISO/TS 80004-1:2010, definition 2.8]

3.12
hazard category
division of criteria within each hazard class as used in GHS

[GHS:2011]

3.13
hazard class
nature of the physical, health or environmental hazard as used in GHS

[GHS:2011]

3.14
hazard statement
statement assigned to a hazard class and category as used in GHS that describes the nature of the hazards of a hazardous substance or mixture, including, where appropriate, the degree of hazard

[ISO 11014:2009, definition 3.6]

3.15
incidental nanomaterial
nanomaterial generated as an unintentional by-product of a process

[ISO/TS 80004-1:2010, definition 2.10]

Note 1 to entry: The process includes manufacturing, bio-technological or other processes.

Note 2 to entry: See ISO/TR 27628:2007[10], definition 2.21, for definition of "ultrafine particle".

3.16
manufactured nanomaterial
nanomaterial intentionally produced for commercial purposes to have specific properties or specific composition

[ISO/TS 80004-1, definition 2.9]

3.17
mixture
mixture or solution composed of two or more substances in which they do not react

[GHS:2011]

3.18
nanoaerosol
aerosol comprised of, or consisting of, nanoparticles and nanostructured particles

[ISO/TR 27628:2007, definition 2.11]

Note 1 to entry: Nanostructured particles mean particles having a composition of inter-related parts, in which one or more of those parts is a nanoscale region.

3.19
nanofibre
nano-object with two similar external dimensions in the nanoscale and the third dimension significantly larger

[ISO/TS 27687:2008, definition 4.3]

Note 1 to entry: A nanofibre can be flexible or rigid.

Note 2 to entry: The two similar external dimensions are considered to differ in size by less than three times and the significantly larger external dimension is considered to differ from the other two by more than three times.

Note 3 to entry: The largest external dimension is not necessarily in the nanoscale.

3.20
nanomaterial
material with any external dimension in the nanoscale or having internal structure or surface structure in the nanoscale

[ISO/TS 80004-1:2010, definition 2.4]

Note 1 to entry: This generic term is inclusive of nano-object and nanostructured material.

Note 2 to entry: See also engineered nanomaterial, manufactured nanomaterial and incidental nanomaterial.

3.21
nano-object
material with one, two or three external dimensions in the nanoscale

[ISO/TS 27687:2008, definition 2.2; ISO/TS 80004-1:2010, definition 2.5]

Note 1 to entry: Generic term for all discrete nanoscale objects.

3.22
nanoparticle
nano-object with all three external dimensions in the nanoscale

[ISO/TS 27687:2008, definition 4.1]

Note 1 to entry: If the lengths of the longest to the shortest axes of the nano-object differ significantly (typically by more than three times), the terms nanofibre or nanoplate are intended to be used instead of the term nanoparticle.

3.23
nanoplate
nano-object with one external dimension in the nanoscale and the two other external dimensions significantly larger

[ISO/TS 27687:2008, definition 4.2]

Note 1 to entry: The smallest external dimension is the thickness of the nanoplate.

Note 2 to entry: The two significantly larger dimensions are considered to differ from the nanoscale dimension by more than three times.

Note 3 to entry: The larger external dimensions are not necessarily in the nanoscale.

3.24
nanoscale
size range from approximately 1 nm to 100 nm

[ISO/TS 80004-1:2010, definition 2.1; ISO/TS 27687: 2008, definition 2.1]

Note 1 to entry: Properties that are not extrapolations from a larger size will typically, but not exclusively, be exhibited in this size range. For such properties the size limits are considered approximate.

Note 2 to entry: The lower limit in this definition (approximately 1 nm) is introduced to avoid single and small groups of atoms from being designated as nano-objects or elements of nanostructures, which might be implied by the absence of a lower limit.

3.25
nanostructure
composition of inter-related constituent parts, in which one or more of those parts is a nanoscale region

[ISO/TS 80004-1, definition 2.6]

Note 1 to entry: A region is defined by a boundary representing a discontinuity in properties.

3.26
nanostructured material
material having internal nanostructure or surface nanostructure

[ISO/TS 80004-1:2010, definition 2.7]

Note 1 to entry: This definition does not exclude the possibility for a nano-object to have internal structure or surface structure. If external dimension(s) are in the nanoscale, the term nano-object is recommended.

3.27
nanostructured particle
particle with structural features smaller than 100 nm, which may influence its physical, chemical and/or biological properties

[ISO/TR 27628:2007, definition 2.13]

Note 1 to entry: A nanostructured particle may have a maximum dimension substantially larger than 100 nm.

EXAMPLE A 500 nm diameter agglomerate of nanoparticles would be considered a nanostructured particle.

3.28
particle
minute piece of matter with defined physical boundaries

[ISO/TS 27687:2008, definition 3.1, ISO/TR 27628:2007, definition 2.13]

Note 1 to entry: A physical boundary can also be described as an interface.

Note 2 to entry: A particle can move as a unit.

Note 3 to entry: This general particle definition applies to nano-objects.

3.29
safety data sheet
SDS
document that provides information on the properties of hazardous chemicals, how they affect health and safety in the workplace and how to manage the hazardous chemicals in the workplace

[Safe Work Australia]

3.30
substance
chemical elements and their compounds in the natural state or obtained by any production process, including any additive necessary to preserve the stability of the product and any impurities deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition

[GHS:2011]

3.31
surface area
area of external surface plus the internal surface of its accessible macro- and mesopore

[ISO/TR 13014:2012, definition 2.28]

Note 1 to entry: Includes mass-specific surface area or volume-specific surface area.

4 SDS preparation

4.1 General

4.1.1 It is advised to prepare an SDS for all manufactured nanomaterials, regardless of whether or not the bulk (non-nanoscale) material is classified as hazardous, except when

- testing or assessment results that meet requirements of competent authorities, or are based upon national or international standards, or generally accepted scientific practices, have indicated they are non-hazardous, or when
- it is not envisaged that manufactured nanomaterials can be released as nano-objects or agglomerates/aggregates (NOAAs) under reasonably anticipated conditions of use to be exposed to humans, and the matrix (including the manufactured nanomaterial) does not exhibit a hazard, or when
- the hazard class of manufactured nanomaterials is known and the manufactured nanomaterials are present in concentrations lower than the cut-off levels identified in 5.1.

4.1.2 The information in the SDS should be written in a clear and concise manner. The SDS should be prepared by one or more competent persons who should take into account the specific needs of the intended audience, as far as they are known. The SDS should provide comprehensive information and/or conclusions about the data that are evaluated, making it easy for any reader to identify all of the hazards, including those associated with the material's nanostructure. In addition to the minimum information requirements, the SDS should contain available information relevant to the safe use of the material.

4.1.3 The format of the SDS should conform to ISO 11014[1].

NOTE The format of the SDS may also be subject to applicable legal requirements.

4.1.4 If relevant information for any of the required 16 SDS sections cannot be found, this fact should be indicated on the SDS in the appropriate section using phrases such as "not available". The SDS should have no blanks under any of the headings.

4.1.5 Separate SDSs should be provided for different forms of the same chemical if they pose different hazards.

4.1.6 The preparation of an SDS may involve confidential business information about the ingredients or characteristics of the manufactured nanomaterials (or preparations containing them) that are the subject of the SDS. The legal requirements regarding confidential business information established by competent authorities in the markets in which the SDS will be used must be followed. When information that might be relevant to the SDS is not disclosed for reasons of confidentiality, alternative methods should be considered to provide users with relevant information (for example providing information using generic terminology, providing ranges for concentrations, or providing points of contact with which users can communicate to obtain more detailed information).

4.2 Content and general layout of an SDS

4.2.1 Chemical product and company identification

Due to the rapidly changing state of knowledge in the area of nanomaterial safety, the date the SDS was prepared and the identity of the organization that prepared the SDS should be included. The SDS should include a revision number and the superseding date or other indications of what version has been replaced.

4.2.2 Hazard identification

The SDS should describe all of the hazards associated with the manufactured nanomaterial or mixture for which the SDS is being prepared. It is recommended that GHS hazard statements be used to describe hazards. Vague and potentially misleading descriptions such as "may be dangerous", "no health effects", "safe under most conditions of use" or "harmless" should not be used. If the manufactured nanomaterial or mixture is classified according to GHS, the specific hazard and category should be identified. Also, hazards which do not result in classification or are not currently covered by GHS should be included in the "hazard identification" section of the SDS. For example, possible dust formation should be mentioned among the potential hazards as well as other hazards with no relevance to classification such as suffocation, skidding or specific hazards to the environment. Further guidance on evaluating exposure scenarios is provided in 4.2.8. When no (or only limited) data on potential hazards are known, general information will be recommended (see Reference [12]) (see formulation of the Swiss guide for SDS, section 5.1.2).

4.2.3 Composition of ingredients and related information

4.2.3.1 If a nanomaterial has the same Chemical Abstracts Service (CAS) number as the bulk (non-nanoscale) material, use that CAS number, but also state that the material is a manufactured nanomaterial according to ISO's definition or other applicable definitions, e.g. Anatase TiO_2, CAS Number 1317-70-0, (manufactured nanoform).

4.2.3.2 Identify the composition of manufactured nanomaterials, including stabilizing additives and, where applicable, impurities, to the extent necessary for classification and identification of occupational health and safety measures. If the manufactured nanomaterial is surface-coated, the hazardous properties of the surface coating should also be evaluated. The information on the chemical composition of the nanomaterial should include all ingredients.

NOTE 1 General information on the status of the surface, such as surface charge and surface chemistry of the manufactured nanomaterial, should be given where necessary for classification, risk assessment and development of occupational health and safety measures.

NOTE 2 Solubility information should be included for determining relevant hazard profiles, if applicable.

NOTE 3 A listing of all substances having an associated occupational exposure limit is required. This should include substances where the exposure limit is for bulk (non-nanoscale) materials or manufactured nanomaterials. These limits are listed in 4.2.8.

4.2.3.3 The SDS should describe whether the manufactured nanomaterial is pure or a component of another material or product. For mixtures, identify the manufactured nanomaterial(s) and concentration(s), or concentration ranges, or proportion ranges of all ingredients which are hazardous within the context of GHS and present above the cut-off levels given in 5.1. For materials or products that contain manufactured nanomaterials, identify the manufactured nanomaterial(s) of all ingredients which are hazardous within the context of GHS. If the mixed material or product has not been tested as a whole, the manufactured nanomaterial and common name(s) of all ingredients which have been determined to be hazardous should be listed.

NOTE When using a proportion range, refer to the concentration or percentage range of the manufactured nanomaterial in the mixture.

4.2.3.4 If the mixture has been tested as a whole to determine its hazards, then the manufactured nanomaterial and common name(s) of the ingredients which contribute to these known hazards, and the common name(s) of the mixture itself should be included. If the mixture has not been tested as a whole, the manufactured nanomaterial and common name(s) of all ingredients which have been determined to be hazardous, and where concentrations are equal to or greater than the cut-off levels as described in 5.2, should be listed. The manufactured nanomaterial and common name(s) of all ingredients which have been identified as posing a physical hazard when present in the mixture as described in 5.2 should also be listed.

4.2.4 First-aid measures

Information provided in this section of the SDS should be based on ISO 11014[1]. There is no further guidance specific to manufactured nanomaterials at this time.

4.2.5 Fire-fighting measures

Manufactured nanomaterial forms, particularly powders, of some materials, might show unusually high reactivity, especially for fire, explosion and catalytic reactions, when compared with equivalent materials with larger particle sizes. Nanomaterials have been known to exhibit characteristics of reactivity that would not be anticipated from their chemical composition alone (see Reference [13]). Decreasing the particle size of combustible materials has the potential to reduce minimum ignition energy and increase combustion potential and rate. Some normally stable powders become pyrophoric if deposited on a filter and subject to high airflow, such as the conditions inside a vacuum cleaner. This means that they can release energy at a much faster rate, tending towards to the explosion scenario. This suggests that some manufactured nanomaterials should be handled as sources of ignition that have the potential to result in fire or explosion.

Generally, the maximum explosion pressure, rates of pressure rise and equivalent $\mathrm{K_{St}}$ (dust deflagration index) of powders containing manufactured nanomaterials have been found to be broadly similar to conventional micron-scale powders probably due to the agglomeration of particles. However, if particles are dispersed more efficiently, then the $\mathrm{K_{St}}$ and P_{max} (peak maximum explosion pressure) might be increased beyond those of micron-scale powders. Therefore, the minimum ignition energies of some powders containing manufactured nanomaterials have been found to be lower than those for the equivalent micron-scale material (see Reference [14]).

All recommended agents have to be checked for ingredient compatibility with the nanomaterials, with a focus on their potential content of water. Some metallic dusts react with water to form, among other things, hydrogen gas which ignites very easily. The conductive nanopowders, such as the carbon nanopowders, are not likely to be an electrostatic hazard but, should these powders penetrate into electric and electronic equipment, they could give rise to short circuits and constitute sources of ignition. The possibility of nanopowders penetrating into electrical and electronic equipment might be greater as a result of their reduced particle size (see Reference [14]). Use of dry sand can also quench and exclude oxygen from the burning material without disturbing the burning mass of the material. Additional information on fire-fighting measures can be obtained from ISO/TR 12885[15] and ISO/TS 12901-1[16].

4.2.6 Accidental release measures

4.2.6.1 The description of measures that should be taken in response to accidents (especially worst-case scenarios), such as spills or releases involving manufactured nanomaterials, should be based on the hazardous properties of the nanomaterial and take into account hazard statements and toxicological and ecological information created pursuant to 4.2.3, 4.2.11 and 4.2.12. Methods for cleaning up spills and leaks of manufactured nanomaterial should describe, as appropriate, measures to avoid dispersion, e.g. atmospheric re-suspension, runoff or tracking through the premises, uncontrolled accumulation or explosion. Cleanup methods should be described in sufficient detail to prevent or minimize adverse effects due to spills or leakages on persons or the environment. Before selecting a cleaning method, consider the potential for complications due to the physical and chemical properties of the manufactured nanomaterial, particularly in the case of larger spills. Complications could include reactions with cleaning materials and other materials in the locations where wastes generated by cleanup activities will be stored, e.g. vacuum cleaner filters and canisters. Such waste storage locations include vacuum cleaner filters and canisters.

4.2.6.2 Possible cleanup methods for dry manufactured nanomaterials include

a) using a dedicated high-efficiency particulate air (HEPA) vacuum cleaner intended for use in industrial or laboratory settings,

b) wet wiping, and

c) other facility-approved methods that do not involve dry sweeping or use of compressed air.

Using a dedicated HEPA-filtered vacuum cleaner such as type H industrial vacuum cleaners for dusts hazardous to health (see BS 5415-2.2:Supplement No. 1[17]) can avoid mixing waste nanomaterials with other wastes, thereby decreasing the amount of waste nanomaterials, avoiding potential contamination of the waste nanomaterials with other wastes, and decreasing the likelihood of unintentional releases of nanomaterials by making it known that the vacuum cleaner is dedicated to that use (see ISO/TS 12901-1:2012, Clause 13[16]).

Consider possible pyrophoric hazards associated with the vacuuming of manufactured nanomaterials, such as spontaneous combustion or ignition.

4.2.6.3 For spills of liquids containing manufactured nanomaterials, the wet-wiping method is recommended for cleanup. In order to prevent the spread of liquids containing suspended manufactured nanomaterials during cleanup, it is recommended that the access to the spill area be controlled and absorbent walk-off mats placed where cleanup personnel will exit the spill area, and/or that barriers be installed to minimize air currents across the surface affected by the spill. A HEPA-filtered vacuum cleaner dedicated to the cleanup of manufactured nanomaterials can also be used to cleanup residual manufactured nanomaterials left behind after the spill area has dried. Additional information can be obtained from ISO/TS 12901-1[16].

NOTE There are non-resolved problems with using vacuum cleaners for nanomaterials: a) the motor produces tiny nanoparticles (potential contamination of product and/or trigger of alarm system when measuring nanoparticle concentration), and b) HEPA filters that are used in commercially available vacuum cleaners have been shown to not always fulfil industry standards on HEPA.

4.2.6.4 The SDS should outline ways of managing cleanup materials, including the collected spilled materials and the materials used to clean up the spill according to the hazard classification of manufactured nanomaterials. If the waste nanomaterials are not classified, it is recommended that they be managed as if they were hazardous, unless testing or assessment results that meet the requirements of the competent authorities, or are based upon national or international standards, or generally accepted scientific practices, have indicated they are non-hazardous. If the waste nanomaterials are not classified, a competent person should be consulted to determine how they should be managed.

4.2.7 Handling and storage

Scenarios that might result in exposure to manufactured nanomaterials (e.g. formation of aerosols), for which risk management measures are necessary, should be identified. A statement identifying the method for measuring and assessing exposure for the substance should be given, if available. Preventive occupational health and safety measures should be recommended as necessary in accordance with the hierarchy of controls (see Reference [16]). Manufactured nanomaterial exposure can be mitigated by implementing engineering control (see Reference [18]). Therefore the SDS should contain details on storage, e.g. temperature or humidity.

Measures described should adequately protect all people that might enter the workplace. Where applicable, it should be stated that the provided safety information does not apply to all uses. The same principles that apply to bulk (non-nanoscale) materials which generate dust and fine powders might need to be applied to manufactured nanomaterials, with additional consideration given to account for the typically long settling times for nanoparticles. As an example, attention should be given to oxidizable metallic manufactured nanomaterials.

If the manufactured nanomaterials are classified as hazardous or regarded as potentially hazardous, recommended work practices include the following:

— Appropriate engineering controls, such as HEPA filtered ventilation in the work space, etc., should be described if required by the specific characteristics of the manufactured nanomaterials and the involved processes.

- Some manufactured nanomaterials might warrant the use of controlled-atmosphere production and storage processes using carbon dioxide, nitrogen or another inert gas to reduce the risk of fire and deflagration. Equipment which will be exposed to certain manufactured nanomaterials may be required to be explosion-proof.
- Transfer manufactured nanomaterial samples between workstations such as exhaust hoods, glove boxes and furnaces, inside a sealed, labelled container such as a marked, self-sealing bag. The container or bag should be placed in a second clean container or bag.
- Take reasonable precautions to minimize the likelihood of skin contact with manufactured nanomaterials or nanomaterial-containing materials which are likely to release manufactured nanomaterials.
- When small amounts of powders containing manufactured nanomaterials are handled without the use of exhaust ventilation such as a laboratory exhaust hood or without an enclosure such as a glovebox, alternative work practice controls to reduce the potential for contamination and exposure events should be implemented.
- Handle manufactured nanomaterial-bearing waste according to the local guidelines on hazardous chemical waste, unless testing or assessment results that meet the requirements of competent authorities have indicated they are non-hazardous.
- Use only a dedicated HEPA-filtered vacuum cleaner, such as Type H vacuum cleaner intended for use in industrial or laboratory settings, to clean dry nanomaterials.
- Organizational protective measures should be considered. Examples of such measures include decreasing exposure time, decreasing the number of persons exposed, implementing access restrictions, and training personnel on the risks associated with working with manufactured nanomaterials. Alternative work practice controls to reduce the potential for contamination and exposure events should be implemented.
- Personal protective equipment (PPE) should be identified as a last step after all other measures to limit exposure have been implemented. Examples include face shields, anti-static shoes, jumpsuits, hair bonnets, respiratory protection (stating respirator type and use procedures) and hand protection (stating penetration time and glove material). The suitability of PPE, for example respirator and gloves, should be sufficiently substantiated. If necessary, differentiations of protective measures should be made according to different uses of the manufactured nanomaterial.

NOTE Although current methods for certification of respirator filters do not routinely require test at particle sizes below 100 nm, recent research indicates that a number of respirators can offer levels of protection against nanomaterials (see Reference [19]), assuming the respirator is well fitted.

More detailed information and references about occupational safety measures for manufactured nanomaterials can be found in ISO/TR 12885[15], ISO/TS 12901-1[16] and ISO/TS 12901-2[20].

4.2.8 Exposure controls and personal protection

4.2.8.1 People undertaking a wide range of different roles and tasks, including factory workers, researchers in laboratories, cleaning and maintenance staff, and worksite visitors, can potentially be exposed to manufactured nanomaterials in locations where they are used. Conditions that should be taken into account in evaluating the potential for occupational exposure (and thus identifying recommended protective measures) include those given in References [18], [21] and [22]:

- working with nanomaterials in liquid media, presenting a risk of skin and eye exposure. If pouring, mixing or agitation is involved, there is an increase in the likelihood of inhalable and respirable droplets forming.
- generating gas-phase nanoparticles in non-enclosed systems and handling nanostructured powders, increasing the chance of aerosol release into the workplace.

- — cleaning and maintaining manufacturing equipment, PPE and dust collection systems used to capture aerosol nanomaterials that pose a risk to skin and eyes and could lead to potential inhalation.
- — dust formation, or the possibility of nano-objects such as nanoparticles or nanofibres (including persistent nanofibres or fibrous structures) being released into the air during expected conditions of use (including release of agglomerates or aggregates of nano-objects), leading to potential inhalation and skin and eye exposure.
- — working with manufactured nanomaterials in powdered form that carry a risk of oxidation, auto-ignition, fire or explosion (e.g. oxidizable metallic powders).

This evaluation should assess the most important routes of exposure.

4.2.8.2 Existing occupational exposure limit values for all ingredients listed under 4.2.3 should be given. This should include, if available, a statement identifying occupational exposure limit values for specific decomposition products, if any, which can be formed during intended use of the material.

The information should state whether the workplace limit is for the bulk (non-nanoscale) or nanomaterial form of the material. Occupational exposure limits for bulk (non-nanoscale) materials are not necessarily protective for the nanomaterial form of the material. Therefore, if occupational exposure limits are not available for the manufactured nanomaterial form of the material, protective measures, such as those described in 4.2.7, should be recommended to minimize exposure.

NOTE In cases where primary nanoparticles are likely to aggregate and/or agglomerate in the workplace atmosphere to form inhalable non-nanoscale particles (see Reference [22]), the occupational exposure limits for the primary nanoparticles (where available) should be documented in the SDS and constitute the basis for engineering control requirements.

4.2.9 Physical and chemical properties

4.2.9.1 In addition to the physical and chemical properties listed in A.10 of ISO 11014:2009, it is recommended that the following information and measurement methods also be included:

a) primary particle size (average and range);

b) size distribution;

c) aggregation and/or agglomeration state;

NOTE 1 The relationship between aggregation, agglomeration and hazard is variable and dependent on the dispersant and the composition of the aggregate and/or agglomerate.

NOTE 2 Aggregation and/or agglomeration states are described qualitatively.

d) shape and aspect ratio;

NOTE Aspect ratio is frequently used to describe nanofibres.

e) crystallinity;

f) specific surface area (m^2/cm^3 or m^2/g);

g) dispersibility;

NOTE It is important to consider dispersants such as air, water, media or other materials when evaluating the risk from manufactured nanomaterials. The degree to which the manufactured nanomaterial is dispersed and interacts with the media in which it will be used is important for understanding potential hazards.

h) dustiness.

4.2.9.2 Descriptors of manufactured nanomaterial physical and chemical properties and methods for measuring these properties are available in the ISO/TR 13014[11] (See Annex A). Information on measuring dustiness from nanomaterials is available in EN 15051:2006[9].

4.2.10 Stability and reactivity

4.2.10.1 External conditions influencing the stability of the product should be specified. Any stabilizers required or recommended to avoid decomposition should be documented and bear a statement of whether their effect is limited in time (the potential for some manufactured nanomaterials to ignite is discussed in more detail in 4.2.5). If available, upper and lower explosion limits should be identified.

4.2.10.2 The following risks should be documented as appropriate:

a) conditions promoting exothermic reaction;

b) decomposition reactions resulting from contact with other substances;

c) formation of hazardous decomposition products.

4.2.11 Toxicological information

Any available toxicological information on the manufactured nanomaterial should be evaluated and the scientifically valid conclusions from such information summarized in the SDS. Where possible, potential adverse effects should be identified, together with the probable dose required to cause those effects.

If toxicological hazards have been identified for the bulk (non-nanoscale) material, this information should also be included. If no effects are known, it should be clearly stated whether this is due to a lack of testing data or if the studies reviewed showed no effect for particular end-points. If there are any data gaps due to missing toxicological test work, reference should be made to appropriate scientific studies and ongoing research projects. This includes toxicological information that is available to the manufacturer with respect to the product or, if appropriate, a product, material or substance that has similar properties, including any evidence based on established scientific principles.

In addition to the items listed in A.12 of ISO 11014:2009[1], the following information should be provided as applicable:

a) biodurability;

b) biopersistence.

Further toxicological and ecotoxicological information can be obtained from the OECD WPMN sponsorship programme website [23] in which physical, health and environmental hazards of representative manufactured nanomaterials are reported.

If information on the toxicological properties of manufactured nanomaterial is not available, the SDS should state: “The toxicological properties of this material have not been determined. Therefore, appropriate precautions should be taken when using, storing, handling or disposing of this material.”

NOTE All protection measures recommended in 4.2.8 should be consistent with the stated toxicological properties in the SDS.

4.2.12 Ecological information

4.2.12.1 Any available ecotoxicological information on the manufactured nanomaterial should be evaluated and the scientifically valid conclusions from such information should be summarized in the SDS. In addition to the items listed in A.12 of ISO 11014:2009[1], the following information regarding the ecological and ecotoxicological properties of the manufactured nanomaterial and its degradation products should be provided where available and appropriate:

a) aquatic toxicity

b) biodegradability, where appropriate.

4.2.12.2 Depending on the specific case and in line with potential exposure scenarios, the following information about the manufactured nanomaterial and its degradation products should be included in the SDS where available and appropriate:

a) fate and behaviour in the environment: adsorption/desorption screening;

b) appropriate long-term aquatic toxicity;

c) bioaccumulation in aquatic species;

d) biodurability;

e) biopersistance.

Accidental release and disposal instructions recommended in the SDS should be consistent with all properties described.

For preparations consisting of individual components, the ecological and ecotoxicological information provided should be clearly identified in relation to that respective component. Where necessary, notes should be inserted regarding the applicability of any ecological and ecotoxicological tests performed to evaluate the manufactured nanomaterial(s).

4.2.13 Disposal considerations

The management and disposal of waste that contains nanomaterials may be subject to applicable legal requirements. Where there are no explicit applicable legal requirements, and the manufactured nanomaterials are considered hazardous or potentially hazardous and might be released from the waste during handling or disposal, safe handling practices preventing exposure to the environment should be implemented and disposal methods, which include placing manufactured nanomaterials and manufactured nanomaterial-contaminated items in separate, sealed containers, should be recommended. The measures listed here should be congruent with the statements under the “Accidental release measures” section in the SDS. Any residues which might pose a hazard during disposal should also be mentioned. Descriptions of handling waste residues and disposal methods for contaminated packaging are available in ISO/TS 12901-1[16].

Waste that contains nanomaterials that are free or risk being released into the atmosphere should be disposed of as potentially hazardous waste, unless testing or assessment results that meet the requirements of competent authorities, or are based upon national or international standards or generally accepted scientific practices, have indicated they are non-hazardous.

4.2.14 Transportation information

Any manufactured nanomaterial that meets the definition of a hazardous material according to applicable national regulations should be packaged, marked, labelled, documented and shipped according to national regulations. Nanomaterials that do not meet the hazard criteria as listed in GHS might still pose health and safety issues to personnel handling the material if they are released during transport. All shipments of manufactured nanomaterials, regardless of whether they meet the definition for hazardous materials or not, must be consistently packaged in accordance with local or regional regulations or, if applicable, the United Nations Model Regulation.

4.2.15 Regulatory information

There is no additional guidance provided for manufactured nanomaterials.

4.2.16 Other information

There is no additional guidance provided for manufactured nanomaterials.

5 Cut-off values/concentration limits

5.1 An SDS should provide information based on the generic cut-off values/concentration limits indicated in Table 1, unless there is reason to suspect that an ingredient present at a concentration lower than those listed is still relevant for classifying the mixture for the relevant hazard class.

Table 1 — Cut-off values/concentration limits from each health and environmental hazard class from GHS (GHS Table 1.5.1)

Hazard class	Cut-off value/concentration limit
Acute toxicity	≥ 1,0 %
Skin corrosion/irritation	≥ 1,0 %
Serious eye damage/eye irritation	≥ 1,0 %
Respiratory/skin sensitization	≥ 0,1 %
Germ cell mutagenicity (Category 1)	≥ 0,1 %
Germ cell mutagenicity (Category 2)	≥1,0 %
Carcinogenicity	≥ 0,1 %
Reproductive toxicity	≥ 0,1 %
Specific target organ toxicity (single exposure)	≥ 1,0 %
Specific target organ toxicity (repeated exposure)	≥ 1,0 %
Aspiration hazard (Category 1)	≥ 10 % of Category 1 ingredient(s) and kinematic viscosity ≤ 20,5 mm^2/s at 40 °C
Aspiration hazard (Category 2)	≥ 10 % of Category 2 ingredient(s) and kinematic viscosity ≤ 14 mm^2/s at 40 °C
Hazardous to the aquatic environment	≥ 1,0 %

5.2 If a mixture contains manufactured nanomaterials classified as hazardous, in concentrations above the cut-off values in Table 1 for the relevant hazard classes, the SDS for the mixture should be prepared as described in this Technical Report. In the case of mixtures, it is not necessary to give the full composition.

NOTE Although current cut-off values for mixtures specified by GHS are based on weight, this might not be the most appropriate metric for some nano-objects. The person preparing an SDS should include other metrics (e.g. number or surface concentration) when data are available. (For example, in some jurisdictions, the exposure limit value for friable asbestos is based on number concentration measured in number of fibres/cc.)

5.3 If a mixture in concentration below the cut-off values in Table 1 has been shown to have hazardous effects, the SDS for this mixture should be prepared as described in this Technical Report.

Annex A
(informative)

Example measurement methods and standards (ISO/TR 13014)[11]

Examples of measurement methods are provided for the benefit of the user so he/she is aware of at least a number of currently available methods. The user is cautioned that these methods have not necessarily been validated for use in characterizing multiple types of NOAAS (nano-objects, and their aggregates and agglomerates greater than 100 nm). Due to the diversity of NOAAs, most of the listed methods will be applicable only for a minority of the NOAAs, and only for part of the possible concentrations in which the NOAAs are presented in the toxicological tests. Thus, there is an urgent need for development and validation of (additional) measuring methods for these parameters.

A list of current standards on how to measure this parameter is also provided. Standardization of new, relevant, validated methods is currently being undertaken by ISO/TC 229 and other relevant ISO technical committees such as ISO/TC 201, *Surface chemical analysis*, and ISO/TC 24, *Particle characterization including sieving* (information available at http://www.iso.org). Other measurement methods and procedures are being used or recommended by some international organizations (e.g. OECD, ASTM International) and host nation organizations (e.g. EPA Harmonized Test Guidelines, NCI Nanotechnology Characterization Laboratory), and the interested reader can consult those organizations as well.

NOTE 1 ISO continually updates its documents, which might supplant the information presented here.

NOTE 2 The parameters listed are considered to be the most relevant to toxicological testing but others might also be relevant with respect to the preparation of SDS.

Table A.1 — Measurement methods and relevant standards

Parameter	Measurement methods	Relevant standards
Particle size	Dynamic light scattering (also known as photon correlation spectroscopy)	- ISO 9276-1:1998, *Representation of results of particle size analysis — Part 1: Graphical representation* - ISO 9276-1:1998/Cor 1:2004, *Representation of results of particle size analysis — Part 1: Graphical representation —* Technical Corrigendum 1 - ISO 9276-2:2001, *Representation of results of particle size analysis — Part 2: Calculation of average particle sizes/diameters and moments from particle size distributions* - ISO 9276-3:2008, *Representation of results of particle size analysis — Part 3: Adjustment of an experimental curve to a reference model* - ISO 9276-4:2001, *Representation of results of particle size analysis — Part 4: Characterization of a classification process* - ISO 9276-5:2005, *Representation of results of particle size analysis — Part 5: Methods of calculation relating to particle size analyses using logarithmic normal probability distribution* - ISO 9276-6:2008, *Representation of results of particle size analysis — Part 6: Descriptive and quantitative representation of particle shape and morphology* - ISO 9277:2010, *Determination of the specific surface area of solids by gas adsorption — BET method* - ISO 13318-1:2001, *Determination of particle size distribution by centrifugal liquid sedimentation methods — Part 1: General principles and guidelines* - ISO 13318-2:2007, *Determination of particle size distribution by centrifugal liquid sedimentation methods — Part 2: Photocentrifuge method* - ISO 13318-3:2004, *Determination of particle size distribution by centrifugal liquid sedimentation methods — Part 3: Centrifugal X-ray method* - ISO 13320:2009, *Particle size analysis — Laser diffraction methods* - ISO 13321:1996, *Particle size analysis — Photon correlation spectroscopy* - ISO 13322-1:2004, *Particle size analysis — Image analysis methods — Part 1: Static image analysis methods* - ISO 13322-2, *Particle size analysis — Image analysis methods — Part 2: Dynamic image analysis methods*
	Small-angle X-ray scattering	
	Size exclusion chromatography	
	Analysis of scanning electron microscopy (SEM) or transmission electron microscopy (TEM) or scanning probe microscopy (SPM) images	
	Differential mobility analysis	
	Separation techniques such as field-flow -fractionation or sedimentation (centrifugal or other)	
	Raman (tube diameter)	
	Laser-induced incandescence (LII)	

Table A.1 — (*continued*)

Parameter	Measurement methods	Relevant standards
		- ISO 14488:2007, *Particulate materials — Sampling and sample splitting for the determination of particulate properties* - ISO 14887:2000, *Sample preparation — Dispersing procedures for powders in liquids* - ISO 15900:2009, *Determination of particle size distribution — Differential electrical mobility analysis for aerosol particles* - ISO 20998-1:2006, *Measurement and characterization of particles by acoustic methods — Part 1: Concepts and procedures in ultrasonic attenuation spectroscopy* - ISO 21501-1:2009, *Determination of particle size distribution — Single particle light interaction methods — Part 1: Light scattering aerosol spectrometer* - ISO 21501-2:2007, *Determination of particle size distribution — Single particle light interaction methods — Part 2: Light scattering liquid-borne particle counter* - ISO 22412:2008, *Particle size analysis — Dynamic light scattering (DLS)* - ASTM E2490-09, *Standard Guide for Measurement of Particle Size Distribution of Nanomaterials in Suspension by Photon Correlation Spectroscopy (PCS)*
Aggregation/ agglomeration state	Analysis of SEM or TEM or SPM image	See section “Particle Size” (above) for measurement methods. ISO/TC 24, *Particle characterization*, has started the development of: - ISO/TR 13097, *Guide for the characterization of dispersion stability* - ISO/TS 12025, *Nanotechnologies — Quantification of nano-object release from powders by generation of aerosols* - ISO 13322-1:2004, *Particle size analysis — Image analysis methods — Part 1: Static image analysis methods*
	Angle-dependent scattering at different wavelengths	
	Static light scattering	
	Small-angle X-ray scattering	
	X-ray diffraction	
	Small-angle neutron scattering	
	Rheology methods	
	Centrifugal liquid sedimentation	
	Laser diffraction	
	Nanoparticle tracking analysis	
Shape	Analysis of SEM or TEM or SPM images	- ISO 16700:2004, *Microbeam analysis — Scanning electron microscopy — Guidelines for calibrating image magnification* - ISO 13322-1:2004, *Particle size analysis — Image analysis methods — Part 1: Static image analysis methods*
	Scattering techniques	

Table A.1 — (*continued*)

Parameter	Measurement methods	Relevant standards
Surface area	Methods based on gas or liquid adsorption isotherms	- ISO 15901-1:2005, *Pore size distribution and porosity of solid materials by mercury porosimetry and gas adsorption — Part 1: Mercury porosimetry* - ISO 15901-2:2006, *Pore size distribution and porosity of solid materials by mercury porosimetry and gas adsorption — Part 2: Analysis of mesopores and macropores by gas adsorption* - ISO 15901-3:2007, *Pore size distribution and porosity of solid materials by mercury porosimetry and gas adsorption — Part 3: Analysis of micropores by gas adsorption* - ISO 18757:2003, *Fine ceramics (advanced ceramics, advanced technical ceramics — Determination of specific surface area of ceramic powders by gas adsorption using the BET method* - ISO 9277:2010, *Determination of the specific surface area of solids by gas adsorption — BET method (under revision)* - ISO 13322-1:2004, *Particle size analysis — Image analysis methods — Part 1: Static image analysis methods*
	Liquid porosimetry	
	Image analysis	
	Laser-induced incandescence (LII)	
Composition	X-ray fluorescence – chemical purity	- ISO 22309:2011, *Microbeam analysis — Quantitative analysis using energy-dispersive spectrometry (EDS)* - ISO 22489:2006, *Microbeam analysis — Electron probe microanalysis — Quantitative point analysis for bulk specimens using wavelength-dispersive X-rays pectroscopy* - ISO 24173:2009, *Microbeam analysis — Guidelines for orientation measurement using electron backscatter diffraction* - ISO 13084:2011, *Surface chemical analysis — Secondary-ion mass spectrometry — Calibration of the mass scale for a time-of-flight secondary-ion mass spectrometer* - ISO 18114:2003, *Surface chemical analysis — Secondary-ion mass spectrometry — Determination of relative sensitivity factors from ion-implanted reference materials*
	X-ray photoelectron spectroscopy – chemical purity	
	Auger electron spectroscopy – chemical purity	
	X-ray diffraction – crystallinity, relative amount of different crystal phases, purity	
	Raman and other molecular spectroscopies	
	Thermogravimetric analysis-purity	
	Ultra-violet/visible spectrometry	
	Scanning electron microscopy	
	Nuclear magnetic resonance (NMR)	
	Inductively coupled plasma-optical emission spectrometer (ICP-OES)	
	Inductively coupled plasma-mass spectrometer (ICP-MS)	

Table A.1 — (*continued*)

Parameter	Measurement methods	Relevant standards
Surface chemistry	Auger electron spectroscopy (AES)	- ISO/TR 14187:2011, *Surface chemical analysis — Characterization of nanostructured materials* - ISO 18115-1:2010, *Surface chemical analysis — Vocabulary — Part 1: General terms and terms used in spectroscopy* - ISO 18115-2:2010, *Surface chemical analysis — Vocabulary — Part 2: Terms used in scanning-probe microscopy* - ISO 24236:2005, *Surface chemical analysis — Auger electron spectroscopy — Repeatability and constancy of intensity scale* - ISO 15471:2007, *Surface chemical analysis — Auger electron spectroscopy — Description of selected instrumental performance parameters* - ISO/TR 19319:2003, *Surface chemical analysis — Auger electron spectroscopy and X-ray photoelectron spectroscopy — Determination of lateral resolution, analysis area and sample area viewed by the analyser* - ISO 17973:2002, *Surface chemical analysis — Medium resolution Auger electron spectrometers — Calibration of energy scales for elemental analysis* - ISO 18118:2004, *Surface chemical analysis — Auger electron spectroscopy and X-ray photoelectron spectroscopy — Guide to the use of experimentally determined relative sensitivity factors for the quantitative analysis of homogeneous materials* - ISO 20903:2006, *Surface chemical analysis — Auger electron spectroscopy and X-ray photoelectron spectroscopy — Methods used to determine peak intensities and information required when reporting results* - ISO/TR 18394:2006, *Surface chemical analysis — Auger electron spectroscopy — Derivation of chemical information* - ISO 23830:2008, *Surface chemical analysis — Secondary-ion mass spectrometry — Repeatability and constancy of the relative intensity scale in static secondary ion mass spectrometry* - ISO 17560:2002, *Surface chemical analysis — Secondary-ion mass spectrometry — Method for depth profiling of boron in silicon* - ISO 18114:2003, *Surface chemical analysis — Secondary-ion mass spectrometry — Determination of relative sensitivity factors from ion implanted reference materials*
	X-ray photoelectron spectroscopy (XPS)	
	Secondary ion mass spectroscopy (SIMS)	
	3D atom probe tomography	
	Energy dispersive X-ray spectrometry	
	Electron energy loss spectroscopy (EELS)	
	Low-energy ion spectroscopy	
	Raman and other molecular spectroscopies	

Table A.1 — (*continued*)

Parameter	Measurement methods	Relevant standards
		- ISO 20341:2003, *Surface chemical analysis — Secondary-ion mass spectrometry — Method for estimating depth resolution parameters with multiple delta-layer reference materials* - ISO 15472:2002, *Surface chemical analysis — X-ray photoelectron spectrometers — Calibration of energy scales* - ISO 21270:2004, *Surface chemical analysis — X-ray photoelectron and Auger electron spectrometers — Linearity of intensity scale* - ISO 24237:2005, *Surface chemical analysis — X-ray photoelectron spectroscopy — Repeatability and constancy of intensity scale* - ISO 15470:2004, *Surface chemical analysis — X-ray photoelectron spectroscopy — Description of selected instrumental performance parameters* - ISO 19318:2004, *Surface chemical analysis — X-ray photoelectron spectroscopy — Reporting of methods used for charge control and charge correction* - ISO/TR 18392:2005, *Surface chemical analysis — X-ray photoelectron spectroscopy — Procedures for determining backgrounds* - ISO 18516:2006, *Surface chemical analysis — Auger electron spectroscopy and X-ray photoelectron spectroscopy — Determination of lateral resolution* - ISO 18117:2009, *Surface chemical analysis — Handling of specimens prior to analysis* - ISO 23812:2009, *Surface chemical analysis — Secondary-ion mass spectrometry — Method for depth calibration for silicon using multiple delta-layer reference materials*
Surface charge	Isoelectric point	ISO 20998-1:2006, *Measurement and characterization of particles by acoustic methods — Part 1: Concepts and procedures in ultrasonic attenuation spectroscopy*
	Electrophoretic light scattering	
	Electrophoresis	
	Electrosmosis	
	Electric sonic amplitude	
	Colloidal vibration current	
Solubility	There are no specific methods for the assessment of the solubility of nano-objects	No standards available
Dispersibility	Most common methods to assess the dispersibility of nano-objects are based on particle size measurements (see above)	ISO/TC 24, *Particle characterization*, has started the development of: ISO/TR 13097, *Guidelines for the characterization of dispersion stability*

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