Technical Specification

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Nanomaterials — Preparation of safety data sheets (SDS)

Nanomatériaux — Préparation des fiches de données de sécurité (FDS)

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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This document was prepared by Technical Committee 229 *Nanotechnologies*.

This second edition cancels and replaces the first edition (ISO/TR 13329:2012), which has been technically revised.

The main change is as follows:

— The document has been changed to a Technical Specification.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Manufactured nanomaterials are defined as materials that are intentionally produced to have specific properties or a specific composition and which have any external dimension in the nanoscale or internal structure or surface structure in the nanoscale. This document is not a stand-alone document and should be used in conjunction with ISO 11014.[1] This document takes into account the *Globally harmonized system of classification and labelling of chemicals (GHS)* document on hazard communication, i.e. 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.

Currently, there is limited information on the possible hazards of some nanomaterials. In some cases, the degree of risk to workers or others who can be exposed to nanomaterials is partly unknown, as the possible toxicological effects of nanomaterials are not yet well known and exposure is difficult to measure. Most hazard information and communication approaches necessitate 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 can 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 issues or toxicity for manufactured nanomaterials need to be determined and included in the preparation of an SDS. Within the European Union and the UK, the legislation that addresses industrial substances including nanomaterials specifies that hazardous substances and mixtures are accompanied by an SDS when placed on the market.

The most fundamental ethical responsibility faced by manufacturers is to make users aware that nanomaterials have been added to a product and to communicate, in an SDS, the hazards the product can present and the most effective ways to mitigate those hazards, relying on the hierarchy of controls. The hierarchy of controls is a method that is found in nearly every international guidance document on responsible management of nanomaterials. This document considers the precautionary approach in terms of toxicity and other risks associated with nanomaterials. It recommends providing an SDS for nanomaterials and nanomaterial-containing products, regardless of whether or not the material is classified as hazardous, unless there are 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 safety data sheets (SDS)

1 Scope

This document 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 materials or products that contain manufactured nanomaterials). It provides additional information on safety issues associated with manufactured nanomaterials. It provides supplemental guidance to ISO 11014[1] on the preparation of SDSs.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 80004-1, *Nanotechnologies – Vocabulary — Part 1: Core vocabulary*

Globally harmonized system of classification and labelling of chemicals (GHS). United Nations Economic Commission for Europe, Tenth revised edition, 2023

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 80004-1, GHS and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

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

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.

[SOURCE: ISO 80004-1:2023, 3.2.4]

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

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.

[SOURCE: ISO 80004-1:2023, 3.2.5]

3.3
bioaccumulation
process of accumulation of a substance in organisms or parts thereof

[SOURCE: ISO 6107:2021, 3.64]

3.4
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.*

3.5
biopersistence
ability of a material to persist in a tissue in spite of the tissue's physiological clearance mechanisms and environmental conditions

[SOURCE: EU R 18748:1999, 1.2, modified — The word "fibre" has been removed and the word "lung" replaced by "tissue".]

3.6
biodegradability
susceptibility of an organic substance to biodegradation

[SOURCE: ISO 6107:2021, 3.68]

3.7
chemical product
substance or mixture

[SOURCE: ISO 11014:2009, 3.1]

3.8
crystallinity
presence of three-dimensional order at the level of molecular dimensions

[SOURCE: ISO 472:2013, 2.240]

3.9
dustiness
propensity of materials to produce airborne dust during handling

Note 1 to entry: Dustiness is not an intrinsic property as it depends on how it is measured.

[SOURCE: EN 1540:2021, 3.1.2.9]

3.10
engineered nanomaterial
nanomaterial designed for a specific purpose or function

[SOURCE: ISO 80004-1:2023, 3.1.8]

3.11
hazard class
nature of the physical, health or environmental hazard as used in GHS

[SOURCE: GHS:2023, Chapter 1.2, modified — Examples removed from definition and "as used in GHS" added.]

3.12
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

[SOURCE: ISO 11014:2009, 3.6, modified — "Hazardous product" replaced with "hazardous substance or mixture" and "as used in GHS" added.]

3.13
incidental nanomaterial
nanomaterial generated as an unintentional by-product of a process

Note 1 to entry: The process includes manufacturing, biotechnological or other processes, including natural processes.

Note 2 to entry: Used as a synonym for “ultrafine particle” in ISO/TR 27628:2007.

[SOURCE: ISO 80004-1:2023, 3.1.10]

3.14
manufactured nanomaterial
nanomaterial intentionally produced to have selected properties or composition

[SOURCE: ISO 80004-1:2023, 3.1.9]

3.15
mixture
mixture or solution composed of two or more substances in which they do not react

[SOURCE: GHS:2023, Chapter 1.2]

3.16
nanofibre
nano-object with two similar external dimensions in the nanoscale and the third dimension significantly larger

Note 1 to entry: The largest external dimension is not necessarily in the nanoscale.

[SOURCE: ISO 80004-1:2023, 3.3.5]

3.17
nanomaterial
material with any external dimension in the nanoscale or having internal structure or surface structure in the nanoscale

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.

Note 3 to entry: The nanoform of a material is a nanomaterial.

[SOURCE: ISO 80004-1:2023, 3.1.4, modified — Notes to entry have been changed.]

3.18
nano-object
discrete piece of material with one, two or three external dimensions in the nanoscale

[SOURCE: ISO 80004-1:2023, 3.1.5]

3.19
nanoparticle
nano-object with all three external dimensions in the nanoscale

Note 1 to entry: If the dimensions differ significantly (typically by more than three times), terms such as nanofibre or nanoplate are preferred to the term nanoparticle.

[SOURCE: ISO 80004-1:2023, 3.3.4]

3.20
nanopowder
particulate material only composed of nano-objects

Note 1 to entry: Nanopowder can include *agglomerates* and/or *aggregates* in the *nanoscale* (largest dimension ≤ 100 nm).

[SOURCE: ISO 18451-1:2019, 3.85]

3.21
nanoscale
length range approximately from 1 nm to 100 nm

[SOURCE: ISO 80004-1:2023, 3.1.1]

3.22
nanostructure
surface or internal feature with one or more dimensions in the nanoscale

Note 1 to entry: A feature includes but is not limited to nano-objects, structures, morphologies or other identifiable areas of nanoscale dimensions. For example, the nanostructure can be a nanopore or a solid feature on an object.

[SOURCE: ISO 80004-1:2023, 3.1.6]

3.23
nanostructured material
material having internal nanostructure or surface nanostructure

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

[SOURCE: ISO 80004-1:2023, 3.1.7]

3.24
particle
minute piece of matter with defined physical boundaries

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

Note 2 to entry: This general particle definition applies to nano-objects.

[SOURCE: ISO 26824:2022, 3.1.1, modified — A note to entry has been deleted.]

3.25
primary particle
original source particle of agglomerates or aggregates or mixtures of the two

Note 1 to entry: Constituent particles of agglomerates or aggregates at a certain actual state can be primary particles, but often the constituents are aggregates.

Note 2 to entry: Agglomerates and aggregates are also termed secondary particles.

[SOURCE: ISO 26824:2022, 3.1.4]

3.26
safety data sheet
SDS
document specifying the properties of a substance, its potential hazardous effects for humans and the environment, and the precautions necessary to handle and dispose of the substance safely

[SOURCE: ISO 11139:2018, 3.239]

3.27
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 can be separated without affecting the stability of the substance or changing its composition

[SOURCE: GHS:2023, Chapter 1.2]

3.28
surface area
area of the external surface of a solid plus the internal surface of its accessible macro-, meso- and micropores

[SOURCE: ISO 9277:2022, 3.10]

4 SDS preparation

4.1 General

4.1.1 An SDS should be prepared 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 the requirements of competent authorities, or are based upon national or international standards, or generally accepted scientific practices, have indicated they are non-hazardous; or

— it is not envisaged that manufactured nanomaterials can be released as nano-objects or agglomerates and 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

— 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. The specific needs of the intended audience should be taken into account. The SDS should provide either comprehensive information or conclusions, or both, 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 necessary, the SDS should contain any 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 can also be subject to applicable legal requirements.

4.1.4 If relevant information for any of the 16 SDS sections cannot be found, this 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.

NOTE Mixtures of different formulations do not necessitate separate SDSs for each formulation, they can be tested as any other mixture, as per 4.2.3.4. For instance, a graphene additive for cement can be recommended in different concentrations for specific applications or in concrete for other purposes, but one SDS is possibly sufficient.

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 that an 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 the hazards associated with the manufactured nanomaterial or mixture for which the SDS is being prepared. In line with ISO 11014, GHS hazard statements should be used to describe hazards. Vague and potentially misleading descriptions such as "can be dangerous", "no health effects", "safe under most conditions of use" or "harmless" are not recommended. If the manufactured nanomaterial or mixture is classified according to GHS, the specific hazard and category should be identified. Also, hazards associated with the intended use of the material, but 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 if the material is milled or ground. Further guidance on evaluating exposure scenarios is provided in 4.2.8.

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, the CAS number should be used and a statement should be included that the material is a manufactured nanomaterial according to ISO's definition or other applicable definitions, e.g. Anatase TiO2, CAS Number 1317-70-0, (manufactured nanomaterial).

4.2.3.2 The composition of manufactured nanomaterials, including stabilizing additives and impurities, should be identified to the extent necessary for classification and identification of occupational health and safety measures. If the manufactured nanomaterial is chemically modified, the hazardous properties of modified nanomaterial should also be evaluated. Manufacturer or suppliers may choose to list all ingredients, including non-hazardous ingredients. If coating ingredients are proprietary, the manufacturer should, at a minimum, identify the impact the coating can have on behaviour of the nano-object.

General information on the status of the surface, such as chemical modifications of the manufactured nanomaterial, should be provided where necessary for the classification, risk assessment and development of occupational health and safety measures.

Solubility information should be included for the determination of relevant hazard profiles, if applicable.

All substances having an associated occupational exposure limit must be listed. 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.

NOTE Regulations can apply regarding confidential business information taking precedence over product identification. Refer to the relevant competent authority for further information.

If confidential information about the composition was omitted, this should be specified.

4.2.3.3 The SDS should describe whether the manufactured nanomaterial is pure or an additive. For mixtures, the SDS should identify the manufactured nanomaterials and concentrations, or concentration ranges, or proportion ranges of all ingredients which are hazardous as specified in GHS, and should provide the cut-off levels given in 5.1. Materials or products that contain manufactured nanomaterials should identify all manufactured nanomaterials, which are hazardous as specified in GHS. If the mixed material or product has not been tested as a whole, the manufactured nanomaterial and common names of all ingredients which have been determined to be hazardous should be listed.

When using a proportion range, the concentration or percentage range of the manufactured nanomaterial in the mixture should be taken into account, such as mass, volume, or any other appropriate metric for nanomaterials.

4.2.3.4 If the mixture has been tested as a whole to determine its hazards, then the manufactured nanomaterial and common names of the ingredients which contribute to these known hazards, and the common name of the mixture itself should be included. If the mixture has not been tested as a whole, the manufactured nanomaterial and common names 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 names 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 the "first-aid measures" 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 nanomaterials of some materials, particularly powders, can 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 are not able to be anticipated from their chemical composition alone (see Reference [11]).

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 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 K_{St} and P_{max} (peak maximum explosion pressure) can 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 [12]).

All recommended agents should 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 hydrogen gas, among other things, which ignites very easily. The conductive nanopowders, such as the carbon nanopowders, are not likely to be an electrostatic hazard but, if these powders penetrate into electric and electronic equipment, they can give rise to short circuits and constitute sources of ignition. The possibility of nanopowders penetrating into electrical and electronic equipment can be greater as a result of their reduced particle size (see Reference [12]). 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[13] and ISO/TS 12901-1.[14]

4.2.6 Accidental release measures

4.2.6.1 The measures specified in the SDS 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. Clean-up 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, the potential for complications due to the physical and chemical properties of the manufactured nanomaterial should be taken into account, particularly in the case of larger spills. Complications can include reactions with cleaning materials and other materials in the locations where wastes generated by clean-up activities will be stored, e.g. vacuum cleaner filters and canisters.

4.2.6.2 Possible clean-up 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;

c) other facility-approved methods that do not involve dry sweeping or the 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) can avoid mixing waste nanomaterials with other wastes, thereby decreasing the amount of waste nanomaterials. This avoids potential contamination of the waste nanomaterials with other wastes, and decreases 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[14]).

Possible pyrophoric hazards associated with the vacuuming of manufactured nanomaterials should be taken into account, such as spontaneous combustion or ignition. Clean-up equipment should be grounded and bonded if any flammable hazard exists.

4.2.6.3 For spills of liquids containing manufactured nanomaterials, the wet-wiping method is recommended for clean-up. In order to prevent the spread of liquids containing suspended manufactured nanomaterials during clean-up, it is recommended that the access to the spill area be controlled and either that absorbent walk-off mats are placed where clean-up personnel will exit the spill area, or that barriers are installed to minimize air currents across the surface affected by the spill, or both. A HEPA-filtered vacuum cleaner dedicated to the clean-up of manufactured nanomaterials can also be used to clean-up residual manufactured nanomaterials left behind after the spill area has dried. Additional information can be obtained from ISO/TS 12901-1.[14]

NOTE There are unresolved problems with using vacuum cleaners for nanomaterials:

a) the motor produces nanoparticles (causing either potential contamination of product or trigger of alarm system when measuring nanoparticle concentration, or both);

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 clean-up 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 manufactured nanomaterial in the waste stream 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 can 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 in accordance with the hierarchy of controls (see ISO/TS 12901-1[14]). Manufactured nanomaterial exposure can be mitigated by implementing engineering control (see Reference [16]). Therefore, the SDS should contain details on storage, e.g. temperature or humidity.

Measures described should provide protection for all people that can enter the workplace. Where applicable, it should be stated that the safety information provided does not apply to all uses. The same principles that apply to bulk (non-nanoscale) materials which generate dust and fine powders can 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 stored nanomaterials exhibit properties of self-heating, guidance on the maximum container size and container proximity should be included in the SDS.

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 necessitated by the specific characteristics of the manufactured nanomaterials and the involved processes.

— Some manufactured nanomaterials can 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 can 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 glove-box, 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.

— Administrative 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 (including information on respirator type and use procedures) and hand protection (including information on 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 [17]), 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,[13] ISO/TS 12901-1[14] and ISO/TS 12901-2[18].

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 [16], [19] and [20], as well as the following:

— 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 can 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 limits for all ingredients listed under 4.2.3 should be given. 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, protective measures, such as those described in 4.2.7, should be recommended to minimize exposure.

In cases where primary nanoparticles are likely to either aggregate or agglomerate, or both, in the workplace atmosphere to form inhalable non-nanoscale particles (see Reference [12]), the occupational exposure limits for the primary nanoparticles (where available) should be documented in the SDS and constitute the basis for engineering control requirements.

For substances without occupational exposure limits, limiting exposure by all routes to levels as low as possible should be taken into account. This approach is recommended for carcinogens with a designation of (L) by The American Conference of Governmental Industrial Hygienists (ACGIH).

4.2.9 Physical and chemical properties

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

a) Primary particle size (average and range).

Mean, median and mode are all acceptable measures, but it should be stated which is being used. Multimodal distributions may also be used.

b) Size distribution.

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

c) Shape and aspect ratio.

Aspect ratio is frequently used to describe nanofibres.

d) Crystallinity.

e) Specific surface area (m^2/cm^3 or m^2/g).

f) Dispersion stability.

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.

g) Bulk density.

h) Specific density.

i) Dustiness.

j) Functional groups and coatings.

k) Surface hydrophobicity.

4.2.9.2 Descriptors of manufactured nanomaterial physical and chemical properties and methods for measuring these properties are available in ISO/TR 13014:2012 (See Annex A).[9] Information on measuring dustiness of nanomaterials is available in EN 15051:2006[6] and EN 17199-5.[7]

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 a statement included specifying 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;

d) risk of dust explosion.

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 needed 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. 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 ISO 11014:2009 A.12,[1] the following information should be provided if applicable:

a) biodurability;

b) biopersistence.

Further toxicological and ecotoxicological information can be obtained from the OECD WPMN sponsorship programme website[21] 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."

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 of ISO 11014:2009 A.12,[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) toxicity to aquatic species or sediment toxicity;

b) abiotic degradation and 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 and desorption screening;

b) appropriate long-term toxicity to aquatic species;

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 can 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 can be released from the waste during handling or disposal, safe handling practices preventing exposure to the environment should be implemented. Furthermore, disposal methods, which include placing manufactured nanomaterials and manufactured nanomaterial-contaminated items in separate, sealed containers, should be recommended. The measures listed should be congruent with the statements in the "Accidental release measures" section in the SDS. Any residues which can 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.[14]

Waste that contains nanomaterials that are free or are at risk of 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

National regulations or, if applicable, the United Nations Model Regulation prescribe how manufactured nanomaterials, regardless of whether they meet the definition for hazardous materials or not, are packaged, marked, labelled, documented and shipped. Nanomaterials that have not been tested can pose health and safety issues to personnel handling the material if they are released during transport.

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 and concentration limits

5.1 General

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

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

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 %

SOURCE: Table 1.5.1 from *Globally harmonized system of classification and labelling of chemicals (GHS)*. United Nations Economic Commission for Europe, Fourth Edition, 2011. Reproduced with the permission of the authors.

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 document. In the case of mixtures, it is not necessary to give the full composition.

Although current cut-off values for mixtures specified by GHS are based on weight, this is not the most appropriate metric for some nano-objects. The SDS should include other metrics (e.g. number or surface concentration) when the 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 document.

Annex A
(informative)

Example measurement methods and standards (ISO/TR 13014)

Examples of measurement methods are provided for the benefit of users so that they are 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 nano-objects, and their aggregates and agglomerates greater than 100 nm (NOAAs). Due to the diversity of NOAAs, most of the listed methods are 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 provided in Table A.1. Standardization of new, relevant, validated methods is currently being undertaken.

Other measurement methods and procedures are available from international organizations (e.g. OECD, ASTM International) and host nation organizations (e.g. EPA Harmonized Test Guidelines, NCI Nanotechnology Characterization Laboratory).

NOTE 1 ISO continually updates its documents, which can supersede the information presented here.

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

Table A.1 — Measurement methods and relevant standards (modified from ISO/TR 13014)

Parameter	Measurement methods	Relevant standards
Particle size	Dynamic light scattering (also known as photon correlation spectroscopy) 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)	— 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 9276-2:2014, *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 9277:2022, *Determination of the specific surface area of solids by gas adsorption — BET method* — ISO 13318-1:—[1], *Determination of particle size distribution by centrifugal liquid sedimentation methods — Part 1: General principles, requirements and guidance* — 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 13320:2020, *Particle size analysis — Laser diffraction methods* — ISO 13321:1996, *Particle size analysis — Photon correlation spectroscopy* — ISO 13322-1:2014, *Particle size analysis — Image analysis methods — Part 1: Static image analysis methods* — ISO 13322-2:2021, *Particle size analysis — Image analysis methods — Part 2: Dynamic image analysis methods* — 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 15900:2020, *Determination of particle size distribution — Differential electrical mobility analysis for aerosol particles* — ISO 17200:2020, *Nanotechnology - Nanoparticles in powder form - Characteristics and measurements* — 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 21501-2:2019, *Determination of particle size distribution — Single particle light interaction methods — Part 2: Light scattering liquid-borne particle counter* — ISO 22412:2017, *Particle size analysis — Dynamic light scat-*

Table A.1 *(continued)*

Parameter	Measurement methods	Relevant standards
		tering (DLS) — ASTM E2490-09, *Standard Guide for Measurement of Particle Size Distribution of Nanomaterials in Suspension by Photon Correlation Spectroscopy (PCS)*
		1) Under preparation. Stage at the time of publication: ISO/FDIS 13318-1:2024.
Aggregation/ agglomeration state	Analysis of SEM or TEM or SPM image	See section "Particle Size" (above) for measurement methods.
	Angle-dependent scattering at different wavelengths	— ISO/TR 13097:2013, *Guide for the characterization of dispersion stability*
	Static light scattering	— ISO/TS 12025:2021, *Nanotechnologies — Quantification of nano-object release from powders by generation of aerosols*
	Small-angle X-ray scattering	— ISO 13322-1:2014, *Particle size analysis — Image analysis methods — Part 1: Static image analysis methods*
	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 16700:2016, *Microbeam analysis — Scanning electron microscopy — Guidelines for calibrating image magnification*
	Scattering techniques	— ISO 13322-1:2014, *Particle size analysis — Image analysis methods — Part 1: Static image analysis methods*
Surface area	Methods based on gas or liquid adsorption isotherms	— ISO 15901-1:2016, *Pore size distribution and porosity of solid materials by mercury porosimetry and gas adsorption — Part 1: Mercury porosimetry*
	Liquid porosimetry	
	Image analysis	— ISO 15901-2:2022, *Pore size distribution and porosity of solid materials by mercury porosimetry and gas adsorption — Part 2: Analysis of mesopores and macropores by gas adsorption*
	Laser-induced incandescence (LII)	— 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 9277:2022, *Determination of the specific surface area of solids by gas adsorption — BET method (under revision)* — ISO 13322-1:2014, *Particle size analysis — Image analysis methods — Part 1: Static image analysis methods*

Table A.1 *(continued)*

Parameter	Measurement methods	Relevant standards
Composition	X-ray fluorescence – chemical purity	— ISO 22309:2011, *Microbeam analysis — Quantitative analysis using energy-dispersive spectrometry (EDS)*
	X-ray photoelectron spectroscopy – chemical purity	— ISO 22489:2016, *Microbeam analysis — Electron probe microanalysis — Quantitative point analysis for bulk specimens using wavelength-dispersive X-ray spectroscopy*
	Auger electron spectroscopy – chemical purity	— ISO 24173:2009, *Microbeam analysis — Guidelines for orientation measurement using electron backscatter diffraction*
	X-ray diffraction – crystallinity, relative amount of different crystal phases, purity	— ISO 13084:2018, *Surface chemical analysis — Secondary-ion mass spectrometry — Calibration of the mass scale for a time-of-flight secondary-ion mass spectrometer*
	Raman and other molecular spectroscopies	— ISO 18114:2021, *Surface chemical analysis — Secondary-ion mass spectrometry — Determination of relative sensitivity factors from ion-implanted reference materials*
	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)	
Surface chemistry	Auger electron spectroscopy (AES)	— ISO/TR 14187:2020, *Surface chemical analysis — Characterization of nanostructured materials*
	X-ray photoelectron spectroscopy (XPS)	— ISO 18115-1:2023, *Surface chemical analysis — Vocabulary — Part 1: General terms and terms used in spectroscopy*
	Secondary ion mass spectroscopy (SIMS)	
	3D atom probe tomography	— ISO 18115-2:2021, *Surface chemical analysis — Vocabulary — Part 2: Terms used in scanning-probe microscopy*
	Energy dispersive X-ray spectrometry	
	Electron energy loss spectroscopy (EELS)	— ISO 24236:2005, *Surface chemical analysis — Auger electron spectroscopy — Repeatability and constancy of intensity scale*
	Low-energy ion spectroscopy	— ISO 15471:2016, *Surface chemical analysis — Auger electron spectroscopy — Description of selected instrumental performance parameters*