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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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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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is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.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.

