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Nanomaterials — Preparation of material safety data sheet (MSDS)

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National foreword

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TECHNICAL REPORT

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

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is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.

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

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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.

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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.

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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]

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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.

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