Technical Specification

ISO/TS 13329

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.