



BSI Standards Publication

Nanomaterials — Preparation of safety data sheets (SDS)

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National foreword

This Published Document is the UK implementation of ISO/TS 13329:2024. It supersedes PD ISO/TR 13329:2012, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee NTI/1, Nanotechnologies.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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Nanomaterials — Preparation of safety data sheets (SDS)

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

ISO/TS 13329

**Second edition
2024-09**

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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.

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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.

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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.