Technical

ISO/TS 13329

Nanomaterials — Preparation of safety data sheets (SDS)

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

Second edition
2024-09

Reference number
ISO/TS 13329:2024(en)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

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.

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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

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.

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.