TECHNICAL REPORT

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Nanotechnologies — Compilation and description of sample preparation and dosing methods for engineered and manufactured nanomaterials

Nanotechnologies — Compilation et description de la préparation des échantillons et des méthodes de dosage pour les nanomatériaux d'ingénierie et manufacturés

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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.

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 documents 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).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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

For an explanation on 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 the following URL: www.iso.org/iso/foreword.html.

The committee responsible for this document is ISO/TC 229, *Nanotechnologies.*

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Introduction

This document provides guidance regarding the preparation of nanomaterials for toxicological, including eco-toxicological, testing. The goal of this document is to assist health and environmental scientists and scientists and experts from other disciplines to understand, plan, choose and address issues relevant to nanomaterials before and during conducting toxicological tests. These issues include the effects of the properties of the material on preparation methods and of the media into which the samples of nanomaterials will be added. Failure to consider these effects might lead to erroneous conclusions regarding the relationship between the nature of the nanomaterial and observed toxicological responses. In particular, the composition and other characteristics of test media can affect the dose to which an organism that is the subject of a test will be exposed. Information on preparation of the test material is necessary prior to any biological or ecological evaluation. Information such as this is consistent with other ISO documents. For example, ISO 10993-18[1] specifically addresses the evaluation of the chemical characterization of materials used in medical devices, ISO 14971[2] specifies that a toxicological risk analysis should take into account the chemical nature of the materials, ISO/TR 13014[3] addresses issues pertaining to the materials themselves and ISO/TS 19337[55] points out the need to clarify whether observed toxic effects come from tested nano-objects themselves or from other uncontrolled sources. Some examples are provided of methods that establish test conditions that are relatable to environmentally relevant conditions.

This document uses a number of technical terms which have been defined earlier in other documents. Some of these terms have been defined in multiple documents, in different areas of science and technology, providing potentially or seemingly conflicting definitions. This document does not provide new, authoritative definitions for the terms used herein. Instead, this clause provides short descriptions for the terms used. Where possible, reference is made to existing documents.

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Nanotechnologies — Compilation and description of sample preparation and dosing methods for engineered and manufactured nanomaterials

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1 Scope

This document provides guidance regarding the preparation of nanomaterials for eco- and bio-toxicological testing. It provides guidance regarding factors pertaining to sample preparation and dose determination that might be useful in toxicological, including ecotoxicological, testing of engineered and manufactured nanoscale materials.

The descriptions of sample preparation method factors for both *in vitro* and *in vivo* toxicological testing of engineered and manufactured nanoscale materials include considerations about physico-chemical properties, media, methods for transformation and accumulation studies, health effects and dosimetry. The document is not intended to be a literature review nor a thorough assessment of the quality of the methods or data generated. The document is intended to complement other international efforts.

The focus of this document is on factors that might lead to results that are not relevant to safety evaluations. When featured, referenced methods are considered for their general interest and potential applicability. It is likely that most of the described methods are not generally applicable to all nanomaterials but they do demonstrate important factors and limitations that are common for a variety of nanomaterials.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at http://www.iso.org/obp

3.1
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: A particle can move as a unit.

Note 3 to entry: This general particle definition applies to nano-objects.

[SOURCE: ISO/TS 80004-2:2015, 3.1]

3.2
structure
arrangement defined by four different aspects (crystallinity, crystal structure, molecular structure and microstructure)

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