INTERNATIONAL STANDARD

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Nanotechnologies — Characterization of nanoparticles in inhalation exposure chambers for inhalation toxicity testing

Nanotechnologies — Caractérisation des nanoparticules dans les chambres d'inhalation par exposition pour les essais de toxicité par inhalation

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 10808 was prepared by Technical Committee ISO/TC 229, *Nanotechnologies*.

Introduction

The number of nanotechnology-based consumer products containing silver, gold, carbon, zinc oxide, titanium dioxide and silica nanoparticles is growing very rapidly. The population at risk of exposure to nanoparticles continues to increase as the applications expand. In particular, workers in nanotechnology-based industries are at risk of being exposed to nanoparticles. If nanoparticles are liberated from products, the public could be exposed as well. Although toxicity screening using instillation of nanomaterials provides important information, it does not reflect the actual scenario of inhalation exposure and does not provide the data required for inhalation exposure risk assessment. In addition, while inhalation toxicology using rats is the norm at this time, it is desirable to replace this antiquated method with a human-relevant assay[10].

The inhalation toxicity of nanoparticles is of particular concern in ensuring the health of workers and consumers. In order to conduct inhalation toxicity studies of nano-sized particles, the monitoring of concentration, size and distribution of nano-sized particles in the inhalation chamber is necessary. The conventional methods of fine or coarse particle monitoring, such as weight-based mass dose monitoring, are considered insufficient for nanoparticles, since nano-specific parameters (particle surface area, particle number, etc.) might be critical determinants, and if so, should also be monitored.

This International Standard proposes a battery of inhalation toxicity testing chamber monitoring, including a differential mobility analyzing system (DMAS), for measuring particle number, size, distribution, surface area and estimated mass dose, as well as morphological examination using transmission electron microscopy (TEM) or scanning electron microscopy (SEM) equipped with an energy dispersive X-ray analyzer (TEM-EDXA) for chemical composition.

This International Standard also includes conventional mass dose monitoring and other physicochemical monitoring, for use when deemed a necessary parameter for toxicity determination. This method evaluates nano-sized particle surface area, mass dose, particle distribution, composition and dispersion to support effective analysis of inhalation toxicity testing results [15][17][18].

Nanotechnologies — Characterization of nanoparticles in inhalation exposure chambers for inhalation toxicity testing

1 Scope

This International Standard specifies requirements for, and gives guidance on, the characterization of airborne nanoparticles in inhalation exposure chambers for the purpose of inhalation toxicity studies in terms of particle mass, size distribution, number concentration and composition.

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 10312, *Ambient air —Determination of asbestos fibres — Direct transfer transmission electron microscopy method*

ISO 15900, *Determination of particle size distribution — Differential electrical mobility analysis for aerosol particles*

ISO/TS 27687, *Nanotechnologies — Terminology and definitions for nano-objects — Nanoparticle, nanofibre and nanoplate*

OECD Test Guideline 403 (TG 403), *Acute Inhalation Toxicity*[1)]

OECD Test Guideline 412 (TG 412), *Subacute Inhalation Toxicity: 28-Day Study*[1)]

OECD Test Guideline 413 (TG 413), *Subchronic Inhalation Toxicity: 90-Day Study*[1)]

OECD Guidance Document 39 (GD 39), *Acute Inhalation Toxicity Testing*[1)]

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 15900 and ISO/TS 27687 and the following apply.

1) Organization for Economic Cooperation and Development (OECD) publication.