Irish Standard
I.S. EN ISO 10808:2010

Nanotechnologies - Characterization of nanoparticles in inhalation exposure chambers for inhalation toxicity testing (ISO 10808:2010)

I.S. EN ISO 10808:2010

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 10808

December 2010

ICS 07.030

English Version

Nanotechnologies - Characterization of nanoparticles in inhalation exposure chambers for inhalation toxicity testing (ISO 10808:2010)

Nanotechnologies - Caractérisation des nanoparticules dans les chambres d'inhalation par exposition pour les essais de toxicité par inhalation (ISO 10808:2010)

Nanotechnologien - Charakterisierung von Nanopartikeln in Inhalationskammern zur Prüfung auf Toxizität nach Inhalation (ISO 10808:2010)

This European Standard was approved by CEN on 10 December 2010.

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Foreword

This document (EN ISO 10808:2010) has been prepared by Technical Committee ISO/TC 229 “Nanotechnologies” in collaboration with Technical Committee CEN/TC 352 “Nanotechnologies” the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by June 2011, and conflicting national standards shall be withdrawn at the latest by June 2011.

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Endorsement notice

The text of ISO 10808:2010 has been approved by CEN as a EN ISO 10808:2010 without any modification.

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I.S. EN ISO 10808:2010

INTERNATIONAL STANDARD

ISO 10808

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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.

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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 [13][17][18].