Nanotechnologies - Generation of metal nanoparticles for inhalation toxicity testing using the evaporation/condensation method (ISO 10801:2010)

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NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 10801:2010 sisaldab Euroopa standardi EN ISO 10801:2010 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 10801:2010 consists of the English text of the European standard EN ISO 10801:2010.
Standard on kinnitatud Eesti Standardikeskuse 31.12.2010 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 31.12.2010 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
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English Version

Nanotechnologies - Generation of metal nanoparticles for inhalation toxicity testing using the evaporation/condensation method (ISO 10801:2010)

Nanotechnologies - Génération de nanoparticules de métal pour essais de toxicité par inhalation en utilisant la méthode de condensation/évaporation (ISO 10801:2010)

Nanotechnologien - Erzeugung von Metall-Nanopartikeln zur Prüfung auf Toxizität nach Inhalation unter Verwendung des Verdampfungs-/Kondensationsverfahrens (ISO 10801:2010)

This European Standard was approved by CEN on 14 December 2010.

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Foreword

This document (EN ISO 10801:2010) 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of an identical text or by endorsement, at the latest by June 2011, and conflicting national standards shall be withdrawn at the latest by June 2011.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 10801:2010 has been approved by CEN as a EN ISO 10801:2010 without any modification.

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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 manufactured nanoparticles. If nanoparticles are liberated from products, the public could be exposed as well.

There is currently limited, but growing, knowledge about the toxicity of nano-sized particles. The processes of nanoparticle production include gas-phase, vapour-phase, colloidal and attrition processes. Potential paths of exposure include inhalation, dermal and ingestion. Inhalation may arise from direct leakage from gas-phase and vapour-phase processes, airborne contamination of the workplace from deposition or product recovery and handling of product, or post-recovery processing and packing[7]. Exposure to manufactured nano-sized particles might occur during production, use and disposal in the ambient air or workplace and is of concern for public and occupational health.

There are currently neither generally accepted methods of inhalation toxicology testing for nano-sized particles nor specific nanoparticle generation methods for such testing. The ability to disperse respirable nano-sized particles from powders has been an obstacle to evaluating the effects of inhalation of nano-sized particles on the respiratory system. Although it is possible to disperse nanoparticles in air from powders, the size of the particles so generated may be larger than desired due to aggregation and agglomeration. In order to gain vital information for evaluating the health effects of nanoparticles by inhalation, nano-sized particles need to be generated and transported to a test environment containing experimental animals for testing short- or long-term inhalation toxicity. The nanoparticle generation method based on evaporation of metal (silver in this example) and subsequent condensation is capable of providing a consistent particle size distribution and stable number concentrations, suitable for short- or long-term inhalation toxicity study.

This International Standard provides a method for stable silver nanoparticle generation with particle sizes up to 100 nm. A detailed method is described in Annex A. The generation method provided here has sufficient stability for continuous inhalation toxicity testing up to 90 days. The generated nanoparticles can be used in various experimental systems, including high-throughput human cell-based labs-on-a-chip, a variety of additional *in-vitro* methods [8][9][10][11], as well as the animal experiments that may still be performed at this time, which include, but are not limited to, whole-body, head-only and nose-only. The method is not limited to the silver nanoparticles used in this example and may be used to generate other metallic nanoparticles with a similar melting temperature and evaporation rate, such as gold. However, this method is not applicable to the generation of nanoparticles of all metals.

Nanotechnologies — Generation of metal nanoparticles for inhalation toxicity testing using the evaporation/condensation method

1 Scope

This International Standard gives requirements and recommendations for generating metal nanoparticles as aerosols suitable for inhalation toxicity testing by the evaporation/condensation method. Its application is limited to metals such as gold and silver which have been proven to generate nanoparticles suitable for inhalation toxicity testing using the technique it specifies (see Annex A).

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

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

ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*

OECD Test Guideline (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)]

3 Terms and definitions

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

3.1
differential mobility analysing system
DMAS
system used to measure the size distribution of submicrometre aerosol particles consisting of a DEMC, a particle charge conditioner, flow meters, a particle detector, interconnecting plumbing, a computer and suitable software

NOTE Adapted from ISO 15900:2009, definition 2.8.

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