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

Nanotechnologies — Génération de nanoparticules de métal pour essais de toxicité par inhalation en utilisant la méthode de condensation/évaporation

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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 10801 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 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.