SLOVENSKI STANDARD
kSIST-TS FprCEN ISO/TS 5387:2024

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Nanotehnologije - Merjenje mase nanomaterialov pri obremenitvi pljuč z nanomateriali z inhalacijskimi testi strupenosti (ISO/TS 5387:2023)

Nanotechnologies - Lung burden mass measurement of nanomaterials for inhalation toxicity tests (ISO/TS 5387:2023)

Nanotechnologies - Mesure de la masse de la charge pulmonaire des nanomatériaux pour les études de toxicité par inhalation (ISO/TS 5387:2023)

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Nanotechnologies — Mesure de la masse de la charge pulmonaire des nanomatériaux pour les études de toxicité par inhalation

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Contents

Page

Foreword

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

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Inhalation is a primary route of exposure to aerosolized nanomaterials and therefore appropriate inhalation toxicity tests are required to address risk assessment needs for these materials. For this reason, the Organisation for Economic Cooperation and Development (OECD) recently updated its inhalation toxicity test guidelines 412 (subacute) and 413 (subchronic) to make them applicable to nanomaterials.[1][2] These revised test guidelines require post-exposure lung burden measurements to be undertaken when a range-finding study or other relevant information suggests that inhaled test nanomaterials are poorly soluble with low dissolution rate and likely to be retained in the lung. The measurements of lung burden inform on pulmonary deposition and retention of nanomaterials in the lung. At least three lung burden measurements are needed to evaluate clearance kinetics.

This document gives information on how to derive clearance kinetic parameter values using lung burden measurement data. This document complements OECD TG 412[1] and OECD TG 413[2]. As References [1], [2] and [3] only provide limited information on methods for lung burden measurement for nanomaterials or the derivation of lung clearance kinetics, this document provides useful supporting information for conducting inhalation studies based on OECD TG 412[1] and OECD TG 413[2].

Nanotechnologies — Lung burden mass measurement of nanomaterials for inhalation toxicity tests

1 Scope

The document provides information on the measurement of nanomaterial mass in tissue after inhalation exposure, which can inform on lung clearance behaviour and translocation.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 80004 (all parts), *Nanotechnologies – Vocabulary*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in the ISO 80004 series and the following apply.

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

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

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

3.1
aerodynamic diameter
diameter of a spherical particle with a density of 1 000 kg/m^3 that has the same settling velocity as the particle under consideration

Note 1 to entry: Aerodynamic diameter is related to the inertial properties of *aerosol* (3.2) particles and is generally used to describe particles larger than approximately 100 nm.

[SOURCE: ISO/TR 27628:2007, 2.2[4]]

3.2
aerosol
metastable suspension of solid or liquid particles in a gas

[SOURCE: ISO/TR 27628:2007, 2.3[4]]

3.3
mass median aerodynamic diameter
MMAD
calculated *aerodynamic diameter* (3.1) which divides the particles of a measured *aerosol* (3.2) distribution in half based on the mass of the particles where fifty percent of the particles by mass will be larger than the median diameter and fifty per cent of the particles will be smaller than the median

[SOURCE: EPA IRIS Glossary[11]]

3.4
manufactured nanomaterial
nanomaterial (3.8) intentionally produced for commercial purposes to have selected properties or composition

[SOURCE: ISO 80004-1:2023, 3.1.9, modified — "for commercial purposes" has been added to the definition.]

3.5
mixture
mixture composed of two or more substances in which they do not react

Note 1 to entry: A solution is a mixture as well.

[SOURCE: GHS, 2011[8]]

3.6
mobility
propensity for an *aerosol* (3.2) particle to move in response to an external influence, such as an electrostatic field, thermal field or by diffusion

[SOURCE: ISO/TR 27628:2007, 2.9[4], modified — the domain "<aerosols>" has been removed.]

3.7
nanofibre
nano-object with two similar external dimensions in the nanoscale and the third dimension significantly larger

Note 1 to entry: A nanofibre can be flexible or rigid.

Note 2 to entry: The two similar external dimensions are considered to differ in size by less than three times and the significantly larger external dimension is considered to differ from the other two by more than three times.

Note 3 to entry: The largest external dimension is not necessarily in the nanoscale.

[SOURCE: ISO 80004-1:2023, 3.3.5, modified — Notes 1 and 2 to entry have been added.]

3.8
nanomaterial
material with any external dimension in the nanoscale or having internal structure or surface structure in the nanoscale

Note 1 to entry: This generic term is inclusive of *nano-object* and nanostructured material.

Note 2 to entry: See also engineered nanomaterial, manufactured nanomaterial and incidental nanomaterial.

[SOURCE: ISO 80004-1:2023, 3.1.4, modified — Note 1 to entry has been replaced.]

3.9
nanoparticle
nano-object with all external dimensions in the nanoscale where the lengths of the longest and the shortest axes of the nano-object do not differ significantly

Note 1 to entry: If the dimensions differ significantly (typically by more than 3 times), terms such as *nanofibre* (3.7) or *nanoplate* may be preferred to the term nanoparticle.

Note 2 to entry: Ultrafine particles may be nanoparticles.

[SOURCE: ISO 80004-1:2023, 3.3.4, modified — "where the lengths of the longest and the shortest axes of the nano-object do not differ significantly" has been added to the definition and Note 2 to entry has been added.]

3.10
nanotube
hollow *nanofibre* (3.7)

[SOURCE: ISO 80004-1:2015, 3.3.8]

3.11
single-walled carbon nanotube
SWCNT
SWCNT single-walled carbon nanotube consisting of a single cylindrical graphene layer

Note 1 to entry: The structure can be visualized as a graphene sheet rolled into a cylindrical honeycomb structure.

3.12
multi-wall carbon nanotube
MWCNT
MWCNT multi-walled carbon nanotube composed of nested, concentric or near-concentric graphene sheets with interlayer distances similar to those of graphite

Note 1 to entry: The structure is normally considered to be many *single-walled carbon nanotubes* (3.11) nesting each other, and would be cylindrical for small diameters but tends to have a polygonal cross-section as the diameter increases.

3.13
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 definition applies to particle *nano-objects*.

[SOURCE: ISO 26824:2013, 3.1.1[5]]

3.14
poorly soluble particle
inhaled test particles that are likely to be retained in the lung

[SOURCE: OECD TG 412, paragraph 2[1]]

3.15
primary particle
original source particle of *agglomerates* or *aggregates* or mixtures of the two

Note 1 to entry: Constituent particles of agglomerates or aggregates at a certain actual state may be primary particles, but often the constituents are aggregates.

Note 2 to entry: Agglomerates and aggregates are also termed secondary particles.

[SOURCE: ISO 26824:2022, 3.1.4[5]]

3.16
secondary particle
particle formed through chemical reactions in the gas phase (gas to particle conversion)

[SOURCE: ISO/TR 27628:2007, 2.17[4]]

