



SLOVENSKI STANDARD
SIST-TS CEN ISO/TS 5387:2024

01-december-2024

Nanotehnologije - Merjenje mase nanomaterialov pri obremenitvi pljuč z nanomateriali za inhalacijske teste toksičnosti (ISO/TS 5387:2023)

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

Nanotechnologien - Messung der Massenbelastung der Lunge durch Nanomaterialien für Inhalationstoxizitätstests (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)

Ta slovenski standard je istoveten z: CEN ISO/TS 5387:2024

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TECHNICAL SPECIFICATION
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CEN ISO/TS 5387

September 2024

ICS 07.120

English Version

**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)

Nanotechnologien - Messung der Massenbelastung der
Lunge durch Nanomaterialien für
Inhalationstoxizitätstests (ISO/TS 5387:2023)

This Technical Specification (CEN/TS) was approved by CEN on 16 September 2024 for provisional application.

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European foreword

The text of ISO/TS 5387:2023 has been prepared by Technical Committee ISO/TC 229 "Nanotechnologies" of the International Organization for Standardization (ISO) and has been taken over as CEN ISO/TS 5387:2024 by Technical Committee CEN/TC 352 "Nanotechnologies" the secretariat of which is held by AFNOR.

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TECHNICAL SPECIFICATION

ISO/TS 5387

First edition
2023-10

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

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

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Foreword

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

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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].

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