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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

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**Nanotechnologies - Characterization of nanoparticles in
inhalation exposure chambers for inhalation toxicity testing**

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foreword

This document is in accordance with the provisions of GB/T 1:1-2020 "Guidelines for Standardization Work Part 1: Structure and Drafting Rules for Standardization Documents"

drafting:

This document is equivalent to ISO 10808:2010 "Characterization of Nanoparticles in Respiratory Exposure Chambers for Nanotechnology Inhalation Toxicity Studies":

Please note that some contents of this document may refer to patents: The issuing agency of this document assumes no responsibility for identifying patents:

This document was proposed by the Chinese Academy of Sciences:

This document is under the jurisdiction of the National Nanotechnology Standardization Technical Committee (SAC/TC279):

Introduction

Nanotechnology products containing silver, gold, carbon, zinc oxide, titanium dioxide, and silica nanoparticles are growing rapidly: With the product application range

With the expansion of the scope, the risk of people being exposed to nanoparticles is also gradually increasing, especially the practitioners in the nanotechnology industry are under the influence of nanoparticles:

exposed to risk: The public would also be at risk of nanoparticle exposure if nanoparticles were released from the product: Although toxicology

The toxicity of nanomaterials has been studied using instillation or perfusion methods in medicine and provides some important toxicological information, but it does not reflect

The actual situation of inhalation exposure, also did not provide the data required for inhalation exposure risk assessment: In addition, respiratory toxicology often uses rats as a

It is hoped that human-related experiments can be used to replace this animal experiment method [10]:

A concern in nanoparticle inhalation toxicology is ensuring the health of practitioners and consumers: For respiratory toxicity of nanoparticles

For scientific research, it is necessary to monitor the concentration, size and distribution characteristics of nano-sized particles in the breathing chamber: Monitoring of fine or coarse particles

Traditional methods, such as gravimetric methods, are not sufficient for nanoparticles, as nano-property parameters (e.g., particle surface area, particle number, etc.) may be critical determinants need to be monitored:

This document provides a series of methods for monitoring nanoparticles in the respiratory exposure chamber, including the Differential Migration Analysis System (DMAS), which is used for

Measure particle number, size, distribution, surface area and estimate mass concentration; also includes application of transmission electron microscopy (TEM) or scanning electron microscopy

Microscopy (SEM) was used for morphology characterization; chemical composition analysis was also included using X-ray energy dispersive spectroscopy (TEM-EDXA):

This document also includes traditional mass concentration monitoring and other physical and chemical property monitoring, which can be selected and used according to the needs of toxicological evaluation: this

These methods evaluate the surface area, mass concentration, particle distribution, composition, and dispersibility of nano-sized particles, providing a basis for inhalation toxicity test results:

Effective analytical means [13], [17], [18]:

Nanotechnology Inhalation Toxicity Study

Characterization of Nanoparticles in Respiratory Exposure Chambers

1 Scope

This document provides the characterization of respirable nanoparticles in the respiratory exposure chamber for inhalation toxicity studies, including particle mass, size distribution, number

concentration and composition:

2 Normative references

The contents of the following documents constitute the essential provisions of this document through normative references in the text: Among them, dated references

For documents, only the version corresponding to the date is applicable to this document; for undated reference documents, the latest version (including all amendments) is applicable to

this document:

ISO 10312 Determination of asbestos fibers in ambient air Direct transfer transmission electron microscopy (Ambientair-Determina-

ISO /T S27687 Terms and definitions for nanotechnology nanoobjects Nanoparticles, nanofibers and nanosheets (Nanotechn-

Note: GB/T 32269-2015 Terms and definitions of nanotechnology nano-objects Nanoparticles, nanofibers and nanosheets (ISO /T S27687:2008, IDT)

Note: GB/T 21605-2008 Test methods for acute inhalation toxicity of chemicals (OECD No:403:1981, OECD No:433:2002, MOD)

Note: GB/T 21754-2008 Chemical 28-day/14-day repeated dose inhalation toxicity test method (OECD No:412:2005, IDT)

Note: GB/T 21765-2008 Test method for subchronic inhalation toxicity of chemicals (OECD No:413:1981, IDT)

1) This guideline is published by the Organization for Economic Co-operation and Development (OECD):

3 Terms and Definitions

The following terms and definitions as defined in ISO 15900 and ISO /T S27687 apply to this document:

3:1 Particle measurement system

3:1:1

A classifier that can select the appropriate size of aerosol particles to enter and pass through the corresponding channel: