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**Nanotechnologies. Guidance on toxicological screening
methods for nanomaterials**

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Foreword

This guiding technical document was drafted in accordance with the rules given in GB/T 1.1-2009.

The translation method used in this guidance technical document is equivalent to the adoption of ISO /T R16197.2014 "Nanotechnology Manufacturing Nanomaterial Toxicology Screen

Preparation and description of selection methods.

The Chinese documents that have consistent correspondence with the normatively cited international documents in this guiding technical document are as follows.

---GB/T 30544.1-2014 Nanotechnology terminology Part 1.Core terminology (ISO /T S80004-1.2010, IDT)

This guiding technical document has made the following editorial changes.

--- Amend the standard name to "Nanotechnology and Nanomaterials Toxicology Screening Method Guide";

---Reorder the references.

This guiding technical document was proposed by the Chinese Academy of Sciences.

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

Drafting units of this guiding technical document. Institute of Basic Medicine, Chinese Academy of Medical Sciences, Peking University.

Introduction

This technical guidance document gives general rules for the toxicological screening of nanomaterials. These methods are suitable for the development of nanomaterials.

Before application of comprehensive toxicology testing, analysis and risk assessment. Toxicological screening methods focus on providing information and

tool. For example, this guidance technical document gives information on screening methods that can be used to screen nanomaterials to determine whether to continue

Continue to develop the nanomaterials or products containing the nanomaterials, whether to invest a lot of money to carry out comprehensive toxicology testing, or decide to continue

Have you set up appropriate controls before conducting nanomaterials research?

This guiding technical document and a series of effective test methods provided are compatible with the current testing, utilization and disposal of nanomaterials.

There is no conflict or/and competition between the regulatory requirements of management.

The information provided in this technical guidance document conforms to other international standards. For example, ISO /T R16196.2016 discussed in different media

The method of preparing toxicological test samples in quality; ISO 10993-18 specifically emphasizes the evaluation of the chemical characteristics of materials in medical devices;

ISO 14971 points out that toxicological risk analysis should consider the chemical

properties of the material; ISO /T R13014 discusses the properties of the material itself; ISO /T R13121 describes the process of distinguishing, evaluating and reporting the potential risks of nanomaterials, and provides layered nanomaterial toxicity testing guide.

nanotechnology

Guide to toxicological screening methods for nanomaterials

1 Scope

This technical guidance document provides methods suitable for in vitro and in vivo toxicology and ecotoxicology screening tests for nanomaterials. These parties

The method is helpful for the screening of nanomaterials toxicology including ecotoxicology. The toxicology screening test in this guidance technical document can be used for research and

Early determination of product development, quick feedback on its potential toxicology/safety risks, or preliminary evaluation. This guiding technique

Technical documents can be divided into toxicological screening methods related to human health and environment-related. Screening tests are relatively simple and inexpensive methods

The method is easy to carry out and can provide corresponding indications of whether nanomaterials have potential negative effects on humans and the environment.

This guiding technical document focuses on describing the preliminary screening methods applicable to toxicological evaluation. It is a supplement to other foreign standards and is compatible with other countries.

The relevant documents of international organizations such as OECD are not repeated. If the screening results suggest early indications of hazards, this guidance technical document will quote

Instruct the tester to refer to the documents of other organizations for a comprehensive toxicological evaluation or further comprehensive research.

2 Normative references

The following documents are indispensable for the application of this document. For dated reference documents, only the dated version applies to this document.

For undated references, the latest version (including all amendments) applies to this document.

GB/T 32269-2015 Terms and definitions of nanotechnology and nanoobjects Nanoparticles, nanofibers and nanosheets

ISO /T S80004-1 Nanotechnology terminology Part 1.Core terminology

3 Terms and definitions

The following terms and definitions defined in GB/T 32269-2015 and ISO /T S80004-1 apply to this document.

3.1

Aggregates

The aggregates, aggregates, or mixtures of weakly bound particles have an external surface area similar to the sum of the surface area of individual particles.

Note 1.The forces supporting the agglomerates are weak forces, such as van der Waals forces or simple physical entanglements.

Note 2.Agglomerates are also called secondary particles, while source particles are called primary particles.

[GB/T 32269-2015, definition 3.2]

3.2

Aggregates

The external surface area of new particles composed of strongly bound or fused particles may be significantly smaller than the sum of the surface areas of individual particles.

Note 1.The forces supporting the aggregates are strong forces, such as covalent bonds or derived from sintering or complex physical entanglement.

Note 2.Aggregates are also called secondary particles, while source particles are called primary particles.

[GB/T 32269-2015, definition 3.3]