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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 21759-2025

Replacing GB/T 21759-2008

Chemicals - Test method of chronic toxicity

化学品 慢性毒性试验方法

Issued on: August 29, 2025 **Implemented on: December 1, 2025**

Issued by: State Administration for Market Regulation;
Standardization Administration of the PRC

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Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part 1: Structure and Drafting Rules of Standardization Documents". Drafting.

This document replaces GB/T 21759-2008 "Test Methods for Chronic Toxicity of Chemicals". Compared with GB/T 21759-2008, except for the following.

Aside from structural adjustments and editorial changes, the main technical changes are as follows.

a) A new chapter on "Terms and Definitions" has been added (see Chapter 3);

b) Added general principles of the test methods (see 4.1) and test principles of the test methods (see 4.2);

c) The provisions regarding feeding conditions in the experimental methods have been changed (see 4.3.2, 2.2.4 of the 2008 version);

d) The requirements for animal preparation in the testing methods have been changed (see 4.3.3, 2.2.2 of the 2008 version);

e) The control group for the experimental method was removed (see 2.3.2 in the 2008 version), and the interim dissection of animals, satellite groups, and [other components] were added to the experimental method.

Regulations for sentinel animals (see 4.4.2);

f) The sections on exposure chambers (see 2.4.4.1 in the 2008 edition) and physical measurements (see 2.4.4.2 in the 2008 edition) in the test methods have been removed. Regulation;

g) Added provisions for observation, data, and data in reporting (see 5.2);

h) Some rules for test reports have been changed, with added detailed provisions (see 5.3, 3.3 in the 2008 edition).

Please note that some content in this document may involve patents. The issuing organization of this document assumes no responsibility for identifying patents.

This document was proposed and is under the jurisdiction of the National Technical Committee on Standardization of Hazardous Chemicals Management (SAC/TC251).

This document was drafted by: Shenzhen Customs Industrial Products Testing Technology Center and Ningbo Inspection and Quarantine Science and Technology Research Institute (Ningbo Inspection and Quarantine Trade Convenience Center).

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The release history of this document and the document it replaces is as follows.

- First published in 2008 as GB/T 21759-2008;

- This is the first revision.

Introduction

Since its implementation in 2008, GB/T 21759-2008 has seen advancements in science and technology, updates in assessment methods, and a greater focus on animal welfare.

With increasing emphasis on animal welfare, revisions are necessary to ensure compliance with the latest animal welfare and management regulations. This revision aims to further...

This document comprehensively collects animal testing data and provides more detailed guidance on dosage selection. It is widely applicable to various chemicals, including pesticides and industrial products. Study matter.

Chronic toxicity tests mostly use rodents, and this document also primarily uses such

animals. If the test requires the use of non-rodent animals...

For items, the principles and procedures described in this document, as well as GB/T 21778, are also applied with appropriate adjustments.

Chronic toxicity testing primarily involves three routes of exposure. oral, dermal, and inhalation. The specific route chosen depends on the physicochemical properties of the test substance.

The main routes of exposure for sexual and reproductive populations. This document focuses on the oral route, as it is the most commonly used route in chronic toxicity studies. Although in some...

Under regulatory frameworks, transdermal and inhalation routes are considered essential for assessing human health risks; however, due to their high technical complexity, related research...

It needs to be done according to the specific circumstances. The oral chronic toxicity assessment methods described in this document can provide a basis for dermal and inhalation route studies, such as...

Treatment cycle, clinical and pathological parameters, etc.

Chronic toxicity studies investigate the potential health hazards that may occur in selected test animals after prolonged and repeated exposure to a drug, providing the test substance.

Toxicity effect information, identification of target organs and the likelihood of bioaccumulation, and estimation of the no-visible-adverse-effects dose level (NOAEL) for use in...

Establish safety baselines for human exposure. This document also emphasizes thorough clinical observation of laboratory animals to obtain as much information as possible.

1 Scope

This document describes the test methods for chronic toxicity testing of chemicals and specifies the requirements for data and reporting content.

This document applies to chronic toxicity testing of chemicals.

2 Normative references

GB/T 21753

GB/T 21754

GB/T 21765

GB/T 21778

3 Terms and Definitions

The following terms and definitions apply to this document.

3.1 adverse effects

Adverse changes in the morphology, physiology, growth, development, reproduction, or lifespan of an organism, system, or (sub)population.

Note. These changes can lead to impaired function, reduced ability to cope with additional stress, or increased sensitivity to other influences.

3.2 dose

The amount of test substance administered to laboratory animals.

Note. It is expressed in grams (g) or milligrams (mg), or in the mass of the test substance received by the experimental animal per unit body weight, such as mg/kg.

3.3 The lowest-observed-adverse-effect level (LOAEL)

The minimum effective dose of a test substance that causes adverse effects on the morphology, function, growth and development of experimental animals under specified conditions.

3.4 Chronic toxicity

Adverse effects resulting from ingestion, inhalation, skin contact or injection of a test substance after an exposure period of 12 months or longer.

3.5 Point of departure (POD)

The dose-response curve marks the starting point for low-dose extrapolation.

Note. This is usually the upper limit of the observed incidence rate or the incidence rate estimated by a dose-response model.

3.6

The specific way in which the test substance enters the organism.

Note. Examples include oral administration via gavage, oral administration via food, skin contact, inhalation, and intravenous injection.

3.7 No-observed-adverse-effect-level (NOAEL)