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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 21763-2025

Replacing GB/T 21763-2008

ChemicalsTest method of repeated dose oral toxicity study in rodents

化学品 啮齿类动物亚慢性经口毒性试验方法

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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 supersedes GB/T 21763-2008 "Test Methods for Subchronic Oral Toxicity of Chemicals in Rodents" and is consistent with GB/T 21763-2008. In comparison, aside from structural adjustments and editorial changes, the main technical changes are as follows:

---The "Housing Conditions" section has been modified (see 6.1.2,

4.1.2 from the.2008 version);

---The "Clinical Observation" section has been revised, adding a "Hematological and Clinical Biochemistry Examination" section, and adding endpoints sensitive to endocrine disorders. See section 7.7,

4.6 of the.2008 edition;

---The content of "Pathological Examination" has been revised, and a section on "Pathology of Sexual Organs" has been added (see 7.8,

4.8 in the.2008 edition);

---The "Experimental Data and Reports" section has been revised, primarily focusing on the "Results Evaluation" and "Experimental Report" sections (see Chapter 8,.2008 edition). Chapter 5). 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: Institute of Occupational Health and Poison Control, Chinese Center for Disease Control and Prevention; Shanxi Medical University; and Fujian Ningjiajun Testing. Technical service company. The main drafters of this document are. Chen Xiao, Li Bin, Zhang Hongmei, Zhang Linyuan, Zhang Yi, Xiao Jingwei, Yu Tao, Niu Yong, and Chen Wenting. The release history of this document and the document it replaces is as follows:

---First published in.2008 as GB/T 21763-2008;

---This is the first revision.

In the process of evaluating the toxicity characteristics of chemicals, preliminary toxicity information is obtained through acute toxicity tests or 28-day oral subacute toxicity tests. Subsequently, a subchronic oral toxicity test was conducted. Because the exposure period in this test was extended from 28 days to 90 days, this extension period could cover the animal's recovery period. The post-milk maturation and growth phase transitions into adulthood, thus providing information on potential health hazards during this extended period. This document provides... Information includes major toxic effects, identification of target organs and potential for accumulation, and estimates of the level of unobserved damage. This value can be used as a basis for selecting dose levels in chronic toxicity studies, as well as for establishing safety benchmarks for human exposure. This document further emphasizes endocrine endpoints and integrates them with existing sensitivity studies of neurological, immune, and reproductive effects. In addition, special emphasis is placed on careful observation of animal toxicity to obtain as much information as possible. This document can reveal the potential neurotoxicity of the test chemical. Toxicity, immune, and reproductive organ toxicity effects, in order to provide a basis for further in-depth research. Subchronic oral toxicity of chemicals in rodents Test methods

1 Scope

GB/T 21763-2025 is the Chinese national standard on chemicalstest method of repeated dose oral toxicity study in rodents, in the field of environment and health protection, safety. The /T suffix marks it as a recommended standard: it is not compulsory by itself, but it becomes binding as soon as a contract, a tender or a customer specification calls it up - which in practice is how most foreign buyers meet it. It was issued on 5 October 2025 by the State Administration for Market Regulation; Standardization Administration of China, and has been in force since 1 February 2026. Classification: ICS 13.300, CCS A80. This page is published from the official record of the standard held by the Chinese standards administration: the identification, the dates, the classification and the issuing body are taken from there. The clause text, the tables and the numeric limits are in the document itself, which is delivered complete in English translation.

This document specifies the basic principles, methods, and procedures for testing the subchronic oral toxicity of chemicals in rodents. Experimental data and reports. This document applies to the subchronic oral toxicity testing of chemicals.

2 Normative references

The contents of the following documents, through normative references within the text, constitute essential provisions of this document. Dated citations are not included. For

references to documents, only the version corresponding to that date applies to this document; for undated references, the latest version (including all amendments) applies. This document.

GB 14925 Laboratory Animal Environment and Facilities

3 Terms and Definitions

The following terms and definitions apply to this document.

3.1 dose The amount of the test substance.

Note. The amount of test substance administered per unit body weight of the animal is usually expressed as mass or quantity. It can also be used when the test substance is mixed into feed for poisoning. It is expressed as a constant mass fraction in feed.

3.2 Dosage A general term consisting of the dose, frequency and duration of exposure.

3.3 No-observed-adverse-effect level (NOAEL) No maximum dose was found to be associated with adverse effects from exposure.

3.4 obvious toxicity Significant signs of toxicity appearing after administration of the test substance.

Note. These signs are sufficient for hazard assessment; as the dose increases, they can lead to severe toxic symptoms and death.

3.5 androgenicity The ability of a chemical substance to function in mammals like a natural androgen (such as testosterone).

3.6 Antiandrogenicity The ability of a chemical substance to suppress the effects of natural androgens (such as testosterone) in mammals.