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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 21771-2025

Replacing GB/T 21771-2008

Chemicals - Test method of combined repeated dose toxicity study with the reproductiondevelopmental toxicity screening

化学品 重复剂量毒性合并生殖/发育毒性筛选试验方法

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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 21771-2008 "Screening Test Methods for Repeated Dose Toxicity of Chemicals Combined with Reproductive/Developmental Toxicity". Compared with GB/T 21771-2008, apart from structural adjustments and editorial changes, the main technical changes are as follows:

---The trial period has been changed (see Chapter 4, Chapter 3 of the.2008 edition);

---The experimental methods have been modified, with the addition of "estrous cycle" to screen for female animals with regular estrous cycles; "nest" has also been added. The content regarding "number of pups" has been revised, including adjustments to litter size and assessment of pup endocrine-related indicators; the detection of thyroid hormone levels has been added (see [link]). Chapter 5 (Chapter 4 in the.2008 edition);

---The content on data statistical methods has been revised (see Chapter 6, Chapter 5 of the.2008 edition);

---Added "Thyroid hormone levels", "Number of adult females with normal or abnormal estrous cycles and cycle duration", and "Livestock weight". "Data", "AGD of all pups and weight on the day of AGD measurement", "nipple assessment of male pups" (see 6.3). 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; Hebei Medical University; and Fujian Ningjiajun Testing. Technical service company. The main drafters of this document are. Zhang Rong, Pang Yaxian, Liu Qingping, Bao Lei, Li Bin, Chen Xiao, Bian Hongying, Yu Changyan, and Lin Liwei. The release history of this document and the document it replaces is as follows:

---First published in.2008 as GB/T 21771-2008;

---This is the first revision.

In the evaluation of the toxic characteristics of chemicals, repeated-dose toxicity testing is usually conducted after an acute oral toxicity test. This document provides information on the potential health risks associated with repeated doses of the drug over a limited period of time. For studies not yet approved for 90-day trials... For chemicals under investigation, this document provides basic toxicity data after repeated doses of exposure, which can be used as a pre-test for long-term studies. This document includes reproductive/developmental toxicity screening tests, providing preliminary information on the potential impact of the test substance on male and female reproductive capacity (such as gonads). This document contains data on (function, mating behavior, pregnancy, fetal and pup development). It is applicable to both early risk assessment and severe cases. Chemicals of concern. This document does not provide complete information on all aspects of reproduction/development, but only provides limited means of detecting prenatal [chemicals/chemicals]. Postpartum manifestations of exposure, or effects that may be induced during postpartum exposure. Due to (among other reasons) the relatively small number of animals in the dose group, Due to the choice of endpoints and the short study period, this document cannot be used as conclusive evidence for determining the absence of reproductive/developmental toxicity. Furthermore, if... Lacking data on other reproductive/developmental toxicity tests, a positive result can be used for preliminary risk assessment and help determine whether further testing is needed. And the testing schedule. This document provides data on adverse effects on endocrine-related endpoints, but is insufficient to determine whether a test chemical is an endocrine disruptor. Further evidence is available. In addition, this document may provide information on neurotoxicity. In the absence of data on reproductive/developmental toxicity, endocrine toxicity, and neurotoxicity, positive results can be used for preliminary risk assessment. It helps determine whether additional testing is needed and when to schedule it, for assessing the toxicity of existing chemicals (especially when relevant toxicological information is available). (When rare or absent), and can be used as an alternative to avoid conducting two separate trials. repeated-dose toxicity studies and reproductive/developmental toxicity studies. This document is also applicable to exploring dosage ranges for more comprehensive reproductive/developmental toxicity studies, or in other relevant scenarios. It is generally believed that pregnant and non-pregnant animals have different sensitivities to test substances. This differs from conducting repeated-dose toxicity tests alone. Determining the dose level in combination studies is more complex than in reproductive/developmental toxicity studies, requiring consideration of both general toxicity assessments and reproductive/developmental toxicity. The need for evaluation. Furthermore, because serological and histopathological markers may not be assessed simultaneously during the trial, the impact on general toxicity-related results... The interpretation of these studies may be more challenging than that of independent repeated-dose toxicity tests. Given the aforementioned technical complexity, conducting

such tests requires extensive experience in toxicology. Sexual testing experience. On the other hand, besides requiring a smaller number of animals, combination tests are effective in distinguishing between direct reproductive/developmental toxicity and indirect toxicity. It may have an advantage in terms of sexual effects. This document describes a longer exposure period than the standard 28-day repeated-dose trial. However, it is comparable to conducting a standard 28-day repeated-dose trial and reproductive/spinal tract infection trials simultaneously. Compared to animal toxicity tests, its advantage lies in the smaller amount used in animals. This document describes the oral route of exposure. If other routes of exposure are used, modifications are required. Repeated dose toxicity of chemicals combined with reproductive/developmental factors Toxicity screening test methods

1 Scope

GB/T 21771-2025 is the Chinese national standard on chemicals - test method of combined repeated dose toxicity study with the reproductiondevelopmental toxicity screening, 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 and methods for screening chemical repeated-dose toxicity combined with reproductive/growth and developmental toxicity. Experimental data and reports. This document is applicable to the testing of repeated dose toxicity and teratogenicity of chemicals, screening for reproductive and growth-development toxicity, and is also applicable to teratogenicity testing. Preliminary tests of reproductive toxicity in the first and second generations.

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, Definitions and Abbreviations

3.1 Terms and Definitions The following terms and definitions apply to this document.

3.1.1 androgenicity A chemical substance has the ability to exhibit physiological effects similar to natural androgens (such as testosterone) in mammals.

3.1.2 estrogenicity A chemical substance has the ability to exhibit similar effects to natural estrogens (such as estradiol 17beta) in mammals.

3.1.3 Antiestrogenicity The ability of a chemical substance to inhibit the effects of natural estrogens (such as estradiol 17beta) in mammals.

3.1.4 thyroid activity A chemical substance has the ability to behave like a natural thyroid hormone (such as triiodothyronine, T3) in mammals.

3.1.5 Antithyroid activity A chemical substance inhibits the action of natural thyroid hormones (such as T3) in mammals, affecting metabolism and thyroid dependence. Other physiological processes of hormones.

3.1.6 Structural (organismic defects) or functional abnormalities exhibited by offspring before birth, during the perinatal period, and after birth.