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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 21788-2025

Replacing GB/T 21788-2008

Chemicals - Test method of combined chronic toxicity/carcinogenicity study

化学品 慢性毒性与致癌性联合试验方法

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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 21788-2008 "Combined Test Methods for Chronic Toxicity and Carcinogenicity of Chemicals", and is consistent with GB/T 21788- Compared to 2008, aside from structural adjustments and editorial changes, the main technical changes are as follows.

- The "Animal Selection" section has been revised, including animal selection, animal preparation, animal quantity, and sex (see 5.3.1, 2008 version). 3.3.1);

- The husbandry conditions have been modified (see 5.3.2, version 3.3.2 from 2008);

- The "Animal Quantity and Sex" section has been modified (see 5.3.4, version 3.3.4 from 2008).

- The "Dose Level" section has been revised, adding "Key Considerations for Dosage

Selection," "Solvent Selection," and "Test Substance Concentration" (see...).

5.4 (3.4 in the 2008 edition);

- The "Route of Exposure" section has been revised (see 5.6, 3.6 in the 2008 version);

- The "Exposure Cycle" section has been modified (see 5.7, 3.7 in the 2008 version);

- The "Observation" section has been revised, and two new chapters, "Chronic Toxicity Testing" and "Carcinogenicity Testing," have been added (see sections 5.8 and 5.9, 2008 edition). 3.8);

- The content regarding clinical observation, weight, and food intake has been revised, and water intake has been added (see 5.8.1 and 5.8.2, 3.8.1 in the 2008 edition). 3.8.2 and 3.8.3);

- The content of hematological and clinical biochemistry examinations has been revised, with detailed regulations on testing time, number of animals, and testing indicators (see...).

Versions 5.8.3 and 5.8.4, and versions 3.9 and 3.11 (2008 editions)

- The content of "Gross Autopsy" and "Histopathological Examination" has been revised; the organs for histopathological examination have been updated, specifying that paired organs must be examined in pairs.

Both sides should be saved for inspection (see 5.8.6 and 5.8.7, 3.12.1 and 3.12.2 in the 2008 edition);

- The "Data and Reporting" section has been revised, providing detailed specifications for test substances, solvents, laboratory animals, experimental conditions, results, and discussions (see section [number]).

Chapter 6 (Chapter 4 of 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. the Institute of Occupational Health and Poison Control, Chinese Center for Disease Control and Prevention; and the Shandong Provincial Institute of Occupational Health and Occupational Disease Prevention and Control.

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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 21788-2008;

- This is the first revision.

Introduction

The combined chronic toxicity and carcinogenicity test involves repeated exposure of laboratory animals to the test substance over a period of time during their normal lifespan to detect the potential for carcinogenicity in the body.

Information on potential health hazards, including toxicity of the test substance, carcinogenicity, target organs, accumulation, and doses at which no adverse effects were observed.

Levels (NOAEL), etc. For non-genotoxic carcinogens, these can be used to establish safety standards for human exposure.

This testing guide is used for testing a wide range of chemicals, including pesticides and industrial chemicals, primarily applicable to rodents. Non-rodents...

Animals should be appropriately modified, or refer to OECD DTG 409 and OECD guidance document No. 116.Test substances are typically administered orally or dermally.

For drug administration via inhalation, the choice of route of administration depends on the physicochemical properties of the test substance and the main routes of human exposure. This document focuses on the most...

Commonly used routes of oral exposure. For inhalation exposure, refer to OEC DTG 412, OEC DTG 413, and guidelines for acute inhalation-related exposure.

OECD guidance document; for exposure via skin, refer to OECD TTG 410.

The experimental design includes two parallel parts. a chronic toxicity study and a carcinogenicity study. The objectives of these studies include.

a) Identification based on increased tumor incidence, elevated proportion of malignant tumors, and shortened time to tumor onset, compared with the control group.

Carcinogenicity of the test substance;

b) Determine the time of tumor appearance;

c) Identify the chronic toxicity of the test substance;

d) Identify target organs for chronic toxicity and carcinogenicity;

e) Determine the dose-response relationship;

f) Determine the NOAEL or starting point to establish a baseline dose (BMD);

g) Extrapolating carcinogenic effects to low-dose exposure populations;

h) Predict chronic toxicity at human exposure levels;

i) To provide data for testing hypotheses about the mechanism of action of the test substance.

A combined chronic toxicity and carcinogenicity study was conducted, rather than separate chronic toxicity and carcinogenicity studies. The combined study is superior to two separate studies.

This method is more efficient in terms of both time and cost, while ensuring the quality of experimental data. Dosage selection should be considered when conducting the experiment.

The principle is to conduct separate experiments in special circumstances.

1 Scope

This document specifies the basic principles, test methods, data, and reporting for combined testing of chronic toxicity and carcinogenicity of chemicals.

This document applies to the testing of the chronic toxicity and carcinogenicity of chemicals.

2 Normative references

GB 14925

3 Terms and Definitions

The following terms and definitions apply to this document.

3.1 Chronic toxicity

The health damage effects caused by repeated exposure of animals to the test substance for most of their normal life cycle.

3.2 target organ

The organ in which the test substance causes a significant toxic effect on the body.

3.3 5 Test Methods

Under specified test conditions, using existing technical means and detection indicators, the test substance for which no harmful effects related to poisoning were observed was the least likely to be found. High doses or concentrations.