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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 21610-2025

Replacing GB/T 21610-2008

Chemicals - Test method of rodent dominant lethal

化学品 啮齿类动物显性致死试验方法

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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 21610-2008 "Test Methods for Overt Lethality of Chemicals in Rodents" and is consistent with GB/T 21610-2008.

In comparison, aside from structural adjustments and editorial changes, the main technical changes are as follows.

a) The basic principles of the experiment have been changed (see Chapter 4, Chapter 5 in the 2008 edition);

b) The requirements for laboratory animals have been changed (see 5.1.1, 6.3.1 in the 2008 edition);

c) The positive control and its dosage were changed (see 5.1.3, 6.2.3 of the 2008 edition);

d) The requirements and instructions regarding the period of exposure and mating interval have been revised (see 5.2.1, 6.5.1.4 and 6.5.2 in the 2008 version);

e) The limiting dose level used for the test substance has been changed (see 5.2.2, 6.4.2 of the 2008 edition);

f) The requirements for the method of administration have been changed; the test substance should not be administered via intraperitoneal injection (see 5.2.3, 6.5.1.2 of the 2008 version);

g) Measurements of animal body weight, feed consumption, and drinking water consumption have been added (see 5.2.4);

h) Added calculation formulas for preimplantation loss rate, postimplantation mortality rate, stillbirth rate, and dominant lethality index (see 6.2);

i) Increased the acceptable criteria for the trials (see 6.3);

j) The evaluation and interpretation of results have been revised (see 6.4, 6.6.3 of the 2008 edition, and Chapter 8);

k) The content that should be included in the test report has been changed (see 6.5, Chapter 7 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: Institute of Occupational Health and Poison Control, Chinese Center for Disease Control and Prevention; and CCIC (Tianjin) Inspection and Testing Co., Ltd. Ren Company.

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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 21610-2008;

- This is the first revision.

Introduction

The purpose of dominant lethality tests is to investigate whether chemical substances cause chromosomal damage in male germ cells, and can be used to further confirm the presence of certain substances.

Positive results obtained from external testing or other testing systems can also predict the

harm and risk of germline-transmitted genetic diseases. This document...

This test method can simultaneously examine the genotoxicity, developmental toxicity, or reproductive toxicity of the test substance, but this test method consumes a relatively large number of animals.

It is relatively expensive and time-consuming. Furthermore, because the spontaneous frequency of dominant lethal mutations is quite high, this document [is necessary] when the mutation detection frequency increases slightly.

The sensitivity of the test methods is relatively limited. Therefore, the test methods recommended in this document are intended as a supplementary test method, in the absence of other regulatory requirements. Use when needed.

1 Scope

This document establishes the basic principles of dominant lethality testing in rodents, describes the testing methods, and specifies the testing data and reporting procedures. Content requirements.

This document applies to tests used to detect damage to chromosomes in male reproductive cells of rodents caused by chemicals.

2 Normative references

GB 14925

3 Terms and Definitions

The following terms and definitions apply to this document.

3.1 corpora luteum

Hormone secretion structures that further develop after ovulation from a mature follicle.

Note. The number of corpora lutea in the ovary corresponds to the number of ovulations.

3.2

Variations that occur in spermatogenic cells, do not cause ligand dysfunction but cause death of fertilized eggs or developing embryos.

3.3 fertility rate

The percentage of pregnant mice in the total number of mating female mice.

3.4 mating interval

The time period between the end of drug treatment and mating in the males of the treatment group.

Note. Different intervals can assess the effect of the test substance on different germ cell types. For example, in mice, the effects can be assessed at mating intervals of 1, 2, 3, 4, 5, 6, 7, and 8 weeks.

For sperm, condensed spermatids, round spermatids, pachytene spermatocytes, early spermatocytes, differentiated spermatogonia, and differentiating spermatogonia.

And the effects on stem cells and spermatogonia.

3.5 Preimplantation loss

The difference between the number of implantations and the number of corpus luteum.

3.6 Postimplantation loss

The difference between the number of stillbirths and the number of implantations.

4 Basic Principles of the Experiment

Male animals were exposed to the test substance via an appropriate route of exposure, and then mated with unexposed and unmated female animals.

After completion, the female animal was removed. The female animal was euthanized in the second half of pregnancy, and the abdominal cavity was opened to remove the uterus and ovaries for examination of the number of corpora lutea and implantation sites.

The number of stillbirths and live births were used to calculate parameters such as conception rate, pre-implantation loss rate, and post-implantation mortality rate. Male animals then mated again at certain intervals.

Another group of untreated and unmated female animals were mated. The specific exposure period and mating interval were determined based on the different experimental objectives.

5.1.1 Laboratory Animals

Mice are preferred, followed by rats. Reasons should be given for using other mammal species. Healthy, sexually mature animals should be selected.

After purchase, experimental animals should be allowed to acclimatize for at least 5 days, and the rearing environment should comply with the requirements of GB 14925.Non-invasive or minimally invasive methods should be used for the treatment of