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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 21826-2025

Replacing GB/T 21826-2008

Chemicals - Test method of acute oral toxicity - Up-and-down procedure (UDP)

化学品 急性经口毒性试验方法 上下增减剂量法（UDP）

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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 21826-2008 "Acute Oral Toxicity Test Methods for Chemicals - Dosage Increase/Decrease Method (UDP)".

Compared with GB/T 21826-2008, apart from structural adjustments and editorial changes, the main technical changes are as follows.

a) The requirements for animal selection have been changed (see 5.1.1.1, 2008 version 5.1.1.1);

b) The husbandry conditions have been changed (see 5.1.2, 2008 version 5.1.2);

c) The classification requirements for the 2000 mg/kg dose have been changed (see Appendix A, Appendix C 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: Shenzhen Customs Industrial Products Testing Technology Center and Ningbo Inspection and Quarantine Science and Technology Research Institute (Ningbo International 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 21826-2008;

- This is the first revision.

Introduction

The up-and-down dosing method was first proposed by Dixon and Mood. In 1985, Bruce suggested using the up-and-down dosing method (UDP).

The experimental design for estimating LD50 using the incremental dosing method for determining the acute toxicity of chemicals has undergone several revisions. This document is based on Bruce's work.

Materials (ASTM) adopted it and revised it in 1990.In 1995, it was published using UDP, the conventional LD50 test method, and...

The results of studies using three methods in the fixed-dose method. Starting with the early papers by Dixon and Mood, many studies have used these methods to obtain results.

Research on component optimization has appeared in biological and applied papers. Several expert meetings held in 1999 gave the following recommendations regarding this method.

In fact, a consensus has been reached on the unified use of LD50 for classifying chemicals; it is generally believed that the sex of model organisms (usually) It is sufficient to test females; to make the estimates more meaningful, confidence intervals (CIs) need to be estimated.

Acute oral toxicity test methods for chemicals Dosage adjustment method (UDP)

1 Scope

This document describes the dosing-up-down method (UDP) for acute oral toxicity testing of chemicals.

This document applies to the use of UDP for testing the acute oral toxicity of chemicals. This method is more suitable for use within one or two days after exposure.

The substance that causes death.

This document does not apply to substances that may significantly delay the expected time to death (5 days or more) after exposure.

2 Normative references

This document has no normative references.

3 Terms and Definitions

The following terms and definitions apply to this document.

3.1 dose

The amount of test substance administered to laboratory animals.

Note. Expressed in mass (g or mg), or in the mass of test substance received by the test animal per unit body weight (e.g., mg/kg).

3.2

When an animal survives, the dose for the next animal is increased by a factor of (i.e., the dose order); or when an animal dies, the dose for the next animal is increased by a factor of (i.e., the dose order).

The divisor for dose reduction.

Note. Also known as the dose interval factor. The recommended dose order factor is 1/(the

antinominal of the estimated slope of the dose-response curve). The default dose order factor is...

3.2, which is 0.5 or 1/2 of the antinomies.

3.3 Limit dose

The upper limit of the dose to be administered for the test substance. Note..2000mg/kg or 5000mg/kg.

3.4 Nominal sample size

The total number of experimental animals is determined by subtracting a certain number of animals from the total number of animals according to one of the following rules.

- Minus the number of test animals preceding the last animal that showed the same response at the beginning of the toxication sequence;

- Minus the number of test animals before the first pair of animals that underwent reversal.

The actual number of animals tested was 8, and the nominal number of experimental animals was 6.

Note. In this example, there are 4 animals after the reversal. Note that in other sections of this document, "number" refers to the nominal number of experimental animals or the experimental animal population. Total number of items.

Example 2.The maximum number of experimental animals is 15.When the experiment is terminated at the maximum number of experimental animals, the nominal number of experimental animals will be less than or equal to 15.

The number of animals tested starts from the (r-1)th animal (the one before the second animal that produces the reversal pair, see 3.5).