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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB/T 27823-2011

**Chemicals -- Test method of acute dermal toxicity -- Fixed dose
procedure**

化学品 急性经皮毒性 固定剂量试验方法

(English Translation)

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2.1 Terms and Definitions

Foreword

This standard was drafted in accordance with GB/T 1.1-2009 given rules.

The Standards and Organisation for Economic Co-operation and Development (OECD) chemical testing methods No.434 (2004) "fixed dose acute dermal toxicity Law "(in English) The content of the technical.

This standard configuration and do the following editorial changes.

- Increasing the range chapter (see Chapter 1);
- Change the unit of measure of legal units of measurement;
- The OECD434 Appendix 1, "Definitions" as Chapter 2 of this standard;
- The OECD434 "before the test should be considered the" introduction into this standard.

This standard is managed by the National Standardization Technical Committee chemicals dangerous (SAC/TC251) and focal points.

This standard was drafted. Chinese Center for Disease Prevention and Control of Occupational Health and Poison Control, Tianjin Exit Inspection and Quarantine, in China Technology Development Center Industry Economy, Jiangsu CIQ.

Introduction

According to the scientific development and animal welfare requirements, the need for periodic testing of chemicals OECD guidelines for review visits. acute Dermal toxicity Guide TG402 [1] was adopted in 1987. In the revised acute oral toxicity test fixed dose method (FDP) (OECD420 [2]) after the start of use, and in December 2001 began after the abolition OECD Guideline 401, proposed fixed dose acute percutaneous Law (FDP) is appropriate. The main method is to use several fixed-dose exposure, the use of single-sex animal (generally use a female) to Detection of acute dermal toxicity.

Traditional methods in the evaluation of acute toxicity often with death as the only animal toxicity endpoints. In 1984, the British made a toxicology New acute toxicity test items, that is, choose a fixed dose of the test substance exposure [3]. This method avoids the animal death as a final observation Point, but in a few fixed-dose dose of obvious symptoms of end point, this is also a test dose toxicity stars Level basis. This test also using the above method. OECD guidelines in order to achieve the end point of the humanitarian requirements [4], it is recommended to test side Optimization method so that animal suffering is minimized as much as possible to reduce the use of animals. FDP test statistical rationality has been Mathematical models were evaluated [5].

This method provides information on hazardous properties of the test substance. For can cause acute toxicity of the test substance, according to the results of this test, press Global harmonized classification and labeling of chemicals according to the United Nations (GHS) for the test substance toxicity grading and classification [6].

All information should be considered prior to the test subjects was obtained, such as the name of the test substance, chemical structure, physical and chemical properties, and any other body Within or in vitro toxicity tests, quantitative - structure activity relationship (Quantitativestructure-activityrelationship, QSAR) data, Structurally similar chemical toxicological data, the intended use of the test substance and the possible extent of human exposure to the test substance. With the above information, the election Choose a suitable initial dose tested.

Acute dermal toxicity of chemicals Fixed-dose test methods

1 Scope

This standard specifies the terms, definitions and abbreviations, principles of testing, test methods chemicals fixed dose acute dermal toxicity test method, Test data and reports.

This standard applies to fixed-dose dermal toxicity test method chemicals.

2 Terms, definitions and abbreviations

The following terms, definitions and abbreviations apply to this document.

2.1 Terms and Definitions

2.1.1

Acute dermal toxicity the harmful effects of the test substance in a short time (24h or less) disposable percutaneous exposure generated.

2.1.2

Significant toxicity evidenttoxicity Significant toxicity manifestations animals after exposure,

if using higher fixed concentration exposure, most of the animals are expected to be significant pain Suffering, and even death near-death state.

2.1.3

Dose dose

The dose of the test substance. Test expressed as a volume per body weight given test animals (e.g., mg/kg).

2.1.4

Moribund impending death A manifestation of animals dead or moribund before appearing. Performance rodent approach of death include convulsions, lateral, recumbency and tremors.

2.1.5

Median lethal dose LD₅₀ the oral administration of disposable substance causing 50% of the dose animal deaths occurred. LD₅₀ value of the test substance with the amount of weight of test animal unit (Mg/kg) Fig. Statistical derivatives.

2.1.6

Limit dose the upper limit of the test dose (2000mg/kg or 5000mg/kg).

2.1.7

Moribund status Even in the case of treatment given, the animals are still dying or unable to survive the state.

2.1.8

Foreseeable death predictable death the clinical manifestations of certain animals prompted the end of the test at some time prior to death, for example, loss of drinking water and eating