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

GB/T 21778-2008

**Chemicals -- Test method of repeated dose 90-day oral toxicity
in non-rodents**

化学品 非啮齿类动物亚慢性（90天）经口毒性试验方法
(English Translation)

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Foreword

This standard is identical with the Organisation for Economic Co-operation and Development (OECD) Chemical Test Method No. 409 (1998), "Non-rodent chemicals Animals sub-chronic (90 days) oral toxicity test method has been "(in English).

This standard made the following editorial changes.

- Press on the text format GB/T 1.1-2000 made editorial changes;
- Increase "OECD Introduction" section;
- To increase the "scope" chapter;
- OECD Chemical Test Method No. 409 Appendix (definitions) section included in the standard Chapter 2, "Terms and Definitions";
- OECD Chemical Test Method No. Tests Notices section 409 included in the standard "OECD Introduction" of;
- Remove the OECD Chemical Test Method No. "References" section 409.

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

Introduction

Organisation for Economic Co-operation and Development (OECD) guidelines for testing of chemicals on the development of science periodic review. Original Guide 409 1981 adopted the revised edition of the purpose is to get more information from the test animals.

This revised edition of the guide 409 is largely based on sub-chronic and slow on November 1995 2 to 3 days OECD held in Rome an expert consultation meeting of toxicity tests concluded.

Test Conditions

After the chemical characterization and toxicity evaluation, should from acute or repeated exposure to 28 days to obtain preliminary toxicity test toxicity data only Repeated exposure can be sub-chronic oral toxicity test. 90-day study provides from fast growing to maturity due to repeated exposure by Health test substance which may cause hazard information. The main toxicity study available information, target organ toxicity and potential for accumulation Use, and can estimate the harmful effect levels were not observed. The levels can be used to select the chronic toxicity test dose level of violence and the establishment of the human body Lu safety standards.

Revised guidelines take into account the chemical exposure identification of non-rodent damage in animals, the guide only for.

--- In other studies observed injury, we need another non-rodents further verification/identification, or

--- Kinetics of drug-generation shows that a specific non-rodent animals is most appropriate, or

--- Other specific reasons indicate the need to use non-rodent.

Non-rodent chemicals sub-chronic (90 days) Oral Toxicity Test Methods

1 Scope

This standard specifies the chemical non-rodent sub-chronic (90 days) oral toxicity test method scope, terms and definitions, the original test Then, test methods, data and reports.

This standard applies to non-rodent chemicals sub-chronic (90 days) oral toxicity test.

2 Terms and definitions

The following terms and definitions apply to this standard.

It refers to the amount of test substance administered. Dose mass (g, mg) or test substance using the mass per mass of experimental animals (i.e., mg/kg), in food or a constant test substance concentration (mg/kg) Fig.

It is a generic term, including dose, frequency and time.

It refers not observed any toxic effects of the highest dose level.

3 Test principle

Each dose each with a group of animals with daily oral administration of the test substance, a total of 90 days. During exposure, close observation of animal poisoning shape. During the trial, death or the need for an autopsy of animals sacrificed at the end of the test,

surviving animals should be sacrificed and body Anatomy.

Test Method 4

4.1.1 Selection of experimental animals

Commonly used non-rodent animals are dogs, dogs need a test to determine the strain, Beagles are commonly used strain. You can also choose which test His species of animals, such as. pigs, miniature pigs. Primates are not recommended, if the choice of test primates, need to explain the reason. should the selection of young adults, healthy animals. If you use dogs, exposure should begin at 4 months to 6 months, no more than 9 months. As will be present again Experience as a pre-test and chronic toxicity test, the two tests should be used in the same species, the same strain of animals.

4.1.2 Feeding Conditions

Conventional animal diet, no restrictions on drinking water. If the test substance incorporated in the feed were exposed, then select the feed and make sure that the test substance Form a suitable feed mixture. Different species of animals should be used in different cages. The best use of artificial lighting, 12 hours light, 12 hours when darkness alternately. Feeding conditions of animals should comply with the special requirements of the relevant regulations and standards in the selection of animal species.

4.1.3 Animal Preparation

Test animals should be tamed healthy adult, and have not done animal testing.
Domestication of the species and origin of animals selected summary