

ICS 13.300; 11.100
CCS A 80



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

GB/T 21799-2008

Chemicals -- Test method of mouse spot

化学品 小鼠斑点试验方法

(English Translation)

Issued on: May 12, 2008

Implemented on: September 1, 2008

**Issued by: General Administration of Quality Supervision, Inspection and
Quarantine of the People's Republic of China, Standardization
Administration of the People's Republic of China**

Table of Contents

Foreword
1 Scope
2 Test the basic principles
3 Test methods
3.1 Test sample
3.2 Test animals
3.3 Quantity and gender
3.4 Exposure routes
3.5 Dose
3.6 Control
3.7 Exposure procedures
3.8 Results observed

Foreword

This standard is identical with the Organization for Economic Co-operation and Development (OECD) Guide to Testing Chemicals. 484 (1986) "Genotoxicity. small Mouse Spot Test "(in English).

This standard made the following editorial changes.

- Increased range of parts;
- Unit of measurement into China's legal units of measurement;
- Removed the introduction.

This standard by the National Standardization Technical Committee of hazardous chemicals management (SAC/TC251) and focal point.

1 Scope

This standard specifies the scope of the mouse spot test, test the basic principles, test methods, test data and reports.

This standard applies to the detection of chemical-induced mouse somatic mutations.

2 Test the basic principles

This is an in vivo test that exposes developing embryos to compounds. Target cells are melanocytes that develop embryos, and target genes are controlled Fur coat pigmentation genes. Many of the fur pigment genes in developing mouse embryos are heterozygous. Into melanoma cells dominant Allelic mutations (through a variety of genetic events) result in the expression of recessive phenotypes in the cells of their offspring so that in the test mouse's coat in the formation of a change of color spots. The frequency of occurrence of such spots in the test group was then compared with that in the control group.

3.1 Test sample

Test substance should be dissolved or suspended in isotonic saline solution. Water-insoluble compounds can be dissolved or suspended in suitable excipients in. The excipients used should neither interfere with the test substance, nor should it produce toxic effects. The test substance should be used before the fresh configuration.

3.2 Test animals

T-type mice (non-tachycardia, a/a; squirrel, pink eye, cchp/cchp; brown, b/b; light, short, dse/dse;

In combination with the HT line (light, non-agouti, short foot, paabp/paabp; lead gray fluff, 1nfz/1nfz; blue gray pe/pe) or C57/B1 Mouse, a/a) mating. Other suitable hybridizations such as NMRI (non-tachycardia, a/a; albino, c/c) and DBA (non-tachycardia, a/a;

Color d/d) Non-agouti mice can also be used.

3.3 Quantity and gender

Adequate exposed pregnant mice should be used in each dose group to breed a sufficient number of surviving mice. By observing the number of spots in the treatment group and the proportion of control group to determine the size of the sample.

3.4 Exposure routes

Commonly used route of exposure for oral administration of intragastric and intraperitoneal injection of pregnant rats, if necessary, can also be inhaled or other appropriate routes of exposure. Abdominal cavity Injections may be more suitable for identifying congenital mutations. Exposure to human exposure to the same way, the resulting test results on the risk assessment Set the most practical.

3.5 Dose

Use at least two appropriately spaced dosages, including a dose that produces signs of toxic effects or reduces the number of pups. Test substance Relatively non-toxic when the test dose should reach $1\text{g}/(\text{kg} \cdot \text{d})$, if such a high dose can not be reached, the highest dose should be tested.

3.6 Control

An excipient-only negative control should be given in conjunction with the exposed mice. Historical data from the same mouse from the same laboratory is also available as comparison. Satisfactory positive control results from the same laboratory in the near future (usually not more than 12 months) can also be used instead of synchronization Positive result.

3.7 Exposure procedures

Pregnant rats are usually exposed once on the 8th, 9th and 10th day of conception, and the day when the vaginal suppository is found is counted as the first day. These days and 7.25 days after conception, 8.25 days and 9.25 days. It is also possible to continue the exposure for these days.

3.8 Results observed

Mice were numbered and counted 3 to 4 weeks after birth in mice spots, divided into three categories.