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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB 15193.15-2015

Replacing GB 15193.15-2003

National food safety standard -- Genotoxicity test

食品安全国家标准 生殖毒性试验

(English Translation)

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Foreword

This standard replaces GB 15193.15-2003 "reproduction test." this standard compared with GB 15193.15-2003, the main changes are as follows.

--- Standard name was changed to "national food safety standard genotoxicity tests";

--- Added "reproductive toxicity", "developmental toxicity" and "maternal toxicity" terms and definitions;

--- Modified "test method", the "experimental animals," "dose and grouping", "Procedure" incorporated "test method";

--- Modify the contents of "test report";

--- Added "explained test" content.

National Food Safety Standard Reproductive toxicity test

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1 Scope

This standard specifies the technical requirements and test methods for genotoxicity tests.

This standard applies to the evaluation of the reproductive toxicity of the test substance.

2.1 Reproductive toxicity

Damage and harmful effects on male and female reproductive function or capability of future generations. Reproductive toxicity can occur in pregnancy, it can also be made Born in pre-pregnancy and lactation. It showed the impact of exogenous chemicals on the reproductive process, such as changes in the endocrine system and reproductive organs, sexual Affect cycle and sexuality, as well as the impact on fertility and pregnancy outcomes like.

2.2 Developmental Toxicity

Individuals prenatal exposure to the test substance, and development before becoming adult (including embryo, fetal and postnatal) harmful effects occur, table Now the development of the organism structural abnormalities, altered growth, dysfunction and death.

2.3 Maternal toxicity

Effects of test substances cause health damage, direct or indirect parent females pregnant animals, expressed as weight reduction, dysfunction, and signs of poisoning, even death.

3 Test purposes and principles

Where the test substance can cause reproductive dysfunction, interfere with the formation of gametes or reproductive cells are damaged, in addition to the results and the impact of a fertilized egg Bed and lead to infertility, can still affect embryogenesis and development, such as embryonic death cause spontaneous abortion, fetal growth retardation and fetal malformation.

If maternal adverse effects occur during pregnancy, childbirth and lactation abnormalities can also occur after abnormal fetal postnatal development.

Test Method 4

4.1 Test substance

The test substance should be used in the original sample, if it can not use the original sample, the test should be treated in accordance with the principles of the test substance for proper disposal. will Test was incorporated into feed, drinking water or gavage

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administration.

4.2 Experimental Animals

Experimental animals should be selected in line with national standards and regulations. Preferred rats, the choice of 7 weeks to 9 weeks of age, when the start of the test animals Weight difference should not exceed the average weight of ± 20%. Before the test, animals in the experimental animal room should be at least 3d ~ 5d environmental adaptation and seizure Phytophthora observation. Each group should have enough males and females mate, produce about 20 pregnant females. To this end, usually in the beginning of the test both sexes each group requires parental (F0 generation) 30 rats; continuing tests to mate each rat [first generation (F1 generation), of the second generation (F2 Generation) and a sub-three generations (F3 generation)] need 25 of each sex in each group (male and female from each litter at least one, male and female from each litter up to two).

Chosen by the F0 females should be non-producing mouse, non-pregnant rats.

Dose group and 4.3

Animals were randomly grouped test was set up at least three of the test substance group and a control group. You should consider the characteristics of the test substance (such as biological metabolic and bioaccumulation characteristics) influence. If the test substance use vehicle control group should be given the maximum use of solvents. If the test substance primer when dropped from animal food intake and utilization, the need to control animals fed experimental animals pairing. Some high test substance Dose of the test substance group design should consider its impact on the balance of nutrients for non-nutrient test substance dose should not exceed 5% of the feed.

In a test of physical and biological characteristics of the conditions allowed, the highest dose should be made to the F0 animals significant toxicity, but does not cause Animal deaths; intermediate doses can cause mild toxicity; low dose should not cause the parent and offspring of any animal toxicity (according to the maximum was not observed adverse effect level of 1/30, or human recommended intake of 10 times).

4.4.1 Administered test substance

4.4.1.1

During the test, all animals should be administered the same test substance; at the same time daily administration of the test substance, weekly 7d.

Test substances should be administered prior to mating successive generations of rats of both sexes at least 10 weeks, and the test was continued until the end of the test, in which the offspring the males and females after weaning daily administration. Each rat was tested dose administered (administered by the animal weight, mg/kg body weight or g/kg Body weight), the same feed and water.

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4.4.1.2

according to the characteristics of the test substance or test purposes, select the appropriate mode of administration. The preferred feed incorporation, if the test substance added to the feed or drink Water affect animal palatability, oral administration of the test substance should be selected.

4.4.1.3

test was orally administered to the test substance is dissolved or suspended in a suitable vehicle, the preferred solvent is water, water-insoluble test substance You can use vegetable oils (such as olive oil, corn oil, etc.), do not dissolve in water or oil test substance may be used as carboxymethyl cellulose, starch, etc. dubbed suspension or paste like. The test substance should be freshly prepared, our data show that with the exception of their storage solution or suspension stabilizer. Should at the same time daily irrigation Stomach 1, weighed twice weekly gavage volume weight adjustment. Gavage volume of generally not more than 10mL/kg body weight, such as an aqueous solution , The maximum volume of fed up to 20mL/kg body weight; as an oily liquid, orally should not exceed the volume of 4mL/kg body weight; each group was given body Product consistency.

4.4.1.4

incorporated into feed or drinking water test substance administered to the test substance and feed (or water) and mixed well to ensure the stability of the test substance formulation Qualitative and uniformity, without affecting the animal feeding, nutritional balance and water intake to the principle of the test substance incorporated into feed ratio is generally less than the mass fraction of 5%, while if more than 5% (maximum not more than 10%), to adjust the feed nutrient levels in the control group (no heat or if the test substance is a nutritional Time division and the addition ratio of more than 5% in the control group diet should be filled methyl cellulose, incorporated in an amount equivalent to the high dose), feed it with dose group Consistent levels of nutrients, while additional untreated control group; the heat was also a visual test or nutrient status adjusted dose feed Camp the level of nutrients to the control group diet nutrient levels consistent. Test substance dosage units per kilogram of body weight is ingested test substance cents G (or g) number, namely mg/kg body weight (or g/kg body weight), when the test was incorporated into feed dosage unit can also be expressed as mg/kg (or g/kg) of feed, the incorporation of water is expressed as mg/mL of water. When the test was incorporated into the feed, the need to test substance dose (mg/kg body weight) by animals Food intake per 100g of body weight of the test substance converted into feed concentration (mg/kg feed).

4.4.2 Mating

When each mating, each female is to be a single male with cage (1.1 mating) from the same group of subjects was randomly selected until after the female Plug, or after three estrus or two weeks. Found after vaginal plug should be female, male separately, if after

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