JFRL

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REPORT

Client: Japan Spatial Hygiene Association
6-27-28, Shinjuku, Shinjuku-ku, Tokyo, 160-0022, Japan

Test sample(s): 200-GM

Title: Acute Oral Toxicity Test in Female Mice

Received date of test sample(s): December 10, 2019

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Signed for and on behalf of JFRL

JAPAN FOOD RESEARCH LABORATORIES

M. Yamada — Jul. 30, 2020

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Section of Analysis Documentation

Date

Acute Oral Toxicity Test in Female Mice

Abstract

The test sample, 200-GM, was tested for acute oral toxicity in female mice. The test sample was orally administered to animals at a single dose of 2000 mg/kg b.w. (body weight), and they were observed for 14 days. As a result, the test sample caused neither abnormalities nor death in any of the mice during the observation period. Consequently, the LD50 value (single dose, oral administration) of the test sample is considered to be more than 2000 mg/kg b.w. in female mice.

1. Client

Japan Spatial Hygiene Association

2. Test sample

200-GM

3. Test facility

Tama Laboratory, Japan Food Research Laboratories
6-11-10 Nagayama, Tama-shi, Tokyo 206-0025, Japan

4. Test period

From December 10, 2019 to January 30, 2020

5. Purpose

The acute oral toxicity in female mice of the test sample is evaluated according to OECD Guideline for Testing of Chemicals 420 (2001).

6. Preparation of test dilution

The test sample was diluted with water for injection to make 100 mg/mL test dilution.

7. Experimental animals

Female mice of ICR strain, at an age of 4 weeks, were purchased from Japan SLC, Inc. Before test, they were acclimated to laboratory conditions for about 2 weeks to verify that no abnormalities were shown in general conditions. They were housed in plastic cages (five animals per cage) under standard laboratory conditions (Temperature: 23 ˚C ± 3 ˚C, Light-dark cycle: 12/12 hours). Feed (Labo MR Stock diet, Nosan Corporation) and tap water were provided *ad libitum* throughout the experiment.

8. Procedures

Female mice were allocated into experimental and control groups each consisting of five mice.

The mice were not fed for about 4 hours before administration. After measurement of body weight, the animals in the experimental group were orally administered with the test dilution at a single dose of 20 mL/kg b.w. (at a dosage of 2000 mg/kg b.w. test sample) using a stomach tube. The animals in the control group were administered with water for injection, as vehicle control, at the same dose.

The clinical observation was carried out frequently on the day of the administration and once a day for the following 13 days. The body weight was measured after 7 and 14 days of the administration. The mean body weight values of the experimental group and the control group were assessed for homogeneity of variance by Levene's test. Since the Levene's test was not significant, Student's t-test was applied for the comparison of two groups ($\alpha = 0.05$).

At the completion of the test, all of the mice were sacrificed for necropsy.

9. Results

1) Death of animals

None of the mice died during the experimental period.

2) Clinical observations

No abnormalities were observed in any of the mice during the experimental period.

3) Body-weight changes (Table 1)

No significant difference in body weight was detected between the experimental and control groups.

4) Necropsy

No remarkable changes were found in any of the mice.

10. Conclusion

The acute oral toxicity in female mice of the test sample was determined.

Oral administration of 2000 mg/kg b.w. test sample caused neither abnormalities nor death in any of the mice during the observation period.

Consequently, the LD50 value (single dose, oral administration) of the test sample is considered to be more than 2000 mg/kg b.w. in female mice.

Table 1. Body-weight changes

Group	Body weight (Units: g)		
	Pre-administration	7 days	14 days
Experimental group	28.0 ± 1.4 (5)	30.6 ± 1.4 (5)	33.1 ± 2.4 (5)
Control group	27.9 ± 1.5 (5)	31.1 ± 1.6 (5)	33.1 ± 2.9 (5)

The values are mean ± SD.
The values in parentheses represent the number of animals.

End of Report