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REPORT

January 05, 2009

Acute Oral Toxicity Test of PacificBeam MOLD/DeoSpray in Mice

Requested by: M.I.C. (Medical Intelligence Corporation) Co., Ltd.
2-2-15 Higashiasahina, Kanazawa-ku, Yokohama-shi,
Kanagawa 236-0033, Japan

Received: November 06, 2008

I, the undersigned, hereby declare that the work detailed in this report was prepared under my supervision as Study Director, and that the report provides a true and accurate record of the results obtained.

This report has been translated into English from the Japanese report No. 508110296-001.

Study Director

Y. Kawamoto

April 08, 2009

Yasuharu Kawamoto
Section of Biological Safety Research
Tama Laboratory
Japan Food Research Laboratories

Date

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Other contributors:
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Acute Oral Toxicity Test of PacificBeam MOLD/DeoSpray in Mice

1. Abstract

The test sample, PacificBeam MOLD/DeoSpray, was tested for acute oral toxicity in male and female mice.

To the experimental animals, the test sample was administered orally at a dose of 2,000 mg/kg b.w. (body weight), and the experimental period was 14 days. The control animals were given water for injection as vehicle control. As a result, the test sample caused no death in any of the mice during the observation period.

Consequently, we concluded that the LD50 value of PacificBeam MOLD/DeoSpray was more than 2,000 mg/kg b.w. in male and female mice.

2. Test sample

PacificBeam MOLD/DeoSpray
Character: colorless transparent liquid

3. Test period

From November 20, 2008 to January 05, 2009

4. Preparation of test dilution

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

5. Experimental animals

Male and female mice of ICR strain were purchased from Japan SLC, Inc. The mice were obtained at an age of five weeks. They were acclimated to the laboratory conditions for a week to verify that no abnormalities were shown in general condition. They were housed in plastic cages (five animals per cage) under the standard laboratory conditions (Temperature: 23 ℃±2 ℃, Light-dark cycle: 12/12 hours). And, they were given Labo MR Stock diet [Nihon Nosankogyo K.K.] and tap water *ad libitum*.

6. Procedures

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

The mice were not fed for about 4 hours prior to administration, and then they were weighed.

To the experimental group, the test sample was administered orally at a dose of 2,000 mg/kg b.w. of the test sample (at the dosage of 20 mL/kg b.w. test dilution) using a stomach tube.

To the control group, 20 mL/kg b.w. of water for injection, as vehicle control, was administered in the same manner as described above.

The clinical observations were made frequently on the day of administration and once a day during the observation period (for 14 days). The mice were weighed at 7 and 14 days after administration, and the mean body weight values of the experimental and the control groups were statistically analyzed by t-test ($p=0.05$).

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

7. Results

1) Death of animals

Neither male nor female mice died during the experimental period.

2) Clinical observations

No abnormalities were observed in male and female mice during the experimental period.

3) Body-weight changes (Tables 1 and 2)

No significant differences in body weight of male mice were detected between the experimental and the control groups at 7 and 14 days after administration.

In female mice, no significant difference in body weight was detected between the experimental and control groups at 7 days after administration. However, the weight of the experimental group was significantly lower ($p<0.05$) than that of the control group at 14 days after administration.

4) Necropsy

No remarkable changes were found in any of the male and female mice.

8. Conclusion

The acute oral toxicity of PacificBeam MOLD/DeoSpray was tested in male and female mice.

Oral administration of 2,000 mg/kg b.w. of the test sample caused no death in any of the mice during the observation period.

Consequently, we concluded that the LD50 value of the test sample was more than 2,000 mg/kg b.w. in male and female mice.

9. Reference

・ OECD Guidelines for the Testing of Chemicals 420 (2001).

Table 1. Body-weight changes (male)

Group	Body weight (g)		
	Pre-administration	7 days	14 days
Experimental group	32.6±1.2 (5)	36.5±1.7 (5)	38.6±2.6 (5)
Control group	32.9±1.3 (5)	37.4±1.2 (5)	40.0±1.7 (5)

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

Table 2. Body-weight changes (female)

Group	Body weight (g)		
	Pre-administration	7 days	14 days
Experimental group	27.1±1.1 (5)	29.1±0.4 (5)	31.2±0.9* (5)
Control group	27.2±0.9 (5)	29.9±0.7 (5)	32.6±0.6 (5)

The values are mean±SD.
The values in parentheses show the number of animals.
* A significant difference was detected between the experimental and control groups ($p<0.05$).

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REPORT

January 05, 2009

Acute Oral Toxicity Test of PacificBeam MOLD/DeoMist in Mice

Requested by: M.I.C. (Medical Intelligence Corporation) Co., Ltd.
2-2-15 Higashiasahina, Kanazawa-ku, Yokohama-shi,
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Received: November 06, 2008

I, the undersigned, hereby declare that the work detailed in this report was prepared under my supervision as Study Director, and that the report provides a true and accurate record of the results obtained.

This report has been translated into English from the Japanese report No. 508110278-001.

Study Director

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April 08. 2009

Date

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Other contributors:
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Mirai Ozawa
Misora Suzuki

Acute Oral Toxicity Test of PacificBeam MOLD/DeoMist in Mice

1. Abstract

The test sample, PacificBeam MOLD/DeoMist, was tested for acute oral toxicity in male and female mice.

To the experimental animals, the test sample was administered orally at a dose of 2,000 mg/kg b.w. (body weight), and the experimental period was 14 days. The control animals were given water for injection as vehicle control. As a result, the test sample caused neither abnormalities nor death in any of the mice during the observation period.

Consequently, we concluded that the LD50 value of PacificBeam MOLD/DeoMist was more than 2,000 mg/kg b.w. in male and female mice.

2. Test sample

PacificBeam MOLD/DeoMist
Character: pale yellow transparent liquid

3. Test period

From November 20, 2008 to January 05, 2009

4. Preparation of test dilution

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

5. Experimental animals

Male and female mice of ICR strain were purchased from Japan SLC, Inc. The mice were obtained at an age of five weeks. They were acclimated to the laboratory conditions for a week to verify that no abnormalities were shown in general condition. They were housed in plastic cages (five animals per cage) under the standard laboratory conditions (Temperature: 23 ℃±2 ℃, Light-dark cycle: 12/12 hours). And, they were given Labo MR Stock diet [Nihon Nosankogyo K.K.] and tap water *ad libitum*.

6. Procedures

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

The mice were not fed for about 4 hours prior to administration, and then they were weighed.

To the experimental group, the test sample was administered orally at a dose of 2,000 mg/kg b.w. of the test sample (at the dosage of 20 mL/kg b.w. test dilution) using a stomach tube.

To the control group, 20 mL/kg b.w. of water for injection, as vehicle control, was administered in the same manner as described above.

The clinical observations were made frequently on the day of administration and once a day during the observation period (for 14 days). The mice were weighed at 7 and 14 days after administration, and the mean body weight values of the experimental and the control groups were statistically analyzed by t-test ($p=0.05$).

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

7. Results

1) Death of animals

Neither male nor female mice died during the experimental period.

2) Clinical observations

No abnormalities were observed in male and female mice during the experimental period.

3) Body-weight changes (Tables 1 and 2)

No significant differences in body weight of male and female mice were detected between the experimental and the control groups.

4) Necropsy

No remarkable changes were found in any of the male and female mice.

8. Conclusion

The acute oral toxicity of PacificBeam MOLD/DeoMist was tested in male and female mice.

Oral administration of 2,000 mg/kg b.w. of the test sample caused neither abnormalities nor death in any of the mice during the observation period.

Consequently, we concluded that the LD50 value of the test sample was more than 2,000 mg/kg b.w. in male and female mice.

9. Reference

・ OECD Guidelines for the Testing of Chemicals 420 (2001).

Table 1. Body-weight changes (male)

Group	Body weight (g)		
	Pre-administration	7 days	14 days
Experimental group	34.9±1.1 (5)	39.2±1.7 (5)	41.4±2.6 (5)
Control group	34.7±1.6 (5)	39.2±2.3 (5)	41.6±2.9 (5)

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

Table 2. Body-weight changes (female)

Group	Body weight (g)		
	Pre-administration	7 days	14 days
Experimental group	26.3±1.1 (5)	28.2±0.5 (5)	29.9±1.5 (5)
Control group	26.0±1.0 (5)	28.5±1.3 (5)	29.7±1.9 (5)

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