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Section 2, Toxicology Branch 1 (H7509C)

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Section 2, Toxicology Branch 1, (H7509C)

DATA EVALUATION REPORT

STUDY TYPE: Acute Dermal Toxicity in Rats.

TOX. CHEM. NO.: New Chemical 121032

ACCESSION NUMBER: D179381

MRID NO.: 421783-03; Amended MRID #41827-12.

TEST MATERIAL: (2-[1-methyl-2-(4-phenoxyphenoxy) ethoxy] pyridine

SYNONYMS: Sumilarv; S-31183.

STUDY NUMBER(S): GLN 81-2.

SPONSOR: Sumitomo Chemical Co., Osaka, Japan.

TESTING FACILITY: Sumitomo Chemical Company, Limited. 5-33, Kitahama 4-Chome, Chuo-Ku, Osaka, Japan.

TITLE OF REPORT: Sumilary--Acute dermal toxicity of S-31183 in Rats. (Original report written in Japanese, translated by Takachi Suzuki, Research Associate, May 4, 1987).

AUTHOR(S): Takashi Suzuki

REPORT ISSUED: Number NNT-70-0006, February 4, 1987.

GLP Review: Masanori Takatsuka, dated Jan 30, 1987.

CONCLUSIONS:

Sumilarv dissolved in corn oil (400 mg/ml) was applied to the shaven skin of rats at the level of 2000 mg/kg for 24 hours under occlusive tape. No signs of toxicity were observed. Therefore, the acute LD50 by the dermal route was greater than 2000 mg/kg BW.

CLASSIFICATION: Toxicity Category IV. Core guideline data.

A. MATERIALS:

1. <u>Test compound</u>: Sumilary Technical. Synthesized by Sumitomo Chemical Company, Batch # PTG-86011. Purity: 97.2 %.

Impurities listed in composition statement.

2. <u>Test animals</u>: Species: Rats. Strain: Sprague Dawley. Age: six weeks. Weight: Males, 226- 257; Females 153- 169 gm. Source: Charles River Japan, Inc., Knagawa.

B. STUDY DESIGN:

<u>Animal assignment</u> - Animals were randomized using a computer program by Toxipac System 300, Shimadzu Corportion, Kyoto.

Methods: The dorsal hair of the animals (5 x 10 cm. sq.) was sheared with an electric clipper just before application of the test material. Each animal was then fixed on a restraining stand in the prone position. The test material was suspended in corn oil (400 mg/ml) and spread on the clipped area of skin (30 cm. sq.) using a blunt dosing needle and syringe. This was equivalent to 5 ml/kg (2000 mg/kg) body wt. of the test substance. After one hour, the treatment area was covered with surgical tape for the following 24 hours to keep the animals from licking the test substance from the area of application. A control group received corn oil only, 10 ml/kg.

The animals were observed after dosing for possible toxicity at 10 min, 30 min, 1, 2 and 4 hours and daily for 2 weeks thereafter. Body weights were measured before dosing and weekly there after. At the end of the 14 day observation period the animals were subjected to a gross necropsy.

Statistical Methods: Potential differences in mean body weights among the treatment groups were compared using the test. The incidence of gross pathological lesions was compared to that of the vehicle control using the Fisher Exact Test.

C. RESULTS:

There were no deaths or toxicity resulting from the administration of the test material. Body weights of the treated animals were similar to control animals as shown in the attached table (Table 2, page 8 taken from the report).

At necropsy, a white substance was observed in the urinary bladders of male control animals (1/5) and in male treated animals (2/5). No pathological changes were seen in the female control group. A female (1/5) of the treated group had a uterine horn distended with fluid. None of these findings were considered abnormal for these rats.

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