

US EPA ARCHIVE DOCUMENT

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DATA EVALUATION REPORT

STUDY TYPE: Skin Sensitization Study in Guinea Pigs.

TOX. CHEM. NO.: New Chemical 129032

ACCESSION NUMBER: D179381

MRID NO: 421783-06; Amended MRID #41827-15.

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

SYNONYMS: Sumilarv; S-31183.

STUDY NUMBER(S): GLN 81-6. (Carried out by the guideline of the Ministry of Agriculture, Forestry and Fisheries, Japan, 1985).

SPONSOR: Sumitomo Chemical Co., Osaka, Japan.

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

TITLE OF REPORT: Sumilarv -- Skin sensitization test with S - 31183 in Guinea Pigs. (Original report written in Japanese, translated by Takachi Suzuki, May 14, 1987.)

AUTHOR(S): Takashi Suzuki

REPORT ISSUED: Number NNT-70-0022, January 7, 1987

GLP Review: Masanori Takatsuka, Jan. 7, 1987.

CONCLUSIONS:

The skin sensitization potential of Sumilarv was tested in male guinea pigs by the maximization test using 2,4-dinitrochlorobenzene (DNCB) as a positive control. No skin reactions (erythema and swelling) were observed after the 24 and 48 hours in the Sumilarv challenge treatment. The positive control group (DNCB) did produce the expected sensitization reactions. Sumilarv was therefore found not to produce sensitization by this test method.

CLASSIFICATION: Non-Sensitizer. ~~Core guideline.~~ ACCEPTABLE.

A. MATERIALS:

1. Test compound: S-31183, Technical. Description: White solid, manufactured by Sumitomo Chemical Co. Batch # PTG-86011. Purity: 97.2 %, Impurities noted in composition statement. The positive control substance, PNCB, was supplied by Wako Pure Chemical Industries Ltd, Japan.

2. Test animals: Species: Male Guinea Pigs. Strain: Hartley. Age: three weeks. Weight: 300 to 380 gm. Source: Shizuoka Agricultural Association for Laboratory animals (Shizuoka, Japan).

Housing: The animals were housed in suspended wire-mesh floor aluminum cage under standard laboratory conditions and offered water and food ad libitum.

B. STUDY DESIGN:

The study was conducted according to the method of Magnusson and Kigman.

Animal assignment - Animals were randomized using a computer program by Toxipac System 300, Shimadzu Corporation, Kyoto and placed in the following groups:

EXPERIMENTAL GROUPS

GROUP	TREATMENT	NO./GROUP
1	Sumilarv Sensitized	20
2	Sumilarv Control	20
3	DNCB-Sensitized *	10
4	DNCB- Control	10

Pre-induction Testing. Preliminary injections of 0.1, 0.25, 0.5 and 1% Sumilarv in oil showed that 0.5 % solutions could produce erythema and no swelling and 1% produced both. Twenty five % Sumilarv in petrolatum applied to the shaven skin pre-treated with sodium lauryl sulfate produced no signs of irritation. Therefore 0.5% solutions were used during the induction phase and 25% Sumilarv in petrolatum was used during the challenge phase.

Induction Testing. The dorsal skin in the scapular region of each animal was clipped free of hair to prepare for 6 application sites of 2x4 cm each on both sides of the median line of the back. Sumilarv (0.5% in oil) was intradermally injected to the both sides (left and right) of the hair-clipped area for

each animal at the rate of 0.05 ml/injection. Freud's complete adjuvant (FCA, Lot No. 739732, Difco Laboratories, Detroit, USA) mixed with distilled water was injected in the cranial sites, 0.5% sumilarv in corn oil or 0.05% DNCB in corn oil to the intermediate sites, and 1.0% Sumilarv or 0.1% DNCB in FCA mixed with an equal volume of distilled water to the caudal sites. The control animal were treated in a similar manner excluding the test material or the positive control.

The second induction application was applied 6 days after the first and involved the application of 0.2 g/site of 10% sodium laruyl sulfate in petrolatum applied to the subscapular region. The second sensitization by dermal application was carried out on the next day (one week after intradermal injection. Sumilarv, 0.4 g of 25% in petrolatum (for the Sumilarv sensitized group) and 0.4 ml of 0.5% DNCB in corn oil (for the DNCB group) was applied to the skin and covered with an occlusive tape. The control animals received similar dermal applications without the test material or DNCB.

Challenge Phase: The test and control animals received 0.2 gm of 25% Sumilarv in oil and 0.2 ml of 0.5% DNCB in corn oil respectively, applied to clipped flank area and covered with an occlusive tape for 24 hours. The application sites were evaluated for reactions at 24 and 48 hours after the application of the challenge doses.

C. RESULTS:

The resulting scores of the skin reactions were summarized in attached Tables 2 and 3, taken from pages 10 and 11 of the report, respectively. From the tables, it is seen that none of the animals in the Sumilarv sensitization or control groups or the DNCB control groups developed skin reactions during the observations. The DNCB sensitization group of animals did produce the expected reactions (usually slight to moderate) at both the 24 and 48 hour observation periods.

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Reference:

1. Magnusson, B. and Kligman, A. M. (1969). J. Invest. Derm. 52: 268-276.

Pyriproxyfen

RIN 4445-96

P.C. 129032

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Pages 4 through 5 are not included.

The material not included contains the following type of information:

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