UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MEMORANDUM

Date: February 6, 1981 000290

Subject: EPA File Symbol: 39398-RN PESGUARD NS 4/1 WB
Caswell #844,

From: Cheryl A. Peterson
IRB/TSS

To: Mr. Franklin D.R.Gee
Product Manager (17)

Applicant: Sumitomo Chemical America, Inc.
c/o Dr. Eugene J. Gerberg
1330 Dillon Height Ave.
Baltimore, MD 21228

Active Ingredients:

Tetramethrin [(1-cyclohexene-1,2-dicarboximido)methyl 2, 2-dimethyl-3-(2-methylpropenyl) Cyclopropanecarboxylate]	20.00%w/w
d-phenothrin [3-phenoxybenzyl d-cis & trans,2,2-dimethyl-3,2(2-methylpropenyl) Cyclopropanecarboxylate]	4.79%w/w
Other isomers	0.21%w/w
Inert Ingredients	75.00%w/w

Background:

This product is a concentrate intended for manufacturing use only. The company has submitted an application for conditional registration of a new product. The "cite-all" method of support is being used, and acute and subacute inhalation studies, acute oral, acute dermal, primary skin irritation and primary eye irritation studies have been submitted in support of the application. No authorization letters have been included in the file.

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Recommendations:

1. The acute inhalation LC50 done by the Institute for Biological Science, Hyogo, Japan has been classified Core Supplementary Data. Particle size measurements were not provided.

2. A letter of validation was not provided for the Industrial Bio-Test studies in Acc. No. 243970 and 243971.

3. IRB/TSS would have no objection on the basis of hazard to man or domestic animals to the conditional registration of the above product under the "cite-all" method of support with appropriate authorization and with the labeling revisions indicated below.

Labeling:

1. The appropriate signal word is CAUTION, as indicated by the applicant.

2. The STATEMENT OF PRACTICAL TREATMENT should be similar to the following:

   If Swallowed: Do not induce vomiting. Drink glass of water, and get immediate medical attention.

   If in eyes: Flush thoroughly with plenty of water. Get medical attention.

   If contact with skin: Wash thoroughly with soap and water. Get medical attention if irritation persists.

Review:

The following study was conducted for Sumitomo Chemical Co., Ltd., Osaka, Pesticides Division by the Institute for Biological Science, Hyogo, Japan on material unclearly identified as d-Phenothrin (S-2539 Forte). It was received by EPA on 12-17-80, and in Acc.No. 243970.

1. Acute Inhalation LC50-Rat. Dated: October 24, 1977. (Study #ET-70).

Procedure: 3 groups of 20M and 20F Sprague-Dawley rats each received 4 hr. exposure to deo-base (L. Sonneborn Sons, Inc., USA) as a control, and nominal concentrations of 2960 mg/m^3 (d-phenothrin 50%, in deo-base) and 3760 mg/m^3 (d-phenothrin 75%, in deo-base). Air flow rate was 50 l/min., injection rate was 0.42 ml/min. Test compound dissolved in Deo-base was

injected at a constant rate into an atomizer and sprayed under compressed air. Aerial concentration of material was determined by passing the mists at rate of 10 l/min. through finely powdered siligel installed for 10 min. The compound was extracted with acetone and analyzed gaschromatographically. There was a 14 day observation period with survivor sacrifice and necropsy. 5 animals from each group were necropsied.

Results: LC50 is greater than a 4-hr exposure to a nominal concentration of 3760 mg/m^3 (d-phenothrin 75%). No mortalities. No clinical signs. Necropsy showed nothing remarkable. Very minute swellings of sciatic nerve axon were sporadically found in some rats of control & d-Phenothrin treated groups. Neurotic effects of pyrethroidal compounds are found in rats receiving lethal or near-lethal doses. These test concentrations were far lower than lethal doses. It was maintained that the compound could not be sprayed at the higher aerial concentrate than this experimental condition. Animals gained weight during the observation period.

Study Classification: Core Supplementary Data (Particle size measurements were not provided.)

The following study was conducted by Industrial Bio-Test Laboratories, Inc., 1810 Frontage Rd., Northbrook, IL 60062 for Sumitomo Chemical Co. on material unclearly identified as a water-based aerosol F 26541 (NPY 0.4%/SUM 0.1%).

2. Acute Inhalation LC50-Rat. Dated: April 19, 1978 (Study #8562-#1138).

Procedure: 5M and 5F albino rats (unspecified strain) each received 6 hr. exposure to a nominal concentration of 1.83 mg/l test material. An aerosol of water-based aerosol F 26541 was sprayed from a pressurized container through a hole in the front of the exposure chamber. Total duration of the spray release was 30 sec. This was followed by a 10 min. exposure period with chamber sealed, followed by a 20 min. period with chamber partially opened. This procedure was repeated at 30 min. intervals for 6 hrs (12 aerosol bursts). Average amount of test material released during each 30 sec. burst was 24.75 grams. There was a 14-day observation period with survivor sacrifice and necropsy.

Results: No mortalities. LC50 is greater than 6 hr. exposure to a nominal conc. of 1.83 mg/l test material. Clinical signs included squinting, hypoactivity and red nasal discharge. Necropsy showed red foci and consolidation in the lung.

Study Classification: This study has not been validated.

The following studies were performed by Industrial Bio-Test Laboratories, Inc., Decatur Research, 1800 E. Pershing Rd., Decatur, IL 62526 for Sumitomo Chemical Co., Ltd. on material unclearly identified as Premix Concentrate F 26541-6 (NPY 0.4%/SUM 0.1% aerosol.)

3. Acute Oral LD50-Rat. Dated: Unspecified (Study No.: 8530-1137).

Procedure: 4 groups of 5M, 5F albino, Charles River rats each received oral exposure to 4556 mg/kg, 6834 mg/kg, 10250 mg/kg and 15380 mg/kg test material. There was a 14-day observation period with survivor sacrifice and necropsy.

Results: No mortalities. Oral LD50 is greater than 15,380 mg/kg test material. Animals gained weight during the observation period. Clinical signs included hypoactivity and diarrhea. Necropsy showed numerous red foci in lungs, pelvic dilation in kidneys, and horns of uterus enlarged.

Study Classification: This study has not been validated.

4. Acute Dermal LD50-Rabbit. Dated: Unspecified. (Study No. 8530-1137)

Procedure: 3M, 3F albino NZ rabbits each received 24-hr occluded skin exposure to 3,038 mg/kg test material on abraded and nonabraded skin sites. There was a 14-day observation period with survivor sacrifice and necropsy.

Results: No mortalities. Dermal LD50 is greater than 3,038 mg/kg test material. Animals, except 1M & 1F, gained weight during the obsevation period. Clinical signs included severe erythema and moderate edema. Necropsy showed nothing remarkable.

Study Classification: This study has not been validated.

5. Primary Eye Irritation-Rabbit. Dated: Unspecified (Study No. 8530-1137).

Procedure: 9 rabbits each received 0.1 ml test material in the right eye. 3/9 had eyes washed starting no sooner than 30 sec. with 300 ml tap water. Observations were made at 24, 48, 72 hrs and 7 days.

Results: 3 washed eyes showed no corneal opacity. 3 washed eyes showed minor conjunctivitis with clearing by 48 hrs. 6 unwashed eyes showed no corneal opacity. 6 unwashed eyes showed moderate conjunctivitis with clearing by 48 hrs.

Study Classification: This study has not been validated.

6. Primary Dermal Irritation - Rabbit. Dated: Unspecified. (Study No.: 8530-1137).

Procedure: 6 albino NZ rabbits (unspecified sex) each received 24-hr, occluded exposure to 0.5 ml test material on an abraded and a nonabraded skin area. At the end of the 24-hr exposure period, residual test material was removed by rinsing with tap water. Observations were made at 24 and 72 hrs and 7 days.

Results: Primary Irritation Index = 2.8. 6/6 animals showed minor edema with clearing by 72 hrs in 5/6. 6/6 animals showed minor erythema at 72 hrs.

Study Classification: This study has not been validated.

The following study was conducted by Industrial Bio-Test Laboratories, Inc., 1810 Frontage Rd., Northbrook, IL 60062 for Sumitomo Chemical on material unclearly identified as water-based aerosol 2655: (NPV 0.7%/SUM 0.175%).

7. Acute Inhalation LC50 - Rat. Dated: Unspecified. Study No.: 8562-11138.

Procedure: 5M & 5F Sprague-Dawley rats each received 6 hr exposure to a nominal concentration of 2.45 mg/l test material. Test material was sprayed from a pressurized container through a hole in the front of the exposure chamber. Total duration of spray release was 30 sec. followed by 10 min. with the chamber sealed, followed by 20 min. with the chamber partially opened. This was repeated at 30 min. intervals for 6 hrs (a total of 12 aerosol bursts). Average amount of test material released during each 30 sec. burst was 23.66 grams.

Results: No mortalities. LC50 is greater than 6 hr exposure to a nominal conc. of 2.45 mg/l test material. Clinical signs included squinting, hypoactivity and red nasal discharge. Necropsy showed a few minute red foci on lungs.

Study Classification: This study has not been validated.

The following studies were conducted by Industrial Bio-Test Labs, Inc., Decatur Research, 1800 E. Pershing Rd., Decatur, IL 62526 for Sumitomo Chemical Co., Ltd. on material unclearly identified as Premix Concentrate F 26551-6 (For NPY 0.70%/SUM 0.17% aerosol).

8. Acute Oral LD50 - Rat. Dated: May 31, 1978. Study No.: 8530-11137.

Procedure: 4 groups of 4M, 4F albino Charles River rats each received via oral syringe exposure to 4,556 mg/kg, 6,834 mg/kg, 10,250 mg/kg and 15,380 mg/kg test material. There was a 14-day observation period, with survivor sacrifice and necropsy.

Results: No mortalities. LD50 is greater than 15,380 mg/kg test material. Animals gained weight during the observation period. Clinical signs included hypoactivity and diarrhea. Necropsy showed dark red foci on lungs, pelvic dilation of kidneys and horns of uterus enlarged.

Study Classification: This study has not been validated.

9. Acute Dermal LD50 - Rabbit. Dated: Unspecified. Study No.: 8530-11137.

Procedure: 3M, 3F NZ albino rabbits each received 24-hr occluded exposure to 3,038 mg/kg test material on abraded and nonabraded skin areas. Observations were made for 14 days with survivor sacrifice and necropsy.

Results: No mortalities. Dermal LD50 is greater than 3,038 mg/kg test material. Clinical signs included severe erythema and moderate edema. Animals gained weight during the observation period. Necropsy showed yellow focus on one lobe of 1 animal's liver.

Study Classification: This study has not been validated.

10. Primary Eye Irritation. Rabbit. Dated: Unspecified: Study No.: 8530-11137.

Procedure: 9 NZ white rabbits each received 0.1 ml test material in the right eye. 3/9 had eyes washed starting 30 seconds after instillation with 300 ml tap water. Observations were made at 1,24,48,72 hrs and 7 days.

Results: No corneal opacity. All animals showed moderate conjunctivitis with clearing by 48 hrs.

Study Classification: This study has not been validated.

11. Primary Skin Irritation-Rabbit. Dated: Unspecified. Study No.: 8530-11137.

Procedure: 6 NZ white rabbits (unspecified sex) each received 24-hr, occluded exposure on an abraded and a nonabraded skin area to 0.5 ml test material. Observations were made at 24 & 72 hrs & 7 days.

Results: Primary Dermal Irritation Index = 4.1. 4/6 animals showed minor edema at 72 hrs. All animals showed minor erythema at 72 hrs.

Study Classification: This study has not been validated.

The following study was conducted by Industrial Bio-Test Laboratories, Inc., Northbrook, IL for Sumitomo Chemical Co. on material identified as a water based aerosol containing Neopynamin and Sumithrin It was received by EPA on December 17, 1980, and is in Acc. No. 243971.

12. Subacute Inhalation (3-week)-Rat. Dated: January, 1980. Study #8562-11139.

Procedure: 4 groups of 5M & 5F Sprague-Dawley albino rats each received 6 hr exposure per day, 5 days per week for 3 consecutive weeks to F-26542, F-26552, F-26552-C and untreated control. The aerosol was directly released into the test chamber for 15 sec. This was followed by a 20 min. exposure period with chamber sealed followed by a 10-minute period with chamber partially opened. This process was repeated at 30 min. intervals for a period of 6 hrs. (a total of 12 aerosol sprays). The test chamber of 80 l was made of glass and stainless steel. One day after final exposure, all animals from each group were sacrificed and were subjected to gross pathologic examination. Nominal concentrations are given in the following table. Blood collections were made Day 0 and Day 21. Organs were weighed and compared at necropsy.

Results: No mortalities. Clinical signs included red nasal discharge, red ocular discharge, hyperactivity and tremors. Animals on the average gained weight during the exposure period. Results of hematological tests of controls were similar to those of test animals. Urinalysis findings were similar in both control and test animals. On the average treated animals had slightly lighter lungs and heavier livers. Necropsy showed consolidation in lungs and small testis for gross observations.

Study Classification: This study has not been validated.

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