



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

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MEMORANDUM

DATE: December 5, 1980

SUBJECT: EPA Registration No. 4816-482
PYRENONE GARDEN SPRAY CONCENTRATE
Caswell # 715, 670, 646

FROM: Cheryl A. Peterson *CAP*
IRB/TSS

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

Registrant: Fairfield American Corp.
3932 Salt Road
Medina, NY 14103

Active Ingredients:

Pyrethrins.....1.0%
Piperonyl butoxide, technical.....10.0%
Petroleum distillate.....79.0%

Inert Ingredients.....10.0%

Background:

This product is registered as a concentrate for outdoor and greenhouse use against aphids, beetles, etc. Acute oral, acute dermal, acute inhalation, primary skin irritation and primary eye irritation studies conducted on the product have been submitted for the record.

Recommendations:

1. The acute oral, acute dermal, primary eye irritation and primary skin irritation studies are acceptable.
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2. The acute inhalation study has been classified Core Supplementary Data. Actual chamber concentration measurements should be taken during the exposure period to determine if test substance concentration is constant throughout the period.
3. The following labeling revisions should be incorporated at the next label reprinting:

Labeling:

1. The appropriate signal word is CAUTION.
2. The PRECAUTIONARY STATEMENTS on the side panel should be similar to the following:

HAZARDS TO HUMANS

CAUTION: Avoid contact with skin, eyes and clothing. If contact occurs, flush eyes or skin with plenty of water. Remove contaminated clothing and wash before reuse. Wash hands after using. If swallowed: call physician. Do not induce vomiting.

ENVIRONMENTAL HAZARDS

This product is toxic to

Review:

8214-23 The following studies were conducted by Cosmopolitan Safety Evaluation (C.S.E.), Inc. for Fairfield American Corporation on material identified as Pyrenone Garden Spray Concentrate (Study #8214-23). They were received September 3, 1980, and are in Accession No. 243385.

1. Acute Oral LD₅₀ - Rat. Dated: August 6, 1980.

Procedure: In a range-finding test, 3 groups of 1M, 1F rats received oral exposure to 0.5, 2.5 and 5.0 g/kg test material. There were no mortalities. In the main test, 5M, 5F albino rats (unspecified strain) each received via oral gavage exposure to 5.0 g/kg test material. There was a 14-day observation period, with survivor sacrifice and necropsy.

Results: LD₅₀ is greater than 5 g/kg. 0/5 M died, 1/5 F died Day 1. Necropsy showed an excess of yellow fluid in stomach in the rat that died. Necropsy showed nothing remarkable in other animals. Clinical signs included lethargy and diarrhea. All survivors except one female gained weight during the observation period.

Study Classification: Core Minimum Data (Individual body weights should be reported 3-4x weekly.)

Product Classification: Toxicity Category III.

2. Acute Dermal LD₅₀ - Rabbit. Dated: August 6, 1980.

8214-23
Procedure: 5M, 5F NZ, albino rabbits each received 24-hour, occluded exposure to 2.0 g/kg test material on abraded skin over 20% of body surface. There was a 14-day observation period with survivor sacrifice and necropsy.

Results: LD₅₀ is greater than 2.0 g/kg test material. 0 M and 1/5 F died Day 1 (of a broken back caused by struggles against irritation). 2/4 F and 3/5 M gained weight during the observation period. Clinical signs included lethargy, clear nasal discharge and rales. Both erythema and edema were evident after application. Necropsy showed nothing remarkable.

Study Classification: Core Guideline Data.

Product Classification: Toxicity Category III.

3. Acute Inhalation LC₅₀ - Rat. Dated: August 6, 1980.

8214-23
Procedure: 5 M, 5 F rats (unspecified strain) were exposed for four hours to a nominal concentration of 5.63 mg/l test material in a plexiglass chamber with a raised mesh floor. On one side near the top was a portal through which test substance and airflow were introduced; at the opposite side near the bottom was the exhaust portal. Air was supplied at an unspecified flow rate and pressure to a generator. Amount of test article delivered as an aerosol was 13.5 g. Total airflow was 2400 l. Particle size was determined by cascade impactor. There was a 14-day observation period.

Results: Average particle size was 3.65 microns. LC₅₀ is greater than four hour exposure to a nominal concentration of 5.63 mg/l. No mortalities. Necropsy showed nothing remarkable. Clinical signs included clear oral and nasal discharge during exposure period and lethargy for the first 24-48 hours following exposure. All rats exposed to test material gained weight during the observation period except 1 F.

Study Classification: Core Supplementary Data (Actual chamber concentration measurements taken during the exposure period should be reported to determine if test substance concentration is constant throughout the exposure period.)

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4. Primary Eye Irritation - Rabbit. Dated: August 6, 1980.

8214-23
Procedure: 9 NZ albino rabbits received 0.1 ml test material in one eye. 3/9 eyes were flushed for 1 min. with water starting no sooner than 20 sec. after instillation. Observations were made at 24, 48, 72 hours, Days 4 and 7.

Results: No corneal opacity. 1/6 unwashed eyes showed conjunctivitis with clearing by 72 hours. 1/3 washed eyes showed conjunctivitis with clearing by 48 hours.

Study Classification: Core Guideline Data.

Product Classification: Toxicity Category III.

5. Primary Skin Irritation - Rabbit. Dated: August 6, 1980.

8214-23
Procedure: 6 NZ albino rabbits each received 24-hour occluded exposure to 0.5 ml test material applied to two intact and two abraded application sites. Observations were made at 24 and 72 hours, Days 7 and 14.

Results: Primary Irritation Index = 5.16. All animals showed edema at 72 hours with clearing by Day 7. All animals showed erythema through Day 14.

Study Classification: Core Guideline Data.

Product Classification: Toxicity Category III.

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