

11-1-83

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DATE: November 28, 1977
SUBJECT: Pyroicide Intermediate 5192
Caswell #360 (Bagon)

EPA Registration #1021-340

FROM: William Dykstra, Ph.D
Toxicology Branch
TO: Charles Mitchell (17)

WSD 11/28/77
E 12/9/77

Action Type: Resubmission with DATA
Product Manager: Charles Mitchell (17)

Recommendations:

1. Piperonyl butoxide which is an active ingredient in the formulation is an RPAR Chemical.
2. It is concluded that the toxicity studies reviewed are acceptable as core-minimum data.
3. It is recommended that an acute inhalation LC₅₀ be determined for this formulation.

Review:

Toxicity Studies (Biosearch Inc., Philadelphia, July 1, 1975; submitted by McLaughlin Gormley King Co., 1/13/77)

1. Acute Oral Toxicity - Rats (Male) Test Material - Pyroicide Intermediate 5192

Five groups of 5 male albino rats of the Sherman - Wistar Strain weighing between 200 and 300 grams were employed in this study. The rats, ^{were fasted} for 24 hours prior to dosing. Each animal was weighed and dosed by direct administration of test material into the stomach by means of a syringe and dosing needle. The sample was dosed as supplied. The following dosage levels were administered 2.0, 4.0, 8.0, 16.0, 32.0 ml/Kg. Following administration the animals were observed for 14 days during which time the rats were observed for signs of toxicity and mortalities.

Toxicity: not reported

Necropsy: Not reported

LD₅₀ = 13.0 ml/Kg or > 5.0 gm/Kg

Classification: Core-Minimum Data

TOX Cat. IV Caution

2. Acute Oral Toxicity to Rats (Female)

Material Tested: Pyrocide Intermediate 5192

Procedure: the same as in part 1.

Results:

Toxic Signs: not reported

Necropsy: not reported

LD₅₀ = 11.3 ml/Kg or >5.0 gm/Kg

Classification: Core Minimum DATA

TOX Category: IV Caution

3. Primary Skin Irritation Study - Rabbits

Material Tested: Pyrocide Intermediate 5192

A group of six albino rabbits were clipped over a wide area. One side of the animals backs was abraded at one site with a lancet sufficiently deep to penetrate the stratum corneum but not enter the derma to produce bleeding. The skin of the other side was allowed to remain intact. A 0.5 ml portion of material was applied to an abraded and intact skin site on the same rabbit. Gauze patches were then placed over the treated areas and an impervious cuff was placed around the animals. The wrap was removed after 24 hours Readings were made at 24 + 72 hours. The Draize method of scoring was employed.

Results: P. I. = 0.5

Classification: Core Minimum DATA

TOX Category: IV Caution

4. Primary Eye Irritation Study - Rabbits

Material Tested: Pyrocide Intermediate 5192

Six healthy young adult albino rabbits were used in this study 0.1 ml of the test material was instilled into the right eyes of the test animals while the other eyes remained untreated to serve as controls.

The test material was not washed from the eyes. The treated eyes were examined at 1, 24, 48 and 72 hours following instillation. Graded according to "Illustrated Guide for Grading Eye Irritation by Hazardous Substances conjunctivitis at 24 hours but,

Results: No ocular irritation at 72 hours

Classification: Core Minimum DATA

Tox Category: IV Caution

5. Acute Dermal Toxicity - Rabbits (Males)

Material Tested: Pyrocide Intermediate 5192

Four groups of 8 albino rabbits (males) weighing between 2.5 and 3.5 Kg each were employed in this study. All animals had their backs clipped free of hair 24 hours prior to testing. One half of the animals has their backs abraded prior to dosing. The following dosage levels were administered 0.5, 1.0, 2.0, 4.0 ml/Kg. All rabbits were weighed and the correct amount of experimental material was applied to the back of each animal. These treated areas were covered with large gauze patches and an impervious material was wrapped snugly around the trunk of each animal. The dressings were removed after twenty-four hours and any excess material was removed and the approximate amount ~~XXXXXX~~ remaining was noted. The animals were observed for a 14 day period for signs of toxicity and for mortalities. gross autopsies were performed on all animals which died during the 14 day observation period.

Results: No deaths

LD₅₀ > 4.0 ml/Kg or > 2.0 gm/Kg

Classification: Core Minimum DATA

TOX Category: III Caution

6. Acute Dermal Toxicity - Rabbits (Female)

Material Tested: Pyrocide Intermediate 5192

Procedure: Same as in part 5.

Results: No deaths

LD₅₀ > 4.0 ml/gm or > 2.0 gm/Kg

Classification: Core Minimum DATA

TOX Category: III Caution