5-16-84

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

003831

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: ORTHO Home and Garden Spray - 0.25% Resmethrin

TO: Tim Gardner (PM-17)
Registration Division (TS-767)

FROM: Byron T. Backus BTBackus 5-16-84
Toxicology Branch
HED (TS-769)

THROUGH: William Butler, Head William Butler 5-23-84
Review Section III
and
William Burnam, Chief
Toxicology Branch

Product: ORTHO Home and Garden Spray

Registration # 239-2378

Tox. Chem. 83E

Registrant: Chevron Chemical Co.

Actives:

| | |
|---|---|
| Resmethrin | 0.250% |
| Related compounds | 0.034% |
| Aromatic petroleum hydrocarbons | 0.331% |
| Petroleum distillate | 6.500% |

Action:

This product is currently registered for use as a multi-purpose spray, both in the home and outdoors. There are no registered uses for food crops.

The registrant wishes to add a claim for use against black widow spiders.

Acute oral $LD_{50}$, dermal $LD_{50}$, inhalation $LC_{50}$, and primary eye and dermal irritation studies have been submitted.

Conclusions:

1. The acute oral $LD_{50}$, dermal $LD_{50}$ (male), primary eye and dermal

87

irritation studies have been classified as Core Minimum Data.

2. The acute inhalation $LC_{50}$ study has been classified as Core Supplementary as no data are provided as to actual concentration of product and/or its active ingredients. Additionally, there is no information as to particle size distribution of the material tested.

3. There is nothing in the acute toxicity data received 11-15-83 to indicate that any revisions in the product's current precautionary labeling are necessary.

Data Evaluation Report

003831

Compound: 0.25% Resmethrin Spray

Reviewed by:

Byron T. Backus
Toxicologist

1. Acute oral $LD_{50}$ - rat

Citation:

Spence, J.A., Ph.D. The acute oral toxicity of Ortho Home and Garden Spray (PN 1000-57C). S-833. Study conducted by the Standard Oil Company of California (SOCAL) Safety Division, 225 Bush St, San Francisco, CA 94120 under SOCAL 833/XXII:42. Study dated 9-30-75. Received at EPA 11-15-83; in Acc. 251823.

Materials:

Pressurized can of the test material, coded SX 747, identified as ORTHO Home and Garden Spray (PN 1000-57C); described as a white foamy liquid after being sprayed.

Ten adult male (230-248 g) and 10 adult female (210-234 g) fasted Sprague-Dawley rats (no source indicated).

Procedure:

Contents of the pressurized can were sprayed into a partially covered beaker, and administered at a dose of 15 g/kg to 5 fasted rats of each sex, with subsequent 14-day observation. An additional 5 rats of each sex served as controls. Individual weights were recorded before dosing, and 7 and 14 days afterwards. Rats were sacrificed at 14 days and examined for gross pathological changes. It is reported that the following were examined: salivary glands, thymus, heart, lungs, kidneys, adrenal glands, spleen, liver, gonads, pancreas, gastro-intestinal tract, bladder, lymph nodes, body fat, skeletal muscle,teeth, eyes and skin.

Weights of treated and control rats were compared using Student's t-test.

Results:

Reported that there were no deaths or observed symptoms of toxicity during the 14-day period, nor were there any observed gross pathological changes "attributable to the test material."

It is reported that there were no significant differences between weights of treated and control rats; however averages (no individual values are given) for treated rats were lower than those of controls for day 7, but not day 14.

Oral $LD_{50} > 15$ g/kg.

Conclusion:

The study adequately demonstrates that the condensate from the subject product has a rat oral $LD_{50}$ > 15 g/kg.

Tox. Category IV

Core Classification: Minimum

2. Acute dermal $LD_{50}$ - rabbit (male)

Citation:

Spence, J.A., Ph.D. The acute dermal toxicity of Ortho Home and Garden Spray (PN-1000 57C). S-768. Study conducted by the Standard Oil Company of California (SOCAL) Safety Division, 225 Bush St., San Francisco, CA 94120 under SOCAL 694/XV:101. Study dated 4-21-75. Received at EPA 11-15-83; in Acc. 251823.

Materials:

Pressurized can of the test material, coded SX 663, identified as ORTHO Home & Garden Spray (PN 1000-57C); described as a white foamy liquid after being sprayed.

Six adult male NZ white rabbits, 3 with intact, 3 with abraded skin.

Procedure:

A dose of 5 g/kg (determined by weight loss of the can) was sprayed directly onto each rabbit. There was 24-hr occluded exposure, with 14-day observation. Rabbits were fitted with collars for 2 days after exposure to prevent ingestion of test material. Rabbits were sacrificed at 14 days and examined for gross pathological changes. It is reported that the following were examined: thymus, heart, lungs, liver, kidneys, adrenal glands, spleen, gonads, gastro-intestinal tract, pancreas, salivary glands, body fat, skeletal muscle, eyes, teeth and skin.

Weights were apparently taken pre-test, and at 7 and 14 days.

Results:

No mortality. No symptoms of "systemic toxicity." Severe edema and necrosis were observed at treated areas at 24 hrs. At autopsy, there was sloughing, thickened and necrotic skin. No other effects could be attributed to the exposure.

There are no individual or average weight data reported, although the statement is made that one subject showed a weight loss at 7 days but all had gained weight at 14 days.

Rabbit dermal $LD_{50}$ > 5 g/kg.

Conclusions:

The study adequately demonstrates that the product has a rabbit dermal $LD_{50}$ > 5 g/kg.

Tox. Category: III

Core Classification: Minimum

*3. Primary eye irritation - rabbit

Citation:

Spence, J.A., Ph.D. The eye irritation potential of Ortho household insect control (PN 1000-52). S-696. Study conducted by the Standard Oil Company of California (SOCAL) Safety Division, 225 Bush St., San Francisco, CA 94120 under SOCAL 619/XX:46. Study dated 6-24-74. Received at EPA 11-15-83; in Acc. 251823.

Materials:

A spray can of the test material.

Six NZ white rabbits.

Procedure:

The test material was sprayed directly from the can into one eye of each of the rabbits from a distance of 6 inches. Eyes were examined at 1, 24, 48 and 72 hrs.

Results:

Minimal conjunctival redness in 2 eyes at 1-hr; all eyes were clear at 24 hrs.

Conclusion:

Although it is not completely certain as to the amount of material that was introduced into each rabbit eye, this type of exposure is what is anticipated for normal use. The study adequately demonstrates a low hazard by this exposure route.

Tox. Category: IV

Core Classification: Minimum

4. Primary dermal irritation - rabbit

Citation:

Spence, J.A., Ph.D. The skin irritation potential of Ortho household insect control (PN 1000-52). S-697. Study conducted by the Standard Oil Co. of California (SOCAL) Safety Division, 225 Bush St., San Francisco, CA 94120 under SOCAL 620/XX:46. Study dated 6-24-74. Received at EPA 11-15-83; in Acc. 251823.

Materials:

Pressurized can of the test material.

Six male NZ white rabbits.

Procedure:

Approximately 0.5 g test material (determined by weight loss of the can) was sprayed directly on an intact and an abraded skin site on each of 6 rabbits, with subsequent 24-hr occluded dermal exposure.

Results:

Reported that no irritation was observed and PIS = 0.

Discussion:

It is noteworthy that severe edema and necrosis were observed at 24 hrs in the acute dermal $LD_{50}$ study but not here. However, if the rabbits in the dermal $LD_{50}$ study each weighed 2 kgs then they each received exposure to at least 10 ml/kg, or 20x the amount (0.5 ml) received in the dermal irritation study. The difference in reactions is simply due to differences in amounts of material applied.

Conclusion:

This study adequately defines the product hazard by this exposure route.

Tox. Category: IV

Core Classification: Minimum

5. Acute inhalation $LC_{50}$ - rat

Citation:

Spence, J.A., Ph.D. The acute inhalation toxicity of Ortho home and garden spray (PN 1000-57-C). S-769. Study conducted by the Standard Oil Co. of California (SOCAL) Safety Division, 225 Bush St., San Francisco, CA 94120 under SOCAL 695/XXI:68. Study dated 4-21-75. Received at EPA 11-15-83; in Acc. 251823.

Materials:

Two pressurized cans of Ortho Home and Garden Spray, coded SX 663.

Five male and 5 female adult Sprague-Dawley rats.

A 380-liter inhalation chamber.

Procedures:

The entire contents (893.1 g) from two cans were emptied into the chamber (with the rats inside) over a 31-minute period. The chamber was then sealed for an additional 29 minutes, after which the rats were removed. A control group was exposed to air only. Rats were observed for 14 days, then sacrificed. The following are reported as having been examined: thymus, heart, lungs, bladder, pancreas, salivary glands, lymph nodes, body fat, skeletal muscle, teeth, eyes and skin.

Weights were taken pre-exposure, and at 1, 7 and 14 days afterwards. Weights of exposed rats were compared to those of controls using Student's t-test.

Results:

Reported that no mortalities or signs of toxicity occurred, and that weights of exposed animals were not statistically different from those of controls. However, neither individual nor group average weights are given. Reported that at autopsy no gross pathological changes were observed that could be attributed to the test material; however, no individual necropsy reports are given.

Conclusion:

The maximum possible nominal concentration to which rats could have been exposed would be 2350 mg/L (= 893.1 g x 1000 mg/g ÷ 380 L), reached at 31 minutes after exposure initiation.

Since there is no analytical data as to the actual product concentration (and/or its active), the study must be classified as supplementary. The analytical data are particularly relevant as the product is described in another study as a foamy white liquid, and it is not known how much of this, if any, would vaporize under the study conditions.

Tox. Category: Not defined

Study Classification: Supplementary