UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

003928

DATE: August 27, 1978

SUBJECT: Ortho Hi-Power Indoor Insect Fogger (Active Ingredients: Pyrethrins, piperonyl butoxide, N-Octyl bicycloheptene dicarboximide, petroleum distillate) - Amendment (Label Revision) with Data, EPA Reg. No. 239-2429 Caswell Nos. 715, 670, (613) 646, [redacted]

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Recommendations

Acute oral LD_{50}, acute dermal LD_{50}, skin irritation, and eye irritation studies are adequate. The acute inhalation LD_{50} study is inadequate for reasons stated in the review. Nonetheless, the hazards associated with the formulation are considered to be sufficiently defined to support use of the label, based on the signal word CAUTION, proposed by the registrant; however, the following revision of the precautionary statements is mandatory:

CAUTION: Keep Out of Reach Of Children.

Harmful if swallowed, inhaled, or absorbed through the skin. Avoid contact with skin, eyes and clothing.

FIRST AID: In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes.

* No RPAR criteria have been exceeded. However, piperonyl butoxide is an RPAR candidate on the basis of oncogenic potential.

Review

Acute Toxicity Studies of ORTHO Hi-Power Indoor Insect Fogger (Standard Oil Co. of Ca., Nos. S-1239, S-1240, S-1241, S-904, S-1242, 3/2/78 and 8/21/75, submitted by the Chevron Chemical Co., 4/21/78, Acc. No. 234217).

A. Acute Oral LD_{50} Study in Rats

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1. Procedure

Twenty Sprague-Dawley rats, 207-257g, were divided into 2 groups of 10 animals each (5 males and 5 females) which were given 0 g/kg or 5 g/kg of test material orally. Animals were observed for mortality, body weight changes, and toxic signs during 14 days

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INFORMATION WHICH MAY REVEAL THE IDENTITY OF AN INERT INGREDIENT IS NOT INCLUDED

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post-treatment. Necropsies were done.

2. Results

a. Mortality: None, $LD_{50} > 5$ g/kg

b. Toxic Signs: Hyperactivity, depression.

c. Body Weight Changes: Unremarkable

d. Necropsy: Unremarkable.

3. Conclusions

a. Core Minimum Data

i. Body weights in conjunction with food intake were not determined daily.

b. Tox. Cat.: IV

B. Acute Dermal LD_{50} Study in Rabbits

1. Procedure

Twelve male New Zealand White rabbits, 2.18 - 2.82, were divided into 2 groups of 6 animals each which received dermal applications of 0 g/kg or 5 g/kg of test material as a spray under occlusive dressing. Control and treated animals were maintained similarly. Dressing and residual test material were removed at 24 hours post-exposure. Observations of mortality, toxic signs, and body weight changes were made over 14 days following treatment.

2. Results

a. Mortality: None, $LD_{50} > 5$ g/kg

b. Toxic Signs: Reddening and flaking of skin at test sites

c. Body Weight Changes: Unremarkable

d. Necropsy: Cyst over the submaxillary gland in 1 treated rabbit.

3. Conclusions

a. Classification: Core Minimum Data

i. Body weights in conjunction with food intake were not determined daily.

b. Tox. Cat.: III

C. Skin Irritation Study in Rabbits

1. Procedure

Six male New Zealand White rabbits, weights not stated, were used. Onto both intact and abraded test sites was applied 0.5 ml of test substance as a spray under occlusive dressing. Dressing and residual test material were removed at 24 hours after treatment. Irritation was scored according to a modification of the method of Draize et.al. (1944) at 24, 48 and 72 hours and 6 days post-treatment.

2. Results

P.I. Index = 2.8/8.0. By 6 days post-treatment, scores had increased, and skin at the test sites was sloughing, bleeding, and broken.

3. Conclusions

a. Classification: Core Guidelines

b. Tox. Cat.: III

D. Eye Irritation Study in Rabbits

1. Procedure

Six male New Zealand White rabbits were used. Into 1 eye of each rabbit was sprayed test material from a pressurized can for 1 second at a distance of 6 inches from the eye. Untreated eyes served as controls. Injuries were scored according to a modification of the method of Draize et. al. (1944) at 1, 24, 48 and 72 hours post-application.

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2. Results

Eye Injuries: Conjunctivitis during 24 hours following treatment. No corneal opacities were observed.

3. Conclusions

a. Classification: Core Minimum Data

i. The actual amount of test material sprayed into the eyes was not estimated; however, the eye irritation potential is considered to be sufficiently defined.

ii. Possible benefit of washing eyes following treatment was not estimated.

b. Tox. Cat.: III

E. Acute Inhaltion LC_{50} Study in Rats

1. Procedure

Ten (5 males and 5 females) Sprague-Dawley rats, 233-299g, were placed into a 380 L inhalation chamber and were exposed for 1 hour to 9.1 g of test material sprayed into the chamber as an aerosol. The exposure was conducted under static conditions. Five untreated rats of each sex served as controls. Observations of mortality, toxic signs, and body weight changes were made during 14 days post-treatment. Necropsies were done.

2. Results

a. Mortality: None. $LD_{50} > 2.3$ mg/L (1 hour)

b. Toxic Signs: Unremarkable

c. Body Weight Changes: Unremarkable

d. Necropsy: Unremarkable

3. Conclusions

a. Classification: Supplementary Data

i. In static exposures loss of material/time/chamber volume must be reported.

ii. Body weights in conjunction with food intake were not reported daily.

iii. Particle size was not stated.

b. Tox. Cat.: IV (Provisional)

F. Final Conclusions

The following hazard indicators support use of the label signal word CAUTION proposed by the registrant:

Hazard Indicator	Tox. Cat.
Acute Oral LD_{50}	IV
Acute Dermal LD_{50}	III
Skin Irritation	III
Eye Irritation	III
Acute Inhalation LC_{50}	IV (Provisional)

R/D init:REngler 8/22/78
LAnderson:km