UNIT STATES ENVIRONMENTAL PROTE ION AGENCY 4-10-78

CASWELI FILE

DATE: April 10, 1978

SUBJECT: Neuropathology of Sumithrin by route of inhalation. Acute studies on "prototype" Sumithrin, Allethrin, Tetramethrin Spray. Caswell#652B,25,844

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Conclusion

1. The acute studies performed on the prototype formulation are acceptable and can be used for classification and labeling purposes of similar formulations containing about equal or less amounts of active, inerts, and emulsifies. These formulations will fall in TOX Category III and can be classified for general use.

2. Any reference to spraying food handling establishments must be deleted from labels.

3. For the registration of formulations used in and around the home a teratology study on each active ingredient must be references or submitted.

4. The neuropathology study by inhalation route did not show any damage to nerves at levels as high as 3760 mg/m^3. An effect level could not be reached by this route of exposure. We therefore can conclude, that the risk if any associated with spraying 0.2% solutions is minimal.

5. Should other uses in the future increase the likelyhood of oral exposur neuropathology test using that route will be necessary.

Review

The registrant has tested the acute toxicity of a prototype formulation, intending to use this data to register similar formulations which are permutations of the prototype formulation.

The composition of the prototype formulation is as follows, and carries cod X-3240-78

Sumithrin (Phenotrin) 1.0%
By-products of Sumithrin 0.08%
Pynamin Forte (allethrin) 1.0%
By-products of Allethrin) 0.07%
Neo-Pynamin (Tetramethrin) 1.0%
By-products of Teramethrin) 0.05%
Repellent 874 3.0%

INERT INGREDIENT INFORMATION IS NOT INCLUDED

EPA FORM 1320-6 (REV. 3-76)

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1. Acute toxicity studies, BioRearch, Project No. 78-1172A

a) Dermal LD_{50} in rabbits

Four animals per sex dose were used. The dose levels were 4,8,16, and 20 ml/kg. Half of the animals had their skin abraded.

Results: In the intact skin group one female died at 20 ml/kg level, on day 4 in the abraded group both females and one male died at the 20 ml/kg group within 3 days. Gross observation showed lethargy and weight loss at the two higher levels and no effects at the lower levels. Gross pathology was unremarkable.

The LD_{50} (dermal) is greater than 16 ml/kg. Core-Minimum Study.

b) Skin irritation study (rabbits)

Essentially the Draize protocol was followed. The skin irritation score was 2.25/8.0. Core-Minimum Study.

c) Eye irritation study (rabbits)

0.1 ml of material was instilled into one eye of six rabbits each. The irritation score was zero throughout the 7 days of observation. Core-Guideline Study.

d) Acute Oral Toxicity (rats)

5 animals per sex per dose were used, the doses were 1,2,4,16 ml/kg. A 16 ml/kg one male died on day 7. Animals dosed 16 ml/kg were ataxic fo about 8 hours and returned to normal. Gross pathology was unremarkable

The oral LD_{50} is greater than 16 ml/kg. Core-Minimum Study.

2. Acute inhalation toxicity with Phenothrin (S-2539 Forte) in rats. Sumitomo Chemical Co., Report No. ET-70, Oct. 24, 1977.

The material used was technical phenothrin c/t ratio 18.1/81.9. The compound was disolved and sprayed into exposure chamber. Large particl were removed before introducing the air stream into the exposure chambe The chamber concentration was determined by analytical method, but no particle size distribution is given. 20 animals per sex per dose were exposed for 4 hours. The groups consisted of diluent (control), 2,960 mg/m^3 and 3,760 mg/m^3. On the third and seventh day 5 rats per sex per group were sacrificed for neurological examination. Myelin degeneratio axonal swelling and sisintegration were measured. Body weights and clinical symptoms were observed.

Results: No clinical effects were noted, and body weight gains were normal in all groups. Histopathology of the sciatic nerves showed no effects rela to compound administration.

S.F.W. 4/10/79