UNITED STATES ENVIRONMENTAL PROTECTION AGENCY (10-2-79)58.

CASWELL FILE

DATE: September 18, 1979

SUBJECT: EPA File No. 1021-1383, Toxicity Studies to Add to Files. Multicide Sumithrin Concentrate

FROM: John Doherty
Toxicology Branch/HED (TS-769)

Caswell #25, 613, 652B, 844

TO: F.D.R. Gee
Product Manager, #17, Registration Div. (TS-767)

Action requested: Review acute toxicity studies and a sensitization study.

Conclusion:

All studies were CORE GUIDELINES, no action is necessary.

Remarks:

The company letter states that the purpose of testing the concentrated form was to cover a wide variety of other formulations without having to do additional acute toxicity testing. The letter states that this has been acceptable in the past and that they assume that it will continue to be so in the future.

The company should be advised that some products may have to have acute toxicity tests conducted in order to support labelling because the "inerts" have various toxicological properties.

Summary Tables

A. Studies with TL-1998

	Test	Results	TOX Cat.	CORE Classification
1.	Acute Oral LD50-rats	2.1 gm/kg males 2.0 gm/kg female	III	GUIDELINES
2.	Acute Dermal LD50-rabbits	> 20.0 gm/kg	IV	GUIDELINES
3.	Eye Irritation-rabbits	No corneal involvement	IV	GUIDELINES
4.	Skin Irritation-rabbits	Not irritating Draize Score= 1.0	III	GUIDELINES
5.	Guinea Pig Sensitization	0.3 ml not a sensitizer		GUIDELINES

B. Study with TL-1999

1. Acute Inhalation LC50 -rats > 842.9 mg/1i for 1 hour IV. GUIDELINES

All studies were conducted by BIORESEARCH Inc. and dated January 24, 1979.

The test material used for these studies was labelled as TL-1999 or TL-1998 and the compositions were as follows:

TL-1999	TL-1998
2.0% Neo-pynamin (844)	15.0%
.14% Neo-pynamin tech ingred.	1.01%
2.0% Sumithrin (652B)	15.0%
.23% Sumithrin tech. ingred.	1.67%
2.00% MGK-264 (613)	15.00%
2.00% Piperonyl butoxide, tech. (670)	15.00%
2.00% d-trans allethrin (25)	15.00%
.23% d-trans allethrin tech.	1.67%
[redacted]	

(Caswell No.)

CONFIDENTIAL

INERT INGREDIENT INFORMATION IS NOT INCLUDED

Review of Studies

1. Acute Oral Toxicity - rats

5 groups of 5 male and 5 female albino rats were dosed with either 1.0 , 2.0, 4.0, 8.0 or 16.0 gm/kg of TL-1998. The rats were observed for toxicity for 14 days.

Results:

LD_{50} males 2.1 gm/kg (1.5 to 3.0) 19/20 confid limits LD_{50} females 2.0 gm/kg (1.4 to 2.8) 19/20 confid. limits. Symptoms included ataxia and comatose; survivors were normal in 24 hours.

CORE GUIDELINES: TOX. Cat. III

2. Acute Dermal Toxicity - rabbits

4 groups of eight albino rabbits (4 male and 4 female) were prepared by clipping and abrading. They were dosed with 4.0, 8.0, 16.0 or 20.0 gm/kg of TL-1998 and the test material was kept in place for 24 hours.

Results:

No rabbits died. At 16 and 20 gm/kg, the rabbits were depressed, cold and lethargic and some weight loss resulted. Gross pathologic examination revealed nothing remarkable.

CORE GUIDELINES, Toxicity category IV

3. Eye Irritation - rabbits

Six albino rabbits were instilled with 0.1 gm of the test material (TL-1998) and there eyes were examined at 1, 24, 48, and 72 hours and 5 and 7 days later.

Results:

No corneal damage is reported. Transient conjunctivae irritation that diminished in 24 (or at most 48 hours) resulted.

CORE GUIDELINES, Toxicity Category III.

4. Primary Skin Irritation - rabbits

6 albino rabbits were clipped over a wide area, one side was additionally abraded. 0.5 gm of test material was applied to an abraded and intact skin site on each rabbit. The material was kept in place for 24 hours.

Results:

A Draize score of 1.00 was determined. Mild irritation only resulted.

CORE GUIDELINES, Toxicity Category III.

5. Guinea Pig Contact Dermal Irritation/Sensitization

6 guinea pigs were shaved and dosed with 0.3 ml of TL-1998 by application (topical). The material was kept in place for 24 hours. The animals were allowed a days rest and then on each of the following 10 days subsequent applications were made. After the 10th application the guinea pigs were rested for 14 days and a challenge application was applied.

Results:

No signs of irritation were reported.

CORE GUIDELINES (upgraded from MINIMUM at least 10 animals should have been used).

6. Acute Inhalation - rats (dilute formulation)

Three groups of 10 rats (5 male and 5 female) were used to determine the acute inhalation toxicity of TL-1999. These groups were exposed to atmospheric concentrations of 162.8, 375.7 and 842.9 mg/L. These concentrations were obtained by spraying the aerosol can for 10 seconds, 30 seconds, or 60 seconds into the chamber each 10 minute period. The cans were then weighted for the amount of test material disbursed

Results:

No rats died. All animals showed signs of depression and agitation. These symptoms were dose dependent. Ataxia and labored breathing were apparent in the highest dose group. After 72 hours the animals were recovered. Gross pathologic examination revealed nothing remarkable.

CORE GUIDELINES, Toxicity Category IV.