9/13/92

MEMORANDUM:

Subject: EPA File Symbol/EPA Reg. No.:7173-113

From: Lucy D. Markarian, Biologist 9/13/92
Precautionary Review Section
Registration Support Branch
Registration Division (H7505C)

To: Rob Forrest, PM 14
Insecticide-Rodenticide Branch
Registration Division (H7505C)

Thru: Thomas C. Ellwanger, Section Head E 3/3/92
Precautionary Review Section
Registration Support Branch
Registration Division (H7505C)

Applicant: Lipha Tech
3600 West Elm Street
Milwaukee, WI 53209

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
2-[(p-chlorophenyl)phenylacetyl]1,3-indandione.....	0.2 %
Inert Ingredient(s):	
.....	99.8 %
Total:	100.0 %

BACKGROUND

Lipha Tech has applied to change the signal word of the product Rozol Tracking Powder for Indoor Use from WARNING to DANGER based on the dermal toxicity as tested with the 100 % active ingredient. The dermal toxicity of the 100 % active ingredient was shown to be 0.326 mg/kg. They have extrapolated the toxicity of the end use product to be 165.9 mg/kg and claim that this places the dermal toxicity in category I.

RECOMMENDATION

The dermal LD_{50} of the undiluted active ingredient according to the cited and reviewed test under MRID 417028-01 is 0.326 mg/kg. This would place the active ingredient in category I toxicity, but not necessarily the end use product that is 500 times more dilute. The extrapolation, while mathematically correct, does not justify the change in the signal word, because the extrapolation is not toxicologically valid. Granted that the active ingredient is highly toxic, it is recognized that very often the more dilute form of an active ingredient is not as toxic or not toxic at all. PRS is of the opinion that a 500 fold dilution would make a significant difference in the toxicity, but the LD_{50} cannot be simply calculated. The total product will have to be tested.

There is not enough acceptable toxicological data in the file on the end use product to form a meaningful opinion. If Lipha Tech would like a more stringent label, then tests with the end use product that show the necessity of such a label change must be submitted. PRS does not encourage either over-or under-labeling of pesticides.

LABELING

The label at this time is appropriate as it was prior to the application for change.

DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (§81-2)

Product Manager: 14
MRID No.: 417028-01
Testing Laboratory: Toxicon Corporation
Author(s): Herman S. Lilja
Species: Rabbit, New Zealand White
Weight: 2.0 - 3.0 kg
Source: Pine Acres Rabbitry, Norton, Ma
Test Material: Chlorophacinone Powder, Lot CLOMO15
Quality Assurance (40 CFR §160.12): Included

Reviewer: L. Markarian
Report Date: 1/13/92
Report No.: 89G-0146D

Summary:

1. LC_{50} (mg/kg): **Males** = 0.329 (0.207 - 0.524)
   Females =Not Tested

2. **Tox. Category:** I **Classification:** Core minimum

Procedure (Deviation From §81-2):
The test material was suspended in acetone (250 mg/ 10 ml) and stirred for 10 minutes. The stirred suspension was placed in a graduated cylinder and QS to 25 ml with acetone. Appropriately calculated dosages for each animal was placed over a Scotch-Pack (2 x 2 cm)and allowed to evaporate in the laboratory hood for 5 - 10 minutes. these patches were applied to the shaved dorsum of the rabbits at three dose levels in groups of ten animals per level. At 24 hours the patches were removed and the site wiped and rinsed with water. The dermal reactions were recorded according to Draize. It is stated that the animals were observed for 21 days; however, it is not clear as to how often and when the observed symptoms appeared and ended. Body weights were recorded at initiation and at weekly intervals for 21 days and at death. Necropsy was performed on all animals.

Results:

Reported Mortality

DOSAGE mg/kg	(NUMBER KILLED/NUMBER TESTED)		
	Males	Females	Combined
0.75	9/10		
0.50	6/10		
0.25	4/10		

Symptoms & Gross Necropsy Findings:

Mortality occurred as late as day 19 at the lowest dose level. Symptoms of toxicity included lethargy, labored respiration

(abdominal breathing), pallor of the eyes and ears, hemorrhage and discharge from the nostrils, watery stools, tachypnea, somnolence and weight loss. No dermal reactions were present.
Necropsy of most of the decedents and some of the survivors showed lesions of the respiratory and gastrointestinal organs as well as that of the liver and kidneys that were associated with internal hemorrhage.

Tox Chem No 211C **Current Date** 1/13/92

Laboratory: Toxicon Corporation,225 wildwood Avenue, Woburn, Ma01801

Acute Dermal LD_{50} Dtudy in Rabbits 89G-0146D 8/21/90	Chlorophacinone Lot CLOMO15	MRID 417028-01	LD_{50} mg/kg 0.329(0.207-0.685)	Tox Cat I	Core Minimum

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