

US EPA ARCHIVE DOCUMENT



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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

July 13, 1990

MEMORANDUM

SUBJECT: EPA Reg. No./File Symbol 9688-IG
Chemsico Lawn & Garden Insect Control

FROM: Olga Odiott *Olga O.D.M.*
Precautionary Review Section
Registration Support Branch
Registration Division (H75-05C)

E 7/23/90

TO: George La Rocca (PM 15)
Insecticide - Rodenticide Branch
Registration Division (H75-05C)

APPLICANT: Chemsico Inc.
8494 Chapin Industrial Dr.
St-Louis, MO 63114

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
<u>Permethrin</u>	<u>0.25%</u>
_____	_____
_____	_____
_____	_____
<u>Inert Ingredient(s):</u>	<u>99.25%</u>
Total	100.0%

BACKGROUND

Acute oral, acute dermal, acute eye, skin irritation and skin sensitization studies were submitted to support Reg. No. 9688-IG. The studies were performed at Tox Monitor Lab. Inc. and Biologic Safety Research. MRID No. 415013-01 through 415013-05.

An acute inhalation study was not submitted.

RECOMMENDATION

RSB/PRS finds the studies acceptable to support this registration.

The skin sensitization study is considered core minimum data because the amount of test material used for the induction applications was half the amount specified by the Buehler's method.

An acute inhalation study is required for proper registration of this product.

LABELING

The signal word is Caution.

Revise the first sentence of the Precautionary statements to read as follows:

"Harmful if absorbed through skin. Causes moderate eye irritation."

Revise the Statements of Practical treatment as follows:

The "If on skin" and "If in eyes" statements should precede the other statements.

The "If on skin" statement should read as follows: "Wash with plenty of soap and water. Get medical attention."

Note:

Further label revisions may be necessary upon submittance of outstanding data.

DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (§81-1)

Product Manager: (15) Reviewer: O. Odiott
 MRID No.: 415013-03 Report Date: Apr/20, 1990
 Testing Facility: Tox Monitor Lab, Inc. Report No. 90-61-3
 Author(s): Michael Kukulinski
 Species: Sprague-Dawley rats
 Age: 6-10 weeks Observation Days (Post Exposure): (14); other ()
 Weight: 200-300 gms
 Source: Bio Lab, Inc. St. Paul, Minnesota
 Test Material: Lawn & Garden Insect Control
 Quality Assurance (40 CFR §160.12): attached

Conclusion:

1. LD₅₀ (mg/kg): Males = _____; Females = _____; Combined = _____
2. The estimated LD₅₀ is > 5 gm/kg.
3. Tox. Category: IV. Classification: Guideline

Procedure (Deviations From §81-1): _____

Results:

Reported Mortality

DOSAGE (/kg)	(NUMBER KILLED/NUMBER TESTED)		
	Males	Females	Combined
<u>5 gm/kg</u>	<u>0/5</u>	<u>0/5</u>	<u>0/10</u>

Symptomology & Gross Necropsy Findings:

Animals appeared normal throughout the study.
No abnormalities observed at necropsy:

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

Product Manager: (15)
 MRID No.: 415013-04
 Testing Laboratory: Tox Monitor Lab
 Author(s): Michael Fekulewski
 Species: New Zealand albino Rabbits
 Sex: male & female Wt.: 2-3 kg.
 Test Material: Lamin & Garden Insect Control
 Quality Assurance (40 CFR §160.12): attached

Reviewer: O. Odiott
 Report Date: April 20, 1990
 Report No. 90-61-4

Summary:

- LD₅₀ (mg/kg): Males = _____; Females = _____; Combined = _____
- The estimated LD₅₀ is 22 gm/kg.
- Tox. Category: III. Classification: *flu delene*

Procedure (Deviations From §81-2): _____

Results:

DOSAGE (/kg)	Reported Mortality		
	(NUMBER KILLED/NUMBER TESTED)		
	Males	Females	Combined
2 gm/kg.	0/5	0/5	0/10

Symptomology & Gross Necropsy Findings:

Erythema and edema were observed in all animals 1 day after treatment. Symptoms cleared by day 2. No other symptoms observed. No abnormalities at gross necropsy.

DATA REVIEW FOR ACUTE EYE IRRITATION TESTING (§81-4)

Product Manager: (15) Reviewer: O. Odiott
 MRID No.: 415013-01 Report Date: April 20, 1990
 Testing Laboratory: Tox Monitor Lab. Inc. Report No. 90-61-1
 Author(s): Michael Kukulinski
 Species: New Zealand white rabbit
 Sex: females Weight: 2008 - 2219 gm
 Source: Scientific Small Animal Lab. & Farm Arlington Heights, IL
 Dosage: 0.1 ml
 Test Material: Lawn & Garden Insect Control
 Quality Assurance (40 CFR §160.12): Attached

Summary:

Tox. Category: III Classification: Guideline

Procedure (Deviation From §81-4):

Results:

	Observations (number "positive"/number tested)							
	Hour	Days						
	1	1	2	3	4	7	14	21
Cornea Opacity	0/6	2/6	1/6	1/6		0/6		
Iris	0/6	2/6	0/6	0/6		0/6		
Conjunctivae Redness	5/6	2/6	1/6	0/6		0/6		
Chemosis	4/6	2/6	1/6	0/6		0/6		
Discharge	6/6	2/6	1/6	0/6		0/6		

Comments:

DATA REVIEW FOR SKIN IRRITATION TESTING (§81-5)

Product Manager: (15) Reviewer: O. Odiott
MRID No.: 415013-02 Report Date: April 24, 1990
Testing Laboratory: Tox Monitor Lab. Inc. Report No. 90-61-2
Author(s): Michael Kukulinski
Species: New Zealand white Rabbit
Age: 8-10 weeks old
Sex :
Weight: 2009-2342 gm
Dosage: 0.5 gm
Test Material: Lawn & Garden Insect Control
Quality Assurance (40 CFR §160.12): attached.

Summary:

The Primary Irritation Index = _____

Toxicity Category: IV

Classification: Guideline

Procedure (Deviations From §81-5): _____

Results:

Edema or erythema were not observed throughout the study

Special Comments:

DATA REVIEW FOR SKIN SENSITIZATION TESTING (§81-6)

Product Manager: (15)
MRID No.: 415013-05
Testing Laboratory: Biologic Safety Research
Author(s): Michael Kukulinski
Species: Hartley albino quinea pig
Sex: male
Weight: 243-328 gm
Source: Harlan Sprague Dawley, Indianapolis, Inc.
Test Material: Lawn & Herben Insect Control
Positive Control Material: DNCB
Quality Assurance (40 CFR §160.12): attached
Method: Büchler's

Summary:

1. This product is / (is not a dermal sensitizer.
2. Classification: core minimum

Procedure (Deviation From §81-6): 0.2 gm of test material
was used for induction & challenge treatments instead
of 0.4 gm as specified by the Büchler's method

Results: The test group (10) was treated with the undiluted
test material 3 times a week for 3 weeks for a
total of 10 induction exposures. A challenge
application was performed 2 weeks after the
last induction.

Using the same schedule, 6 animals were treated
with 0.1% DNCB in DMSO (positive control) and
1 animal served as negative control.

The test group did not show irritation during
induction or at challenge.

The positive control group showed sensitization.