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 Od.
Precautionary Review Section
Registration Support Branch
Registration Division (H75-05C) E 7/23/90

TO: Georg 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:

Active Ingredient(s):	% by wt.
Permethrin	0.25%
Inert Ingredient(s):	99.25%
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)
MRID No.: 415013-03
Testing Facility: Tox Monitor Lab, Inc.
Author(s): Michael Kukulinski
Species: Sprague-Dawley rats
Age: 6-10 weeks
Weight: 200-300 gms
Source: Bio Lab, Inc. St. Paul, Minnesota
Test Material: Lawn & Garden Insect Control
Quality Assurance (40 CFR §160.12): attached

Reviewer: O. Odiott
Report Date: April 20, 1990
Report No. 90-64-3

Observation Days (Post Exposure): (14); other ( )

Conclusion:

1. LD_{50} (mg/kg): Males = _____; Females = _____; Combined = _____
2. The estimated LD_{50} 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
5 gm/kg	0/5	0/5	0/10

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 Fukuchinski
Species: New Zealand albino Rabbits
Sex: male & female Wt.: 2-3 KG.
Test Material: Lawn & Garden Insect Control
Quality Assurance (40 CFR §160.12): attached

Reviewer: O. Odiott
Report Date: April 30, 1990
Report No. 90-01-4

Summary:

1. LD_{50} (mg/kg): Males = _____; Females = _____; Combined = _____;
2. The estimated LD_{50} is 2 gm/kg - Guideline
3. Tox. Category: III. Classification: Guideline

Procedure (Deviations From §81-2): _____

Results:

Reported Mortality

DOSAGE (/kg)	(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)
MRID No.: 415013-01
Testing Laboratory: Tox Monitor Lab. Inc.
Author(s): Michael Kukulinski
Species: New Zealand white Rabbit
Sex: females
Weight: 2208 - 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): & Hachek

Reviewer: O. Odiott
Report Date: April 20, 1990
Report No. 90-61-1

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)
MRID No.: 415013-02
Testing Laboratory: Tox Monitor Lab. Inc.
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.

Reviewer: O. Odiott
Report Date: April 20, 1990
Report No. 90-61-2

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 guinea pig
Sex : male
Weight: 243-328 gm
Source: Harlan Sprague Dawley, Indianapolis, Inc.
Test Material: Sawn & Garden Insect Control
Positive Control Material: DNCB
Quality Assurance (40 CFR §160.12): attached

Reviewer: O. Odiott
Report Date: April 18, 1990
Report No. 022-004

Method: Buehler's

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

Procedure (Deviation From §81-6): 0.2gm of test material was used for induction & challenge treatments instead of 0.4gm as specified by the Buehlers 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 pchedule, 6 animals were treated with 0.1% DNCB in DMSO (positive control) and 4 animal served as negative control.
The test group did not show irritation during induction or at challenge.
The positive control group showed sensitization.