

US EPA ARCHIVE DOCUMENT



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

OFFICE OF
PREVENTION, PESTICIDES
AND
TOXIC SUBSTANCES

22/JUNE/2000

MEMORANDUM

Subject: File Symbol/EPA Reg. No.: 9688-RAR Chemsico Insecticide
DP Barcode: D266549 Concentrate N30-A
Case No: 068129
PC Code: 209500

From: Eugenia McAndrew, Biologist *Em*
Technical Review Branch *SCR*
Registration Division (7505C)

To: Leonard Cole, PM Team 03
Insecticide Branch
Registration Division (7505C)

Applicant: Chemsico
Division of United Industries Corp.
P.O. Box 15842
St. Louis, MO 63114

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
209500 Permethrin	1.25
<u>Inert Ingredient(s):</u>	<u>98.75</u>
	Total: 100.00%

ACTION REQUESTED: PM requests review of acute toxicity data for EPA File Symbol No. 9688-RAR, Chemsico Insecticide Concentrate N30-A.

BACKGROUND: Chemsico has submitted a six pack of acute toxicity studies in support of registration of EPA File Symbol No. 9688-RAR, a new product known as Chemsico Insecticide Concentrate N30-A, which is a combination fertilizer and insecticide. MRID # are 450589-03 to -08. The studies were conducted at Product Safety Labs, East Brunswick, New Jersey.

RECOMMENDATIONS: The six studies have been reviewed and are classified as acceptable.

The acute toxicity profile for EPA File Symbol No. 9688-RAR is as follows:

acute oral toxicity	IV	Acceptable
acute dermal toxicity	IV	Acceptable
acute inhalation toxicity	IV	Acceptable
primary eye irritation	III	Acceptable
primary skin irritation	IV	Acceptable
dermal sensitization	No	Acceptable

LABELING: Based on the toxicity profile above, the following are the precautionary and first aid statements for this product as obtained from the Label Review System.

Date: 06/22/00 LABEL REVIEW SYSTEM

ID #: 009688-00161 Concentrate N30-A

SIGNAL WORD: CAUTION

PRECAUTIONARY STATEMENTS:

Causes moderate eye irritation. Avoid contact with eyes or clothing.
Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.

STATEMENT OF PRACTICAL TREATMENT (SOPT):

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (870.1100)

Product Manager: 03
MRID No.: 45058903

Reviewer: Eugenia McAndrew
Study Completion Date: February 29, 2000
Study No.: 8688

Testing Facility: Product Safety Labs
Author: George E. Moore, B.S.

Quality Assurance (40 CFR §160.12): Included

Test Material: Chemsico Insecticide Concentrate N30-A; Lot # 00-01-PS-P9; 1.25% Permethrin; clear lightly tinted liquid

Species: Rat; albino, Sprague-Dawley derived

Age: Young adult

Weight (fasted): Males: 216-231 g; Females: 174-200 g

Source: Ace Animals, Inc., Boyertown, PA

Conclusion:

- LD₅₀ (mg/kg):**
Males: > 5000 mg/kg
Females: > 5000 mg/kg
Combined: > 5000 mg/kg
- The estimated LD₅₀ is** > 5000 mg/kg
- Tox. Category:** IV **Classification:** Acceptable

Procedure (Deviations from 870.1100): None

Results:

Dosage (mg/kg)	Number of Deaths/Number Tested		
	Males	Females	Combined
5000	0/5	0/5	0/10

Observations: All animals survived and gained weight during the study. Piloerection and anogenital staining were observed in three animals for the first three hours after dosing. No other clinical signs were noted during the 14-day observation period.

Gross Necropsy: No gross abnormalities were noted.

DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (870.1200)

Product Manager: 03
MRID No.: 45058904

Reviewer: Eugenia McAndrew
Study Completion Date: February 28, 2000
Study No.: 8689

Testing Facility: Product Safety Labs
Author: George E. Moore, B.S.

Quality Assurance (40 CFR §160.12): Included

Test Material: Chemsico Insecticide Concentrate N30-A; Lot # 00-01-PS-P9; 1.25% Permethrin; clear lightly tinted liquid

Species: Rat; albino, Sprague-Dawley derived

Age: Young adult

Weight (fasted): Males: 200-212 g; Females: 163-178 g

Source: Ace Animals, Inc., Boyertown, PA

Dermal LD₅₀ Testing:

Conclusion:

- LD₅₀ (mg/kg):**
Males: > 5000 mg/kg
Females: > 5000 mg/kg
Combined: > 5000 mg/kg
- The estimated LD₅₀ is** > 5000 mg/kg
- Tox. Category:** IV **Classification:** Acceptable

Procedure (Deviations from 870.1200): None

Results:

Dosage (mg/kg)	Number of Deaths/Number Tested		
	Males	Females	Combined
5000	0/5	0/5	0/10

Observations: All animals survived and gained weight during the study. Yellow discoloration of the dose site was noted in all animals between days 2 and 9. "There were no other signs of gross toxicity, adverse pharmacologic effects or abnormal behavior."

Gross Necropsy: No gross abnormalities were noted.

DATA REVIEW FOR ACUTE INHALATION TOXICITY TESTING (870.1300)

Product Manager: 03
MRID No.: 45058905

Reviewer: Eugenia McAndrew
Study Completion Date: March 1, 2000
Study No.: 8690

Testing Facility: Product Safety Labs
Author: George E. Moore, B.S.

Quality Assurance (40 CFR §160.12): Included

Test Material: Chemsico Insecticide Concentrate N30-A; Lot # 00-01-PS-P9; 1.25% Permethrin; clear lightly tinted liquid

Species: Rat; albino, Sprague-Dawley derived
Age: Young adult
Weight (fasted): Males: 216-243 g; Females: 187-208 g
Source: Ace Animals, Inc., Boyertown, PA

Conclusion:

1. **LC₅₀ (mg/L):**
Males: > 2.07 mg/L
Females: > 2.07 mg/L
Combined: > 2.07 mg/L
2. **The estimated LC₅₀ is** > 2.07 mg/L
3. **Tox. Category: IV** **Classification: Acceptable**

Procedure (Deviations from 870.1300): None

Exposure Concentration mg/L (Gravimetrically Determined)	Number of Deaths/Number Tested		
	Males	Females	Combined
2.07	0/5	0/5	0/10

Clinical Observations: Ocular and nasal discharge, irregular respiration, hunched posture and hypoactivity were observed in all animals during the exposure. All animals recovered from these symptoms after removal from the chamber and no other symptoms were noted.

Necropsy Findings: No gross abnormalities were noted.

Chamber Atmosphere		
Gravimetric conc.	MMAD	GSD
2.07 mg/L	3.5 μ m	1.60

Chamber Environment^a	
Chamber Volume	150 L
Airflow	45.7 LPM
Temperature	19-22°C
Relative Humidity	32-72%

^aWhole body

DATA REVIEW FOR PRIMARY EYE IRRITATION TESTING (870.2400)

Product Manager: 03
MRID No.: 45058906

Reviewer: Eugenia McAndrew
Study Completion Date: February 29, 2000
Study No.: 8691

Testing Facility: Product Safety Labs
Author: George E. Moore, B.S.

Quality Assurance (40 CFR §160.12): Included

Test Material: Chemsico Insecticide Concentrate N30-A; Lot # 00-01-PS-P9; 1.25% Permethrin; clear lightly tinted liquid

Dosage: 0.1 mL

Species: Rabbit; New Zealand albino

Age: Adult

Sex: 1 male and 2 females

Source: Davidson's Mill Farm, South Brunswick, NJ

Conclusion:

1. **Toxicity Category:** III
2. **Classification:** Acceptable

Procedure (Deviations from 870.2400): None

Observations	Number "positive"/number tested			
	Hours			
	1	24	48	72
	Unwashed eyes			
Corneal Opacity	0/3	0/3	0/3	0/3
Iritis	1/3	1/3	1/3	0/3
Conjunctivae:				
Redness*	2/3	2/3	2/3	0/3
Chemosis*	2/3	0/3	0/3	0/3
Discharge*	2/3	2/3	0/3	0/3

*Score of 2 or more required to be considered "positive."

Summary: No corneal opacity was observed. One hour after installation, 2/3 eyes showed conjunctivitis and 1/3 had iritis. The irritation decreased until 72 hours when all eyes were free of irritation.

DATA REVIEW FOR PRIMARY DERMAL IRRITATION TESTING (870.2500)

Product Manager: 03
MRID No.: 45058907

Reviewer: Eugenia McAndrew
Study Completion Date: February 28, 2000
Study No.: 8692

Testing Facility: Product Safety Labs
Author: George E. Moore, B.S.

Quality Assurance (40 CFR §160.12): Included

Test Material: Chemsico Insecticide Concentrate N30-A; Lot # 00-01-PS-P9; 1.25% Permethrin; clear lightly tinted liquid

Dosage: 0.5 mL

Species: Rabbit; New Zealand albino

Age: Adult

Sex: 1 male and 2 females

Source: Davidson's Mill Farm, South Brunswick, NJ

Conclusion:

1. **Toxicity Category:** IV
2. **Classification:** Acceptable

Procedure (Deviations from 870.2500): None

Results: PDII = 0.8 All test sites had very slight erythema and edema (grade 1) one hour after patch removal. The edema subsided by 24 hours. All sites were free of irritation by 72 hours.

DATA REVIEW FOR DERMAL SENSITIZATION TESTING (870.2600)

Product Manager: 03
MRID No.: 45058908

Reviewer: Eugenia McAndrew
Study Completion Date: March 2, 2000
Study No.: 8693

Testing Facility: Product Safety Labs
Author: George E. Moore, B.S.

Quality Assurance (40 CFR §160.12): Included

Test Material: Chemsico Insecticide Concentrate N30-A; Lot # 00-01-PS-P9; 1.25% Permethrin; clear lightly tinted liquid

Positive Control Material: 1-Chloro-2,4-dinitrobenzene (DNCB)

Species: Guinea pig; Hartley albino

Age: Young adult

Sex: 3 male and 31 female

Weight: 291-383 g

Source: Davidson's Mill Farm, South Brunswick, NJ

Method: Buehler

Conclusion:

1. There is no indication that this product is a dermal sensitizer.
2. Classification: Acceptable

Procedure (Deviations from 870.2600): None

Procedure: Preliminary irritation testing was conducted to determine the correct concentrations for induction and challenge. For the induction, 0.4 mL of undiluted test substance was applied to 20 female test animals under occlusion for a period of six hours. The procedure was repeated once a week for three weeks for a total of three applications. Reactions were scored 24 and 48 hours after each induction. The animals rested for two weeks. For the challenge, 0.4 mL of undiluted test substance was applied to a naive site on each test animal and to 10 female naive control animals using the same procedures. Reactions were scored 24 and 48 hours after the challenge application.

Results: Very faint to faint erythema (0.5-1) was noted at 13/20 test sites during the induction phase. One naive control animal died prior to the challenge. Results following the challenge were similar in test and naive control animals. Very faint erythema (0.5) was noted at 9/20 test animal sites and at 5/9 naive control animal sites. A positive control study using DNCB was conducted within six months of the main study to validate the test system. The results were appropriate.