



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

OFFICE OF
PREVENTION, PESTICIDES
AND
TOXIC SUBSTANCES

18/MAR/2002

MEMORANDUM

Subject Name of Pesticide Product Chemsico Insecticide Concentrate 5L
EPA Reg. No. /File Symbol 9688-183
DP Barcode D280468
Case No: 070361
PC Code: 128897

From Eugenia McAndrew, Biologist
Technical Review Branch
Registration Division (7505C)

To William Sproat, PM Team 03
Insecticide Branch
Registration Division (7505C)

Applicant Chemsico
Division of United Industries Corp.
P.O. Box 142642
St. Louis, MO 63114-0642

William Sproat
pm - 03

FORMULATION FROM LABEL

Active Ingredient(s)	% by wt
128897 Lambda-cyhalothrin	0.5
Inert Ingredient(s)	99.5
Total	100.0%

ACTION REQUESTED: PM requests review of acute oral toxicity study for Chemsico Insecticide Concentrate 5L, EPA Reg. No. 9688-183

BACKGROUND: Chemsico has submitted a new acute oral toxicity study (MRID 45575201) in support of eliminating the requirement for Child Resistant Packaging (CRP) for its product Chemsico Insecticide Concentrate 5L, EPA Reg. No. 9688-183. A previous acute oral toxicity study submitted (MRID 45397803) triggered CRP because the LD₅₀ was between 500 and 5000 mg/kg. Both studies were conducted at Product Safety Labs, East Brunswick, New Jersey.

RECOMMENDATIONS: The acute oral toxicity study has been reviewed and is classified as acceptable. An LD₅₀ of 1750 mg/kg was determined using the data obtained from both acute oral toxicity studies. Therefore, CRP is no longer required.

The acute toxicity profile for Chemsico Insecticide Concentrate 5L, EPA Reg. No. 9688-183, is as follows:

acute oral toxicity	III	Acceptable	MRID 45575201
acute dermal toxicity	IV	Acceptable	MRID 45397804
acute inhalation toxicity	IV	Acceptable	MRID 45397805
primary eye irritation	IV	Acceptable	MRID 45397806
primary skin irritation	IV	Acceptable	MRID 45397807
dermal sensitization	No	Acceptable	MRID 45397808

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.

PRODUCT ID #: 009688-00183

PRODUCT NAME: CHEMSICO INSECTICIDE CONCENTRATE 5L

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals:

SIGNAL WORD: CAUTION

Harmful if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

First Aid:

If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

DATA EVALUATION RECORD

STUDY TYPE: ACUTE ORAL TOXICITY TESTING (870.1100 formerly §81-1)

Product Manager: 03

Reviewer: Eugenia McAndrew

TEST MATERIAL PURITY: Chemsico Insecticide Concentrate 5L; 0.5% Lambdacyhalothrin

CITATION: Merkel, D. (2001) Chemsico Insecticide Concentrate 5L; acute oral toxicity in rats. Product Safety Labs, East Brunswick, New Jersey. Laboratory Report Number 11333. November 12, 2001. MRID 45575201. Unpublished.

SPONSOR: Chemsico, Division of United Industries Corp., 8825 Page Blvd., St. Louis, MO 63114

EXECUTIVE SUMMARY: In an acute oral toxicity study (MRID 45575201), five young adult Sprague-Dawley derived albino rats/sex (Weight: 202-230 g males; 181-204 g females; Source: Ace Animals, Inc., Boyertown, PA) were given a single oral dose of Chemsico Insecticide Concentrate 5L (0.5% Lambdacyhalothrin; Lot # PSL-0201-0012; slightly yellow solution). Based on the results of previous PSL study number 10356, during which dose levels of 500 and 5000 mg/kg were tested, a dose level of 1500 mg/kg was selected. Animals were observed for clinical signs of toxicity and mortality for 14 days post dosing. Gross necropsies were performed on all animals.

Oral LD₅₀ Males and Females is estimated to be 1750 mg/kg (determined graphically using data from previous acute oral toxicity study - PSL study number 10356 with MRID 45397803)

Chemsico Insecticide Concentrate 5L is classified as Toxicity Category III based on the LD₅₀ values in the males and females.

One male and one female died within 3 hours of test substance administration. Toxic signs noted prior to death included facial staining and hypoactivity. The surviving rats exhibited facial staining, abnormal posture, hypoactivity and/or a reduced fecal volume. The survivors recovered by day 2 and gained weight during the study. Gross necropsy of the decedents revealed discoloration of the lungs and intestines. No gross abnormalities were noted for the animals necropsied at the end of the study.

This study is classified as Acceptable (870.1100) and satisfies the guideline requirement for an acute oral study in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided.

RESULTS:

Dosage (mg/kg)	Number of Deaths/Number Tested		
	Males	Females	Combined
500 ¹	0/5	0/5	0/10
1500	1/5	1/5	2/10
5000 ¹	5/5	5/5	10/10

¹ Data obtained from:

Merkel, D. (2001) Chemsico Insecticide Concentrate 5L; acute oral toxicity in rats. Product Safety Labs, East Brunswick, New Jersey. Laboratory Report Number 10356. April 17, 2001. MRID 453978-03. Unpublished.

OBSERVATIONS: One male and one female died within 3 hours of test substance administration. Toxic signs noted prior to death included facial staining and hypoactivity. The surviving rats exhibited facial staining, abnormal posture, hypoactivity and/or a reduced fecal volume. The survivors recovered by day 2 and gained weight during the study.

GROSS NECROPSY: Gross necropsy of the decedents revealed discoloration of the lungs and intestines. No gross abnormalities were noted for the animals necropsied at the end of the study.

ACUTE TOX ONE-LINERS

1. DP BARCODE: D280468
2. PC CODE: 128897
3. CURRENT DATE: 18/MAR/2002
4. TEST MATERIAL: Chemsico Insecticide Concentrate 5L (0.5% Lambdacyhalothrin; Lot # PSL-0201-0012; slightly yellow solution)

Study/Species/Lab Study # /Date	MRID	Results	Tox. Cat.	Core Grade
Acute oral toxicity/rat Product Safety Labs 11333/11-12-2001	45575201	LD ₅₀ = 1750 mg/kg (males and females combined)	III	A

Core Grade Key: **A** =Acceptable, **S** = Supplementary, **U** = Unacceptable, **V** = Self Validated