



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

OFFICE OF
PREVENTION, PESTICIDES
AND
TOXIC SUBSTANCES

27/JULY/2001

MEMORANDUM

Subject: Name of Pesticide Product: Chemsico Insecticide Concentrate 5L
EPA Reg. No. /File Symbol: 9688-RIG
DP Barcode: D275715
Case No: 070361
PC Code: 128897

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

To: Tracy Keigwin, PM Team 03
Insecticide Branch
Registration Division (7505C)

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

FORMULATION FROM LABEL

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
128897 Lambdacyhalothrin	0.5
<u>Inert Ingredient(s):</u>	<u>99.5</u>
Total:	100.00%

ACTION REQUESTED: PM requests review of acute toxicity data for Chemsico Insecticide Concentrate 5L, EPA File Symbol 9688-RIG.

BACKGROUND: Chemsico has submitted a six pack of acute toxicity studies in support of registration of Chemsico Insecticide Concentrate 5L, EPA File Symbol 9688-RIG. Studies were assigned MRID numbers 453978-03 to -08. The studies were conducted at Product Safety Labs, Dayton and East Brunswick, New Jersey.

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

The acute toxicity profile for Chemsico Insecticide Concentrate 5L, EPA File Symbol 9688-RIG, is as follows:

acute oral toxicity	III	Acceptable	MRID 453978-03
acute dermal toxicity	IV	Acceptable	MRID 453978-04
acute inhalation toxicity	IV	Acceptable	MRID 453978-05
primary eye irritation	IV	Acceptable	MRID 453978-06
primary skin irritation	IV	Acceptable	MRID 453978-07
dermal sensitization	No	Acceptable	MRID 453978-08

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.

ID #: 009688-00183 Chemsico Insecticide Concentrate 5L

CHILD RESISTANT PACKAGING REQUIRED

SIGNAL WORD: CAUTION

PRECAUTIONARY STATEMENTS:

Harmful if swallowed. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.

STATEMENT OF PRACTICAL TREATMENT (SOPT):

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 by mouth to an unconscious person.

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% Lambda-Cyhalothrin

CITATION: 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.

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

EXECUTIVE SUMMARY: In an acute oral toxicity study, five young adult albino Sprague-Dawley derived rats/sex (Weight: 212-256 g males; 170-220 g females; Source: Ace Animals, Inc., Boyertown, PA) were given a single oral dose of Chemsico Insecticide Concentrate 5L (0.5% Lambda-Cyhalothrin; Lot # PLS-0201-0012; light, yellow liquid) at 500 mg/kg and 5000 mg/kg. Animals were observed for clinical signs of toxicity and mortality for 14 days post dosing.

Oral LD₅₀ Males = > 500 mg/kg and < 5000 mg/kg (observed); Oral LD₅₀ Females = > 500 mg/kg and < 5000 mg/kg (observed).

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

At 500 mg/kg, all animals survived and gained bodyweight during the study. No gross abnormalities were noted at necropsy.

At 5000 mg/kg, all animals died within two hours of test substance administration. Clinical signs noted prior to death were hypoactivity, facial staining and/or hunched posture. Gross necropsy of the decedents revealed discoloration of the lungs, intestines and stomach and injection of blood vessels noted in the stomach.

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	0/5	0/5	0/10
5000	5/5	5/5	10/10

OBSERVATIONS: At 500 mg/kg, all animals survived and gained bodyweight during the study. No gross abnormalities were noted at necropsy.

At 5000 mg/kg, all animals died within two hours of test substance administration. Clinical signs noted prior to death were hypoactivity, facial staining and/or hunched posture.

GROSS NECROPSY: At 500 mg/kg, no gross abnormalities were noted at necropsy. At 5000 mg/kg, gross necropsy of the decedents revealed discoloration of the lungs, intestines and stomach and injection of blood vessels noted in the stomach.

DATA EVALUATION RECORD

STUDY TYPE: ACUTE DERMAL TOXICITY TESTING (870.1200 formerly §81-2)

Product Manager: 03

Reviewer: Eugenia McAndrew

TEST MATERIAL (Purity): Chemsico Insecticide Concentrate 5L; 0.5% Lambda-Cyhalothrin

CITATION: Merkel, D. (2001) Chemsico Insecticide Concentrate 5L; acute dermal toxicity in rats. Product Safety Labs, East Brunswick, New Jersey. Laboratory Report Number 10357. April 17, 2001. MRID 453978-04. Unpublished.

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

EXECUTIVE SUMMARY: In an acute dermal toxicity study, five young adult albino Sprague-Dawley derived rats/sex (Weight: 192-220 g males; 176-200 g females; Source: Ace Animals, Inc., Boyertown, PA) were dermally exposed to a single application of Chemsico Insecticide Concentrate 5L (0.5% Lambda-Cyhalothrin; Lot # PLS-0201-0012; light, yellow liquid) at 5000 mg/kg (limit dose) for 24 hours. The test substance was applied to > 10% of the total body surface area. Animals were observed for clinical signs of toxicity and mortality at 1 and 5 hours after application and once daily for 14 days.

Dermal LD₅₀ Males = > 5000 mg/kg (observed); Dermal LD₅₀ Females = > 5000 mg/kg (observed)

Chemsico Insecticide Concentrate 5L is classified as Toxicity Category IV based on the observed LD₅₀ values in both sexes.

All animals survived and gained weight during the 14-day study. No dermal irritation was noted at any test site. No gross abnormalities were noted at necropsy.

This study is classified as Acceptable (870.1200) and satisfies the guideline requirement for an acute dermal 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
5000	0/5	0/5	0/10

OBSERVATIONS: All animals survived and gained weight during the 14-day study. No dermal irritation was noted at any test site.

GROSS NECROPSY: No gross abnormalities were noted.

DATA EVALUATION RECORD

STUDY TYPE: ACUTE INHALATION TOXICITY TESTING (870.1300 formerly §81-3)

Product Manager: 03

Reviewer: Eugenia McAndrew

TEST MATERIAL (Purity): Chemsico Insecticide Concentrate 5L; 0.5% Lambda-Cyhalothrin

CITATION: Merkel, D. (2001) Chemsico Insecticide Concentrate 5L; acute inhalation toxicity in rats. Product Safety Labs, East Brunswick, New Jersey. Laboratory Report Number 10358. April 19, 2001. MRID 453978-05. Unpublished.

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

EXECUTIVE SUMMARY: In an acute inhalation toxicity study, five young adult albino Sprague-Dawley derived rats/sex (Weight: 270-302 g males; 188-222 g females; Source: Ace Animals, Inc., Boyertown, PA) were exposed by whole body inhalation to Chemsico Insecticide Concentrate 5L (0.5% Lambda-Cyhalothrin; Lot # PLS-0201-0012; light, yellow liquid) at 2.05 mg/L for 4 hours. All animals were observed for clinical signs of toxicity and mortality during the exposure and for 14 days post exposure

Inhalation LC₅₀ Males = > 2.05 mg/L (observed); Inhalation LC₅₀ Females = > 2.05 mg/L (observed)

Chemsico Insecticide Concentrate 5L is classified as Toxicity Category IV based on the observed LC₅₀ values in both sexes.

One female was found dead on day 2; all other animals survived and gained weight. In-chamber observations included ocular and nasal discharge, hunched posture and/or hypoactivity. Upon removal from the exposure chamber, the surviving animals exhibited hypoactivity and/or hunched posture but recovered from these symptoms by day 2 and appeared active and healthy for the remainder of the study. Toxic signs noted in the decedent prior to death included irregular respiration, hypoactivity, abnormal posture, ano-genital staining and reduced fecal volume. The gravimetric chamber concentration was 2.05 mg/L. The mass median aerodynamic diameter was estimated to be 2.9 µm. Necropsy after 14 days revealed no gross abnormalities in the surviving animals. The decedent had discoloration of the lungs, liver and intestines.

This study is classified as Acceptable (870.1300) and satisfies the guideline requirement for an acute inhalation study in the rat.

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

RESULTS:

Exposure Concentration mg/L (Gravimetrically Determined)	Number of Deaths/Number Tested		
	Males	Females	Combined
2.05	0/5	1/5	1/10

Chamber Atmosphere		
Gravimetric conc.	MMAD	GSD
2.05 mg/L	2.9 µm	2.07 - 2.22

Chamber Environment ^a	
Chamber Volume	150 L
Airflow	50.7 LPM
Temperature	19-20 °C
Relative Humidity	42-90%

^aWhole body

OBSERVATIONS: One female was found dead on day 2, all other animals survived and gained weight. In-chamber observations included ocular and nasal discharge, hunched posture and/or hypoactivity. Upon removal from the exposure chamber, the surviving animals exhibited hypoactivity and/or hunched posture but recovered from these symptoms by day 2 and appeared active and healthy for the remainder of the study. Toxic signs noted in the decedent prior to death included irregular respiration, hypoactivity, abnormal posture, ano-genital staining and reduced fecal volume.

GROSS NECROPSY: Necropsy after 14 days revealed no gross abnormalities in the surviving animals. The decedent had discoloration of the lungs, liver and intestines.

DATA EVALUATION RECORD

STUDY TYPE: PRIMARY EYE IRRITATION TESTING (870.2400 formerly §81-4)

Product Manager: 03

Reviewer: Eugenia McAndrew

TEST MATERIAL (Purity): Chemsico Insecticide Concentrate 5L; 0.5% Lambda-Cyhalothrin

CITATION: Merkel, D. (2001) Chemsico Insecticide Concentrate 5L; primary eye irritation in rabbits. Product Safety Labs, Dayton, New Jersey. Laboratory Report Number 10359. April 17, 2001. MRID 453978-06. Unpublished.

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

EXECUTIVE SUMMARY: In a primary eye irritation study, 0.1 mL of Chemsico Insecticide Concentrate 5L (0.5% Lambda-Cyhalothrin; Lot # PLS-0201-0012; light, yellow liquid) was placed into the conjunctival sac of the right eye of three young adult New Zealand albino rabbits (1 male and 2 female; Source: Davidson's Mill Farm, South Brunswick, New Jersey). All animals were observed for ocular irritation at 1, 24, 48 and 72 hours post-installation.

Chemsico Insecticide Concentrate 5L is classified as Toxicity Category IV based on the observations and resolution of ocular irritation by 24 hours.

No corneal opacity or iritis was noted for any treated eye during the study. Conjunctivitis (discharge) was present in all eyes at the one hour observation. No positive effects were noted at 24 hours.

This study is classified as Acceptable (870.2400) and satisfies the guideline requirement for a primary eye irritation study in the rabbit.

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

RESULTS:

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

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

OBSERVATIONS: No corneal opacity or iritis was noted for any treated eye during the study. Conjunctivitis was present in all three treated eyes at the one hour observation. No positive effects were noted at 24 hours.

DATA EVALUATION RECORD

STUDY TYPE: PRIMARY DERMAL IRRITATION TESTING (870.2500 formerly §81-5)

Product Manager: 03

Reviewer: Eugenia McAndrew

TEST MATERIAL (Purity): Chemsico Insecticide Concentrate 5L; 0.5% Lambda-Cyhalothrin

CITATION: Merkel, D. (2001) Chemsico Insecticide Concentrate 5L; primary skin irritation in rabbits. Product Safety Labs, Dayton, New Jersey. Laboratory Report Number 10360. April 17, 2001. MRID 453978-07. Unpublished

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

EXECUTIVE SUMMARY: In a primary skin irritation study, three young adult New Zealand albino rabbits (2 male and 1 female; Source: Davidson's Mill Farm, South Brunswick, New Jersey) were dermally exposed to 0.5 mL of Chemsico Insecticide Concentrate 5L (0.5% Lambda-Cyhalothrin; Lot # PLS-0201-0012, light, yellow liquid) for 4 hours. The test substance was applied to a single 6 cm² intact dose site on each animal. Animals were observed 1, 24, 48 and 72 hours after patch removal.

Chemsico Insecticide Concentrate 5L is classified as Toxicity Category IV based on the observations and resolution of dermal irritation by 48 hours.

Primary Dermal Irritation Index (PDII) = 0.4 Very slight to well defined erythema was observed at all three test sites one hour after patch removal. All dermal irritation resolved by 48 hours.

This study is classified as Acceptable (870.2500) and satisfies the guideline requirement for an primary skin irritation study in the rabbit.

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

RESULTS: PDII = 0.4

OBSERVATIONS: Very slight to well defined erythema was observed at all three test sites one hour after patch removal. All dermal irritation resolved by 48 hours.

DATA EVALUATION RECORD

STUDY TYPE: DERMAL SENSITIZATION TESTING (870.2600 formerly §81-6)

Product Manager: 03

Reviewer: Eugenia McAndrew

TEST MATERIAL (Purity): Chemsico Insecticide Concentrate 5L; 0.5% Lambda-Cyhalothrin

CITATION: Merkel, D. (2001) Chemsico Insecticide Concentrate 5L; dermal sensitization in guinea pigs Product Safety Labs, Dayton, New Jersey. Laboratory Report Number 10361. April 19, 2001. MRID 453978-08. Unpublished.

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

EXECUTIVE SUMMARY: In a dermal sensitization study conducted with Chemsico Insecticide Concentrate 5L (0.5% Lambda-Cyhalothrin; Lot # PLS-0201-0012; light, yellow liquid) 30 young adult male and female Hartley albino guinea pigs (Source: Elm Hill Breeding Labs, Chelmsford, MA) were tested using methods based on those derived by Buehler. Preliminary testing was conducted to determine the correct concentrations for induction and challenge. Twenty test animals were induced with three applications (six hours/exposure, once per week for three weeks) of 0.4 mL of undiluted test substance. Twenty-seven days after the first induction dose, 0.4 mL of a 75% w/w solution of the test substance in distilled water was applied to the twenty test guinea pigs and to ten naive control guinea pigs for a six-hour challenge exposure. Reactions were scored 24 and 48 hours after each induction and after the challenge. A positive control study using 1-Chloro-2, 4-Dinitrobenzene (DNCB) was conducted within six months of the main study to validate the test system.

Chemsico Insecticide Concentrate 5L is classified as a non-sensitizer based on the observations in this study.

Very faint to faint erythema (0.5-1) was noted at 19/20 test animal sites during the induction phase. Following the challenge, very faint erythema was noted at 15/20 test animal sites and at 7/10 naive control sites but no positive responses were noted. The positive response observed in the DNCB study validates the test system used in this study.

This study is classified as Acceptable (870.2600) and satisfies the guideline requirement for an dermal sensitization study in the guinea pig.

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

PROCEDURE: In a dermal sensitization study conducted with Chemsico Insecticide Concentrate 5L (0.5% Lambda-Cyhalothrin; Lot # PLS-0201-0012; light, yellow liquid) 30 young adult male and female Hartley albino guinea pigs (Source: Elm Hill Breeding Labs, Chelmsford, MA) were tested using methods based on those derived by Buehler. Preliminary testing was conducted to determine the correct concentrations for induction and challenge. Twenty test animals were induced with three applications (six hours/exposure, once per week for three weeks) of 0.4 mL of undiluted test substance. Twenty-seven days after the first induction dose,

0.4 mL of a 75% w/w solution of the test substance in distilled water was applied to the twenty test guinea pigs and to ten naive control guinea pigs for a six-hour challenge exposure. Reactions were scored 24 and 48 hours after each induction and after the challenge. A positive control study using 1-Chloro-2, 4-Dinitrobenzene (DNCB) was conducted within six months of the main study to validate the test system.

RESULTS: Very faint to faint erythema (0.5-1) was noted at 19/20 test animal sites during the induction phase. Following the challenge, very faint erythema was noted at 15/20 test animal sites and at 7/10 naive control sites but no positive responses were noted. The positive response observed in the DNCB study validates the test system used in this study.

ACUTE TOX ONE-LINERS

1. DP BARCODE: D275715
2. PC CODE: 128897
3. CURRENT DATE: 27/JULY/2001
4. TEST MATERIAL: Chemsico Insecticide Concentrate 5L (0.5% Lambda-Cyhalothrin; Lot # PLS-0201-0012; light, yellow liquid)

Study/Species/Lab Study # /Date	MRID	Results	Tox. Cat.	Core Grade
Acute oral toxicity/rat Product Safety Labs 10356/4-17-2001	453978-03	LD ₅₀ > 500 mg/kg and < 5000 mg/kg (males females combined)	III	A
Acute dermal toxicity/rat Product Safety Labs 10357/4-17-2001	453978-04	LD ₅₀ > 5000 mg/kg (males females combined)	IV	A
Acute inhalation toxicity/rat Product Safety Labs 10358/4-19-2001	453978-05	LC ₅₀ > 2.05 mg/L (males females combined)	IV	A
Primary eye irritation/rabbit Product Safety Labs 10359/4-17-2001	453978-06	Minimal irritant	IV	A
Primary dermal irritation/rabbit Product Safety Labs 10360/4-17-2001	453978-07	PDII = 0.4 No irritation at 72 hours.	IV	A
Dermal sensitization/guinea pig Product Safety Labs 10361/4-19-2001	453978-08	Not a sensitizer	-	A

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