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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

January 25, 1996

MEMORANDUM

EPA ID No.:	000432-IRR Intercept Lawn & Garden Insect Control Granules
DP Barcode:	D217164
Test Material:	Deltamethrin 0.1% Granule
Chemical:	097805 Deltamethrin
From:	S. Oonnithan Precautionary Review Section Registration Support Branch Registration Division (H7505W)
To:	George LaRocca, PM 13 Insecticide-Rodenticide Branch (H7505C) Registration Division
Applicant:	AgrEvo Environmental Health 95 Chestnut Ridge Road Montvale, NJ 07645

BACKGROUND

AgrEvo Environmental Health has submitted acute oral toxicity (MRID No. 436956-04), acute dermal toxicity (MRID No. 436956-05), primary eye irritation (MRID No. 436956-06), primary skin irritation (MRID No. 436956-07), and dermal sensitization (MRID No. 436956-08) studies on Deltamethrin 0.1% Granule insecticide. The formulation used for acute toxicity testing was a tan granule (RUC #789; Lot NB94-0112-3; RUC R94-529) and the studies were performed by Stillmeadow, Inc., 12852 Park One Drive, Sugar Land, TX 77478.

FORMULATION FROM LABEL

Ingredient(s)	% by wt.
Deltamethrin	0.1
Inerts	99.9
Total	100.0

USE DIRECTIONS

Intercept Lawn & Garden Insect Control Granules is a ready to use insecticide for the control of insects, ticks, and fleas outdoors in home lawns. Single to repeated applications with a spreader are recommended to lawns, soil treatments to flower, shrub, and ornamental plant beds, band treatments around house foundation, and spot applications to ant mounts and wasp nests.

RECOMMENDATION

81-1. Acute Oral: Category III. The submitted study is acceptable.

81-2. Acute Dermal: Category IV. The submitted study is acceptable.

81-3. Acute Inhalation: The registrant has requested a waiver for this requirement. Grinding the test substance in a roller mill for 24 hours produced particles >1000 ppm with traces at <150 ppm. Therefore inhalable particles are not expected to form during shipping, handling, and application of the Deltamethrin granule. The submitted waiver request is acceptable.

81-4. Eye Irritation: Category III. The submitted study is acceptable.

81-5. Skin Irritation: Category IV. The submitted study is acceptable.

81-6. Dermal Sensitization: Not a skin sensitizer to guinea pigs. The submitted study is acceptable.

LABELING

The appropriate signal word is **CAUTION**.

PRECAUTIONARY STATEMENT

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling.

STATEMENTS OF PRACTICAL TREATMENT

IF SWALLOWED: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. If person is unconscious, do not give anything by mouth and do not induce vomiting.

IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

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

Product Manager: 13
MRID No.: 436956-04
Author(s): J. Kuhn

Reviewer: S. Oonnithan
Report No.: 1747-94
Report Date: 03/23/95

Testing Facility: Stillmeadow, Inc., 12852 Park One Drive, Sugar Land, TX 77478.
Test Material: Deltamethrin 0.1% Granule; RUC# 789 was mixed with water to prepare a 70% (w/v) concentration.

Test Animal: Rat; Sprague-Dawley; **Age:** Young adults; **Weight:** Males 189-246 g; Females 192-230 g; **Source:** Harlan Sprague Dawley Inc., Houston, TX.

Test Conditions: The slurry was administered at 2.14 to 7.21 ml/kg.

Results: The estimated oral LD_{50} for male and female rats are 3385 and 2243 mg/kg, respectively.

Dosage (mg/kg)	Number Dead/Tested		
	Males	Females	Combined
1500	--	0/5	0/5
2000	0/5	4/5	4/10
3500	3/5	3/5	6/10
5050	5/5	5/5	10/10

Symptoms & Gross Necropsy Findings: Toxicologic symptoms included decreased activity, diarrhea, nasal discharge, piloerection, polyuria, ptosis, and salivation. Body weight gain was normal except in one female. Gross necropsy of the dead animals revealed signs of clinical symptoms and discoloration of the liver, lungs, and lymph nodes. Animals that survived indicated discoloration of liver.

Conclusion:
LD_{50}: Females: 2243 mg/kg; Males: 3385 mg/kg; Combined: 2613 mg/kg.
Toxicity Category: III
Classification: Acceptable
Statement of Compliance (40 CFR §160.12): Included
Procedure Deviations from §81-1: None

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

Product Manager: 13
MRID No.: 436956-05
Author(s): J. Kuhn

Reviewer: S. Oonnithan
Report No.: 1748-94
Report Date: 02/28/95

Testing Facility: Stillmeadow, Inc., 12852 Park One Drive, Sugar Land, TX 77478.

Test Material: Deltamethrin 0.1% Granule; RUC# 789 was mixed with water at 0.182 ml/g.

Test Animal: Rabbit; New Zealand White
Age: Young adult (3-6 Months)
Weight: Males 2.1-2.8 kg; Females 2.4-3.0 kg
Source: Ray Nichols Rabbitry, Lumberton, TX.

Test Conditions: The test animals were applied with the test substance at 5050 mg/kg, covered with 4 x 4 inch surgical gauze, and secured with adhesive tape. Then the entire trunk was wrapped with a thin plastic film.

Results: There was no mortality during the study.

Dosage	Number Dead/Tested		
	Males	Females	Combined
5050 mg/kg	0/5	0/5	0/10

Symptoms & Gross Necropsy Findings: Clinical symptoms included slight diarrhea. Slight erythema was observed in two males and one female. Body weight gain was unaffected. Necropsy of live animals revealed cecum distended with gas and the contents were green.

Conclusion:
LD_{50}: Males/Females: >5050 mg/kg.
Toxicity Category: IV
Classification: Acceptable
Statement of Compliance (40 CFR §160.12): Included
Procedure Deviations from §81-2: None

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

Product Manager: 13
MRID No.: 436956-06
Author(s): J. Kuhn

Reviewer: S. Oonnithan
Report No.: 1749-94
Report Date: 04/04/95

Testing Facility: Stillmeadow, Inc., 12852 Park One Drive, Sugar Land, TX 77478.

Test Material: Deltamethrin 0.1% Granule; RUC# 789 was ground to a fine powder.

Test Animal: Rabbit; New Zealand White; 3/sex
Age: Young adult (3-6 Months)
Weight: Males: 2.60-2.75 kg; Females: 2.35-2.70 kg.
Source: Ray Nichols Rabbitry, Lumberton, TX.

Test Conditions: Used ≈ 0.1 ml (98.17 mg) of powdered sample of the test substance. The treated eyes were not washed and were examined with fluorescein pre- and posttreatment (when required) for irritation.

Results: Conjunctival irritation cleared in 72 hours.

Observations	Number positive/Tested at			
	1 Hr	24 Hrs	48 Hrs	72 Hrs
Cornea Opacity	0/6	0/6	0/6	0/6
Iris	0/6	0/6	0/6	0/6
Conjunctivae: Redness	6/6	5/6	1/6	0/6
Chemosis	6/6	0/6	0/6	0/6
Discharge	6/6	2/6	0/6	0/6

Conclusion:
Toxicity Category: III
Classification: Acceptable
Statement of Compliance (40 CFR §160.12): Included
Procedure Deviations from §81-4: None

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

Product Manager: 13
MRID No.: 436956-07
Author(s): J. Kuhn

Reviewer: S. Oonnithan
Report No.: 1750-94
Report Date: 02/02/95

Testing Facility: Stillmeadow, Inc., 12852 Park One Drive, Sugar Land, TX 77478.

Test Material: Deltamethrin 0.1% Granule; RUC# 789.

Test Animal: Rabbit, New Zealand White
Age: Young adult (3-6 Months)
Weight: Male: 2.3-2.7 kg; Female: 2.3-2.9 kg.
Source: Ray Nichols Rabbitry, Lumberton, TX.

Test Conditions: Tested as un-abraded and semi-occluded. A 500 mg sample of test material was moistened with 0.05 ml water and applied to the test site. The treated area was covered with 5 x 5 cm two layer gauze patch securing with non-irritating tape and then wrapping the entire trunk loosely with a semi-permeable dressing.

Results: Very slight erythema was observed for a day.

Conclusion:
Toxicity Category: IV
Classification: Acceptable
Statement of Compliance (40 CFR §160.12): Included
Procedure Deviations from §81-5: None

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

Product Manager: 13
MRID No.: 436956-08
Author(s): J. Kuhn

Reviewer: S. Oonnithan
Report No.: 1751-94
Report Date: 03/02/95

Testing Facility: Stillmeadow, Inc., 12852 Park One Drive, Sugar Land, TX 77478.

Test Material: Deltamethrin 0.1% Granule; RUC# 789
Positive Control: 2,4-Dinitro-1-chlorobenzene (DNCB)

Test Animal: Guinea pig (Hartley-Albino)
Age: NA
Weight: Males: 333-404 g; Females: 329-368 g
Source: SASCO Inc., Madison, WI.

Test Method: In a range finding study using Buehler's method, dilutions of the test substance were tested at 25, 50, and 75% (w/v) in water and 100% (400 mg moistened with 0.05 ml water) to pick the induction and challenge dosages. From the above study, undiluted test substance (Solution A) was picked for induction and challenge. Based on previous studies, the positive control (DNCB) concentrations selected for induction and challenge were 1.0% in 80% ethanol (w/v) (Solution B) and 0.1% (w/v) in acetone (Solution C).

A group of ten animals (5/sex) was subjected to induction treatment with the test substance (Solution A) at 0.4 ml/site, at weekly intervals for three weeks. Following a two week rest period, a single challenge application was made at a virgin site at 0.4 ml/site using the test substance (Solution A). Along with the challenge, a second group of ten animals (5/sex) were treated at the challenge dose of test substance as naive controls. Observations for skin reactions were made at 24, and 48 hours after induction and challenge. The registrant reported that the positive control study with DNCB was performed in a similar manner (Solutions B and C), but independent of and within six months of the main study.

Results: The results summarized below indicate that the test substance is not a skin sensitizer.

Treatment	No. of animals with 0, 0.5, and ≥1 erythema scores[a]	
	Deltamethrin 0.1%	DNCB[b]
Induction #1	10, 0, 0	9, 1, 0
Induction #2	10, 0, 0	0, 0, 10
Induction #3	5, 1, 2[c]	0, 0, 10
Challenge	10, 0, 0	0, 4, 6
Naive Control	8, 2, 0	10, 0, 0

[a] 24 Hr scoring: 0 = no reaction, 0.5 = very faint erythema, and ≥1 = faint to strong erythema with edema; sum of scores = total number of animals used.
[b] The test dates of DNCB and main study were 07/13/94 and 12/28/94, respectively.
[c] Two animals died of unknown causes during the test.

Conclusion:
Toxicity Category: Non-sensitizer
Classification: --
Statement of Compliance (40 CFR §160.12): Included
Procedure Deviations from §81-6: None

ACUTE TOXICITY ONE-LINER

EPA ID No.: 000432-IRR; Intercept Lawn & Garden Insect Control Granules
DP Barcode: D217164
Chemical(s): 097805; Deltamethrin
Applicant: AgrEvo Environmental Health
Test Material: Deltamethrin 0.1% Granule
Date: January 25, 1996

G.L. #, Animal, Test Laboratory, Study #, Date	MRID No.	Results	Tox. Cat.	Core Grade[a]
81-1, Rat, Stillmeadow, Inc., 1747-94, 03/23/95	436956-04	LD_{50} 2243 mg/kg (Female)	III	A
81-2, Rabbit, Stillmeadow, Inc., 1748-94, 02/28/95	436956-05	LD_{50} >5050 mg/kg	IV	A
81-4, Rabbit, Stillmeadow, Inc., 1749-94, 04/04/95	436956-06	Conjunctival irritation cleared in 72 hours.	III	A
81-5, Rabbit, Stillmeadow, Inc., 1750-94, 02/02/95	436956-07	Very slight erythema cleared in 1 day.	IV	A
81-6, Guinea Pig, Stillmeadow, Inc., 1751-94, 03/02/95	436956-08	Not a sensitizer	--	A

[a] A = Acceptable