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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

Subject: EPA Reg. No.: 9779-206

From: Mark J. Perry, Biologist
Precautionary Review Section
Registration Support Branch
Registration Division (7505W)

MJP 6-22-94

To: Rob Forrest, PM 14
Insecticide-Rodenticide Branch
Registration Division (7505C)

Applicant: Riverside/Terra Corp.
600 Fourth St.
P.O. Box 6000
Sioux City, Iowa 51102

FORMULATION FROM LABEL:

	% by wt.
Active Ingredient(s): Dimethoate (o,o-dimethyl S-[N-(methylcarbamoyl)methyl] phosphorodithioate ...	31.0
Inert Ingredient(s):	69.0
Total:	100%

BACKGROUND

Riverside/Terra Corp. submitted acute oral, acute dermal, acute inhalation, dermal irritation and dermal sensitization studies at the request of the Agency. The Agency request is in response to adverse effect eye irritation data previously submitted for this product. The product, Dimate 2.67, is an agricultural use insecticide with 31.0% dimethoate as the active ingredient. All five studies were performed by Stillmeadow, Inc. and the MRID numbers are 432503-01 through 432503-05.

RECOMMENDATION

1. **Acute Oral; III/Guideline**

2. **Acute Dermal; III/Minimum**

- The study does not clearly state that the test material was applied to approximately 10% of the test animal surface area. The study report does describe the clipped area, but an approximation of the actual exposure area in reference to total body surface is also needed.

3. **Acute Inhalation; III/Guideline**

4. **Dermal Irritation; IV/Guideline**

5. **Dermal Sensitization; Non-sensitizer/Guideline**

LABELING

1. The appropriate signal word is "caution."

2. The statements of practical treatment should read as follows:

IF SWALLOWED: Call a physician or poison control center. Do not induce vomiting. Drink promptly a large quantity of milk, egg whites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol.
IF ON SKIN: Wash with plenty of soap and water. Get medical attention.
IF INHALED: Remove victim to fresh air. If not breathing give artificial respiration, preferably mouth to mouth. Get medical attention.

3. The precautionary labeling should read as follows:

Harmful if swallowed, inhaled or absorbed through skin. Avoid contact with skin, eyes or clothing. Avoid breathing vapor or spray mist. Remove contaminated clothing and wash contaminated clothing and wash before reuse. Wash thoroughly with soap and water after handling.

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

Product Manager:14
MRID No.:432503-02
Testing Facility:Stillmeadow
Author(s):J. Kuhn
Species:Rat
Age:Young adult
Weight:194-285 g
Source:Harlan Sprague Dawley
Test Material:Dimate 2.67
Quality Assurance (40 CFR §160.12):Present

Reviewer:M. Perry
Report Date:2/1/94
Report No.:0559-93

Conclusion:

1. LD_{50} (mg/kg): Males= 607.9 mg/kg
   Females= 685.2 mg/kg
   Combined > 500 mg/kg
2. The estimated LD_{50} is > 500 mg/kg
3. Tox. Category:III Classification:Guideline

Procedure: The fasted test animals were dosed at 500, 750, 1000 and 5050 mg/kg by oral intubation. The animals were observed for mortality and signs of toxicity at least once daily during the 14 day observation period. Body weights were recorded just before treatment and on Days 7 and 14.

Results:

Dosage mg/kg	(Number Killed/Number Tested)		
	Males	Females	Combined
500	1/5	0/5	1/10
750	4/5	4/5	8/10
1000	5/5	5/5	10/10
5050	5/5	5/5	10/10

Symptoms & Gross Necropsy Findings: Clinical observations included salivation, chromodacryorrhea, activity decrease, diarrhea, gasping, nasal discharge, lacrimation, polyuria, body tremors and staggered gait. Necropsy revealed discoloration of contents of gastrointestinal tract, liver, lungs, kidneys and urine in some animals.

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

Product Manager:14
MRID No.:432503-03
Testing Laboratory:Stillmeadow
Author(s):J. Kuhn
Species:Rabbit
Weight:2.050 - 3.000 kg
Source:Ray Nichols Rabbitry
Test Material:Dimate 2.67
Quality Assurance (40 CFR §160.12):Present

Reviewer:M. Perry
Report Date:1/14/94
Report No.:0560-93

Summary:

1. LC_{50} (mg/kg): Males= --
Females= --
Combined > 2020 mg/kg

2. The estimated LD_{50} is > 2020 mg/kg

3. Tox. Category:III Classification:Minimum

Procedure: The undiluted liquid test material was applied to the clipped exposure sites at a dose level of 2020 mg/kg and occluded for a period of 24 hours. After the exposure period the remaining test material was removed. The animals were observed for mortality and signs of toxicity at least daily during the 14 day observation period. Animal body weights were recorded on Days 0, 7 and 14.

Deviation From §81-2:See recommendations

Results:

Reported Mortality

DOSAGE mg/kg	(NUMBER KILLED/NUMBER TESTED)		
	Males	Females	Combined
2020	0/5	0/5	0/10

Symptoms & Gross Necropsy Findings: Clinical signs included diarrhea and decreased defecation. Necropsy revealed discoloration of the contents of the intestinal tract.

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DATA REVIEW FOR ACUTE INHALATION TOXICITY TESTING (§81-3)

Product Manager:31
MRID No.:432503-04
Testing Laboratory:Stillmeadow
Author(s):M. Holbert
Species:Rat
Weight:207-289 g
Source:Harlan Sprague Dawley
Test Material:Dimate 2.67
Quality Assurance (40 CFR §160.12):Present

Reviewer:M. Perry
Report Date:2/8/94
Report No.:0561-93

Summary:

1. LC_{50} (mg/kg): Males= --
Females= --
Combined= 1.34 mg/L

2. The estimated LC_{50} is 1.34 mg/L
3. Mean Concentration: --

4. Tox. Category:III Classification:Guideline

Procedure:
The selected test animals were exposed to the test atmosphere for four hours within a 200 liter NYU design exposure chamber. A DeVilbiss atomizer with a nebulizing ball attached was used for atmosphere generation. A baffling chamber was also employed. The concentration was determined analytically once per hour during the exposure period. Particle size was determined twice with a cascade impactor. After the exposure period, the animals were observed daily during the 14 day observation period. Body weights were recorded on Days 0, 7 and 14.

Results:

Reported Mortality

Exposure Concentration mg/L	(NUMBER KILLED/NUMBER TESTED)		
	Males	Females	Combined
0.717	0/5	0/5	0/10
1.73	5/5	4/5	9/10
3.31	5/5	5/5	10/1

Symptoms & Gross Necropsy Findings: Clinical signs included activity decrease, ptosis, lacrimation, piloerection, salivation, nasal discharge and polyuria. Necropsy revealed gastrointestinal tract distended with gas as well as lungs discolored and slightly swollen.

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mg/l							
Nom Conc	Grav Conc	Analyt Conc	MMAD	GSD	Temp[C]	Hum%	Air Flow [l/m]
10.1	---	0.717	1.27	2.06	71	57	90.6
16.4	---	1.73	1.58	2.15	74	56	90.6
23.7	---	3.31	1.75	2.00	70	56	90.6

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

Product Manager:14
MRID No.:432503-01
Testing Laboratory: Stillmeadow
Author(s):J. Kuhn
Species: Rabbit
Age: Young adult
Sex: Three male, three female
Weight: --
Dosage:0.5 ml
Test Material: Dimate 2.67
Quality Assurance (40 CFR §160.12): Present

Reviewer:M. Perry
Report Date:11/16/93
Report No.:0563-93

Summary:

1. **The Primary Irritation Index=** --

2. **Toxicity Category:**IV

3. **Classification:**Guideline

Procedure: A 0.5 ml dose of the liquid test material was applied to the clipped exposure sites under a 2.5 x 2.5 cm gauze patch and occluded for a period of 4 hours. Excess test material was removed following the exposure period. Dermal evaluations were performed at 3/4, 24, 48 and 72 hours.

Results: Grade 2 erythema was present in some animals at 3/4 and 24 hours. All irritation cleared by 72 hours.

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

Product Manager:14
MRID No.:432503-05
Testing Laboratory:Stillmeadow
Author(s):J. Kuhn
Species:Guinea pig
Weight:315-400 g
Source:SASCO Inc.
Test Material:Dimate 2.67
Positive Control Material:DNCB
Quality Assurance (40 CFR §160.12):Present

Reviewer:M. Perry
Report Date:2/2/94
Report No.:0564-93

Method:Buehler

Summary:

1. Based on the results of this study, the subject product is not a dermal sensitizer.

2. Classification:Guideline

Procedure: The test animals were induced at clipped exposure sites with 0.4 g of the 100% liquid test material once a week for three weeks. Each application was occluded and contact was maintained for six hours. After a two week rest period, the test group and a naive control group were challenged at a naive site for 6 hours. Challenge was also performed with 0.4 g of the 100% test material. A concurrent positive control study with DNCB was performed and successfully demonstrated sensitization.

Results:

24 Hours

Test group:	grade 0 =	6/10
	grade 0.5 =	3/10
	grade 1 =	1/10
Naive control group:	grade 0 =	7/10
	grade 0.5 =	3/10
	grade 1 =	0/10

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ACUTE TOX ONE-LINER

1. PC CODE: 035001

2. CURRENT DATE: 6/21/94

3. TEST MATERIAL: Dimethoate 31.0%

Study/Species/Lab/ Study#/Date	MRID No.	Results	Tox. Cat.	e
81-1, RAT, Still-meadow, 0559-93, 2/1/94	432503-02	LD 50 > 500 mg/kg	III	G
81-2, RABBIT, Still-meadow, 0560-93, 1/14/94	432503-03	LD 50 > 2020 mg/kg	III	M
81-3, RAT, Still-meadow, 0561-93, 2/8/94	432503-04	LC 50 = 1.34 mg/L	III	G
81-5, RABBIT, Still-meadow, 0563-93, 11/16/93	432503-01	All irritation cleared by 72 hours.	IV	G
81-6, GUINEA PIG, Stillmeadow, 0564-93, 2/2/94	432503-05	Non-sensitizer	---	G

Core Grade Key:

G = Guideline
M = Minimum
S = Supplementary