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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA Reg. No./File Symbol 9779-GNT
Malathion R.T.U.

FROM: Sheila A. Moats 3/15/90 E 3/16/90
Precautionary Review Section
Registration Support Branch
Registration Division (H75-05C)

TO: Miller/Lochman (PM 16)
Insecticide - Rodenticide Branch
Registration Division (H75-05C)

APPLICANT: Riverside/Terra Corporation
P.O Box 171376
Memphis, Tennessee 38187-1376

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Malathion (O,O-dimethyl phosphorodithioate of diethyl mercaptosuccinate	46.2
Inert Ingredient(s):	53.8
Total	100.0%

(1)

Background

The Riverside/Terra Corporation submitted acute oral, dermal, inhalation, primary eye + skin irritation and dermal sensitization studies to support registration of Malathion RTU

MRID nos used were: 409551-02-07

Recommendations

1. The acute toxicity studies submitted by Riverside/Terra Corporation are acceptable to RSB/PRS.

2. No further acute toxicity tests are required.

Labeling

1. The CAUTION signal word is acceptable.

2. Precautionary Statements are acceptable

3. The Statement of Practical Treatment is acceptable, except as explained below:
According to agency guidelines the toxic category for the acute dermal test is III, therefore the statement of Practical Treatment "IF ON SKIN" should also include "get medical attention".

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

Product Manager: (16) Reviewer: S. Hoats
MRID No.: 409551-02 Report Date: 3/13/90
Testing Facility: Stillmeadow Inc. Report No. 5621-88
Author(s): Kuhn, Janice. O
Species: Harlan Sprague Dawley - rats.
Age: Young adults. Observation Days (Post
Weight: 180 - 299 g. Exposure): (14); other ( )
Source: Harlan Sprague Dawley Inc. Houston Texas.
Test Material: Malathion
Quality Assurance (40 CFR §160.12): Adequate

Conclusion: * = 95% confidence limits (mg/kg)

1. LD_{50} (mg/kg): Males = 5150 mg/kg * 4940 - 5380 Females = 4380 mg/kg * 4210 - 4560 Combined = ____
2. The estimated LD_{50} is 4810 mg/kg. * 4550 - 5080.
3. Tox. Category: III. Classification: Guidelines

Procedure (Deviations From §81-1): Young adult ♂ + ♀ rats were administered undiluted doses of the test material. Observations for toxicity + mortality were made 3 times on the day of treatment + once daily thereafter for 14 days.

Results:

Reported Mortality

DOSAGE (mg/kg)	(NUMBER KILLED/NUMBER TESTED) Males	Females	Combined
4000	0/5	0/5	0/10
4500	0/5	4/5	4/10
4800	0/5	5/5	5/10
5050	3/5	5/5	8/10
5200	2/5	—	2/5

Symptomology & Gross Necropsy Findings:

Toxicological signs included, decreased activity, ataxia, tremors, chromodacryorrhea, diarrhea, epistaxis gasping, nasal discharge, pilo-erection etc.
Gross necropsy findings included, signs of chromodacryorrhea, diarrhea, lacrimation, nasal discharge, polyuria + salivation + distended gastrointestinal tract.

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

Product Manager: (16) Reviewer: S. Yoats
MRID No.: 409551-03 Report Date: 3/14/90
Testing Laboratory: Stillmeadow Inc. Report No. 5622-88
Author(s): Kuhn, Janice O
Species: New Zealand Whites - rabbits
Sex: males + females Wt.: 2.800 — 3.675 kg.
Test Material: malathion
Quality Assurance (40 CFR §160.12): Adequate

Summary:

1. LD_{50} (mg/kg): Males = ____; Females = ____; Combined = > 2020 mg/kg.;
2. The estimated LD_{50} is > 2020 mg/kg.
3. Tox. Category: III. Classification: Guidelines

Procedure (Deviations From §81-2): 5 ♂s + 5 ♀s were used for the study. Fur was clipped + undiluted test article was applied over the clipped area. Gauze 10x10 cm & two layers thick was applied to the trunk of the animal + held in place with non-irritating tape. The entire trunk of each animal was next wrapped with semi-permeable stockinette. After 24-hrs exposure to the test material the wrappings were removed. Exposure sites were cleaned to remove residues. Animals were observed at 1/2, 3 + 6 hrs after treatment, + once daily thereafter for 14 days.

Results:

Reported Mortality

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

Symptomology & Gross Necropsy Findings:

Clinical signs were minimal, limited to decreased defecation, no defecation + diarrhea. No animals died during the study. All animals were sacrificed + necropsied. Necropsy examinations revealed, signs of diarrhea, discoloration of the gastrointestinal tract, + empty large intestine.

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

Product Manager: (16) Reviewer: S. Moats
MRID No.: 409551-04 Report Date: 3/14/90
Testing Laboratory: Stillmeadow Inc. Report No. 5623-88
Author(s): Kuhn, Janice. O
Species: New Zealand White - rabbits
Sex: males & females Weight:
Source: Ray Nichols Rabbitry, Lumberton, Texas.
Dosage: 0.1 ml.
Test Material: Malathion
Quality Assurance (40 CFR §160.12): Adequate

Summary:

Tox. Category: III Classification: Guidelines.

Procedure (Deviation From §81-4): A dose of 0.1ml of undiluted test material was instilled into the conjunctival sac of the left eye of each of 9 rabbits. The right eye served as the untreated control. The lids were held tog. for 1sec. Three of the 9 treated eyes were washed for 1mt baginning 30secs. after treatment. The eyes were examined & results recorded at 1, 24, 48 & 72 hrs after treatment.

Results:

Observations (number "positive"/number tested)

	Hour	Days						
	1	1	2	3	4	7	14	21
Cornea Opacity	0/6	0/6	0/6	0/6				
Iris	0/6	0/6	0/6	0/6				
Conjunctivae Redness	6/6	6/6	4/6	0/6				
Chemosis	6/6	2/6	1/6	0/6				
Discharge	6/6	3/6	0/6	0/6				

Comments: All eye involvement +/or irritation cleared in 7 days or less (3 days in this case).

DATA REVIEW FOR SKIN IRRITATION

Product Manager: (16)
MRID No.: 409551-05
Testing Laboratory: Stillmeadow
Author(s): Kuhn, Janice. O
Species: New Zealand White - rabbits
Age: Young adults
Sex: ♂s + ♀s.
Weight:
Dosage: 0.5 ml - Malathion F/J-1A-115
Test Material: Malathion
Quality Assurance (40 CFR §160.12): Adequate

Reviewer: S. Watts
Report Date: 3/14/90
Report No.: 5624-88

Summary:

The Primary Irritation Index = 1.8

Toxicity Category: IV

Classification: Guidelines

Procedure (Deviations From §81-5): Each test site of six rabbits were dosed with 0.5ml of the test material introduced beneath a gauze patch. 2 layers in thickness. Each patch was secured in place with non-irritating tape. & the entire trunk loosely wrapped with a semi-permeable stockinette. The wraps were removed after 4 hrs. The sites were washed to remove residues. The animals were examined for irritation as follows: 1, 24, 48 + 72 hrs + on days 7, 10 + 14.

Results

The mean irritation score at 72 hrs is 1.3. The test material causes mild or slight irritation to rabbits

Special Comments:

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

Product Manager: (16) Reviewer: S. Moats
MRID No.: 409551-06 Report Date: 3/14/90
Testing Laboratory: Stillmeadows Inc Report No. 5626-88
Author(s): Holbert
Species: Harlan sprague Dawley - Rats
Sex: males + females Weight:
Source: Harlan Sprague Dawley Inc.
Test Material: Malathion
Quality Assurance (40 CFR §160.12): Adequate.

Summary:

1. LC_{50} (mg/kg): Males = ; Females = ; Combined = > 7.92 mg/L.
2. The estimated LC_{50} is > 7.92 mg/L.
3. Mean Concentration: 7.918 mg/L
4. Tox. Category: IV. Classification: Guidelines

Procedure (~~Deviations From §81-2~~): The test animals were housed individually in cages within a 200 L stainless steel dynamic inhalation chamber, during the exposure period. The animals were exposed to an aerosol generated undiluted test material observations were made on the day of exposure + once daily for 14 days. The aerosol was generated by pumping the test material through a pressure operated spray nozzle. The concentrated aerosol was diluted with dried + filtered air + drawn thru the exposure chamber. Air flow Results: was monitored + recorded every 30mts. Andersen 2 Cascade impactor was used to Reported Mortality determine particle size.

Exposure Concentration (mg/L)	(NUMBER KILLED/NUMBER TESTED) Males	Females	Combined
7.92 mg/L.	0/5	0/5	0/10

Symptomology & Gross Necropsy Findings:

Clinical signs included activity decrease, dilated pupils, lacrimation, nasal discharge, piloerection, polyuria ptosis + salivation. No animals died during the study. Gross necropsy examination at the end of the study revealed no observable abnormalities.

MMAD + Geometric Std deviation at 1 1/4 hour distribution is 2.406 µm + 1.988 respectively +.

MMAD - at 3 1/2 hrs — 2.418 µm.
Geometric Std devn — 2.155

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

Product Manager: (16) Reviewer: S. Moats
MRID No.: 409551-07 Report Date: 3/15/90
Testing Laboratory: Stillmeadow Inc Report No. 5625-88
Author(s): Kuhn, Janice O
Species: Hartley strain - albino guinea pigs.
Sex: males Weight: 295-375 g.
Source: Harley Sprague Dawley Inc. Houston, Texas
Test Material: Malathion
Positive Control Material: Dinitno chlorobenzene (DNCB)
Quality Assurance (40 CFR §160.12): Adequate

Method: Open Epicutaneous

Summary:
1. This product is (is not a dermal sensitizer.)
2. Classification: Guidelines.

Procedure (Deviation From §81-6): Gp I. 10 animals were treated with 0.05% w/v soln of DNCB (Positive control) - Gp. II ten animals were treated with the test material: 1.0% v/v malathion for both the induction + challenge phases. Prior to dosing back trunk of each animal was clipped to expose a 6 x 10 cm area. Each test or control material was placed appropriately under a gauze pad & secured with adhesive dressing. The entire trunk was next wrapped in clear plastic & the animals were restrained for 6 hrs. At the end of the exposure period the patches were removed & the animals were returned to their cages. Same test location was used on each animal on all treatment days. On Day-36, all animals were treated in an identical manner as on the previous 10 treatment days, in addn a 2nd test site was chosen in the right rear of the exposed area. Observations for skin reactions were made 24 hrs after each treatment for each test site. & 48 hrs after treatment 1 & 10 & the challenge treatment on Day 36.

Results: 1.0% v/v soln of the test material did not produce a sensitizing reaction, whereas 0.05% w/v soln of DNCB produced a sensitizing reaction in guinea pigs

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