1-25-94

FINAL

DATA EVALUATION REPORT

Rejex-it TP-40

Study Type: Dermal Sensitization Study in Guinea Pigs

Prepared for:

Health Effects Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by:

Clement International Corporation
9300 Lee Highway
Fairfax, VA 22031

January 1994

Principal Reviewer	Kate Rantz, M.P.H.	Date 1/24/94
Independent Reviewer	Carrie Rabe, Ph.D.	Date 1/24/94
QA Reviewer	William McLellan, Ph.D.	Date 1/25/94

Contract Number: 68D10075
Work Assignment Number: 3-36
Clement Number: 168
Project Officer: Caroline Gordon

1

Guideline Series 81-6: Dermal Sensitization Study in Guinea Pigs

EPA Reviewer: J. Thomas McClintock
Biological Section, Science Analysis Branch
Health Effects Division

Signature: [signature]
Date: 2/9/94

EPA Section Head: Roy Sjoblad
Biological Section, Science Analysis Branch
Health Effects Division

Signature: [signature]
Date: 4/4/94

DATA EVALUATION REPORT

STUDY TYPE:	Guideline series 81-6; dermal sensitization study in guinea pigs
CAS NUMBER:	
TOX CHEM NUMBER:	
MRID NUMBER:	426089-06
PC NUMBER:	128725
TEST MATERIAL:	Rejex-it TP-40
SYNONYM(S):	Methyl anthranilate (active ingredient)
SPONSOR:	ERM Program Management Company McLean, Virginia
STUDY NUMBER:	HWI 20305710
TESTING FACILITY:	Hazleton Wisconsin, Inc. Madison, Wisconsin
TITLE OF REPORT:	Dermal Sensitization Study of Rejex-it TP-40 in Guinea Pigs – Closed Patch Technique
AUTHOR:	Steven M. Glaza
STUDY COMPLETED:	July 27, 1992
QUALITY ASSURANCE:	The test was performed under Good Laboratory Practice Standards. A Quality Assurance Statement signed July 27, 1992, was submitted.
CONCLUSIONS:	Delayed contact hypersensitivity was not observed in guinea pigs exposed to Rejex-it TP-40 under the conditions of this test. Very faint erythema was seen in 2/9 surviving guinea pigs at the challenge site. No erythema was observed in any of the 10 naive control animals at challenge.

2

CORE CLASSIFICATION: Core Supplementary. This study satisfies the guideline requirements (81-6) for a dermal sensitization study in guinea pigs. However, data describing the test material were lacking (e.g., purity, stability, and lot number/identification number). This study may be upgraded pending submission of these data.

TOXICITY CATEGORY: Not applicable

A. MATERIALS

Test Compound

Test material:	Rejex-it TP-40
Identification no.:	Not reported
Purity:	Determined by sponsor
Physical description:	Blue liquid
Storage condition:	Room temperature
Stability:	Determined by sponsor
Positive control material:	2,4-dinitrochlorobenzene (DNCB) (lot number 80H0121; 99.9% pure)
Naive control material:	Rejex-it TP-40 (animals treated at challenge only)
Irritation screening conc.:	Four animals each received two different concentrations of the test material, either undiluted or in 25%, 50%, or 75% w/v in mineral oil.
Main study test material conc.:	Induction/challenge - 0.4 mL Rejex-it TP-40 (undiluted)

Test Animals

Species:	Albino guinea pigs
Strain:	Haz:(DH)fBR
Source:	Hazleton Research Products, Inc., Denver, PA
Sex:	19 males and 9 females
No./group:	4 in irritation screening group (1 male, 3 females); 10 in test group (8 males, 2 females); 10 in naive control group (8 males, 2 females); 4 in positive control group (2 males, 2 females)
Age:	Young adult
Initial body weights:	396-540 g, males; 410-470 g, females
Temperature:	14-25°C
Relative humidity:	30-66%
Photoperiod:	12-hour light/12-hour dark cycle
Feeding:	Purina Certified Guinea Pig Chow #5026, *ad libitum*
Water:	*Ad libitum*
Acclimation period:	At least 7 days

Housing:	Individual
Identification:	Ear tags
Selection:	Healthy animals within unspecified body weight limits were selected

B. TEST PERFORMANCE

Skin Preparation

The back of the animal was used as the test site. The hair on the back of each animal in the test and positive control groups was removed the day of test material application. Animals were depilatated with Neet 3 hours prior to the 24-hour examination.

Induction Phase

(a) Route of administration: The test material (0.4 mL) was applied to a 25 mm diameter adhesive patch. The patch was placed on the test site (anterior left flank), covered with dental dam, and wrapped with Elastoplast tape. The patch was removed after 6 hours and the test site cleaned with a wet paper towel.

(b) Solutions used: Test group - 0.4 mL test material; positive control group - 0.4 mL 0.3% w/v DNCB in 80% v/v ethanol in deionized water; naive irritation control - untreated.

(c) Frequency of exposure: Test and positive control groups - 1 application per week for 3 weeks for a total of 3 applications.

(d) Duration of exposure: 6 hours

(e) Rest period: 2 weeks

(f) Observation period: 24 and 48 hours after each exposure

Challenge Phase

(a) Route of administration: Administration was the same as for the induction phase, except that the test material was placed on the right flank. The naive irritation control group of 10 was also given the challenge dose of 0.4 mL test material.

(b) Solutions used: Test group and naive irritation control groups - 0.4 mL test material; positive control group - 0.1% w/v DNCB in acetone.

(c) Duration of exposure: 6 hours

(d) Number of exposures: 1

(e) Observation period: 24 and 48 hours after application

Scoring System

A modification of the Buehler method was used.

C. RESULTS

Mortality

One animal in the test group was found dead on day 4. Gross necropsy revealed red mucoid semifluid in the abdominal cavity.

Body weights

Body weight gain was normal in all animals, except for a weight loss of 86 grams during the last 4 days of the study in 1 animal from the naive control group.

Skin reactions

By the third induction dose, all of the surviving test group animals showed very faint to faint erythema (average Buehler scores, 0.1-0.5; high scores, 0.5-1.0). Following challenge, 2 of the surviving test group animals had very faint erythema reactions (nonsensitizations) to the test material (Buehler score, 0.5). None of the naive control group animals showed skin reactions after challenge application of the test material.

Clinical signs

One animal in the naive control group had soft stool on days 8-14.

D. REVIEWERS' COMMENTS

A dermal sensitization reaction was not observed under the present study conditions in guinea pigs treated with Rejex-it TP40. Based on these data, the test material was not considered to be a dermal sensitizer in guinea pigs.

FINAL

DATA EVALUATION REPORT

Rejex-it TP-40

Study Type: Primary Dermal Irritation Study in Rabbits

Prepared for:

Health Effects Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by:

Clement International Corporation
9300 Lee Highway
Fairfax, VA 22031

Janaury 1994

Principal Reviewer Kate Rantz Date 1/24/94
Kate Rantz, M.P.H.

Independent Reviewer Carrie Rabe Date 1/24/94
Carrie Rabe, Ph.D.

QA Reviewer William L. McLellan Date 1/25/94
William McLellan, Ph.D.

Contract Number: 68D10075
Work Assignment Number: 3-36
Clement Number: 167
Project Officer: Caroline Gordon

6

Guideline Series 81-5: Primary Dermal Irritation Study in Rabbits

EPA Reviewer: J. Thomas McClintock
Biological Section, Science Analysis Branch
Health Effects Division

Signature: J. Thomas McClintock
Date: 2/9/94

EPA Section Head: Roy Sjoblad
Biological Section, Science Analysis Branch
Health Effects Division

Signature: Roy D. Sjoblad
Date: 4/14/94

DATA EVALUATION REPORT

STUDY TYPE: Guideline series 81-5; primary dermal irritation study in rabbits

CAS NUMBER:

TOX CHEM NUMBER:

MRID NUMBER: 426089-05

PC NUMBER: 128725

TEST MATERIAL: Rejex-it TP-40

SYNONYM(S): Methyl anthranilate (active ingredient)

SPONSOR: ERM Program Management Company
McLean, Virginia

STUDY NUMBER: HWI 20305702

TESTING FACILITY: Hazleton Wisconsin, Inc.
Madison, Wisconsin

TITLE OF REPORT: Primary Dermal Irritation Study of Rejex-it TP-40 in Rabbits

AUTHOR: Steven M. Glaza

STUDY COMPLETED: June 5, 1992

QUALITY ASSURANCE: The test was performed under Good Laboratory Practice Standards. A Quality Assurance Statement, signed June 5, 1992, was submitted.

CONCLUSIONS: Dermal application of Rejex-it TP-40 under 4-hour semi-occluded conditions produced very slight to severe erythema (Draize scores 0-3), very slight edema (Draize scores 0-1), and desquamation at day 7. The primary irritation index of 1.9 indicated that the test material is a slight irritant.

7

Guideline Series 81-5: Primary Dermal Irritation Study in Rabbits

CORE CLASSIFICATION: Core Supplementary. This study satisfies the guideline requirements (81-5) for a primary dermal irritation study in rabbits. However, data describing the test material were lacking (e.g., purity, stability, and lot number/identification number). This study may be upgraded pending submission of these data.

TOXICITY CATEGORY: IV (Caution)

A. MATERIALS

Test Compound

Test material:	Rejex-it TP-40
Identification no.:	Not reported
Purity:	Determined by sponsor
Physical description:	Blue liquid; pH not determined
Storage condition:	Room temperature
Stability:	Determined by sponsor
Dose level:	0.5 mL (as received)

Test Animals

Species:	Albino rabbits
Strain:	Hra:(NZW)SPF
Source:	Hazleton Research Products, Inc., Kalamazoo, MI
Sex:	3 males and 3 females
Age:	Adult
Mean body weight:	2190-2442 g, males; 2082-2380 g, females
No. animals:	3/sex/dose
Temperature:	20-25°C
Relative humidity:	40-65%
Photoperiod:	12-hour light/12-hour dark cycle
Feeding:	Purina High Fiber Rabbit Chow #5326, measured amount daily
Water:	*Ad libitum*
Acclimation period:	At least 7 days
Housing:	Individual
Identification:	Ear tags

B. TEST PERFORMANCE

Test Material Application

The back and flanks of each rabbit were clipped the day before application of the test material. The test material (0.5 mL) was applied to the intact clipped skin of each animal. The treated area was covered with a 2.5 cm x 2.5 cm gauze patch, which was fastened with paper tape, loosly wrapped in Saran Wrap, and secured with Elastoplast tape to provide a semi-occlusive dressing. After 4 hours of exposure, the patch and wrappings were removed and the test site was washed with tap water and dried with disposable paper towels.

8

Observation Period

The degree of erythema and edema at the test site was determined about 30 minutes after removal of the test material and was recorded as the 4-hour score. Additional examinations were made at 24, 48, 72, and 96 hours, and day 7. The Draize scoring system for primary dermal irritation was used.

C. RESULTS

A summary of dermal irritation scores is presented in Table 1.

Table 1. Summary of Positive[a] Dermal Irritation Scores (sexes combined) (Draize Technique)

	Observation Intervals (hours)					
	4	24	48	72	96	day 7
Erythema	4/6	6/6	5/6	5/6	5/6	0/6
mean score	1.0	1.2	1.7	1.7	1.7	0
Edema	3/6	4/6	3/6	3/6	3/6	0/6
mean score	1.0	1.0	1.0	1.0	1.0	0

[a] The following dermal irritations scores are considered positive:
Erythema - Grades 1, 2, 3, and 4
Edema - Grades 1, 2, 3, and 4

Erythema (Draize scores 0-3) was observed in all animals by 24 hours and increased in severity until 48 hours, when the severity plateaued through 96 hours. Slight edema (Draize scores 0-1) was observed in 3-4 rabbits through 96 hours. The erythema and edema resolved by day 7, but desquamation was observed in all animals at day 7. The average primary dermal irritation scores were 1.2 at 4 hours; 1.8 at 24 hours; 2.2 at 48, 72, and 96 hours, and 0 at day 7. The average of the 4-, 24- 48- and 72-hour scores is 1.9, which is considered slightly irritating. Based on these findings, Rejex-it TP-40 is classified as Toxicity Category IV (Caution).

D. REVIEWERS' COMMENTS

Dermal application of Rejex-it TP-40 produced very slight to severe erythema, very slight edema, and desquamation under the 4-hour semi-occluded conditions of this study. Based on these findings, Rejex-it TP-40 is classified Toxicity Category IV (Caution).

9

FINAL

DATA EVALUATION REPORT

Rejex-it TP-40

Study Type: Primary Eye Irritation Study in Rabbits

Prepared for:

Health Effects Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by:

Clement International Corporation
9300 Lee Highway
Fairfax, VA 22031

January 1994

Principal Reviewer Kate Rantz Date 1/24/94
Kate Rantz, M.P.H.

Independent Reviewer Carrie Rabe Date 1/24/94
Carrie Rabe, Ph.D.

QA Reviewer William L McLellan Date 1/25/94
William McLellan, Ph.D.

Contract Number: 68D10075
Work Assignment Number: 3-36
Clement Number: 166
Project Officer: Caroline Gordon

10

Guideline Series 81-4: Primary Eye Irritation Study in Rabbits

EPA Reviewer: J. Thomas McClintock
Biological Section, Science Analysis Branch
Health Effects Division

Signature: J. Thomas McClintock
Date: 2/9/94

EPA Section Head: Roy Sjoblad
Biological Section, Science Analysis Branch
Health Effects Division

Signature: Roy D. Sjoblad
Date: 4/4/94

DATA EVALUATION REPORT

STUDY TYPE: Guideline series 81-4; primary eye irritation study in rabbits

CAS NUMBER:

TOX CHEM NUMBER:

MRID NUMBER: 426089-04

PC NUMBER: 128725

TEST MATERIAL: Rejex-it TP-40

SYNONYM(S): Methyl anthranilate (active ingredient)

SPONSOR: ERM Program Management Company
McLean, Virginia

STUDY NUMBER: HWI 20305706

TESTING FACILITY: Hazleton Wisconsin, Inc.
Madison, Wisconsin

TITLE OF REPORT: Primary Eye Irritation Study of Rejex-it TP-40 in Rabbits

AUTHOR: Steven M. Glaza

STUDY COMPLETED: June 16, 1992

QUALITY ASSURANCE: The test was performed under Good Laboratory Practice Standards. A Quality Assurance Statement. signed June 16, 1992, was submitted.

CONCLUSIONS: Under these study conditions, Rejex-it TP-40 produced slight conjunctival irritation in rabbit eyes, which cleared within 24 hours of treatment. The average primary irritation score was 3.3 at 1 hour.

CORE CLASSIFICATION: Core Supplementary. This study satisfies the guideline requirements (81-4) for an eye irritation study in rabbits. However, data describing the

test material were lacking (e.g., purity, stability, and lot number/identification number). This study may be upgraded pending submission of these data.

TOXICITY CATEGORY: IV (Caution)

A. MATERIALS

Test Compound

Test material:	Rejex-it TP-40
Identification no.:	Not reported
Purity:	Determined by sponsor
Physical description:	Blue liquid; pH not determined
Storage condition:	Room temperature
Stability:	Determined by sponsor
Vehicle:	None
Dose volume:	0.1 mL (as received)

Test Animals

Species:	Albino rabbits
Strain:	Hra:(NZW)SPF
Source:	Hazleton Research Products, Inc., Kalamazoo MI
Sex:	3 males and 3 females
Age:	Adult
Mean body weight:	2240-2328 g, males; 2186-2300 g, females
No. animals:	3/sex/dose
Temperature:	20-22°C
Relative humidity:	40-60%
Photoperiod:	12-hour dark/12-hour light cycle
Feeding:	Purina High Fiber Rabbit Chow #5326, measured amount daily
Water:	*Ad libitum*
Selection:	Animals without ocular injury or irritation were selected
Acclimation period:	At least 7 days
Housing:	Individual
Identification:	Ear tags

B. TEST PERFORMANCE

Test Material Application

Eyes were examined the day before application using sodium fluorescein dye procedures. The undiluted test material (0.1 mL) was placed in the everted lower lid of the right eye of each rabbit. The upper and lower lids were held together for 1 second and then released. The left eye of each animal served as the untreated control. The eyes of the rabbits were not flushed.

12

Observation Period

Observations for ocular irritation were made 1, 24, 48, and 72 hours after treatment. Eyes were examined and scored for ocular lesions using the Draize scoring system. At 72 hours after treatment, a sodium fluorescein examination was performed to help assess corneal injury.

C. RESULTS

A summary of positive ocular effects is presented in Table 1.

Table 1. Summary of Positive[a] Ocular Effects (sexes combined)

	Observation Intervals (hours)			
	1	24	48	72
Cornea				
Opacity	0/6	0/6	0/6	0/6
Iris				
Iritis	0/6	0/6	0/6	0/6
Conjunctivae				
Redness	0/6	0/6	0/6	0/6
Chemosis	0/6	0/6	0/6	0/6

[a] The following grades for each tissue are considered positive:
Opacity (density) - Grades 1, 2, 3, and 4
Iris - Grades 1 and 2
Conjunctivae (redness) - Grades 2 and 3
Conjunctivae (chemosis) - Grades 2, 3, and 4

No positive ocular effects were observed. Very slight conjunctival redness (Draize score 1) and chemosis (Draize score 1) were observed at 1 hour, but had cleared by 24 hours. The average primary irritation index at 1 hour was 3.3. Based on these findings Rejex-it TP-40 is classified Toxicity Category IV (Caution) for primary eye irritation.

D. REVIEWERS' COMMENTS

Rejex-it TP-40 was minimally irritating under the conditions of this study. Very slight redness and chemosis of the conjunctivae were clear by 24 hours; therefore the potential of Rejex-it TP-40 for primary eye irritation is Toxicity Category IV (Caution).

13

FINAL

DATA EVALUATION REPORT

Rejex-it TP-40

Study Type: Acute Dermal Toxicity in Rabbits

Prepared for:

Health Effects Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by:

Clement International Corporation
9300 Lee Highway
Fairfax, VA 22031

January 1994

Principal Reviewer	Kate Rantz, M.P.H.	Date 1/24/94
Independent Reviewer	Carrie Rabe, Ph.D.	Date 1/24/94
QA Reviewer	William McLellan, Ph.D.	Date 1/25/94

Contract Number: 68D10075
Work Assignment Number: 3-36
Clement Number: 165
Project Officer: Caroline Gordon

EPA Reviewer: J. Thomas McClintock
Biological Section, Science Analysis Branch
Health Effects Division

Signature: J. Thomas McClintock
Date: 2/9/94

EPA Section Head: Roy Sjoblad
Biological Section, Science Analysis Branch
Health Effects Division

Signature: Roy D. Sjoblad
Date: 2/14/94

DATA EVALUATION REPORT

STUDY TYPE:	Guideline series 81-2; acute dermal toxicity in rabbits
CAS NUMBER:	
TOX CHEM NUMBER:	
MRID NUMBER:	426089-03
PC NUMBER:	128725
TEST MATERIAL:	Rejex-it TP-40
SYNONYM(S):	Methyl anthranilate (active ingredient)
SPONSOR:	ERM Program Management Company McLean, Virginia
STUDY NUMBER:	HWI 20305698
TESTING FACILITY:	Hazleton Wisconsin, Inc. Madison, Wisconsin
TITLE OF REPORT:	Acute Dermal Toxicity Study of Rejex-it TP-40 in Rabbits
AUTHOR:	Steven M. Glaza
STUDY COMPLETED:	July 7, 1992
QUALITY ASSURANCE:	The test was performed under Good Laboratory Practice Standards. A Quality Assurance Statement, signed July 7, 1992, was submitted.
CONCLUSIONS:	Estimated acute dermal LD_{50} for males: >2000 mg/kg body weight Estimated acute dermal LD_{50} for females: >2000 mg/kg body weight Moderate to severe erythema (Draize scores 2-3 through day 7) and slight to severe edema (Draize scores 1-3) was observed in all animals. During

15

the second week the severity of these effects generally declined. However, on day 14, slight to moderate erythema (in 7/10 rabbits), slight edema (in 1/10 rabbits), slight atonia (in 2/10 rabbits), slight desquamation (in 5/10 rabbits), and slight coriaceousness (in 1/10 rabbits) persisted.

CORE CLASSIFICATION: Core Supplementary. This study satisfies the guideline requirements (81-2) for an acute dermal toxicity study in rabbits. However, data describing the test material were lacking (e.g., purity, stability, and lot number/identification number). This study may be upgraded pending submission of these data.

TOXICITY CATEGORY: III (Caution)

A. MATERIALS

Test Compound

Test material:	Rejex-it TP-40
Identification no.:	Not reported
Purity:	Determined by sponsor
Physical description:	Blue liquid
Bulk density:	0.95 g/mL
Storage condition:	Room temperature
Stability:	Determined by sponsor
Dose level:	2000 mg/kg body weight (limit dose)

Controls

There were no controls.

Test Animals

Species:	Albino rabbits
Strain:	Hra:(NZW)SPF
Source:	Hazleton Research Products, Inc., Kalamazoo, MI
Sex:	5 males and 5 females
Age:	Young adult
Initial body weights:	2140-2394 g for males; 2086-2368 g for females
No. animals:	5/sex/dose
Temperature:	20-25°C
Relative humidity:	36-65%
Photoperiod:	12-hour dark/12-hour light cycle
Feeding:	Purina High Fiber Rabbit Chow #5326, measured amount daily
Water:	*Ad libitum*
Acclimation period:	At least 7 days
Housing:	Individual
Identification:	Ear tags

Selection: Healthy animals within unspecified body weight ranges were selected

B. TEST PERFORMANCE

Application

The hair on the back of each rabbit (approximately 10% of the total body surface area) was clipped on the day before dosing. The test material (2000 mg/kg body weight) was applied to the intact skin of the rabbit. The area of application was covered with a gauze patch secured with paper tape and overwrapped with Saran Wrap and Elastoplast tape. After 24 hours the wrappings were removed. Excess test material was washed from the test site with tap water and paper towels.

Observation period

Observations for clinical signs of toxicity were made 1, 2.5, and 4 hours after application of the test material. During the 14-day observation period, clinical observations and mortality checks (morning and afternoon) were made daily. The initial observation for dermal response (Draize technique) was approximately 30 minutes after removal of the test material; subsequent readings were made at days 3, 7, 10, and 14.

Body weight interval

Body weights were measured day 0 (before application) and on observation days 7 and 14.

Gross pathology: Yes
Histopathology: No

C. RESULTS

Mortality

All animals (5 males and 5 females) dosed with 2000 mg/kg body weight survived until study termination.

Clinical observations

No overt signs of toxicity were observed. Signs of dermal irritation included the following: moderate to severe erythema (Draize scores 2-3 through day 7) and slight to severe edema (Draize scores 1-3) in all animals; slight to moderate atonia in 9/10 animals (Draize scores 1-2); slight to moderate coriaceousness in all animals; slight to moderate fissuring in 9/10 animals; and slight desquamation (Draize score 1) in all animals. Blanching was observed in a single female on day 1. During the second week the severity of these effects generally declined. However, on day 14, slight to moderate erythema (in 7/10 rabbits), slight edema (in 1/10 rabbits), slight atonia (in 2/10 rabbits), slight desquamation (in 5/10 rabbits), and slight coriaceousness (in 1/10 rabbits) persisted.

17

Body weights

All rabbits gained weight by study termination. However, minimal (0.4-2.6%) body weight loss was observed in 2 males and 2 females between days 7 and 14.

Gross necropsy

No compound-related gross changes were observed in any rabbit.

LD_{50} determination

The estimated acute dermal LD_{50} was greater than 2000 mg/kg body weight for male and for female rabbits. An acute dermal LD_{50} greater than 2000 mg/kg body weight corresponds to Toxicity Category III (Caution).

D. REVIEWERS' COMMENTS

The estimated acute dermal LD_{50} for male and female rabbits exposed to dermal application of Rejex-it TP-40 under these study conditions was >2000 mg/kg body weight, Toxicity Category III (Caution). The dose level used in this study met the limit dose designated in the guideline.

The moderate to severe signs of dermal irritation reported in this study appear to be more severe than the dermal irritation observed in the primary dermal irritation study in rabbits (MRID 426089-05). In the primary dermal irritation study, very slight to severe erythema (Draize scores 0-3), very slight edema (Draize scores 0-1), and desquamation were observed after dermal application of Rejex-it TP-40 under 4-hour semi-occluded conditions. The primary irritation index of 1.9 indicated that the test material was slightly irritating under conditions of that test.

FINAL

DATA EVALUATION REPORT

Rejex-it TP-40

Study Type: Acute Oral Toxicity in Rats

Prepared for:

Health Effects Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by:

Clement International Corporation
9300 Lee Highway
Fairfax, VA 22031

January 1994

Principal Reviewer _____ Date 1/13/94
Kate Rantz, M.P.H.

Independent Reviewer _____ Date 1/24/94
Carrie Rabe, Ph.D.

QA Reviewer _____ Date 1/25/94
William McLellan, Ph.D.

Contract Number: 68D10075
Work Assignment Number: 3-36
Clement Number: 164
Project Officer: Caroline Gordon

EPA Reviewer: J. Thomas McClintock
Biological Section, Science Analysis Branch
Health Effects Division

Signature: J. Thomas McClintock
Date: 2/9/94

EPA Section Head: Roy Sjoblad
Biological Section. Science Analysis Branch
Health Effects Division

Signature: Roy Sjoblad
Date: 4/14/94

DATA EVALUATION REPORT

STUDY TYPE:	Guideline series 81-1; acute oral toxicity in rodents
CAS NUMBER:	
TOX CHEM NUMBER:	
MRID NUMBER:	426089-02
PC NUMBER:	128725
TEST MATERIAL:	Rejex-it TP-40
SYNONYM(S):	Methyl anthranilate (active ingredient)
SPONSOR:	ERM Program Management Company McLean, Virginia
STUDY NUMBER:	HWI 20305694
TESTING FACILITY:	Hazleton Wisconsin, Inc. Madison, Wisconsin
TITLE OF REPORT:	Acute Oral Toxicity Study of Rejex-it TP-40 in Rats
AUTHOR:	Steven M. Glaza
STUDY COMPLETED:	July 7, 1992
QUALITY ASSURANCE:	The test was performed under Good Laboratory Practice Standards. A Quality Assurance Statement, signed July 7, 1992, was submitted.
CONCLUSIONS:	Estimated acute oral LD_{50} for males: >5000 mg/kg body weight Estimated acute oral LD_{50} for females: >5000 mg/kg body weight
CORE CLASSIFICATION:	Core Supplementary. This study satisfies the guideline requirements (81-1) for an acute oral

toxicity study in rodents. However, data describing the test material were lacking (e.g., purity, stability, and lot number/identification number). This study may be upgraded pending sumbission of these data.

TOXICITY CATEGORY: IV (Caution)

A. MATERIALS

Test Compound

Test material:	Rejex-it TP-40
Identification no.:	Not reported
Purity:	Determined by sponsor
Physical description:	Blue liquid
Bulk density:	0.95 g/mL
Storage condition:	Room temperature
Stability:	Determined by sponsor
Vehicle:	None
Dose volume:	5.26 mL/kg body weight
Dose level:	5000 mg/kg body weight (limit dose)

Controls

There were no controls.

Test Animals

Species:	Albino rat
Strain:	Crl:CD®BR
Source:	Charles River Laboratories, Inc., Portage, MI
Sex:	5 males and 5 females
Age:	Young adult
Initial body weight (fasted):	212-244 g for males; 242-282 g for females
No. animals:	5/sex/dose
Temperature:	22-27°C
Relative humidity:	39-54%
Photoperiod:	12-hour dark/12-hour light cycle
Feeding:	Purina Certified Rodent Chow #5001, *ad libitum*
Water:	*Ad libitum*
Acclimation period:	At least 7 days
Housing:	5/cage; sexes separate
Identification:	Ear tags
Selection:	Healthy animals within unspecified body weight limits were selected

B. TEST PERFORMANCE

Method of administration:	Oral gavage

21

Animals fasted:	Food was withheld 17-20 hours before dosing
Dosing:	Once __x__; Other _____ (describe)
Observation period:	14 days
Observation frequency:	Clinical observations and mortality checks were conducted 1, 2.5, and 4 hours after dosing. Clinical observations were conducted daily and mortality checks were conducted twice daily thereafter for 14 days.
Body weight interval:	Body weights were measured day 0 (before dosing), day 7, and day 14 (study termination).
Gross pathology:	Yes
Histopathology:	No

C. RESULTS

Mortality

There were no deaths during the study.

Clinical observations

Clinical signs of toxicity included soft stool in 1/5 males during the first hour after administration, and hypoactivity in 2/5 females on the day following treatment.

Body weights

All animals gained weight by the end of the observation period.

Gross necropsy

No compound-related changes were observed in any rats.

LD_{50} determination

The estimated acute oral LD_{50} was >5000 mg/kg body weight for both male and female rats, Toxicity Category IV (Caution).

D. REVIEWERS' COMMENTS

The estimated acute oral LD_{50} for both male and female rats administered Rejex-it TP-40 under these study conditions was greater than 5000 mg/kg body weight for both male and female rats, Toxicity Category IV (Caution). The study was done at the limit dose (5 g/kg) specified in guideline series 81-1.