elf atochem

Contains No CBI

ELF ATOCHEM NORTH AMERICA, INC.
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King of Prussia, PA 19406-0018

Tel: 215-337-6500

October 12, 1992

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8EHQ-92-12702
88920010880
INIT

CERTIFIED MAIL

RETURN RECEIPT REQUESTED

Document Processing Center (TS-790)
Office of Toxic Substances
U.S. Environmental Protection Agency
401 M St., S.W.
Washington, D.C. 20460

Attn: Section 8(e) Coordinator (CAP Agreement)

RE: Report Submitted Pursuant to the TSCA Section 8(e) Compliance Audit Program

CAP Identification Number: 8ECAP-0026

Dear Sir/Madam:

Pursuant to the Toxic Substances Control Act (TSCA) Section 8(e) Compliance Audit Program and the Agreement for TSCA Section 8(e) Compliance Audit Program (CAP Agreement) executed by Elf Atochem North America Inc. (Atochem) and the Environmental Protection Agency (EPA), Atochem is submitting the enclosed acute dermal limit test to the EPA. This study does not involve effects in humans.

Nothing in this letter or the enclosed study is considered confidential business information of Atochem.

The enclosed study provides information on the chemical 2-t-butylazo-2-(2-hydroxyethoxy)-4-methylpentane. Its exact chemical name is (1,3-dimethoxy-1,3-dimethylbutyl)(1,1-dimethylethyl)diazine and its CAS number is 52116-07-1.

The title of the enclosed report is Acute Dermal LD_{50} Assay in Rabbits. The following is a summary of the adverse effects observed in this study.

mm
2/9/95

Test material was applied to the skin of groups of six male and six female New Zealand albino rabbits at dosages of 3500, 4183 and 5000 mg/kg under occlusive dressings for 24 hours. The dermal LD_{50} was calculated to be 4456 mg/kg. Some surviving animals at 4183 mg/kg and above were reported to exhibit ataxia and loss of motor control.

To our knowledge, Atochem has not previously submitted any TSCA Section 8(e) notices or premanufacture notifications on the subject chemical.

Further questions regarding this submission may be directed to me at 215 337-6892.

Sincerely,

C.H. Farr, PhD, DABT
Manager, Product Safety
and Toxicology

Enclosures

FILED AN 20997-55

FDRL #8
TR91-1392
N-792

FOOD AND DRUG Research LABORATORIES, INC.

WAVERLY DIVISION
Route 17C
P. O. Box 107
Waverly, N. Y. 14892-010
(607-565-8131)

ACUTE DERMAL LD_{50} ASSAY IN RABBITS

FDRL Test Article ID: 82-0257

Sponsor Test Article ID: 2-t-Butylazo-2-(2-Hydroxyethoxy)-4-methylpentane SN4-5488-52 97.6%

CONCLUSION:

Acute Dermal LD_{50}: (mg/kg)	4456
95% Confidence Intervals:	3915 - 6014
Slope:	8.99

Method of LD_{50} Calculation: Finney, D. J., Statistical Methods in Biological Assay, second edition. London: Griffin Press, 1971.

Submitted to: Pennwalt Corporation
Lucidol Division
1740 Military Road
Buffalo, NY 14240

CAS: 52116-07-1

FDRL Study No. 7314_D

Date: June 21, 1982

Elizabeth L. Reagan, AAS
Assistant Toxicologist/
Study Director

Peter J. Becci, Ph.D.,
Director of Toxicology

This report is submitted for the exclusive use of the person, partnership, or corporation to whom it is addressed, and neither the report nor the name of these Laboratories nor of any members of its staff, may be used in connection with the advertising or sale of any product or process without written authorization.

Table 1

Preliminary Search

Dosage Level mg/kg	No. Rabbits Dosed	Deaths -Day- 1	2	3	4	5	6	7	8	Mortality After 8 Days
50	2	0	0	0	0	0	0	0	0	0/2
126	2	0	0	0	0	0	0	0	0	0/2
316	2	0	0	0	0	0	0	0	0	0/2
795	2	0	0	0	0	0	0	0	0	0/2
2000	2	0	0	0	0	0	0	0	0	0/2
3000	2	0	0	0	0	0	0	0	0	0/2
5000	2	0	0	0	1	0	0	0	0	1/2

FDRL

Table 2

Dermal LD_{50} Assay

Dosage Level mg/kg	Time of Death -Day- 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	Cumulati Mortalit
3500	0	0	1	0	0	0	0	0	0	0	1	0	0	0	0	2/12
4183	0	1	1	0	1	0	0	0	1	1	0	0	0	0	0	5/12
5000	0	0	1	3	1	0	0	1	2	0	0	0	0	0	0	8/12

Table 3

Summary of Observations[a]

Dosage Level mg/kg	Clinical Observations	Necropsy Observations
3500	Decreased activity (2M & 5F), Diarrhea (4M & 2F), Loss of appetite (3M & 6F), Soft stools (4M & 1F), Loss of most of control over body movement (2F), Deaths (2F).	Abdominal cavity filled with urinelike fluid (1F).
4183	Ataxia (5M & 5F), Decreased activity (5M & 4F), Loss of appetite (6M & 3F), Respiration increased (2M & 3F), Nasal discharge (4M & 1F), Total loss of control over body movements (2M & 1F), Loss of most of control over body movements (1M & 1F), Deaths (3M & 2F).	Blood around mouth and nose (2F). Bloodlike fluid in chest cavity (1F).
5000	Ataxia (5M & 6F), Decreased activity (5M & 6F), Loss of appetite (4M & 6F), Soft stools (3M & 2F), Eyes irritated (1M), Total loss of control over body movements (3M & 3F), Loss of most of control over body movements (1F), Deaths (4M & 4F).	Pleural cavity filled with blood (1M & 1F) Intestines filled with red fluid (1M).

The ataxia (abnormal gait) and the loss of motor control may indicate neurotoxicity.

[a] Complete observations are found in Appendis III (raw data). Figures in parenthesis indicate the number and sex of animals affected.

FDRL

Table 4

Mean Body Weights[a]

Sex & Dosage Level mg/kg	Initial[b] (grams)	Day 15 (grams)	At Death (grams)
Males			
3500	1.99 ±0.21(6)	1.94 ±0.37(6)	----
4183	2.73 ±0.74(6)	2.30 ±0.45(3)	2.71 ±0.29(3)
5000	1.98 ±0.25(6)	2.36 ±0.21(2)	1.51 ±0.35(4)
Females			
3500	1.87 ±0.15(6)	2.04 ±0.13(4)	1.29 ±0.16(2)
4183	2.17 ±0.61(6)	2.23 ±0.41(4)	2.13 ±0.37(2)
5000	1.79 ±0.21(6)	1.81 ±0.19(2)	1.35 ±0.21(4)

[a] Values indicated are mean ± S.D. where appropriate. Individual animal weights may be found in Appendix III (raw data).

[b] Fasted body weights.

FDRL

Acute Dermal LD_{50} Study in Albino Rabbits

Purpose: To determine the acute dermal toxicity (LD_{50}) of the test article when administered dermally to rabbits by the method described below.

Compliance with Government Regulations:

This study was conducted in accordance with the regulations for Good Laboratory Practices as described by the FDA (21 CFR Part 58) and FDRL Standard Operating Procedures.

Experimental Procedures:

Animals and Animal Care

Young adult New Zealand White rabbits were purchased from New York State Rabbit Development, Hartwick, NY (an USDA approved supplier) for use in this study.

All animals were acclimated a minimum of 5 days. During this acclimation period, the rabbits were examined with respect to their general health to assure their suitability as test animals. The rabbits were housed individually in wire mesh bottom cages. NIH Animal Feed A (certified) and water were provided ad libitum. Animals were identified by use of ear tags and cage cards. A dose range study was performed to establish dose levels used in the principal study.

Method

The back and flanks of each rabbit were clipped free of fur with electric clippers not more than 24 hours before study initiation. The clipped area constituted approximately 10 percent of the total body surface.

On the day of testing and just prior to the application of the test article, abrasion of the skin was performed on the exposure sites of 3 male and 3 female rabbits per group. The skin of the remaining 3 male and 3 female rabbits was left intact. Abrasions were made with the point of a 22 gauge disposable hypodermic needle.

The abrasions were minor incisions through the stratum corneum that were not sufficiently deep to disturb the derma or to produce bleeding.

The test article was administered under an occlusive binder at levels specified in Appendix III (Raw Data). The occlusive binder consisted of a layer of plastic wrap, a protective cloth and stockinette binder, all securely held in place with masking tape. The occlusive binder is applied to maintain contact and minimize evaporation of the applied test article.

If the test article was solid, it was moistened with physiological saline, (1 ml saline per 1 g of test article) before dermal application. Liquid test articles are administered as received.

Observations

After an exposure period of 24 hours the occlusive binders were removed. The exposure sites were then gently wiped with clean gauze to remove as much non-absorbed test article as possible. Observations for mortality, local reactions, and toxicological findings were recorded for a total of 14 days. Body weights were recorded on the initial day of testing and at study termination or day of death.

Sacrifice and Necropsy

Only those animals that died during the progress of the study were subjected to a gross necropsy.

All original data are stored in the FDRL archives and are available upon request.

Appendix I

Probit Analysis

S7314DC
ENTER DATA (DOSE N RES) WITH SPACE BETWEEN VARIABLES
AFTER LAST ENTRY HIT CARRIAGE RETURN TWICE
3500 12 2
4183 12 5
5000 12 8

PROBIT ANALYSIS ON LOG10(DOSE)

ITERATION	INTERCEPT	SLOPE	MU	SIGMA
0	-27.93650109	9.02592358	3.64910037	0.11079199
1	-27.79434990	8.98739793	3.64892599	0.11126691
2	-27.79452738	8 98744623	3.64892613	0.11126631

COVARIANCE MATRIX

	INTERCEPT	SLOPE
INTERCEPT	176.45484508	-48.62485662
SLOPE	-48.62485662	13.40311581

PRT FILE 6235 FROM LWX COPY 001 NOHOLD

COVARIANCE MATRIX

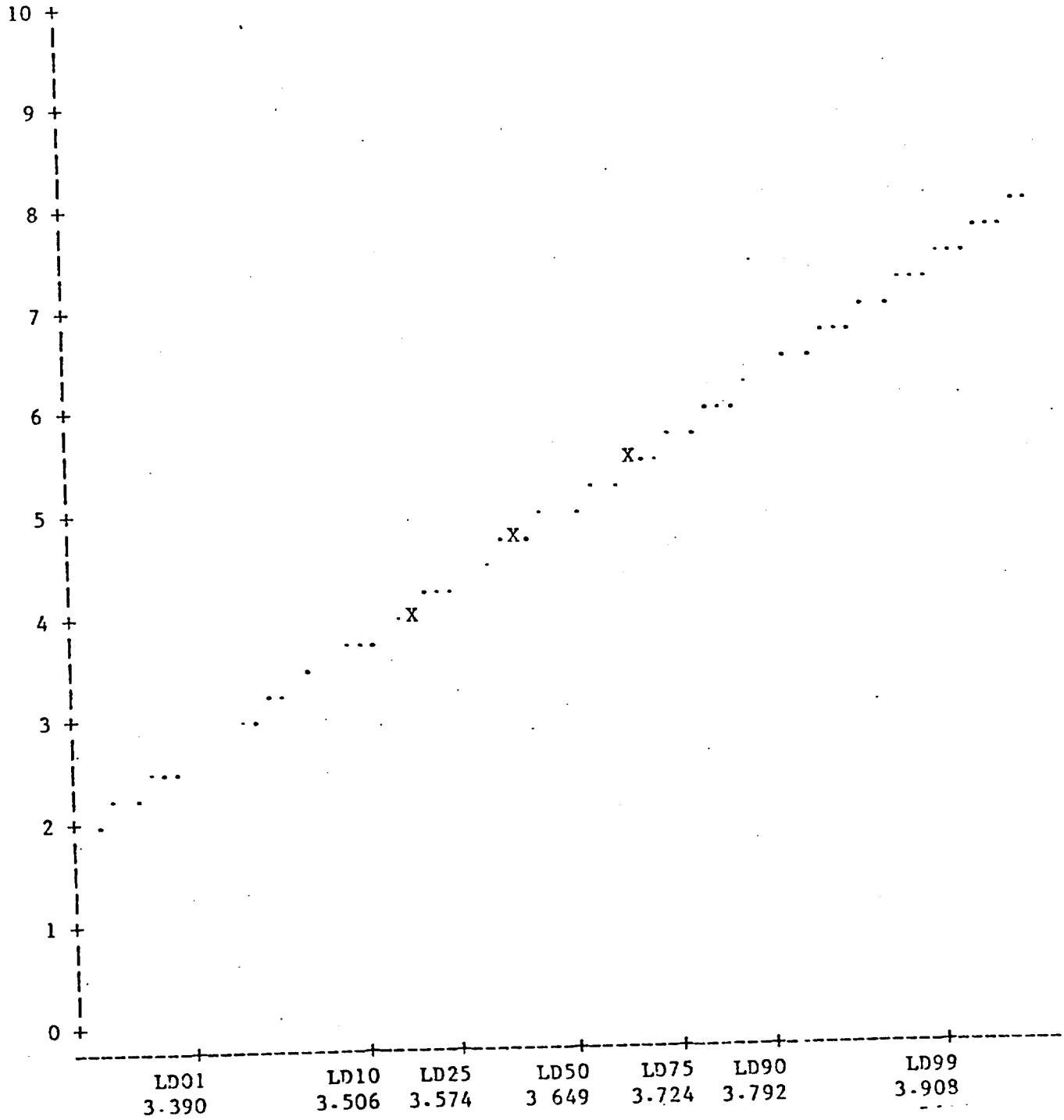
	MU	SIGMA
MU	0.00069058	0.00038862
SIGMA	0.00038862	0 00205428

PRT FILE 6237 FROM LWX COPY 001 NOHOLD

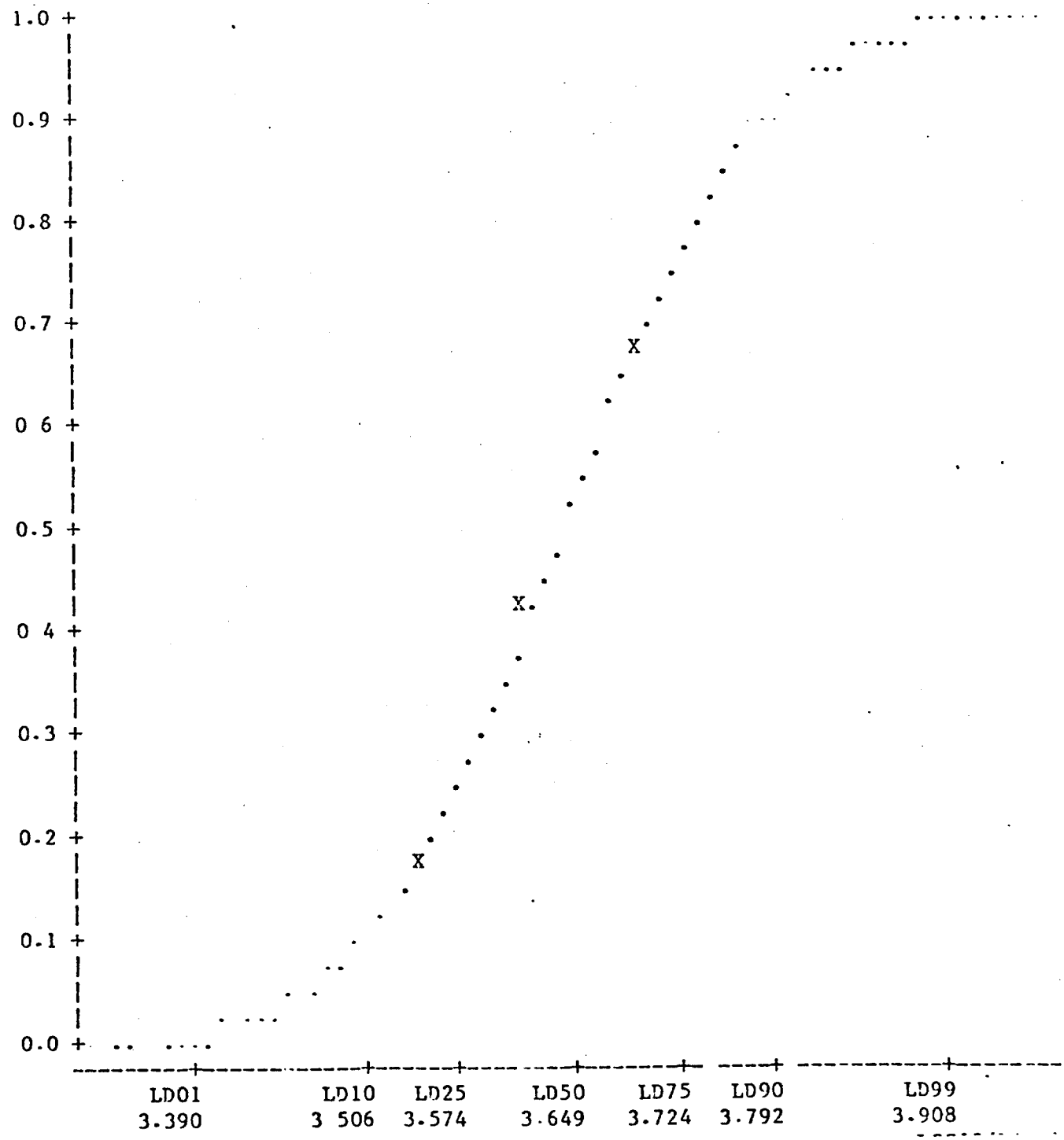
CHI-SQ = 0 0158 WITH 1 DF PROB > CHI-SQ = 0.8999

NOTE SINCE THE CHI-SQUARE IS SMALL (P > 0 10), FIDUCIAL LIMITS WILL BE COMPUTED USING A T VALUE OF 1.96 .

PROBIT ANALYSIS ON LOG10(DOSE)



PROBABILITY PROBIT ANALYSIS ON LOG10(DOSE)



PROBIT ANALYSIS ON LOG10(DOSE)

PROBABILITY	LOG10(DOSE)	95 PERCENT FIDUCIAL LIMITS LOWER	UPPER
0 01	3.39008198	2.44210900	3.50185751
0.02	3.42041306	2.59166941	3.51961737
0.03	3.43965716	2.68641496	3.53103115
0.04	3 45413375	2.75758733	3.53971832
0 05	3.46590933	2.81539941	3 54686582
0 06	3.47593221	2.86453620	3.55301983
0 07	3.48472030	2.90755558	3.55847967
0.08	3.49258900	2.94601421	3.56342838
0.09	3 49974526	2.98093299	3.56798686
0 10	3 50633261	3 01301913	3.57223960
0.15	3.53360601	3.14506209	3.59064928
0 20	3 55528204	3 24848968	3.60679670
0.25	3.57387814	3 33513271	3.62273837
0.30	3.59057802	3.40973610	3.64025922
0 35	3 60605294	3 47361625	3 66174590
0 40	3.62073713	3.52580380	3.69055812
0 45	3 63494426	3.56502576	3.72971421
0 50	3 64892613	3 59273095	3 77913951
0.55	3 66290800	3.61274345	3.83625749
0 60	3 67711513	3.62842549	3.89894851
0 65	3.69179932	3.64184990	3 96652888
0 70	3 70727424	3.65423364	4.03951196
0 75	3 72397412	3 66638968	4.11948015
0.80	3.74257022	3 67902432	4.20943022
0.85	3 76424625	3.69300941	4 31502013
0 90	3.79151965	3.70990999	4.44857220
0 91	3 79810700	3 71391167	4.48090940
0 92	3.80526326	3 71823135	4 51606697
0.93	3.81313196	3.72295161	4.55475407
0 94	3.82192005	3.72819123	4.59799365
0 95	3 83194293	3.73413086	4.64734483
0.96	3.84371851	3.74106665	4.70536861
0.97	3.85819510	3.74954002	4.77675477
0.98	3.87743920	3.76072911	4.87172503
0.99	3.90777028	3.77823006	5 02154434

PROBIT ANALYSIS ON LOG10(DOSE)

PROBABILITY	DOSE	95 PERCENT FIDUCIAL LIMITS LOWER	UPPER
0.01	2455.17233136	276 76361958	3175 83194558
0 02	2632 77086050	390 54349464	3308.39509431
0.03	2752.05533068	485.75241033	3396.49635975
0 04	2845.33723397	572.25201628	3465.12035384
0 05	2923.54196978	653.73148980	3522.62021425
0.06	2991 79757532	732.04233119	3572.89153337
0 07	3052.95431001	808.26835596	3618 09249914
0 08	3108.77291256	883.10879985	3659.55588994
0 09	3160 42335065	957.04639508	3698 16988029
0 10	3208.72585323	1030.43149785	3734 56135429
0 15	3416 69340195	1396.56802196	3896 27214872
0 20	3591.55101141	1772 10591721	4043.86548915
0 25	3748.67804781	2163.37947855	4195 06190104
0 30	3895 63284628	2568 83432203	4367.76453145
0 35	4036.94602500	2975.88571152	4589 29416017
0.40	4175.77540762	3355.89834732	4904.08649483
0.45	4314.63692124	3673.04088721	5366.78519359
0.50	4455 80452462	3914.99264152	6013.66882343
0.55	4601.59089259	4099.61858958	6858.94761281
0.60	4754.61250272	4250 35775599	7924.07377394
0.65	4918.12222375	4383.79155296	9258 24940838
0.70	5096.52596769	4510.59301165	10952.46717249
0.75	5296.31878450	4638.62949061	13166.79734730
0 80	5528 02783493	4775.56016931	16196.83720307
0 85	5810 93812816	4931 84487663	20654.75888767
0.90	6187.56318545	5127.55099278	28091.32361714
0.91	6282 13114473	5175.01563769	30262.82036468
0 92	6386.50506810	5226.74542326	32814.58914845
0 93	6503 27255031	5283.86371704	35871 87401562
0 94	6636.20898867	5347.99796100	39627.22446748
0 95	6791.14381351	5421.64226361	44396.10083621
0.96	6977.79993337	5508 92228411	50742.12075876
0 97	7214.31496682	5617.46045824	59807 37944402
0.98	7541 17810232	5764.06815690	74426.06049374
0.99	8086.68039634	6001.08886628	105085 87447926

Appendix III

Raw Data

and also

Includes:

Abbreviations and Symbols used in Recording Observations

Study Title: Search (Dermal)

FDRL Study No.: 7314D

DOSING SCHEDULE

Instructions: INITIAL + FINAL Body Wts.

Species: Albino Rabbit

FDRL Test Article I. D. No.: 82-0257

Test Article

Diluent: None

Density: ~~N/A~~ BR 5/13/82 1.00

Concentration: undil

Form: as is

Animal Number & Sex	Time Dosed	Body Weight (g) at Day 1	8	~~15~~	WAD	Level Dosage mg/kg	Dose ml (Total)	Date of Death	Comments
*1111 M	1:20	2.05 Kg	2.33 Kg			50 mg/Kg	0.10		
1169 F		2.89 Kg	2.95 Kg			↓	0.14		
1112 M		2.15 Kg	2.28 Kg			126 mg/Kg	0.27		
*1170 F		3.30 Kg	3.45 Kg			↓	0.42		
*1114 M		2.04 Kg	2.41 Kg			316 mg/Kg	0.64		
1171 F		2.67 Kg	2.81 Kg			↓	0.84		
1128 M		2.30 Kg	2.30 Kg			795 mg/Kg	1.83		
*1174 F		2.33 Kg	2.41 Kg			↓	1.85		
*1115 M		2.27 Kg	2.29 Kg			2000 mg/Kg	4.54		
1175 F		2.38 Kg	2.40 Kg			↓	4.76		
Initials & Date	TK, DP 5-6-82	TK 5-6-82	TK 5-13-82			TK 5-6-82	BH 5-6-82		

Reviewed by: BR

Date: 5/13/82

* = dosed

Study Title: Search (Dermal)

FDRL Study No.: 7314 D

DOSING SCHEDULE

Instructions: Initial + Final Body Wts.

Species: Albino Rabbit

FDRL Test Article I. D. No.: 82-0257

Test Article

Diluent: None

Density: 1.00

Concentration: undil

Form: as is

Animal Number & Sex	Time Dosed	Body Weight (Kg) at Day 1	8	15	WAD	Level Dosage mg/kg	Dose ml (Total)	Date of Death	Comments
82- 1301 M	11:35	1.82 Kg	2.12 Kg			3000 mg/kg	5.46		
* 82- 1321 F		2.14 Kg	2.26 Kg			↓	6.42		
* 82- 1304 M		2.25 Kg	2.58 Kg			5000 mg/kg	11.25		
82- 1322 F		1.89 Kg			1.71 Kg	↓	9.45	5-15-82	
Initials & Date	TK, DP 5-12-82	TK 5-12-82	EP 5-19-82			TK 5-12-82	BHO 5-12-82		

These animals were received from the N.I.S. Rabbit Development on 4-30-82.

Reviewed by: BR

III-3

Date: 5/18/82

2 animals fell below the desired weight range. This did not affect the integrity of the study.

Raw Data

Body Weight Sheet

Type of Test: Search (Dermal)

FDRL Study No.: 7314 D

Initiation Date: 5-6-82

Animal Number	Initial Body Weight
82 - 1111 M	2.05 Kg
82 - 1169 F	2.89 Kg
82 - 1112 M	2.15 Kg
82 - 1170 F	3.30 Kg
82 - 1114 M	2.04 Kg
82 - 1171 F	2.67 Kg
82 - 1128 M	2.30 Kg
82 - 1174 F	2.33 Kg
82 - 1115 M	2.27 Kg
82 - 1175 F	2.38 Kg
Tech. Init.: TK	
Date: 5-6-82	5/13/82

Comments:

These animals were received from the N.Y.S. Rabbit Development on 4-8-82.

TEST ARTICLE PREPARATION DATA

Study Title: Acute Dermal Search FDRL Study No.: 7314D

Species: Rabbit FDRL Test Article ID: 82-0257

Concentration Prepared: undil

Test Article Density: 1.00 gm/ml Diluent: none

Total Amount Dispensed: 15 mls Prepared Physical State: asID

PREPARATION PROCEDURES

X Test article dispensed undiluted.

..... Weighed ..... gm test article, Q. S. to ..... ml with ..... .

..... Test article ground with mortar and pestle.

..... Test article blended at ..... speed for ..... .

DOSING INFORMATION

Level	Coefficient*
50mg/kg	0.05
126	0.126
316	0.316
795	0.795

2000 2.0

Special Instructions: EXTREME CAUTION IN HANDLING

Comments:

Calculations: BH 5-6-82 Preparation: BH 5-6-82
Initials/Date Initials/Date

Review: BE 5/13/82
Initials/Date

*Coefficient x kg body weight = dose N/A = Not Applicable

TEST ARTICLE PREPARATION DATA

Study Title: Acute Dermal Search FDRL Study No.: 73140

Species: Rabbit FDRL Test Article ID: 82-0257

Concentration Prepared: undil

Diluent: None

Test Article Density: 1.00 gm/ml

Total Amount Dispensed: 40 mls Prepared Physical State: Solid

PREPARATION PROCEDURES

..... Test article dispensed undiluted.

..... Weighed ..... gm test article, Q. S. to ..... ml with ..... .

..... Test article ground with mortar and pestle.

..... Test article blended at ..... speed for ..... .

DOSING INFORMATION

Level	Coefficient*
3000mg/kg	
5000mg/kg	

Special Instructions: EXTREME CAUTION

Comments:

Calculations: BH 5-12-82 Preparation: BH 5-12-82 DD 5/12/82

Initials/Date Initials/Date

Review: BR 5/18/82

Initials/Date

*Coefficient x kg body weight = dose N/A = Not Applicable

Study Title: Acute Dermal LD 50

FDRL Study No.: 7314D

Instructions:

DOSING SCHEDULE

FDRL Test Article

Species: Albino Rabbit

I. D. No.: 82-0257

Test Article

Diluent: None

Density: 1.00

Concentration: undil

Form: as is

Animal Number & Sex	Time Dosed	Body Weight (Kg) at Day 1	8 N/A	15	WAD	Level Dosage mg/kg	Dose ml (Total)	Date of Death	Comments
* 82-1548 M	10:35	2.19		2.45		3500 mg/kg	7.67 ✓		
* 82-1552 M		2.11		2.14			7.39 ✓		
* 82-1554 M		1.91		1.96			6.69 ✓		
82-1556 M		2.19		1.82			7.67 ✓		
82-1558 M		1.65		1.33			5.78 ✓		
82-1559 M		1.89		1.92			6.62 ✓		
* 82-1595 F		1.71	—	—	1.40 Kg		5.99 ✓	5-29-82	
* 82-1600 F		1.81	—	—	1.17		6.34 ✓	6-6-82	
* 82-1605 F		2.02		2.18			7.07 ✓		
82-1607 F		2.08		2.07			7.28 ✓		
82-1608 F		1.75		1.86			6.13 ✓		
82-1611 F		1.82		2.04			6.37 ✓		
Initials & Date	TK, DP 5-27-82	EP 5-27-82		EP 6-10-82		TK 5-27-82	BH 5-27-82		

These animals were received from the N.Y.S. Rabbit Development on 5-19-82.

Reviewed by: BR III-7 Date: 6/10/82

* Included N/A = not applicable

Study Title: Dermal LD50

FDRL Study No.: 7314 D

DOSING SCHEDULE

Instructions: Abrade 3M 3F

Species: Albino Rabbit

FDRL Test Article I. D. No.: 82-0257

Test Article

Diluent: none

Density: 1.00

Concentration: undil

Form: as is

Animal Number & Sex	Time Dosed	Body Weight (~~g~~ Kg) at Day 1	~~8~~ N/A	15	WAD	Level Dosage mg/kg	Dose ml (Total)	Date of Death	Comments
* 82-1026 M	11:10	2.60		2.77		4183.0 mg/Kg	10.88		
* 82-1018 M		2.84	—	—	2.69		11.88	6-3-82	
* 82-1019 M		3.55	—	—	2.44		14.85	6-11-82	
82-1027 M		3.55	—	—	3.01		14.85	6-6-82	
82-1469 M		1.91		1.88			7.99		
82-1459 M		1.91		2.24			7.99		
* 82-1247 F		3.36	—	—	2.39		14.05	6-10-82	
* 82-1488 F		1.80		2.13			7.53		
* 82-1491 F		1.91		2.51			7.99		
82-1496 F		1.72		1.69			7.19		
82-1513 F		2.05	—	—	1.86		8.58	6-4-82	
82-1064 F		2.15		2.59			8.99		
Initials & Date	TK, DP 6-2-82	TK 6-2-82		TK 6-16-82		TK 6-2-82	BH 6/2/82		

These animals were received from the N.Y.S. Rabbit Development. animal # 1247 was received 4-15-82. Animals # 1026, 1018, 1019, and 1027 were received 3-31-82. The other six were received 5-14-82.

Reviewed by: BR III-8 Date: 6/14/82

* Abraded N/A - Not Applicable

Study Title: Acute Dermal

FDRL Study No.: 7314D

DOSING SCHEDULE

Instructions: Abrade 3M 3F

Species: Albino Rabbit

FDRL Test Article I. D. No.: 82-0257

Test Article

Diluent: None

Density: 1.00

Concentration: undil

Form: as is

Animal Number & Sex	Time Dosed	Body Weight (~~lb~~ Kg) at Day 1	~~8~~ N/A	15	WAD	Level Dosage mg/kg	Dose ml (Total)	Date of Death	Comments
* 82-1449M	11:10	2.16 Kg	—	—	1.42 Kg	5000.0 mg/kg	10.80 ✓	5-23-82	
* 82-1450M		1.77 Kg	—	—	1.62 Kg		8.85 ✓	5-23-82	
* 82-1451M		1.78 Kg	—	—	1.09 Kg		8.90 ✓	5-28-82	
82-1452M		1.71 Kg	—	—	1.40 Kg		8.55 ✓	5-23-82	
82-1453M		2.25 Kg		2.51			11.25 ✓		
82-1454M		2.23 Kg		2.21			11.15 ✓		
* 82-1507F		1.89 Kg	—	—	1.63 Kg		9.45 ✓	5-22-82	
* 82-1509F		1.55 Kg		1.94			7.75 ✓		
* 82-1515F		2.15 Kg	—	—	1.40 Kg		10.75 ✓	5-28-82	
82-1385F		1.67 Kg	—	—	1.22 Kg		8.35 ✓	5-24-82	
82-1396F		1.80 Kg		1.67			9.00 ✓		
82-1341F		1.67 Kg	—	—	1.16 Kg		8.35 ✓	5-27-82	
Initials & Date	TK, OO 5-20-82	TK 5-20-82		DP 6-3-82			BHO 5/20/82		

These animals were received from the N.Y.S. Rabbit Development. All the males and the three females were received on 5-14-82. Numbers 1385F & 1396F were received on 5-7-82. The last female was received on 4-30-82.

Reviewed by: [illegible] Date: 6/3/82

* = Abraded N/A = Not applicable

TEST ARTICLE PREPARATION DATA

Study Title: Acute Dermal FDRL Study No.: 7314D

Species: Rabbit FDRL Test Article ID: 82-0257

Concentration Prepared: undil.

Test Article Density: 1.00 gm/ml Diluent: none

Total Amount Dispensed: 70 mls Prepared Physical State: as is

PREPARATION PROCEDURES

X Test article dispensed undiluted.

..... Weighed ..... gm test article, Q. S. to ..... ml with ..... .

..... Test article ground with mortar and pestle.

..... Test article blended at ..... speed for ..... .

DOSING INFORMATION

Level	Coefficient*
3500mg/kg	3.5

Special Instructions: EXTREME CAUTION

Comments:

Calculations: BH 5-27-82 Preparation: BH 5-27-82
Initials/Date Initials/Date

Review: SK 6/10/82
Initials/Date

*Coefficient x kg body weight = dose N/A = Not Applicable

TEST ARTICLE PREPARATION DATA

Study Title: Acute Dermal FDRL Study No.: 7314D

Species: Rabbit FDRL Test Article ID: 820257

Concentration Prepared: undil

Test Article Density: 1.00 gm/ml Diluent: None

Total Amount Dispensed: 110 mls Prepared Physical State: as is

PREPARATION PROCEDURES

X Test article dispensed undiluted.

..... Weighed ..... gm test article, Q. S. to ..... ml with ..... .

..... Test article ground with mortar and pestle.

..... Test article blended at ..... speed for ..... .

DOSING INFORMATION

Level	Coefficient*
4183 mg/kg	4.183

Special Instructions: EXTREME CAUTION!

Comments:

Calculations: BH 6-2-82 Initials/Date Preparation: BH 6-2-82 Initials/Date

Review: BR 6/16/82 Initials/Date

*Coefficient x kg body weight = dose N/A = Not Applicable

TEST ARTICLE PREPARATION DATA

Study Title: Acute Dermal FDRL Study No.: 7314D

Species: Rabbit FDRL Test Article ID: 82-0257

Concentration Prepared: undil.

Test Article Density: 100 gm/ml Diluent: None

Total Amount Dispensed: 90 mls Prepared Physical State: as is

PREPARATION PROCEDURES

X Test article dispensed undiluted.

..... Weighed ..... gm test article, Q. S. to ..... ml with ..... .

..... Test article ground with mortar and pestle.

..... Test article blended at ..... speed for ..... .

DOSING INFORMATION

Level	Coefficient*
5000mg/kg	5.0

Special Instructions:

EXTREME CAUTION

Comments:

Calculations: BH 5-20-82 Preparation: BH 5-20-82

Initials/Date Initials/Date

Review: BR 6/3/82

Initials/Date

*Coefficient x kg body weight = dose N/A = Not Applicable

Study Title: Acute Dermal LD50

FDRL Study No.: 7314D

Dose Level: 3500 mg/kg

DAILY OBSERVATIONS

Date Dosed: 5-27-82

Species: Albino Rabbit

FDRL Test Article I. D. No.: 82-0257

	Animal No. 1548 M	Animal No. 1552 M	Animal No. 1554 M	Animal No. 1556 M	Animal No. 1558 M	Initials/ Date
Day 1 - Initial	✓	✓	✓	✓	✓	DP 5-27-8
Day 1 - 1:00	✓	✓	✓	✓	✓	TK 5-27-82
Day 1 - 4:00	✓	✓	✓	✓	✓	TK 5-27-82
Day 2 - 8:00	✓	✓	✓	Nd(2)	✓	TK 5-28-82
Day 2 - 4:00	~~AnTK~~ ✓	✓	✓	NC	✓	TK 5-28-8
Day 3	Tiny feces, An(1)	✓	✓	Nd(2), An(2)	Small Amount of feces, An(2)	SS 5-29-8
Day 4	✓	✓	✓	NC	An(1)	SS 5-30-8
Day 5	✓	✓	✓	NC	NC	SS 5-31-8
Day 6	✓	✓	✓	SS, Nd(2), An(2)	NC	TK 6-1-8
Day 7	✓	✓	✓	Di(2) Nd(1), An(1)	✓	TK 6-2-82
Day 8	✓	✓	✓	Di(2), Nd(1), An(2) Ad(1)	Di(1), An(1)	TK 6-3-82
Day 9	✓	SS	✓	NC	Di(1), An(2)	TK 6-4-82
Day 10	✓	Di(1)	✓	NC	NC	DP 6-5-8
Day 11	✓	NC	✓	NC	SS, An(1)	DP 6-6-8
Day 12	✓	NC	✓	NC	NC	TK 6-7-8
Day 13	✓	Di(1), An(2), Ad(1)	✓	NC	An(2), Sew feces	TK 6-8-82
Day 14	✓	NC	✓	Nd(2), An(2), Ad(2) Sew feces	NC	TK 6-9-82
Day 15	SS	NC	✓	NC	NC	TK 6-10-8

Reviewed by: BR

Date: 6/10/82

Study Title: Acute Dermal LD50

DAILY OBSERVATIONS

FDRL Study No. 7314D

Dose Level: 3500 mg/kg

Date Dosed: 5-27-82

Species: Albino Rabbit

FDRL Test Article I. D. No. 82-0257

	Animal No. 1559m	Animal No.	Animal No.	Animal No.	Animal No.	Initials/ Date
Day 1 - Initial	✓					DP 5-27-82
Day 1 - 1:00	✓					TK 5-27-82
Day 1 - 4:00	✓					TK 5-27-82
Day 2 - 8:00	✓					TK 5-28-82
Day 2 - 4:00	✓					TK 5-28-82
Day 3	✓					SS 5-29-82
Day 4	✓					SS 5-30-82
Day 5	✓					SS 5-31-82
Day 6	✓					TK 6-1-82
Day 7	✓					TK 6-2-82
Day 8	Di(1)					TK 6-3-82
Day 9	SS					TK 6-4-82
Day 10	Di(1)					DP 6-5-82
Day 11	SS					DP 6-6-82
Day 12	✓					TK 6-7-82
Day 13	✓					TK 6-8-82
Day 14	✓					TK 6-9-82
Day 15	✓					TK 6-10-82

Reviewed by: BR

Date: 6/10/82

Study Title: Acute Dermal LD 50

DAILY OBSERVATIONS

FDRL Study No. 7314 D

Dose Level: 3500 mg/kg

Date Dosed: 5-27-82

Species: Albino Rabbit

FDRL Test Article I. D. No. 82-0257

	Animal No. 1595 F	Animal No. 1600 F	Animal No. 1605 F 1604 F TK	Animal No. 1607 F	Animal No. 1608 F	Initials/ Date
Day 1 - Initial	✓	✓	✓	✓	✓	CP 5-27-82
Day 1 - 1:00	✓	✓	✓	✓	✓	TK 5-27-82
Day 1 - 4:00	✓	✓	✓	✓	✓	TK 5-27-82
Day 2 - 8:00	At, An(1)	At, Ad(1), SS	✓	✓	An(2), Few Feces Ad(2)	TK 5-28-82
Day 2 - 4:00	NC	NC	✓	✓	NC	TK 5-28-82
Day 3	Found Dead	Small Amount of Feces, Ad(3), At(3), An(2)	An(3), Ad(2) Small Amount of Feces	✓	NO Feces, An(3) Ad(2)	SS 5-29-82
Day 4		NC	An(1), Ad(1)	Tiny Feces, At Small amount	NC	SS 5-30-82
Day 5		Small Amount of tiny Feces, Ad(3), An(3), At(3)	✓	NC	An(3), Ad(2)	SS 5-31-82
Day 6		NC	✓	At(1) An(3), Ad(2), no feces	Ad(1), An(1)	TK 6-1-82
Day 7		NC	✓	At(2) An(2), Ad(2), few feces	✓	TK 6-2-82
Day 8		NC	✓	At(2), An(3), Ad(2)	✓	TK 6-3-82
Day 9		At(2), Ad(3), An(2) mucous in feces	✓	At, An(2), Ad(1)	✓	TK 6-4-82
Day 10		NC	✓	NC	✓	CP 6-5-82
Day 11		Found dead	✓	At, An(1), Ad(1)	✓	CP 6-6-82
Day 12			✓	NC	✓	TK 6-7-82
Day 13			✓	At	✓	TK 6-8-82
Day 14			✓	NC	✓	TK 6-9-82
Day 15			Di(1)	NC	An(3), few feces	TK 6-10-82

Reviewed by: [illegible] Date: 6/10/82

Attach raw comment sheet

Study Title: Acute Dermal LD50

DAILY OBSERVATIONS

FDRL Study No. 7314D

Dose Level: 3500 mg/kg

Date Dosed: 5-27-82

Species: Albino Rabbit

FDRL Test Article I. D. No. 82-0257

	Animal No. 1611F	Animal No.	Animal No.	Animal No.	Animal No.	Initials/ Date
Day 1 - Initial	✓					DP 5-27-82
Day 1 - 1:00	✓					TK 5-27-82
Day 1 - 4:00	✓					TK 5-27-82
Day 2 - 8:00	Di(2), An(2)					TK 5-28-82
Day 2 - 4:00	NC					TK 5-28-82
Day 3	No feces, An(2) Ad(2)					SS 5-29-82
Day 4	Some feces, An(2) Ad(1)					SS 5-30-82
Day 5	An(2); Ad(1)					SS 5-31-82
Day 6	NC					TK 6-1-82
Day 7	✓					TK 6-2-82
Day 8	✓					TK 6-3-82
Day 9	✓					TK 6-4-82
Day 10	✓					DP 6-5-82
Day 11	✓					DP 6-6-82
Day 12	✓					TK 6-7-82
Day 13	✓					TK 6-8-82
Day 14	✓					TK 6-9-82
Day 15	An(2), Sw feces					TK 6-10-82

Reviewed by: [illegible]

Date: 6/10/82

Study Title: Dermal LD_{50}

DAILY OBSERVATIONS

FDRL Study No. 7314D

Dose Level: 4183.0 mg/Kg

Date Dosed: 6-2-82

Species: Albino Rabbit

FDRL Test Article I. D. No. 82-0257

	Animal No. 1036M	Animal No. 1018M	Animal No. 1019M	Animal No. 1027M	Animal No. 1460M	Initials/ Date
Day 1 - Initial	✓	✓	✓	✓	✓	DP 6-2-82
Day 1 - 1:00	✓	✓	✓	✓	✓	TK 6-2-82
Day 1 - 4:00	✓	Nd(2), At	✓	✓	At, Ad(1)	TK 6-2-82
Day 2 - 8:00	Nd(2), An(1), Ad(1) Ri	At^A Nd(2), Ad(3) An(3)	✓	✓	At, Ad(1), An(3)	TK 6-3-82
Day 2 - 4:00	Nd(2), An(1), Ad(1)	Found Dead 8:45	✓	Nd(2)	NC	TK 6-3-82
Day 3	Nd(2)		At, An(1), Ad(1)	Nd(1)	NC	TK 6-4-82
Day 4	Nd(1), An(1)		At, An(2), Ad(1) Few feces	At^A, Ad(2), An(2) Few feces	NC	DP 6-5-82
Day 5	NC		At(2), An(2), Ad(1) Few feces	Found dead	NC	DP 6-6-82
Day 6	NC		At(2), An(3), Ad(2), Nd(3) Ri, no feces		Nd(1), An(2)	TK 6-7-82
Day 7	Nd(1)		NC		An(1)	TK 6-8-82
Day 8	NC		NC		✓	TK 6-9-82
Day 9	NC		At(2), An(3), Ad(4), Nd(3), no feces		✓	TK 6-10-82
Day 10	NC		Dead		✓	TK 6-11-82
Day 11	✓				✓	TK 6-12-82
Day 12	✓				✓	TK 6-13-82
Day 13	✓				✓	TK 6-14-82
Day 14	✓				SS	TK 6-15-82
Day 15	✓				NC	TK 6-16-82

Reviewed by: RR

Date: 6/16/82

At^A - [illegible] + short

Study Title Dermal LD5

Dose Level 4183.0 mg/Kg

Date Dosed 6-2-82

DAILY OBSERVATIONS

FDRL Study No. 7314D

Species Albino Rabbit

FDRL Test Article I. D. No. 82-0257

	Animal No. 1424M	Animal No.	Animal No.	Animal No.	Animal No.	Initials/Date
Day 1 - Initial	✓					EP 6-2-8
Day 1 - 1:00	✓					TK 6-2-82
Day 1 - 4:00	✓					TK 6-2-82
Day 2 - 8:00	At, Ad(1), An(3)					TK 6-3-82
Day 2 - 4:00	NC					TK 6-3-82
Day 3	At, Ad(1), An(1)					TK 6-4-82
Day 4	NC					EP 6-5-8
Day 5	NC					EP 6-6-8
Day 6	An(1)					TK 6-7-82
Day 7	✓					TK 6-8-82
Day 8	✓					TK 6-9-82
Day 9	✓					TK 6-10-8
Day 10	✓					TK 6-11-8
Day 11	✓					TK 6-12-8
Day 12	✓					TK 6-13-8
Day 13	✓					TK 6-14-8
Day 14	✓					TK 6-15-8
Day 15	✓					TK 6-16-

Reviewed by: RL

Date: 6/16/82

Study Title: Dermal LD50

DAILY OBSERVATIONS

FDRL Study No. 7314 D

Dose Level: 4183.0 mg/Kg

Date Dosed: 6-2-82

Species: Albino Rabbit

FDRL Test Article I.D. No.: 82-0257

	Animal No. 1247F	Animal No. 1488F	Animal No. 1491F	Animal No. 1496F	Animal No. 1513F	Initials/ Date
Day 1 - Initial	✓	✓	✓	✓	✓	EP 6-2-82
Day 1 - 1:00	✓	✓	✓	✓	✓	TK 6-2-82
Day 1 - 4:00	Ad(1), Ri	✓	At, Ad(1)	Ri	✓	TK 6-2-82
Day 2 - 8:00	At, Ad(1)	✓	At, Ad(1), An(1)	At, An(2), Ad(1)	✓	TK 6-3-82
Day 2 - 4:00	NC	✓	NC	NC	At, Ad(1)	TK 6-3-82
Day 3	At, Ad(1), An(2)	✓	At	At, Ad(1)	Dead	TK 6-4-82
Day 4	At^A, Ad(2), An(2)	✓	NC	At, Ad(1), An(2)		EP 6-5-82
Day 5	NC	✓	NC	NC		EP 6-6-82
Day 6	At^A, Ad(3), An(3), no feces, No(3), Ri, G	✓	✓	At(2), Ad(1), An(2), G		TK 6-7-82
Day 7	NC	✓	✓	NC		TK 6-8-82
Day 8	NC	✓	✓	NC		TK 6-9-82
Day 9	Dead	✓	✓	At(2), Ad(1), An(1)		TK 6-10-82
Day 10		✓	✓	NC		TK 6-11-82
Day 11		✓	✓	At(2), Ad(1)		TK 6-12-82
Day 12		✓	✓	NC		TK 6-13-82
Day 13		✓	✓	NC		TK 6-14-82
Day 14		✓	✓	At(2), Ad(1), An(2) few feces		TK 6-15-82
Day 15		✓	✓	NC		TK 6-16-82

Reviewed by: BR

Date: 6/16/82

^A - see remark sheet

Study Title: Dermal LD_{50}

DAILY OBSERVATIONS

FDRL Study No. 7314D

Dose Level: 4183.0 mg/Kg

Date Dosed: 6-2-82

Species: Albino Rabbit

FDRL Test Article I. D. No. 82-0257

	Animal No. 1064F	Animal No.	Animal No.	Animal No.	Animal No.	Initials/ Date
Day 1 - Initial	✓					EP 6-2-82
Day 1 - 1:00	✓					TK 6-2-82
Day 1 - 4:00	At, Ri					TK 6-2-82
Day 2 - 8:00	At					TK 6-3-82
Day 2 - 4:00	NC					TK 6-3-82
Day 3	NC					TK 6-4-82
Day 4	NC					EP 6-5-82
Day 5	NC					EP 6-6-82
Day 6	✓					TK 6-7-82
Day 7	✓					TK 6-8-82
Day 8	✓					TK 6-9-82
Day 9	✓					TK 6-10-82
Day 10	✓					TK 6-11-82
Day 11	✓					TK 6-12-82
Day 12	✓					TK 6-13-82
Day 13	✓					TK 6-14-82
Day 14	✓					TK 6-15-82
Day 15	✓					TK 6-16-82

Reviewed by: BL

Date: 6/16/82

Study Title: Acute Dermal

Dose Level: 5000.0 mg/Kg

Date Dosed: 5-20-82

Species: Albino Rabbit

DAILY OBSERVATIONS

FDRL Study No. 7314D

FDRL Test Article I. D. No. 82-0257

	Animal No. 1449 M	Animal No. 1450 M	Animal No. 1451 M	Animal No. 1452 M	Animal No. 1453 M	Initials/ Date
Day 1 - Initial	✓	✓	✓	✓	✓	TK 5-20-82
Day 1 - 1:00	✓	✓	✓	✓	✓	TK 5-20-82
Day 1 - 4:00	✓	✓	✓	✓	✓	TK 5-20-82
Day 2 - 8:00	At, Ad(1), An(2)	✓	At, SS	✓	At, Ad(2), SS, An(1)	TK 5-21-82
Day 2 - 4:00	NC	✓	NC	At, Ad(1)	NC	TK 5-21-82
Day 3	At^A, Ad(1), An(2) few feces	✓	At, An(3), Ad(2) few feces	At^A, Ad(3), An(3) few feces	NC	TK 5-22-82
Day 4	Dead	Dead	At^A, An(3), Ad(3) few feces	Dead	At, Ad(1), An(2), Di(1)	TK 5-23-82
Day 5			At^A, An(3), Ad(3), Ad(1) no feces, Both eyes irritated + discharge		NC	TK 5-24-82
Day 6			NC		✓	TK 5-25-82
Day 7			NC		✓	TK 5-26-82
Day 8			NC		✓	TK 5-27-82
Day 9			Found Dead		✓	TK 5-28-82
Day 10					✓	SS 5-29-8
Day 11					✓	SS 5-30-8
Day 12					✓	SS 5-31-8
Day 13					Di(2)	TK 6-1-82
Day 14					SS, An(2)	TK 6-2-82
Day 15					✓	TK 6-3-82

Reviewed by: GR Date: 6/3/82

Study Title: Acute Dermal

DAILY OBSERVATIONS

FDRL Study No. 7314D

Dose Level: 5000.0 mg/Kg

Date Dosed: 5-20-82 Species: Albino Rabbit FDRL Test Article I. D. No. 82-0257

	Animal No. 1454M	Animal No.	Animal No.	Animal No.	Animal No.	Initials/ Date
Day 1 - Initial	✓					TK 5-20-82
Day 1 - 1:00	✓					TK 5-20-82
Day 1 - 4:00	✓					TK 5-20-82
Day 2 - 8:00	At					TK 5-21-82
Day 2 - 4:00	NC					TK 5-21-82
Day 3	At, Ndan, Adan					TK 5-22-82
Day 4	NC					TK 5-23-82
Day 5	At, Adan					TK 5-24-82
Day 6	NC					TK 5-25-82
Day 7	NC					TK 5-26-82
Day 8	NC					TK 5-27-82
Day 9	At, Adan, SS					TK 5-28-82
Day 10	At, Adan					SS 5-29-82
Day 11	NC					SS 5-30-82
Day 12	NC					SS 5-31-82
Day 13	NC					TK 6-1-82
Day 14	NC					TK 6-2-82
Day 15	At, Adan, Di(2)					TK 6-3-82

Reviewed by: BR Date: 6/3/82

Study Title: Acute Dermal

DAILY OBSERVATIONS

FDRL Study No. 7314D

Dose Level: 5000.0 mg/Kg

Date Dosed: 5-20-82

Species: Albino Rabbit

FDRL Test Article I. D. No. 82-0257

	Animal No. 1507 F	Animal No. 1559 F	Animal No. 1515 F	Animal No. 1385 F	Animal No. 1396 F	Initials/ Date
Day 1 - Initial	✓	✓	✓	✓	✓	TK 5-20-82
Day 1 - 1:00	✓	✓	✓	✓	✓	TK 5-20-82
Day 1 - 4:00	✓	✓	✓	✓	✓	TK 5-20-82
Day 2 - 8:00	At, Ad(1), Di(2) An(3)	At	✓	At, SS	✓	TK 5-21-82
Day 2 - 4:00	At[A], Ad(3), Di(2) An(3), Ri	NC	At	NC	~~At~~ At	TK 5-21-82
Day 3	Dead	NC	At, Ad(1), An(3) no feces	At, Ad(3), An(3) no feces	At, Ad(1), An(2) few feces	TK 5-22-82
Day 4		At, An(3), no feces Ad(1)	At[A], Ad(3), An(3) Ad(1), Ri, no feces discharge both eyes	At[A], Ad(2), An(3) no feces	At, Ad(1), An(1)	TK 5-23-82
Day 5		At, An(2), Ad(2)	NC	Found Dead	At	TK 5-24-82
Day 6		At, An(1)	NC		✓	TK 5-25-82
Day 7		At	NC		✓	TK 5-26-82
Day 8		NC	NC		✓	TK 5-27-82
Day 9		✓	Found Dead		✓	TK 5-28-82
Day 10		✓			✓	SS 5-29-82
Day 11		✓			✓	SS 5-30-82
Day 12		✓			An(3)	SS 5-31-82
Day 13		✓			An(3), Ad(1), no feces	TK 6-1-82
Day 14		✓			NC	TK 6-2-82
Day 15		✓			An(2), Ad(1), few feces	TK 6-3-82

Reviewed by: BR

Date: 6/3/82

A+A - [illegible]

Study Title Acute Dermal

DAILY OBSERVATIONS

FDRL Study No. 7314D

Dose Level 5000.0 mg/Kg

Date Dosed 5-20-82

Species Albino Rabbit

FDRL Test Article I. D. No. 82-0257

	Animal No. 1341F	Animal No.	Animal No.	Animal No.	Animal No.	Initials/ Date
Day 1 - Initial	✓					TK 5-20-82
Day 1 - 1:00	✓					TK 5-20-82
Day 1 - 4:00	✓					TK 5-20-82
Day 2 - 8:00	At					TK 5-21-82
Day 2 - 4:00	NC					TK 5-21-82
Day 3	At, An(3), Ad(1) few fecs					TK 5-22-82
Day 4	At(2), An(3), Ad(1) Di(3)					TK 5-23-82
Day 5	At(2), An(3), Ad(1) no fecs					TK 5-24-82
Day 6	NC					TK 5-25-82
Day 7	NC					TK 5-26-82
Day 8	NC Found Dead 2:30					TK 5-27-82
Day 9						
Day 10						
Day 11						
Day 12						
Day 13						
Day 14						
Day 15						

Reviewed by: GA

Date: 6/3/82

Study No.: 7314D

Date: 5-21-82

COMMENTS

At° = Animal has absolutely no control over the movement of its body. Limbs are usually perpendicularly splayed to the body first day or two. Usually by the third day animal is ~~lon~~ TK on its side

At(2) = Animal has lost most control over its body movements, although it can somewhat coordinate with great difficulty. Often animal's head sways from side to side.

Tech. Init.: TK

Date: 5-21-82

BR 6/3/82

FDRL

Abbreviations and Symbols used in Recording Observations

AD - accidental death

Ad - activity decreased

Ai - activity increased

Al - hair loss

An - loss of appetite

At - ataxia, wobbly gait

Aut - autolysed (determined by necropsy)

B - blood

Ⓒ - clinicals

D - died

DB - dried blood (give location)

DBN - dried blood - nose

Di - diarrhea

Em - emaciated

Ex - eye ball bulgy

FBW - final body weight

FD - found dead

Lac - lacrimation (tearing)

NC - no change

N or ✓ = normal

Nd - nasal discharge

Res - respiratory problem

Rd - respiration rate decreased

Ri - respiration rate increased

Ppp - pin point pupils

S - sacrificed

Sal - salivation

Sb - appears to have blood in stool

Cy - cyanosis

SM - sacrificed moribund

SS - soft stools

T - tremors

Ub - appears to have blood in urine

Ui - wet, yellow belly

V - vomiting

WAD - weight after death

X - escaped, lost, missing

G - Gasping

NNF - no noteworthy findings

Use L - left, R - right, M - middle plus numbers 1-12 for locations of nodules or other conditions where appropriate. Use 1, 2, 3 after appropriate abbreviations to indicate degree of severity of that condition (1 - slight, 2 - moderate, 3 - extreme), i.e. moderately increased activity would be Ai-2.

Appendix IV

Quality Assurance Unit Statement

FDRL

This final report was reviewed as required by Good Laboratory Practice Regulations for non-clinical laboratory studies, 21 CFR Part 58. Inspections were accomplished as noted, and reported to the study director and management immediately following their completion.

STUDY NO. 7314 QAU INSPECTION SCHEDULE (ACUTES)

Type Test	Inspection Dates				
A Dermal	5/4/82 FDP	5/13/82 FDP	Final report reviewed		6/3/82 FDP
B Dermal	5/4/82 FDP	5/28/82 FDP	6/10/82 FDP	(1)	
C Dermal	5/28/82 FDP	6/1/82 CD	Final report reviewed		6/21/82 FDP
D Dermal	5/13/82 FDP	5/28/82 FDP	6/1/82 CD	6/10/82 FDP	(1)
	(1) Final reports B & D reviewed 6/22/82 FDP				

Frederick F. Paul
Frederick F. Paul
Quality Assurance Unit

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

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Atochem North America, Inc.
900 First Avenue
P.O. Box 1536
King of Prussia, Pennsylvania 19406-0018

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

APR 0 6 1995

EPA acknowledges the receipt of information submitted by your organization under Section 8(e) of the Toxic Substances Control Act (TSCA). For your reference, copies of the first page(s) of your submission(s) are enclosed and display the TSCA §8(e) Document Control Number (e.g., 8EHQ-00-0000) assigned by EPA to your submission(s). Please cite the assigned 8(e) number when submitting follow-up or supplemental information and refer to the reverse side of this page for "EPA Information Requests".

All TSCA 8(e) submissions are placed in the public files unless confidentiality is claimed according to the procedures outlined in Part X of EPA's TSCA §8(e) policy statement (43 FR 11110, March 16, 1978). Confidential submissions received pursuant to the TSCA §8(e) Compliance Audit Program (CAP) should already contain information supporting confidentiality claims. This information is required and should be submitted if not done so previously. To substantiate claims, submit responses to the questions in the enclosure "Support Information for Confidentiality Claims". This same enclosure is used to support confidentiality claims for non-CAP submissions.

Please address any further correspondence with the Agency related to this TSCA 8(e) submission to:

Document Processing Center (7407)
Attn: TSCA Section 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
Washington, D.C. 20460-0001

EPA looks forward to continued cooperation with your organization in its ongoing efforts to evaluate and manage potential risks posed by chemicals to health and the environment.

Sincerely,

Terry R. O'Bryan

Terry R. O'Bryan
Risk Analysis Branch

Enclosure

12702A

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Triage of 8(e) Submissions

Date sent to triage: 12/8/95

NON-CAP (CAP)

Submission number: 12702A

TSCA Inventory: (Y) N D

Study type (circle appropriate):

Group 1 - Dick Clements (1 copy total)

ECO AQUATO

Group 2 - Ernie Falke (1 copy total)

(ATOX) SBTOX SEN (w/NEUR)

Group 3 - Elizabeth Margosches (1 copy each)

STOX CTOX EPI RTOX GTOX

STOX/ONCO CTOX/ONCO IMMUNO CYTO NEUR

Other (FATE, EXPO, MET, etc.): _____

Notes:

THIS IS THE ORIGINAL 8(e) SUBMISSION; PLEASE REFILE AFTER TRIAGE DATABASE ENTRY

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entire document: (0) 1 2 **pages** 1,2 **pages** 1,2

Notes:

Contractor reviewer : PK **Date:** 3/14/95

CECATS\TRIAGE TRACKING DBASE ENTRY FORM

CECATS DATA:
Submission # 8EHQ- 1092 -12702 SEQ. A

TYPE: INT SUPP FLWP

SUBMITTER NAME: Elf Atochem North America, Inc.

SUB. DATE: 10/12/92 OTS DATE: 10/26/92 CSRAD DATE: 02/09/95

CHEMICAL NAME:

CAS#
52116-07-1

INFORMATION REQUESTED: FLWP DATE:
0501 NO INFO REQUESTED
0502 INFO REQUESTED (TECH)
0503 INFO REQUESTED (VOL ACTIONS)
0504 INFO REQUESTED (REPORTING RATIONALE)

DISPOSITION:
0629 REFER TO CHEMICAL SCREENING
0678 CAP NOTICE

VOLUNTARY ACTIONS:
0401 NO ACTION REPORTED
0402 STUDIES PLANNED UNDERWAY
0403 NOTIFICATION OF WORKERS/USERS
0404 LABEL/MSDS CHANGES
0405 PROCESS/HANDLING CHANGES
0406 APP./USE DISCONTINUED
0407 PRODUCTION DISCONTINUED
0408 CONFIDENTIAL

INFORMATION TYPE:		P F C
0201	ONCO (HUMAN)	01 02 04
0202	ONCO (ANIMAL)	01 02 04
0203	CELL TRANS (IN VITRO)	01 02 04
0204	MUTA (IN VITRO)	01 02 04
0205	MUTA (IN VIVO)	01 02 04
0206	REPRO/TERATO (HUMAN)	01 02 04
0207	REPRO/TERATO (ANIMAL)	01 02 04
0208	NEURO (HUMAN)	01 02 04
0209	NEURO (ANIMAL)	01 02 04
0210	ACUTE TOX. (HUMAN)	01 02 04
0211	CHR. TOX. (HUMAN)	01 02 04
0212	ACUTE TOX. (ANIMAL)	01 02 04
0213	SUB ACUTE TOX (ANIMAL)	01 02 04
0214	SUB CHRONIC TOX (ANIMAL)	01 02 04
0215	CHRONIC TOX (ANIMAL)	01 02 04

INFORMATION TYPE:		P F C
0216	EPI/CLIN	01 02 04
0217	HUMAN EXPOS (PROD CONTAM)	01 02 04
0218	HUMAN EXPOS (ACCIDENTAL)	01 02 04
0219	HUMAN EXPOS (MONITORING)	01 02 04
0220	ECO/AQUA TOX	01 02 04
0221	ENV. OCCC/REL/FATE	01 02 04
0222	EMER INCI OF ENV CONTAM	01 02 04
0223	RESPONSE REQEST DELAY	01 02 04
0224	PROD/COMP/CHEM ID	01 02 04
0225	REPORTING RATIONALE	01 02 04
0226	CONFIDENTIAL	01 02 04
0227	ALLERG (HUMAN)	01 02 04
0228	ALLERG (ANIMAL)	01 02 04
0239	METAB/PHARMACO (ANIMAL)	01 02 04
0240	METAB/PHARMACO (HUMAN)	01 02 04

INFORMATION TYPE:		P F C
0241	IMMUNO (ANIMAL)	01 02 04
0242	IMMUNO (HUMAN)	01 02 04
0243	CHEM/PHYS PROP	01 02 04
0244	CLASTO (IN VITRO)	01 02 04
0245	CLASTO (ANIMAL)	01 02 04
0246	CLASTO (HUMAN)	01 02 04
0247	DNA DAM/REPAIR	01 02 04
0248	PROD/USE/PROC	01 02 04
0251	MSDS	01 02 04
0299	OTHER	01 02 04

TRIAGE DATA:	NON-CBI INVENTORY	ONGOING REVIEW	SPECIES	TOXICOLOGICAL CONCERN:	USE:	PRODUCTION:
	YES	YES (DROP/REFER)	RBT	LOW Ac. derm. tox		
CAS SR	NO	NO (CONTINUE)		MED		
	DETERMINE	REFER		HIGH		

COMMENTS

12702A

L

Acute dermal toxicity of 2-t-butylazo-2-(2-hydroxyethoxy)-4-methylpentane to rabbits is of low concern based on an LD_{50} of 4456 mg/kg. In a preliminary study, groups of New Zealand albino rabbits (1/sex/dose) received applications of the material to intact and abraded skin for 24 hours. Deaths were as follows: 0/2 at 50, 126, 316, 795, 2000, and 3000 mg/kg, and 1/2 at 5000 mg/kg. In the primary study, groups of rabbits (6/sex/dose) received applications of 3500, 4183, and 5000 mg/kg. Deaths were 2/12, 5/12, and 8/12, respectively. Clinical signs in the second study included deceased activity, loss of appetite, loss of control of movement at all doses, diarrhea and soft stools (3500 mg/kg), ataxia (4183 and 5000 mg/kg), nasal discharge (4183 mg/kg), and irritated eyes (5000 mg/kg). Necropsy revealed fluid-filled abdominal cavity (1F at 3500 mg/kg), blood in the chest (1F at 4183 mg/kg) and pleural cavity (1F/1M at 5000 mg/kg), and red fluid-filled intestines (1M at 5000 mg/kg).