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February 2, 1993



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(Attn: Section 8(e) Coordinator)
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USEPA
401 M Street, SW
Washington, DC 20460



TSCA 8(E) SUBSTANTIAL RISK NOTICE SUPPLEMENT: Follow-up to
October 1 and December 7, 1992, 8(e) on Norpar 13 Solvent®

Dear Sir:

Enclosed is the final report of the acute dermal toxicity study in rabbits of Norpar® 12
described in my letter of December 7, 1993, T-5650.

Please contact me at 612-737-4795, if you have any questions.

Sincerely,
Georgan L. Adams
Georgan L. Adams
Manager, Regulatory Affairs

Enclosure

93 FEB - 8 PM 1:53



19 pgs.

1

 **HAZLETON**
WISCONSIN
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MADISON, WI 53707-7545

"Contains NO CBI"

CORNING Laboratory Services Company

FINAL REPORT

Mr. Steven C. Gordon
3M
Toxicology Services
Building 220-2E-02
St. Paul, MN 55144-1000



HWI Number: 21100409

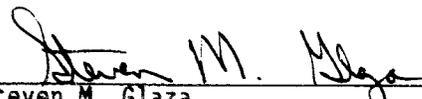
Sample: T-5650

Study Title:

Acute Dermal Toxicity Study
of T-5650 in Rabbits
(OECD Guidelines)

93 FEB -2 PM 1:53

Signed:


Steven M. Glaza
Study Director
Acute Toxicology

Date 1-19-93



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Sample: T-5650

KEY PERSONNEL

Acute Toxicology

Steven M. Glaza
 Study Director
 Manager

Steven R. Sorenson
 Study Coordinator

Patricia Padgham
 In-life Supervisor

Rose M. Bridge
 Report Supervisor

Laboratory Animal Medicine

Cindy J. Cary, DVM
 Diplomate, ACLAM

Anatomical Pathology

Thomas E. Palmer, PhD
 Anatomical Pathologist

Deborah L. Pirkel/
 Jack Serfort
 Supervisors
 Necropsy

Anne Mosher
 Supervisor
 Pathology Data

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Sample: T-5650

OBJECTIVE

The objective of this study was to assess the systemic toxicity and relative skin irritancy of a test material when applied to the skin of rabbits.¹

TEST MATERIAL

Identification

The test material was identified as T-5650 and described as a clear, colorless liquid.

Purity and Stability

The Sponsor assumes responsibility for purity and stability determinations (including under test conditions).

Storage and Retention

The test material was stored at room temperature. Any unused test material will be discarded after issuance of the final report according to Hazleton Wisconsin (HWI) Standard Operating Procedure (SOP).

Safety Precautions

The test material handling procedures were according to HWI SOPs and policies.

TEST SYSTEM

Test Animal

Adult albino rabbits of the Hra:(NZW)SPF strain were procured from Hazleton Research Products, Inc. and maintained at the Hazleton Wisconsin facility at 3802 Packers Avenue, Madison, Wisconsin. Animal husbandry and housing at HWI comply with standards outlined in the "Guide for the Care and Use of Laboratory Animals".² The animals were individually housed in screen-bottom cages in temperature- and humidity-controlled quarters, provided access to water *ad libitum* and a measured amount of High Fiber Rabbit Chow® #5326, Purina Mills, Inc., and held for an acclimation period of at least 7 days. The feed is routinely analyzed by the manufacturer for nutritional components and environmental contaminants. Samples of the water are periodically analyzed by HWI. There were no known contaminants in the feed or water that would have interfered with or affected the results of the study.

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Sample: T-5650

Acclimated animals were selected and maintained during the study in the same manner as for the acclimation period. If variations from the prescribed environmental conditions existed, they were documented and considered to have no effect on the study outcome. Five male and five female rabbits, weighing from 2,438 to 2,681 g, were used for a single dose level of 2,000 mg/kg of body weight. Animals were identified by animal number and corresponding ear tag. Approximately 24 hours before test material application, each rabbit's back was clipped free of hair with an electric clipper. The clipped area made up not less than 10% of the total body surface. The animals were clipped as needed throughout the study.

Justification for Species Selection

Historically, the New Zealand White albino rabbit has been the animal of choice because of the large amount of background information on this species.

PROCEDURES

Preparation of Test Material

The test material was administered as received. An individual dose was calculated and weighed out based upon each animal's body weight on the day of test material administration.

Treatment

The test material was applied to each animal's back at a dose level of 2,000 mg/kg of body weight. The area of application was covered with a 10-cm x 10-cm gauze patch secured with paper tape and overwrapped with Saran Wrap® and Elastoplast® tape. The test material was applied to the test site at a rate of approximately 50 mg/cm² in a thin and uniform layer. Collars were used to restrain the test animals during the 24-hour exposure period.

At the end of the 24-hour exposure period, the restraining collars and bandages were removed and the test sites were washed using tap water and disposable paper towels.

Reason for Route of Administration

Historically, the dermal route has been the route of choice based on the method of Draize.³

Phone

608-241-4471

Fax

608-241-7227

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HWI Number: 21100409

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Sample: T-5650

Observations

Clinical observations and mortality checks were conducted at approximately 1, 2.5, and 4 hours after test material administration. Additional clinical observations and twice a day mortality checks (morning and afternoon) were conducted daily thereafter for 14 days.

Body weights were determined before test material administration (Day 0), at Day 7, and at termination of the experimental phase (Day 14).

The initial dermal irritation reading was made approximately 30 minutes after removal of the test material according to the Draize technique (recorded as the Day 1 score). Subsequent readings of dermal irritation were made on Days 3, 7, 10, and 14.

Pathology

At termination of the experimental phase, all animals were euthanized, subjected to a gross necropsy examination, and any abnormalities were recorded. After necropsy, the animals were discarded and no tissues were saved.

Statistical Analyses

No statistical analyses were required by the protocol.

Location of Raw Data, Records, and Final Report

The raw data, records, and a copy of the final report will be retained in the archives of HWI in accordance with HWI SOP.

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Sample: T-5650

SUMMARY OF RESULTS

Test Animal: Albino Rabbits - Hra:(NZW)SPF
 Source: Hazleton Research Products, Inc., Kalamazoo, MI
 Date Animals Received: 10/21/92

Experimental Start Date: 11/18/92 Experimental Termination Date: 01/22/93

Individual Body Weights

Animal Number	Body Weight (g)		
	Day 0	Day 7	Day 14

Males (2,000 mg/kg)

F43809	2,681	2,456	2,736
F43799	2,517	2,540	2,612
F43803	2,664	2,711	2,821
F43804	2,472	2,383	2,461
F43805	2,502	2,534	2,621
Mean	2,567	2,525	2,650

Females (2,000 mg/kg)

F43800	2,614	2,627	2,679
F43801	2,516	2,564	2,676
F43802	2,642	2,579	2,623
F43806	2,641	2,456	2,739
F43807	2,438	2,475	2,538
Mean	2,570	2,540	2,651

Dermal Reactions

Derma! irritation (based on the most severe score for each animal at any time point) consisted of moderate to severe erythema and edema, slight to severe atonia, slight to moderate coriaceousness and fissuring, and slight desquamation. Subcutaneous hemorrhaging was also observed.





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Sample: T-5650

Individual Clinical Signs

T-5650

Animal Number	Observation	Hour			Day														
		1.0	2.5	4.0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	
Males (2,000 mg/kg)																			
F43809	Appeared normal	✓	✓	✓	-	-	-	-	-	-	-	-	-	-	-	-	-	✓	✓
	Staggered gait	-	-	-	✓	✓	*	*	*	*	*	*	*	*	*	*	*	*	-
	Tremors	-	-	-	*	*	-	-	-	-	-	-	-	-	-	-	-	-	-
F43799	Appeared normal	✓	✓	✓	-	-	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Staggered gait	-	-	-	✓	✓	-	-	-	-	-	-	-	-	-	-	-	-	-
	Vocalization	-	-	-	✓	-	-	-	-	-	-	-	-	-	-	-	-	-	-
F43903	Appeared normal	✓	✓	✓	-	-	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Staggered gait	-	-	-	✓	*	-	-	-	-	-	-	-	-	-	-	-	-	-
	Injected iris	-	-	-	✓	✓	-	-	-	-	-	-	-	-	-	-	-	-	-
F43804	Appeared normal	✓	✓	✓	-	-	-	-	-	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Staggered gait	-	-	-	✓	✓	*	*	*	-	-	-	-	-	-	-	-	-	-
	Decreased righting reflex	-	-	-	✓	-	-	-	-	-	-	-	-	-	-	-	-	-	-
F43805	Appeared normal	✓	✓	✓	-	-	-	-	-	-	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Staggered gait	-	-	-	✓	✓	✓	✓	*	*	-	-	-	-	-	-	-	-	-
	Vocalization	-	-	-	✓	-	-	-	-	-	-	-	-	-	-	-	-	-	-

✓ Condition exists.
 * Slight.

Note: Staggered gait is defined as incoordination of locomotor activity. In this study it included abnormal positioning of the feet, with the toes turned under the foot. The animals also tended to crawl in a low position as opposed to a normal hop.

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HWI Number: 21100409

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Sample: T-5650

Individual Clinical Signs

T-5650

Animal Number	Observation	Hour			Day													
		1.0	2.5	4.0	1	2	3	4	5	6	7	8	9	10	11	12	13	14
<u>Females (2,000 mg/kg)</u>																		
F43800	Appeared normal	/	/	/	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Staggered gait	-	-	-	/	/	/	/	/	/	*	*	*	*	*	-	-	-
	Decreased righting reflex	-	-	-	/	-	-	-	-	-	-	-	-	-	-	-	-	-
F43801	Appeared normal	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/
F43802	Appeared normal	/	/	/	/	-	-	-	-	-	/	/	/	/	/	/	/	/
	Staggered gait	-	-	-	/	/	*	*	*	*	-	-	-	-	-	-	-	-
	Dilated pupils	-	-	-	/	/	*	-	-	-	-	-	-	-	-	-	-	-
	Injected iris	-	-	-	/	/	-	-	-	-	-	-	-	-	-	-	-	-
	Decreased righting reflex	-	-	-	/	*	-	-	-	-	-	-	-	-	-	-	-	-
F43806	Appeared normal	/	/	/	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Staggered gait	-	-	-	/	/	*	*	*	*	*	*	*	*	*	*	*	*
	Tremors	-	-	-	/	*	*	*	*	*	*	*	*	*	*	*	*	*
F43807	Appeared normal	/	/	/	-	-	-	-	-	-	-	-	-	-	/	/	/	/
	Staggered gait	-	-	-	/	/	/	/	/	*	*	*	*	*	-	-	-	-
	Injected iris	-	-	-	/	/	-	-	-	-	-	-	-	-	-	-	-	-

/ Condition exists.
 * Slight.

Note: Staggered gait is defined as incoordination of locomotor activity. In this study it included abnormal positioning of the feet, with the toes turned under the foot. The animals also tended to crawl in a low position as opposed to a normal hop.



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Sample: T-5650

Individual Pathology Comments

Dose Level: 2,000 mg/kg of Body Weight

<u>Animal Number</u>	<u>Sex</u>	<u>Test Day</u>		<u>Necropsy Observation</u>
		<u>Died</u>	<u>Sacrificed</u>	
F43809	M	-	14	No visible lesions.
F43799	M	-	14	No visible lesions.
F43803	M	-	14	No visible lesions.
F43804	M	-	14	No visible lesions.
F43805	M	-	14	No visible lesions.
F43800	F	-	14	No visible lesions.
F43801	F	-	14	No visible lesions.
F43802	F	-	14	No visible lesions.
F43806	F	-	14	No visible lesions.
F43807	F	-	14	No visible lesions.

HWI Number: 21100409

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Sample: T-5650

DISCUSSION

The acute dermal toxicity of T-5650 was evaluated in male and female rabbits when administered as a single topical application at a level of 2,000 mg/kg of body weight. The estimated dermal LD₅₀ for male and female rabbits was determined to be greater than 2,000 mg/kg. Clinical signs of toxicity included staggered gait, tremors, vocalization, injected iris, dilated pupils, and decreased righting reflex. These clinical signs were most evident during the first week of the study. Two males and two females exhibited body weight losses of 63 to 225 g during the first week of the study. There was no other effect on body weight gain. The test material produced slight to severe dermal irritation. Page 11 contains a pathology report by the study pathologist.

REFERENCES

1. "Acute Dermal Toxicity," *Organisation for Economic Cooperation and Development's Guidelines for Testing of Chemicals*, Section 402 (adopted May 12, 1981).
2. NIH Publication No. 86-23 (revised 1985).
3. Draize, J. H., "Acute Dermal Toxicity (Single Exposure)," In: *Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics - Dermal Toxicity*, Association of Food and Drug Officials of the U.S., pp. 54-56 (1975).



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Sample: T-5650

PATHOLOGY REPORT

There were 10 rabbits (five males, five females) euthanized and necropsied at the termination of the study. The dose level, day of death, and gross observations recorded for each animal are in the Individual Pathology Comments that precede this report. There were no visible lesions in any of the animals.

Richard D. Altraker

Thomas E. Palmer, PhD
 Pathologist

Date 1/19/93

for Thomas E. Palmer

0013



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Sample: T-5650

APPENDIX

Raw Data

Phone 608-241-4471

Fax

608-241-7007

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PERSONNEL SIGNATURE SHEET
ACUTE TOXICOLOGY

<u>Name</u>	<u>Job Title</u>	<u>Signature</u>	<u>Initials</u>
Anthony Cass	Lab Animal Caretaker	<i>Anthony Cass</i>	AC
Cindy J. Cary, DVM	Lab Animal Veterinarian	<i>Cindy J. Cary</i>	CC
Kari Garfoot	Lab Animal Technician	<i>Kari Garfoot</i>	KG
Steven M. Glaza	Manager	<i>Steven M. Glaza</i>	SG
Ben Haley	Lab Animal Technician	<i>Ben Haley</i>	BH
Jeff Hicks	Lab Animal Technician	<i>Jeff Hicks</i>	JH
Sharen L. Howery	Research Assistant	<i>Sharen L. Howery</i>	SH
Pam Larson	Senior Clerk	<i>Pamela Larson</i>	PL
Wayne A. Madison	Supervisor	<i>Wayne A. Madison</i>	WM
Doug McConnell	Lab Animal Technician	<i>Douglas B. McConnell</i>	DM
Eileen McConnell	Administrative Clerk	<i>Eileen McConnell</i>	EM
Henry Mikula	Lab Animal Caretaker	<i>Henry Mikula</i>	HM
Albert Oleson	Lab Animal Caretaker	<i>Albert Oleson</i>	AO
Patricia Padgham	Supervisor	<i>Patricia Padgham</i>	PP
John Seitz	Lab Animal Caretaker	<i>John Seitz</i>	JS
Steven R. Sorenson	Study Coordinator	<i>Steven R. Sorenson</i>	SRS
Annette R. Turner	Senior Clerk	<i>Annette R. Turner</i>	AT
Lana M. Weeden	Clerk	<i>Lana M. Weeden</i>	LW
Kevin Grossman	Lab Animal Caretaker	<i>Kevin Grossman</i>	KG
Rose M. Bridge	Report Supervisor	<i>Rose M. Bridge</i>	RB
<i>William J. Kolman</i>	<i>Lab Animal Caretaker</i>	<i>William J. Kolman</i>	WK
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

HWI No.: 21100409

ACUTE DERMAL APPLICATION / BODY WEIGHT RECORD

Test Material: T-51250
 Physical Description: CLEAR COLORLESS LIQUID Initiated in Room No.: 103
 Vehicle: NA Mfg./Lot No. Exp.: NA / NA / NA
 Species/Source Strain/Location: Rabbit/Hra:(NZW)SPF/MI Date Received: 10-21-92
 Dose Level: 2000 mg/kg Tech/Date/Time Clipped: KJ / 11-17-92 / 14:00
 Storage conditions of test material: ROOM TEMPERATURE

Dose Calculations				Compound Preparation Weights		
Animal Number	Body Weight (kg)	Dose Level (mg/kg)	Dose @ Animal (g)	Tare Weight (g)	Total Weight (g)	Sample Weight (g)
243809	2.481	2000	5.36	7.83	13.19	5.36
3799	2.517		5.03	7.71	12.74	5.03
3803	2.474		5.33	7.83	13.16	5.33
3804	2.472		4.94	7.80	12.74	4.94
3805	2.502		5.00	7.75	12.75	5.00
3800	2.484		5.23	7.83	13.06	5.23
3801	2.516		5.03	7.74	12.77	5.03
3802	2.472		5.28	7.91	13.19	5.28
3806	2.471		5.28	7.84	13.12	5.28
3807	2.438		4.88	7.74	12.62	4.88

Calculated by: KJ Date: 11-18-92 Conducted by: KJ Date: 11-18-92
 Verified by: JW Date: 11-18-92 Approved by: JH Date: 11-18-92
 Scale Used: SARTORIUS 2B11002

Animal Number	Skin Prep	Sex	Animal Body Weights (g)		
			Study Day		
			0	7	14
243809	I	♂	2481	2456	2736
3799			2517	2540	2612
3803			2474	2711	2821
3804			2472	2383	2761
3805		♀	2502	2534	2621
3800			2484	2427	2679
3801			2516	2514	2676
3802			2472	2579	2623
3806			2471	2456	2739
3807			2438	2475	2538
Technician	<u>KJ</u>	<u>KJ</u>	<u>KJ</u>	<u>KJ</u>	<u>OH</u>
Date: 1992	<u>11/18</u>	<u>11/17</u>	<u>11/18</u>	<u>11/25</u>	<u>12/2</u>
Scale Used:	<u>A & D</u>	<u>CS-104465</u>	<u>CS-104465</u>	<u>CS-104465</u>	<u>CS604465</u>

① FORM CHANGE.
 11-17-92
 ② APPROXIMATE RATE OF EXPOSURE IS 0.05 g/cm².
 11-18-92

I - Intact
 A - Abraded (with a clipper blade)
 NA - Not applicable

(02/03-01-92) Final data review by/Date: JH / 11-18-92

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0016

HWI No.: 21100408

MORTALITY RECORD

Test Material: T-SL650 Dose Level: 2000 mg/Kg

Animal Number	Observation Period (Days)													
	1	2	3	4	5	6	7	8	9	10	11	12	13	14
	AM	PH	AM	PH	AM	PH	AM	PH	AM	PH	AM	PH	AM	PH
E43809	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
3799	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
3803	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
3804	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
3805	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
3800	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
3801	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
3802	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
3806	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
3807	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Technician	K	K	PH	PH	K	K	K	K	PH	PH	PH	K	PH	PH
Time	8:15	14:10	7:30	12:10	14:10	8:15	8:30	14:40	7:30	7:05	7:00	8:05	14:35	7:00
Date	11/19	11/20	11/21	11/22	11/23	11/24	11/25	11/26	11/27	11/28	11/29	11/30	12/1	12/2

NA - Not applicable.
 X - Dead.
 ✓ - Alive.

Final data review by/Date: PH 12-2-92

(04/03-01-92)

HWI No.: 21100409

Acute Dermal Irritation Observation

Test Material: T-SL450 Dose Level: 2000 mg/kg

	Observation Period (Days)										
	Males					Females					
	1	3	7	10	14	1	3	7	10	14	
	11/19	11/21	11/25	11/28	12/2	11/19	11/21	11/25	11/28	12/2	
	Males					Females					
	Animal No. F43809					Animal No. F43800					
Erythema	2	1	1	1	1	2	1	2	3 ^A	3 ^A	
Edema	3	1	0	0	0	2	1	2	2	2	
Atonia	1	1	2	1	0	1	0	2	2	1	
Desquamation	0	0	0	0	1	0	0	0	0	1	
Coriaceousness	0	0	0	0	0	0	0	1	2	2	
Fissuring	0	0	0	1	1	0	0	2	2	2	
	Animal No. F43809					Animal No. F43801					
Erythema	2	2	2	3 ^A	3 ^A	2	2	2	1	1	
Edema	3	2	2	3	2	2	0	1	0	0	
Atonia	1	1	2	2	2	1	0	0	0	0	
Desquamation	0	0	0	0	1	0	0	0	1	1	
Coriaceousness	0	0	1	2	2	0	0	0	0	0	
Fissuring	0	0	2	2	1	0	0	0	1	1	
	Animal No. F43803					Animal No. F43802					
Erythema	2	1	2	3 ^A	3 ^A	2	1	2	3 ^A	3 ^A	
Edema	2	1	2	2	2	3	1	2	2	2	
Atonia	2	0	2	3	2	1	0	2	2	1	
Desquamation	0	0	0	0	0	0	0	0	0	1	
Coriaceousness	0	0	0	2	2	0	0	1	2	2	
Fissuring	0	0	2	2	2	0	0	1	2	2	
	Animal No. F43804					Animal No. F43806					
Erythema	2	1	1	1	1	2	2	2	3 ^A	3 ^A	
Edema	2	0	0	0	0	3	1	1	2	2	
Atonia	1	0	0	1	0	1	0	1	2	2	
Desquamation	0	0	0	0	1	0	0	0	0	0	
Coriaceousness	0	0	0	0	0	0	0	1	2	2	
Fissuring	0	0	0	1	1	0	0	2	2	2	
	Animal No. F43805					Animal No. F43807					
Erythema	2	1	1	3 ^A	3 ^A	2	1	2	3 ^A	3 ^A	
Edema	3	1	1	2	2	3	1	2	2	2	
Atonia	1	0	0	2	1	1	0	1	2	1	
Desquamation	0	0	0	0	1	0	0	0	0	0	
Coriaceousness	0	0	0	2	1	0	0	0	2	2	
Fissuring	0	0	1	2	2	0	0	1	2	2	
Technician	K2	SH	K2	JH	BJ	K2	SH	G	JH	SH*	
Date	1992	11/19	11/21	11/25	11/28	12/2	11/19	11/21	11/25	11/28	12/2

- A Subcutaneous hemorrhage
- B Blanching
- D Eschar
- N Possible necrotic area
- E Exfoliation

* Animal(s) shaved prior to dermal observation by technician.

(05/11-03-92)

Final data review by/Date: JH 1/27/92

CERTIFICATE OF AUTHENTICITY

THIS IS TO CERTIFY that the microimages appearing on this microfiche are accurate and complete reproductions of the records of U.S. Environmental Protection Agency documents as delivered in the regular course of business for microfilming.

Data produced 1 5 95 Marcia Lubiano
(Month) (Day) (Year) Camera Operator

Place Syracuse New York
(City) (State)

