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Langley A. Spurlink, Ph.D., CAE
Vice President, CHEMSTAR

September 13, 1995

Dr. Lynn Goldman
Assistant Administrator
Office of Prevention, Pesticides and Toxic Substances TS-7101
Environmental Protection Agency
401 M Street, SW, Room 637, East Tower
Washington, DC 20460

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Dear Dr. Goldman:

The Chemical Manufacturers Association makes available to the public and appropriate government agencies final reports of environmental, health and safety research that it manages. In keeping with this policy, the following recently completed reports are enclosed:

- *CHRONIC DERMAL BIOASSAYS*
"Ninety-Day Dermal Dose-Finding Study with Triethylene Glycol Diacrylate (TREGDA)"
- *AND*
"Triethylene Glycol Dimethacrylate (TREGDMA) in C3H/HeNHsd Mice"

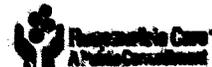
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These reports do not include confidential information.

If you have any questions, please call Marian Stanley of my staff at 202/887-1207.

Sincerely,

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BUSHY RUN RESEARCH CENTER

6702 Mellon Road, E. Mt. Pennsylvania 15632-8902

Telephone (412) 733-5200
Telecopier (412) 733-4804

STUDY TITLE

Triethylene Glycol Diacrylate (TREGDA): Chronic Dermal
Bioassay in C3H/HeNHSd Male Mice

TEST SUBSTANCE

Triethylene Glycol Diacrylate (TREGDA)

DATA REQUIREMENT

Not Applicable

AUTHORS

E. H. Fowler, S. J. Hermansky, and C. L. Benson

STUDY COMPLETION DATE

August 24, 1995

PERFORMING LABORATORY

Bushy Run Research Center (BRRC)
Union Carbide Corporation (UCC)
6702 Mellon Road
Export, PA 15632-8902

LABORATORY PROJECT ID

92N1168A

SPONSOR

Specialty Acrylates and Methacrylates (SAM) Panel
Chemical Manufacturers Association (CMA)
2501 M Street, NW
Washington, DC 20037

CMA REFERENCE NUMBER

SAM-6.0-BIO-BRRC

Page 1 of 710

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Triethylene Glycol Diacrylate (TREGDA): Chronic Dermal
Painting Study in C3H/HeNHSd Male Mice

COMPLIANCE WITH GOOD LABORATORY PRACTICE STANDARDS

The portions of this study conducted by BRRC and the GLP Analytical Skill Center at the UCC South Charleston, WV, Technical Center meet the requirements of Toxic Substances Control Act (TSCA), Good Laboratory Practice Standards, 40 CFR Part 792 with exceptions. The exceptions were:

1. Due to the volatility of the control substance, reserve samples of acetone were not retained.
2. The raw data for certain observations and measurements are unlocatable. A description of the missing raw data has been placed in the raw data file for this study.

Study Director:

Edward H. Fowler 8-29-95
Edward H. Fowler, DVM, Diplomate ACVP Date
Bushy Run Research Center

Submitter/Sponsor:

Marian K. Stanley _____ Date
Panel Manager

TABLE OF CONTENTS

COMPLIANCE WITH GOOD LABORATORY PRACTICE STANDARDS.....	2
LIST OF TABLES AND FIGURES.....	4
SUMMARY.....	5
OBJECTIVE.....	7
BACKGROUND INFORMATION.....	7
DOSE SELECTION.....	9
MATERIALS AND METHODS.....	9
Test Substance.....	9
Animals and Husbandry.....	9
Animal Acclimation.....	10
Study Organization.....	10
Administration of Test Substance.....	11
Preparation of Skin.....	11
Dosing Solution Preparation.....	12
Dosing.....	12
Dosing Solution Analysis.....	12
Observations and Measurements.....	12
In-life Evaluations.....	12
Photography.....	13
Clinical Pathology Evaluations.....	13
Sentinel Animal Evaluations.....	14
Anatomic Pathology Evaluations.....	14
Cell Proliferation - Necropsy.....	14
Cell Proliferation - Histology.....	14
Cell Proliferation - Counting Procedure.....	14
Core Animals - Necropsy.....	15
Core Animals - Histology.....	15
Data Analyses.....	15
RETENTION OF RECORDS.....	16
RESULTS AND DISCUSSION.....	16
Analytical Chemistry.....	16
Clinical Observations, Mortality, and Palpable Masses.....	17
Body Weights.....	18
Clinical Pathology Evaluations.....	18
Cell Proliferation.....	18
Organ Weights, Necropsy Observations, and Microscopic Diagnoses..	19
CONCLUSIONS.....	20
REVIEW AND APPROVAL.....	20
KEY PERSONNEL.....	21
REFERENCES.....	21
TABLES.....	21
QUALITY ASSURANCE STATEMENT.....	101
Analytical Chemistry Report.....	Appendix 1
Anatomic Pathology Report.....	Appendix 2
Clinical Pathology Report.....	Appendix 3
Individual Animal Fate Data.....	Appendix 4
Individual Clinical Observation Data.....	Appendix 5
Individual Palpable Mass Data.....	Appendix 6
Individual Body Weight Data.....	Appendix 7
Individual Cell Proliferation Data.....	Appendix 8
Individual Anatomic Pathology Data.....	Appendix 9
Individual Clinical Pathology Data.....	Appendix 10
Protocol, Protocol Amendments, and Protocol Deviations.....	Appendix 11

LIST OF TABLES AND FIGURES

Table 1 Males - Summary of Mortality.....	22
Figure 1 Males - Graph of Survival Curve.....	23
Table 2 Males - Summary of Clinical Observations.....	24
Table 3 Males - Summary of Body Weight (Grams).....	34
Table 4 Males - Summary of Body Weight Gain (Grams).....	37
Figure 2 Males - Graph of Mean Body Weight Versus Time.....	40
Table 5 Males - Summary of Hematology - Week 52.....	41
Table 6 Males - Summary of Hematology - Week 79.....	43
Table 7 Males - Summary of Clinical Chemistry - Week 52.....	45
Table 8 Males - Summary of Clinical Chemistry - Week 79.....	47
Table 9 Males - Summary of Epidermal Cell Proliferation.....	49
Table 10 Males - Summary of Organ Weights (Grams) - Animals Sacrificed at Week 78.....	50
Table 11 Males - Summary of Organ Weights as % of Final Body Weight - Animals Sacrificed at Week 78.....	51
Table 12 Males - Summary of Organ Weights as % of Brain Weight - Animals Sacrificed at Week 78.....	52
Table 13 Males - Summary of Necropsy Observations - Animals Sacrificed at Week 4.....	53
Table 14 Males - Summary of Necropsy Observations - Animals Sacrificed at Week 13.....	54
Table 15 Males - Summary of Necropsy Observations - Animals Sacrificed at Week 52.....	55
Table 16 Males - Summary of Necropsy Observations - Animals Sacrificed at Week 78.....	56
Table 17 Males - Summary of Necropsy Observations - All Animals Found Dead/Sacrificed Moribund.....	60
Table 18 Males - Summary of Necropsy Observations - Data for All Animals On Study.....	64
Table 19 Males - Summary of Microscopic Diagnoses - Animals Sacrificed at Week 78.....	69
Table 20 Males - Summary of Microscopic Diagnoses by Grade (Skin, Treated) - Animals Sacrificed at Week 78.....	79
Table 21 Males - Summary of Microscopic Diagnoses by Grade (Spinal Cord) - Animals Sacrificed at Week 78.....	81
Table 22 Males - Summary of Microscopic Diagnoses by Grade (Kidneys) - Animals Sacrificed at Week 78.....	82
Table 23 Males - Summary of Microscopic Diagnoses - All Animals Found Dead/Sacrificed Moribund.....	84
Table 24 Males - Summary of Neoplastic Microscopic Diagnoses - Data for All Animals On Study.....	94

Triethylene Glycol Diacrylate (TREGDA): Chronic Dermal
Bioassay in C3H/HeNsd Male Mice

SUMMARY

Concurrent studies were conducted to evaluate the chronic toxicity and carcinogenic potential of triethylene glycol diacrylate (TREGDA, CAS No. 1680-21-3) and triethylene glycol dimethacrylate (TREGDMA, CAS No. 109-16-0). The studies were designed to share the same two control groups and, therefore, all animals for both studies were housed in the same animal room at BRRC. The results and conclusions of the TREGDA dosing are presented in this report. The results and conclusions of the TREGDMA dosing are included in BRRC Report 92N1168B.

This study consisted of 3 TREGDA treatment groups and 2 control groups. Each group consisted of 70 male mice. The dosing solutions were applied to the dorsal skin of the animals at a constant dose volume of 50 μ l/day for 5 days/week for at least 78 weeks at concentrations of 0.05, 0.10, and 0.50% TREGDA in acetone. One control group was treated with acetone (vehicle control) and the other control group was maintained and handled the same as all of the other groups, but was not treated throughout the study (untreated control). Epidermal cell proliferation evaluations were performed on 4-5 mice/group after at least 4, 13, 52, and 78 weeks on study. The remaining animals were administered the test substance for 78 weeks and constituted the core group for the evaluation of chronic toxicity/oncogenicity. This study was being conducted in parallel with the TREGDMA study, and both test compounds shared the same control groups. The mortality observed with the high dose TREGDMA group required that the TREGDMA groups and the shared control groups needed to be sacrificed at 18 months (based on mortality limits described in the original protocol) and consequently the TREGDA dose groups needed to be sacrificed at the same time. Monitors for toxicity included clinical signs, including examination for palpable masses, body weight and weight gain, hematology, clinical chemistry, organ weights, gross pathology, and histopathology.

There were no TREGDA-related changes in survival, hematology, clinical chemistry, mean absolute body weights, body weight gain, or mean absolute or relative organ weights. Clinical signs of irritation, consisting primarily of exfoliation (dark ruff-like scale), were observed in all dose groups. The time of onset, incidence, and severity of exfoliation were related to dose. Similar observations at the site of treatment were made at necropsy. Both epidermal basal cell proliferation and microscopic diagnoses of the treated skin confirmed the presence of cutaneous irritation in the mid and high dose groups. Epidermal basal cell proliferation at the site of treatment in the high dose group was at least 2 fold higher than either of the control groups. Similar increases in basal cell proliferation were observed in the mid dose group at some measurement periods but the rate of increase, as compared to the control groups, was not as high. Microscopic examination indicated chronic cutaneous irritation and epidermal cell necrolysis (suggesting a toxic effect of TREGDA on the cells of the epidermis) in the high dose group. As with cell proliferation measurements, similar microscopic findings of the treated skin (without epidermal cell necrolysis), but to a lesser degree, were observed in the mid dose group. There were no biologically significant differences in the rate of epidermal basal cell proliferation or incidence of microscopic lesions

observed in the low dose group. Therefore, the biological significance of the increased incidence of clinically observed exfoliation was considered to be equivocal. Under the conditions of this study, the No-Observed-Adverse-Effect Level (NOAEL) for TREGDA was considered to be 0.05%. Furthermore, under the conditions of this study, there was no indication of systemic toxicity or carcinogenicity of TREGDA at any dose level.

OBJECTIVE

The objective of this study was to evaluate the chronic toxicity and carcinogenic potential of triethylene glycol diacrylate (TREGDA) when applied to the skin of male mice over a period of at least 78 weeks.

BACKGROUND INFORMATION

A bioassay program was designed to evaluate the chronic toxicity and carcinogenic potential of the test substances. The overall bioassay program and individual study designs were based on the proposed guidelines developed at and modified by the U.S. Environmental Protection Agency (EPA) Dermal Bioassay Workshops (April 28-29, 1987 and May 18-19, 1988). The results and conclusions of the preliminary studies are summarized below.

Two 14-day skin painting studies (BRRRC Report 54-538 and 54-554) were conducted with TREGDA and TREGDMA at BRRRC. In the first study, 5 C3H/HeNHsd mice/group were treated topically with acetone solutions at concentrations of 0.5, 1, 2, 5, 10, and 20% of TREGDA or 25, 50, and 100% TREGDMA at a constant dose volume of 50 μ l for 14 consecutive days. In the second study, 5 C3H/HeNHsd mice/group were treated topically with acetone solutions at concentrations of 0.5, 1, 2, 5, and 10% of TREGDA or 25, 50 and 100% TREGDMA at a constant dose volume of 50 μ l for 14 consecutive days. In both studies, an additional 5 mice were treated topically with 50 μ l of acetone (vehicle control). No mortality, treatment-related clinical signs, except findings in the treated skin, or effects of body weight were observed in either study.

Clinical signs observed for the TREGDA-treated animals during the in-life phase and at necropsy in the first study included exfoliation (present in all mice), ulceration and eschar formation (present in the majority of mice), cutaneous edema (present in 1-5 mice receiving 5% or greater), color change (present in 1-5 mice/group in the top 3 dose groups), ulceration of the skin of the ears (present in several mice in the 10 and 20% groups), cracking and erythema (present in 1 mouse in the 20% group), and open sore (observed in 1 mouse in the 2% group). Some of the skin findings observed in this first 14-day study were considered to have resulted from scratching and rubbing of the treatment area of the mice against the box feeders utilized to measure the food consumption of the individual animals. Based on the results of this study, the 14-day study was repeated using hanging feeders that minimized the potential for the mice to scratch and rub the treatment site.

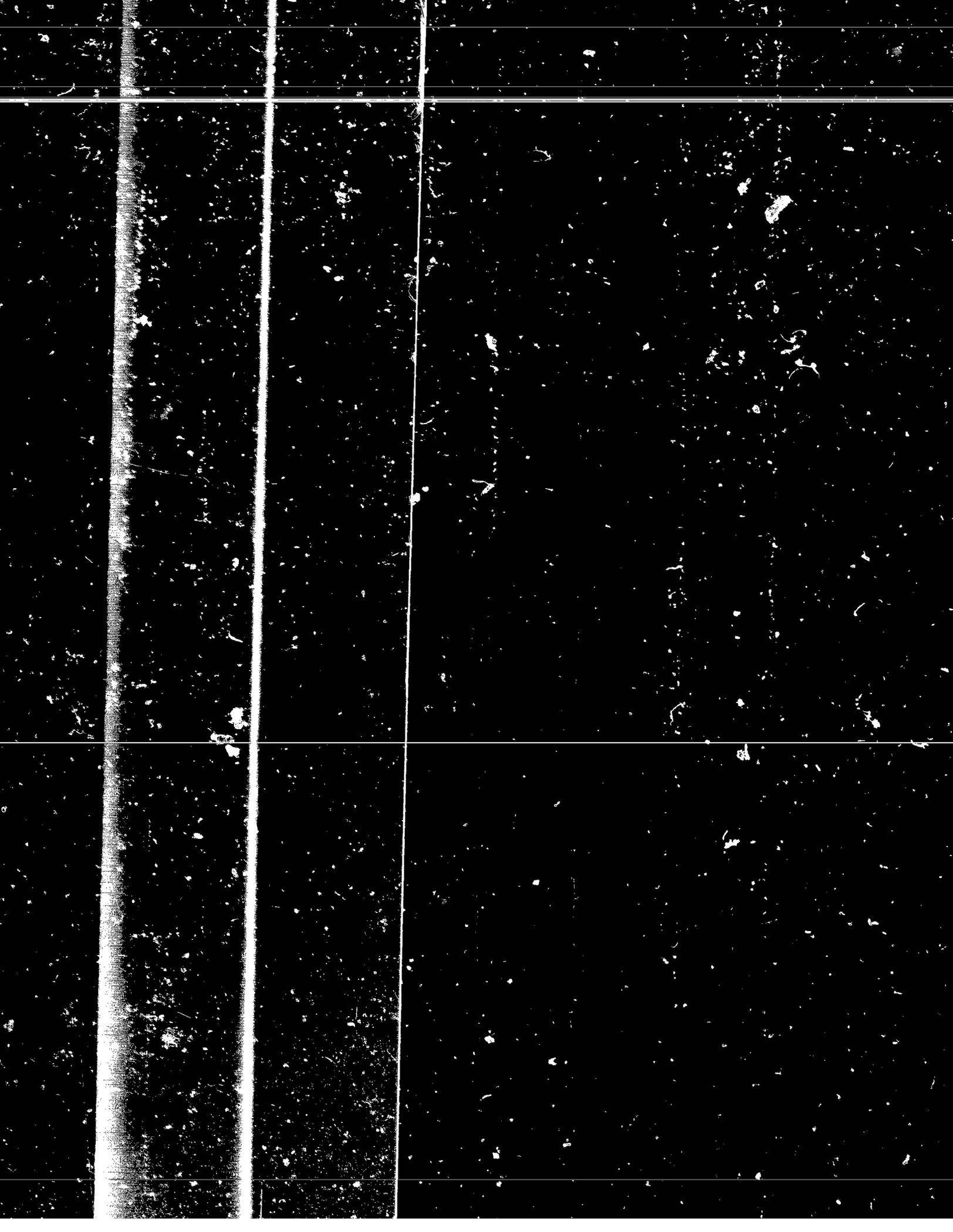
In the repeated 14-day study, the same study design (excluding the 20% TREGDA concentration) was utilized except for the change from box to hanging feeders. The clinical signs noted during the in-life phase and at necropsy for TREGDA-treated animals were exfoliation in all animals and ulceration, eschar formation, discoloration, and open sores mainly in the 5 and 10% groups. Dermatitis, intracorneal pustule formation, acanthosis, hyperkeratosis, dermal fibrosis, and epidermal necrosis were the microscopic findings that were present for at least some mice at all levels. A No-Observed-Effect Level (NOEL) was not established for TREGDA since epidermal toxicity occurred at the lowest level applied (0.5%).

A 14-day study of similar design was conducted on TREGDA and TREGDMA by SRI International (SRI Project LSC-2427) to evaluate the effect of the treatment regimen on epidermal cell proliferation. As with the BRRRC studies, C3H/HeNHsd

male mice were treated topically with acetone solutions at concentrations of 0.5, 1, 2, 5, and 10% of TREGDA or 25, 50, and 100% TREGDMA at a constant dose volume of 50 μ l for 14 consecutive days. Epidermal cell proliferation was measured by determining the labeling index (LI) in basal epithelial cells using nuclear labeling with ^3H -thymidine administered by a 1-day osmotic pump implanted intraperitoneally at the end of the treatment period. Both TREGDA and TREGDMA produced gross and microscopic signs of cutaneous irritation similar to those observed in the BRRC 14-day studies. Both agents also produced very significant increases in cell proliferation in basal epithelium. TREGDA produced dose-related increases in the LI that were up to 19-fold higher than the acetone control. Both compounds were considered to be extremely potent inducers of cell proliferation in mouse skin. However, the dose of TREGDMA required to produce this effect was over two orders of magnitude greater than that of TREGDA. The correlation between cell proliferation, gross irritation, and histopathologic examination was consistent in all dose groups. In general, microscopic lesions were observed at doses where gross irritation was not readily detected. The induction of cell proliferation correlates extremely well with acanthosis, and was observed at all doses of TREGDA and TREGDMA. No other microscopic lesions were observed at the lowest dose of each agent. These results indicated that both TREGDA and TREGDMA produced significant irritation of mouse skin when applied topically, and that this irritation results in a very significant increase in DNA replication in the basal epithelium.

A 90-day dermal dose-finding study (BRRC Report 91N0017) was conducted with TREGDA and TREGDMA at BRRC. In this study, 10 C3H/HeNHSd mice/group were treated topically with acetone solutions at concentrations of 0.05, 0.10, 0.5, and 0.75% of TREGDA or 5, 25, 50, and 100% TREGDMA at a constant dose volume of 50 μ l for 13 weeks (90 days). An additional 10 mice were treated topically with 50 μ l of acetone (vehicle control) while another group was maintained, but not treated throughout the study (untreated control). No mortality occurred. Doses of 0.10, 0.50, and 0.75% of TREGDA or 25, 50, or 75% of TREGDMA resulted in early cutaneous irritation that tended to decrease in severity, but did not entirely resolve, by Day 35. Slight exfoliation/desquamation persisted until the end of the study. Histopathological findings included dermatitis, acanthosis, and hyperkeratosis. The persistence of exfoliation/desquamation and the histopathological findings of acanthosis and hyperkeratosis in the majority of animals in the 0.5 and 0.75% dose groups of TREGDA indicated that the maximum tolerate dose (MTD; as defined by the EPA Dermal Bioassay Workshops) was achieved for these groups. The MTD was not exceeded for any of the TREGDA-treated groups.

Sections of treated skin obtained from animals of all dose groups of the 90-day study were sent to SRI International for evaluation of epidermal cell proliferation using the proliferating cell nuclear antigen (PCNA) technique (SRI Project LSC-2427). SRI also utilized the PCNA technique to evaluate cell proliferation using sections of the skin obtained from the 14-day study conducted at that facility. The PCNA technique confirmed the significant increase in epidermal basal cell proliferation in the 14-day study. Results obtained using the skin sections from the 90-day study indicated that an increased rate of cell proliferation continued even after 90 days of treatment. However, the level of PCNA labeling in controls was much higher after 90 days than after 14 days. Because of the elevated levels of PCNA labeling in the controls, the relative increase in the TREGDA and TREGDMA



groups was modest, approximately 3-fold higher in the top dose groups than in the controls. These increases were statistically significant only in the 100% TREGDMA and 0.5% TREGDA groups.

DOSE SELECTION

The doses were selected by the Sponsor based upon the results of the 14-day and 90-day dose-finding studies with the test substances.

MATERIALS AND METHODS

The protocol and any protocol amendments detailing the design and conduct of this study are included in Appendix 11. Protocol deviations are also included in Appendix 11.

Test Substance

A 1-gallon bottle of TREGDA (CAS Registry No. 1680-21-3), Lot No. 5116-12, was received on February 21, 1992 from Polysciences Inc., Warrington, PA, and assigned BRRC Sample Number 54-44. The test substance was a clear liquid and was stored at room temperature. Related correspondence from the supplier stated the purity of the test substance to be approximately 99%. Based upon a request by the Sponsor and prior to the start of the study, the test substance was stripped of residual benzene. The parent container of the test substance was shipped to The Hinkel Corporation, Ambler, PA for the benzene removal process. Gas chromatographic (GC) analyses of the test substance at BRRC before and after benzene removal indicated that there was no significant change in the composition of the test substance other than removal of the benzene. Samples of the test substance were also periodically shipped to the GLP Analytical Skill Center at the UCC South Charleston, WV, Technical Center for compositional analysis which included analysis of the methyl ether of hydroquinone (polymerization inhibitor) concentration. Analyses of these samples by the Skill Center indicated that the concentration of inhibitor or composition of the test substance (except for benzene removal) did not change over the course of the study. The report issued by the Technical Center is included as Attachment 1 to Appendix 1. No corrections for purity were made in any of the calculations. A reserve sample was not retained because of the relative instability of the compound.

Animals and Husbandry

Seven hundred and fourteen male C3H/HeNHsd mice arrived on October 20, 1992, from Harlan Sprague Dawley, Inc. (Indianapolis, IN). They were designated by the supplier to be approximately 4-5 weeks old (the birth date was recorded as September 18, 1992) upon arrival.

Animals were housed in Room 106 from arrival to termination of the study except for 2 days when the animals were housed in Room 101. The animals were moved to Room 101 due to anticipated noise in Room 106 that was related to maintenance activity in an adjacent room.

Within 2 days of receipt, the animals were examined by a clinical veterinarian and a pretest health screen for representative animals was initiated. The health screen included full necropsy, histologic examination of selected tissues, serum viral antibody analyses, and examinations for fecal parasites.

Based on the results of these data, the clinical veterinarian indicated that these animals were in good health and suitable for use.

All animals were assigned unique numbers and identified by cage tags. Animals considered available for the study were also identified by a toe-clipping and ear-notching procedure.

The animals were housed 2/cage for approximately 6 days in stainless steel, wire mesh cages (22.5 x 10.0 x 12.5 cm). The purpose of the double housing was to help acclimate the animals to their new surroundings. DACB® (Deotized Animal Cage Board; Shepherd Specialty Papers, Inc.) was placed under each cage and changed regularly. Cages were changed and sanitized at least once every 2 weeks. The cages and racks were rotated at least once every 2 weeks according to a predetermined schedule in order to better ensure equivalent environmental conditions for all animals. An automatic timer was set to provide fluorescent lighting for a 12-hour photoperiod (approximately 0500 to 1700 hours for the light phase). Temperature and relative humidity were recorded (Cole-Parmer Hygrothermograph® Seven-Day Continuous Recorder, Model No. 8368-00, Cole-Parmer Instrument Co., Chicago, IL). Temperature was routinely maintained at 65-77°F; relative humidity was routinely maintained at 40-70%. Any minor exceptions to these specified ranges were noted in the raw data.

Tap water (Municipal Authority of Westmoreland County, Greensburg, PA) was available ad libitum and was delivered by an automatic watering system with demand control valves mounted on each rack. Water analyses were provided by the supplier, Halliburton NUS Environmental Laboratories, Professional Service Industries, Inc., and Lancaster Laboratories, Inc. at regular intervals. EPA standards for maximum levels of contaminants were not exceeded. Pelleted, certified AGWAY® PROLAB® Animal Diet Rat, Mouse, Hamster 3000 (Agway Inc.) was available ad libitum. Analyses for chemical composition and possible contaminants of each feed lot were performed by Agway Inc., and the results were included in the raw data.

Animal Acclimation

The acclimation period was approximately 3 weeks. During this period, the animals were weighed 2 times at scheduled intervals. Detailed clinical observations were conducted weekly. Animals were observed once daily for any overt clinical signs of disease or abnormality. The animals were examined just prior to the end of the acclimation period by a clinical veterinarian. Animals considered unacceptable for the study, based on the clinical signs, body weight, or body weight gain, were rejected. The fate of rejected animals and the reasons for rejection were documented in the raw data.

Study Organization

Following the second pretest body weight, the animals were assigned to 6 treatment groups (3 TREGDA and 3 TREGDMA) and 2 control groups using a nonstratified randomization procedure based on body weight. At the time of group assignment, only animals with body weight within $\pm 20\%$ of the population mean were included. The body weight range on the day of first treatment was 22.3 to 28.0 g for TREGDA animals. The following table summarizes the organization of the study.

Group	Number of Animals	Test Substance	Concentration ¹ (%)
Untreated			
Control	70	None	None
Vehicle			
Control	70	Acetone ²	100.00
Low	70	TREGDA	0.05
Mid	70	TREGDA	0.10
High	70	TREGDA	0.50
Low	70	TREGDMA	5.00
Mid	70	TREGDMA	25.00
High	70	TREGDMA	50.00

¹Based on test substances as received.

The first 50 animals/group were designated as core animals. The last 20 animals/group were designated as satellite animals to be utilized for cell proliferation evaluations performed at 4, 13, 52, and 78 weeks. An additional 30 animals not selected for use on the study were designated as sentinel animals. For the week 78 cell proliferation evaluation, animals designated as core animals were used as replacements for satellite animals which died during the study to maintain a satellite group size of 5 animals/group.

The treatment began on November 9, 1992 (Study Day 0). Animals were treated 5 days/week (Monday through Friday) for 78 weeks. Five animals/group were sacrificed for cell proliferation evaluations on December 8, 1992, February 9, 1993, November 9, 1993 (4/group for groups 2-7), and May 10, 1994. All surviving animals were sacrificed between May 12, 1994 and May 19, 1994 after at least 78 weeks of treatment.

Administration of Test Substance

Preparation of Skin

During the week prior to the initial dose administration, the fur was clipped from the dorsal area of the trunk with veterinary clippers. One day prior to the first dose, the fur was clipped again in preparation for dosing.

During the study, animals were clipped as needed in the afternoons (generally more than 3 hours after the completion of dosing). Clipping was generally completed on Monday or Tuesday of each week. The animals from both control groups were clipped before clipping the chemical-treated animals. Clipping of treated animals was completed according to test substance (that is, all of the animals treated with one chemical were clipped before any of the animals treated with the other chemical). The clipping of the treated animals proceeded in a low to high dose group order. The first treated animals to be clipped (TREGDA or TREGDMA) generally rotated from week to week. The clipper blades were cleaned with acetone between clipping animals treated with different chemicals and at the end of each day of clipping.

Dosing Solution Preparation

The 0.5% dosing solution was prepared by adding 0.5 ml of TREGDA to a 100 ml volumetric flask, then diluting to volume with acetone. The 0.05 and 0.1% solutions were prepared by diluting the 0.5% solution with acetone (v/v). Each solution was mixed manually by inversion. After mixing, the solutions were transferred to amber glass dosing bottles equipped with teflon-lined lids. The solutions were stored refrigerated at approximately 4°C between use.

Dosing

The test substance, dissolved in acetone, was applied topically to the clipped interscapular region of the back by an automatic pipette. The pipette was calibrated at least once a month throughout the study. Mice were treated 5 days/week for at least 78 weeks with a single dose of 50µl/animal/day. Vehicle control animals were similarly treated with acetone only. The untreated control group was not treated with either test substance or acetone. However, animals from the untreated control group were picked up on each dose day and the interscapular region of the back of the animals from this group was clipped on the same schedule as the other animals.

Dosing Solution Analysis

Before initiating dosing (the 0.1% solution analysis was conducted concurrently with dosing), the test solutions were prepared to assess the homogeneity and stability. Homogeneity (duplicate sample each from the top, middle, and bottom of the mixing vessel) was determined for the 0.05, 0.1, and 0.5% solutions. Stability was evaluated by determining the test substance concentration in triplicate samples (6 samples used for Day 7) from the 0.05 and 0.5% solution concentrations used for the stability study. Stability of the test substance in the solutions was determined for Day 0 (directly after preparation), Day 7, and Day 14 under storage conditions identical to those used during dosing.

Dosing solutions were prepared weekly during the study and analyzed for concentration of TREGDA prior to the first day of dosing and at 1, 3, 6, 12, and 18 months after initiation of the study.

Standards for acceptable accuracy of mixing were: the mean of the analyzed samples were within ± 10% of nominal; the difference between duplicate analyses did not exceed 15%; and individual analyses were within ± 15% of nominal.

Observations and Measurements

In-life Evaluations

All animals were observed for mortality and overt signs of toxicity twice daily and once each day on the weekends until December 18, 1993. After that date, observations for mortality and overt signs of toxicity were conducted twice daily, seven days/week. Detailed examinations for clinical signs of disease or abnormality, which involve animal handling, were conducted once weekly. All external structures were examined and each mouse was thoroughly palpated for external masses.

Individual body weights were measured weekly for the first 13 weeks of the study and every fourth week thereafter through termination.

Photography

Five surviving animals/group were photographed (treated skin) after 2, 4, 6, 13, 26, 52, and 78 weeks of treatment. The photographs were retained in the raw data. Furthermore, late in the study, photographs of several mice were taken on a Friday followed by photographs of the same mice on the following Monday.

Clinical Pathology Evaluations

Clinical investigations were conducted on 10 core animals/group at 12 (Week 52) and 18 (Week 79) months. Blood was obtained from 5 animals/group for hematology and 5 animals/group for clinical chemistry. All blood samples were obtained from methoxyflurane or halothane anesthetized animals via puncture of the retroorbital sinus.

The following were measured or calculated:

Hematology

hematocrit	mean corpuscular hemoglobin
hemoglobin	concentration (MCEC)
erythrocyte count	total leukocyte count
mean corpuscular volume (MCV)	differential leukocyte count ¹
mean corpuscular hemoglobin (MCH)	platelet count

¹Differential leukocyte counts were performed on high dose groups (Groups 5 and 8) and control groups (Groups 1 and 2).

Clinical Chemistry

glucose (nonfasting)	chloride
urea nitrogen	aspartate aminotransferase (AST)
creatinine	alanine aminotransferase (ALT)
total protein	creatine kinase (CK)
total bilirubin	gamma-glutamyl transferase (GGT)
calcium	alkaline phosphatase (ALK)
phosphorus	albumin
sodium	cholesterol
potassium	

Details of the clinical pathology procedures are included in Appendix 3.

Sentinel Animal Evaluations

Sentinel animals were evaluated at various times throughout the course of the study to check for incorrect infectious diseases. None were found. An additional sacrifice was performed to evaluate for the PVM virus on April 19, 1994. The results were negative.

Anatomic Pathology Evaluations

Cell Proliferation - Necropsy

Cutaneous cell proliferation evaluations were performed on 4-5 mice/group at 4 evaluation periods during the study. Alzet® Osmotic Pumps (Model 1003D) were implanted on Monday morning following the completion of 4, 13, 52, and 78 weeks on study for infusion of bromodeoxyuridine (BrdU; 20 mg/ml in Dulbecco's Phosphate Buffered Saline). Animals were euthanized 24 hours after implanting the pumps for subsequent evaluations of BrdU uptake by epidermal basal cells in the treated skin. Animals were anesthetized by methoxyflurane or halothane and killed by severing the brachial vessels to permit exsanguination 24 hours after the implantation of the pump. All animals received a complete necropsy. All tissues listed in the core animal necropsy section were removed and fixed in 10% neutral buffered formalin (NBF). Selected organs were also weighed for animals sacrificed at Weeks 52 and 78.

Cell Proliferation - Histology

Skins were processed to blocks using xylene substitute and tissue sections were cut at 5µ, mounted on Fisher Plus Slides (Fisher Scientific, Pittsburgh, PA), and stained using routine immunohistochemical procedures for nuclear incorporation of BrdU. Additional tissues for animals sacrificed at Week 78 were processed and evaluated microscopically as described in the core animal - histology section.

Cell Proliferation - Counting Procedure

Two skin sections/animal were evaluated at 40X magnification. Each section was arbitrarily assigned as section 1 or section 2. The stained duodenum (internal control) and skin sections were scanned (at low magnification) for proper and even staining.

Only clearly identified cells in the plane of section were used in the evaluation. Necrotic or pyknotic nuclei or cells not in the plane of section were not counted. To evaluate sections that contained hair follicles, two imaginary lines were drawn on either side of the base of the follicle and no cells in between those 2 imaginary lines were used in the evaluation.

Beginning at one end of each skin section and moving field by field (to avoid overlapping and re-counting cells), labeled and unlabeled cells were identified until at least 500 cells/skin section were counted. The total number of labeled and unlabeled cells/field were entered into a computer program designed to calculate the percent of labeled cells/animal.

Core Animals - Necropsy

At the end of treatment, all surviving animals were anesthetized with halothane and killed by severing the brachial vessels to permit exsanguination. On the day of sacrifice, body weights were obtained to allow expression of relative organ weights. A complete necropsy was performed on all animals. The liver, kidneys, brain, testes, and spleen were weighed for all sacrificed animals. The following tissues were collected for all animals and retained in 10% neutral buffered formalin:

- | | |
|---------------------|---------------------------|
| gross lesions | aorta |
| lungs | skin, treated |
| brain | skin, untreated |
| pituitary | esophagus |
| thyroid/parathyroid | stomach |
| thymic region | duodenum |
| trachea | jejunum |
| heart | ileum |
| bone, sternum | cecum |
| salivary gland | colon |
| liver | rectum |
| spleen | urinary bladder |
| kidneys | lymph node, mesenteric |
| adrenal gland | lymph node, other |
| pancreas | skeletal muscle |
| testes | nerve, sciatic |
| epididymis | eyes and harderian gland |
| prostate | femur |
| seminal vesicles | spinal cord |
| | gall bladder |
| | bone marrow smear (femur) |

Animals found dead or sacrificed in a moribund condition (including satellite animals) were handled as described above, except no body or organ weights were recorded and no bone marrow smears were prepared.

Ears and toe-clipped feet were saved for identification purposes.

Core Animals - Histology

Microscopic examinations were performed on the above listed tissues for all animals from both control and high dose groups. In addition, the lungs, liver, kidneys, spleen, treated skin, untreated skin, stomach, and grossly lesioned tissues were examined from those animals assigned to the mid and low dose groups. All tissues to be examined were paraffin-embedded, sectioned at approximately 5 micrometers, and stained with hematoxylin and eosin. Animals either found dead or sacrificed moribund (including satellite animals) were handled in a similar manner, according to their respective dose groups.

Details of the anatomic pathology procedures are included in Appendix 2.

Data Analyses

The data for quantitative continuous variables and cell proliferation data were intercompared for the 3 treatment groups and the control groups by use of



Levene's test for equality of variances, analysis of variance (ANOVA), and t-tests. The t-tests were used when the F value from the ANOVA was significant. When Levene's test indicated similar variances, and the ANOVA was significant, a pooled t-test was used for pairwise comparisons. When Levene's test indicated heterogeneous variances, all groups were compared by an ANOVA for unequal variances followed, when necessary, by a separate variance t-test for pairwise comparisons.

Nonparametric data were statistically evaluated using the Kruskal-Wallis test followed by the Mann-Whitney U-test. Incidence data were compared using Fisher's Exact Test. Other analyses used included life-table analysis. For all statistical tests, except life-table analyses, the probability value of < 0.05 (two-tailed) was used as the critical level of significance. The probability value of < 0.05 (one-tailed) was used for life-table tumor analyses.

Various models of calculators, computers, and computer programs may have been used to analyze data for this study. Since various models round or truncate numbers differently, values in some tables may differ slightly from those in other tables or from independently calculated data. The integrity of the study and interpretation of the data were unaffected by these differences.

RETENTION OF RECORDS

All raw data, documentation, photographs of animals, paraffin blocks, and tissue slides, the protocol and any amendments, and a copy of the final report generated as a result of this study and as a result of the concurrent study with TREGDMA will be retained together in the BRRC Archives for at least 10 years. Due to the nature of the test substance, a reserve sample was not retained.

RESULTS AND DISCUSSION

All references of differences in group mean values in the following text refer to comparisons of statistically significant differences between the treatment group and the control groups unless otherwise noted. Repeated reference to the control and the statistical significance will not be made in order to simplify the text.

Analytical Chemistry

The report and summary tables for analytical chemistry are included in Appendix 1.

For the stability analyses, the mean measured concentrations of the 0.05 and 0.5% solutions ranged from 100.0 to 102.9 and 105.1 to 107.9% of nominal, respectively. These results indicated that TREGDA in acetone remained stable at the specified concentrations for at least 14 days when stored refrigerated.

For the homogeneity analyses, the mean measured concentrations (\pm SD) of TREGDA in the 0.05, 0.1, and 0.5% solutions were 102.9 (\pm 0.9), 101.8 (\pm 1.0), and 107.9 (\pm 0.6)% of nominal, respectively. The coefficients of variation of the percent of nominal for the 0.05, 0.1 and 0.5% solutions were 0.9, 1.0, and 0.6%, respectively. These results show that the solutions were uniformly prepared.

The mean measured concentrations of the 0.05, 0.1, and 0.5% solutions ranged from 94.5 to 107.0% of nominal for the 6 periods of analysis. TREGDA was not detected in the control dosing solutions.

Clinical Observations, Mortality, and Palpable Masses

A summary of mortality is presented in Table 1. A summary of the clinical observations is presented in Table 2. Individual animal fate data are included in Appendix 4. Individual animal clinical observation data are included in Appendix 5. Individual palpable mass data are included in Appendix 6.

There were no biologically significant differences in the survival or incidence of clinical observations between the vehicle or untreated control groups. There was no difference in the survival between any of the groups treated with TREGDA and either of the control groups. Treatment-related clinical signs of toxicity were limited to local signs of irritation at the site of treatment, although statistical analyses were not performed on these data. Exfoliation (dandruff like scale) was observed in all dose groups including the controls and, therefore, was considered to be at least partially related to the manipulative procedures such as clipping. The slight increase in incidence of exfoliation between the untreated controls (19/70) and vehicle treated controls (25/70) was not considered to be biologically significant. An increased incidence of exfoliation was observed in all TREGDA-treatment groups as compared to both control groups. Exfoliation was first observed on Day 8 in the high dose group and by Day 22 was observed in all TREGDA-treated groups (exfoliation was not observed in either control group until Day 127). While the summary table suggests that the number of animals observed with exfoliation was similar in all groups of TREGDA-treated animals, only the high dose group had a consistently increased incidence of this finding throughout the study as indicated by the following table of randomly selected study periods:

Study Days	Number of Animals with Exfoliation				
	Untreated	Vehicle	0.05%	0.10%	0.50%
25-42	0	0	0	1	13
210-215	0	0	1	1	5
350-355	2	2	7	6	23
440-445	0	1	3	5	32
546-550	3	4	13	19	39

One animal from both the low and mid dose groups and 15 animals from the high dose group were observed with exfoliation of a grade of 1 (compared to "P" for present) while none of the control animals were observed with this greater severity of exfoliation. An exfoliation grade of 1 was subjectively assigned to an animal based upon both the apparent size of the dandruff-like flakes as well as the overall amount of flaking. No animals in the study were assigned exfoliation grades of 2 or 3 that were indicative of large areas of the skin peeling away from the treatment area. Four animals from the high dose group were also observed with erythema at the treatment site late in the study.

There were no other clinical signs of toxicity (including palpable masses) that were considered to be related to treatment.

Body Weights

Summaries of absolute body weight and body weight gain are presented in Tables 3 and 4. A graph of body weight (grams) versus time (weeks) is presented in Figure 1. Individual animal body weight data are included in Appendix 7.

There were no biologically significant effects on absolute body weights or body weight gains observed in the study. Occasional statistically significant differences in the mean body weight or body weight gain values were considered to be spurious.

Clinical Pathology Evaluations

Summaries of the hematology measurements are presented in Tables 5 and 6. Summaries of the clinical chemistry measurements are presented in Tables 7 and 8. Individual clinical pathology data are included in Appendix 10. Detailed results and discussion of the clinical pathology measurements are included in Appendix 3.

There were no treatment-related effects on hematology or clinical chemistry measurements observed in any group. Furthermore, there were no biologically significant differences in any clinical pathology parameter between the untreated and vehicle treated control groups.

Cell Proliferation

The summary data are presented in Table 9. Individual cell proliferation data are included in Appendix 8.

There were no biologically significant differences in the mean rate of epidermal basal cell proliferation between the untreated and vehicle treated control groups. The mean measured rate of epidermal basal cell proliferation in the control groups tended to slightly increase after one year on study. This is opposite of what has generally been observed in human skin where the rate of epidermal cell proliferation tends to decrease with age (Lamminauusta and Maibach, 1988; Roberts and Marks, 1980). However, the increased mean rate of basal cell proliferation observed in this study may have been secondary to greater variability in the animals as they aged (the standard deviations of the control groups tended to gradually increase with age). Therefore, the biological significance of the increased rate of epidermal basal cell proliferation in the older animals from the control groups was not known.

Unlike the control groups, the mean measured rate of epidermal basal cell proliferation of the groups treated with TREGDA did not increase as the animals aged, with the possible exception of the mid dose group. The rate of epidermal basal cell proliferation was increased, but not consistently, in the mid dose group as compared to both control groups. The increased rate of cell proliferation in the mid dose group ranged from approximately 5 to 59% over the 4 evaluation periods. Epidermal basal cell proliferation in the high dose group was consistently increased at least 2 fold over both control groups at all 4 evaluation periods. There were no biologically significant differences

in the rate of epidermal basal cell proliferation between the control groups and the low dose group of TREGDA-treated mice

Organ Weights, Necropsy Observations, and Microscopic Diagnoses

Summary results of organ weights, organ weights relative to final body weight, and organ weights relative to brain weight are presented in Tables 10 to 12. Summary results of necropsy observations are presented in Tables 13 to 18. Summary results of microscopic diagnoses are presented in Tables 19 to 24. Individual anatomic pathology data are included on Appendix 9. Detailed results and discussion of the anatomic pathology results are included in Appendix 2.

A significant increase in both the mean absolute and relative liver weights of the vehicle treated control group as compared to the untreated control and mid and high dose groups was attributed to a few animals in the vehicle treated control group with relatively large liver masses. The overall incidence of tumor masses and nodules was generally similar in all groups and, therefore, the increased liver weight of this dose group was not considered to be biologically significant. There were no other differences in mean absolute or relative organ weights between the control groups and groups treated with TREGDA.

There were no biologically significant differences in the incidence of necropsy findings between the untreated and vehicle treated control groups. As observed during the in-life phase of the study, there was a dose-related increased incidence of exfoliation observed at necropsy in all groups of mice treated with TREGDA. There were no other treatment-related necropsy findings observed in any dose group at either the interim or final sacrifices. Statistical analyses were not performed on the necropsy data.

Upon microscopic examination, there were several statistically significant differences between the untreated and vehicle treated control groups. The incidence of adnexal atrophy was increased in the vehicle treated control group indicating a change in the skin secondary to chronic acetone administration. The incidence of myelin sheath swelling in the spinal cord was increased in the vehicle treated control group. However, these changes were graded as minor and, therefore, the biological significance of this change is equivocal. Furthermore, subchronic oral administration of acetone by other researchers did not produce any neuropathological lesions (Spencer et al., 1978). The only other microscopic lesion in the vehicle treated control group that may have been biologically significant was an increase in lung mineralization. The toxicological significance of this lesion was unknown. Other statistically significant differences in the incidence of microscopic lesions between the untreated and vehicle treated control groups were not considered to be related to acetone treatment due to a similarity of the untreated control with the TREGDA dose groups or overall low incidence of the lesion. These lesions included a decreased incidence of myocardial degeneration/fibrosis, increased incidence of anomalous lobulation of the liver, decreased incidence of thyroglossal duct cyst in the thyroid gland, increased clitoral/preputial gland duct ectasia of the skin, and increased splenic extramedullary hematopoiesis.

Comparison of the incidence of microscopic lesions in the high dose group with both control groups indicated TREGDA-related changes only in the skin.

Chronic cutaneous irritation/inflammation lesions of the treated skin, including fibrotic changes, were primarily confined to the high dose group. These changes included acanthosis, hyperkeratosis/parakeratosis, dermatitis, intracorneal pustule formation, pigmentary incontinence and dermal fibrosis. Furthermore, epidermal cell necrolysis was present in either the superficial portion, basal portion, or full thickness of the epidermis suggesting a toxic effect of the TREGDA on the cells of the epidermis. The mid dose group also had some changes indicative of chronic cutaneous irritation but epidermal cell necrolysis was not present. In the low dose group, there were no findings that were considered to be related to treatment.

CONCLUSIONS

Cutaneous treatment of C3H/HeNHsd male mice with 50 µl of 0.05, 0.10, or 0.50% of TREGDA in acetone 5 days/week for at least 78 weeks did not result in any treatment-related changes in survival, hematology, clinical chemistry, mean absolute body weights, body weight gain, or mean absolute or relative organ weights. All treatment-related findings were related to the local effects of TREGDA at the site of treatment. Clinical signs of irritation, consisting primarily of exfoliation (dandruff-like scale), were observed in all dose groups. The time of onset, incidence, and severity of exfoliation were related to dose. Similar observations at the site of treatment were made at necropsy. Both epidermal basal cell proliferation and microscopic diagnoses of the treated skin confirmed the presence of cutaneous irritation in the mid and high dose groups. Epidermal basal cell proliferation at the site of treatment indicated a sustained increase in cell turnover in the high dose group that was at least 2 fold higher than either of the control groups. While similar increases in basal cell proliferation were observed in the mid dose group at some measurement periods, the rate of increase, as compared to the control groups, was not as high. Microscopic examination indicated chronic cutaneous irritation and epidermal cell necrolysis (suggesting a toxic effect of TREGDA on the cells of the epidermis) in the high dose group. As with cell proliferation measurements, similar microscopic findings of the treated skin without epidermal cell necrolysis, but to a lesser degree, were observed in the mid dose group. There were no biologically significant differences in the rate of epidermal basal cell proliferation or incidence of microscopic lesions observed in the low dose group. Therefore, the biological significance of the increased incidence of clinically observed exfoliation was considered to be equivocal. Under the conditions of this study, the No-Observed-Adverse-Effect Level (NOAEL) for TREGDA was considered to be 0.05%. Furthermore, under the conditions of this study, there was no indication of systemic toxicity or carcinogenicity of TREGDA at any dose level.

REVIEW AND APPROVAL

Study Director:

Edward E. Fowler 8-24-95
 Edward E. Fowler, DVM, Diplomate ACVP Date

Director:

John P. Van Miller 8/24/95
 John P. Van Miller, Ph.D., DABT Date

KEY PERSONNEL

Study Director: E. H. Fowler
 Technical Coordinator: R. A. Loughran
 Supervisors: E. V. Weaver
 L. C. Fisher
 M. A. McGee
 Scientists: D. A. Neptun
 M. A. Vrbanic
 Consultant: R. H. Garman

Additional personnel are listed in the raw data.

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TABLE 1
 TRIETHYLENE GLYCOL DIACRYLATE (TRGDGA): CHRONIC DERMAL
 BIOASSAY IN C3H/HENSED MALE MICE

SUMMARY OF MORTALITY

	MALES				
	DOSE LEVEL				
	<u>0¹</u>	<u>0²</u>	<u>0.05³</u>	<u>0.10³</u>	<u>0.50³</u>
Total Number of Animals	70	70	70	70	70
Number Sacrificed (Week 4)	5	5	5	5	5
Number Sacrificed (Week 15)	5	5	5	5	5
Number Sacrificed (Week 52)	5	4	4	4	4
Number Sacrificed (Week 78)	40	39	44	41	39
Number Found Dead	3	14	9	10	13
Number Sacrificed Moribund	6	3	3	5	5
Number Accidental	1	0	0	0	0
Mean Survival Time (Days)	535	532	531	531	511

Statistical analysis was performed on the mean survival time for all groups combined. No significance was observed.

¹untreated control group

²vehicle treated control group

00025

FIGURE 1
TRIMETHYLENE GLYCOL IMACRYLATE (TREGDA): CHRONIC DERMAL BIOASSAY IN CASTRATED MALE MICE
SURVIVAL CURVES

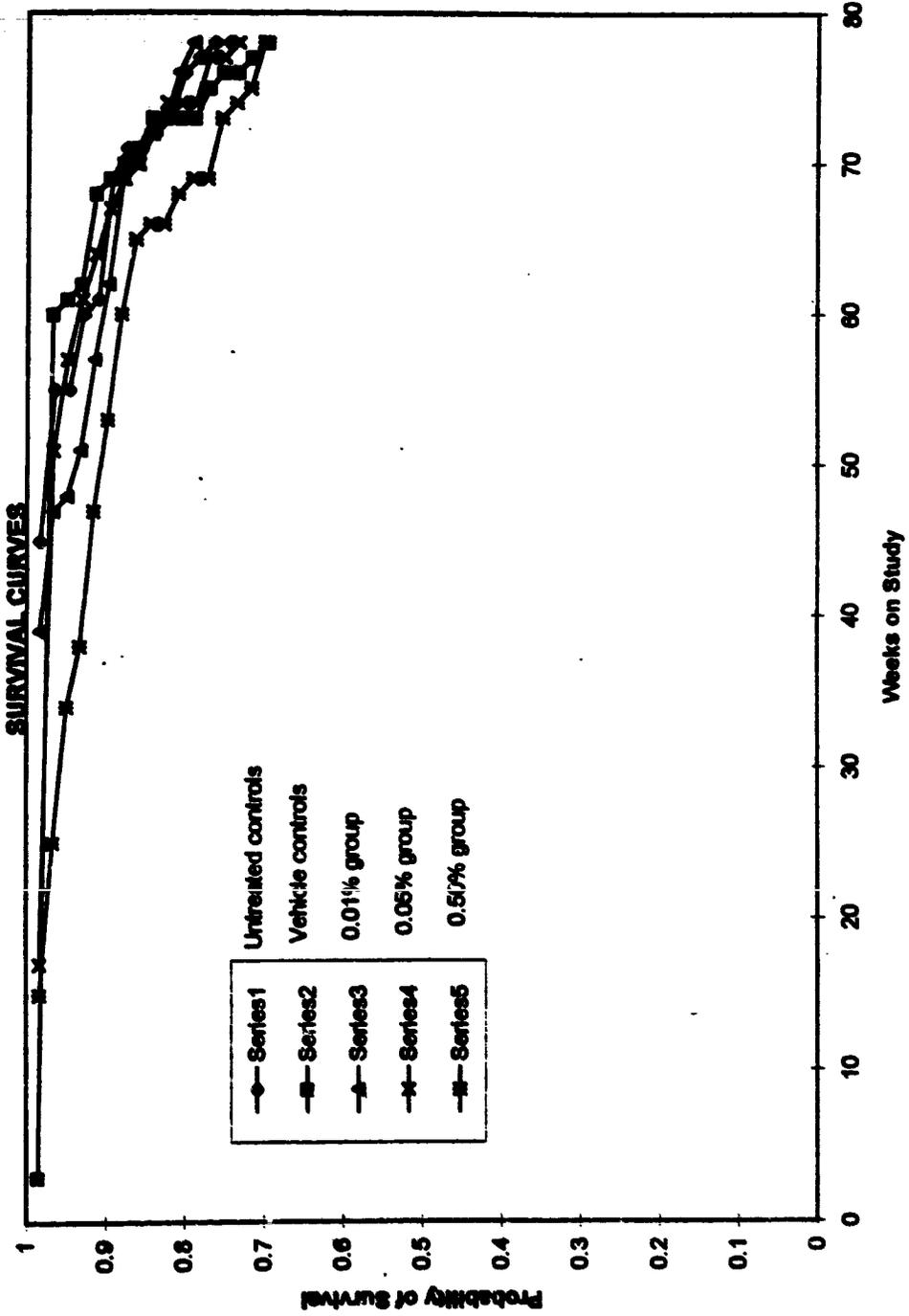


TABLE 2
 TRIETHYLENE GLYCOL DIACRYLATE (TREGDA); CHRONIC DERMAL
 BIOASSAY IN C3H/HEMISP MALE MICE
 SUMMARY OF CLINICAL OBSERVATIONS

MALES

CATEGORY FINDING (LOCATION)	GROUP:	1 GRADE (DAYS)	2 (DAYS)	3 (DAYS)	4 (DAYS)	5 (DAYS)
BEHAVIOR/CNS HYPERACTIVE	P	0	0	0	0	1 (414)
HYPOACTIVE	P	7(388-543)	2(23-494)	1 (401)	3(399-541)	3(371-480)
PARESIS (LEG-HIND-BOTH)	P	1(507-542)	0	0	0	0
PARALYSIS (LEG-HIND-LEFT)	P	1 (494)	0	0	0	0
ATAXIA	P	2(539-543)	0	0	0	1 (480)

GROUP LEGEND: 1 is 0% UNTREATED, 2 is 0% (VEHICLE), 3 is 0.05 %, 4 is 0.10 %, 5 is 0.50 %

Grades: P = present, 1 = mild, 2 = moderate, 3 = severe.
 Numbers represent the number of animals exhibiting the finding at least once during the study.
 Parenthetical numbers "()" represent earliest to latest day a finding of the specified grade was observed.

TABLE 2 (Continued)
 TRINITROBENZENE GLYCOL DIACRYLATE (TRIGDA): CHRONIC DERMAL
 BIOASSAY IN C3H/HEBESD MALE MICE
 SUMMARY OF CLINICAL OBSERVATIONS

MALES

CATEGORY FINDING (LOCATION)	GROUP	GRADE	1 (DAYS)	2 (DAYS)	3 (DAYS)	4 (DAYS)	5 (DAYS)
EMACIATED		P	2(311-543)	2(494-548)	0	1(403)	3(236-464)
DEHYDRATED		P	3(311-555)	1(533-549)	3(274-554)	1(316-550)	0
PROSTRATION		P	0	2(437-548)	1(333)	3(359-519)	2(406-527)
EMACIATED		P	1(388)	6(356-548)	1(512-514)	3(399-541)	2(135-416)
DEHYDRATED		P	9(71-543)	8(239-514)	5(316-533)	7(116-541)	9(127-544)
SWELLING (ABDOMEN)		P	52	54	54	50	55
(CHEST)		P	39(302-556)	35(246-556)	30(302-556)	40(351-556)	39(162-556)
(GENITAL)		P	0	0	1(470)	0	0
(INGUINAL-LEFT)		P	44(78-555)	44(8-556)	46(78-556)	37(99-556)	44(57-556)
(INGUINAL-RIGHT)		P	3(351-494)	0	2(302-548)	0	3(274-463)
		P	1(491)	1(302)	0	0	2(211-556)

GROUP LEGEND: 1 is 0% UNFEDRATED, 2 is 0% (VEHICLES), 3 is 0.05%, 4 is 0.10%, 5 is 0.50%

Grades: P = present, 1 = mild, 2 = moderate, 3 = severe.
 Numbers represent the number of animals exhibiting the finding at least once during the study.
 Parenthetical numbers "-" represent: earliest to latest day a finding of the specified grade was observed.

TABLE 2 (Continued)
 TRIETHYLENE GLYCOL DIACRYLATE (TREGDA); CHRONIC DERMAL
 BIOASSAY IN C3H/HEMISD MALE MICE
 SUMMARY OF CLINICAL OBSERVATIONS

CATEGORY FINDING (LOCATION)	GROUP	MALES					
		GRADE	1 (DAYS)	2 (DAYS)	3 (DAYS)	4 (DAYS)	5 (DAYS)
BODY SWELLING (CONTINUED) (MULTIPLE AREAS-NOS)		P	0	0	1(274-281)	0	0
(NECK)		P	0	0	2(67-463)	0	0
(PENIS)		P	7(323-555)	20(239-555)	12(71-555)	11(71-553)	11(127-554)
(SIDE-LEFT)		P	4(494-540)	1(519-526)	2(414-540)	3(274-549)	1(498-505)
(SIDE-RIGHT)		P	0	4(463-540)	3(274-505)	1(442-449)	3(470-540)
(SHOULDER-LEFT)		P	0	1(519-533)	0	0	0
(SHOULDER-RIGHT)		P	0	1(442-456)	0	0	0
(TAIL)		P	0	0	0	0	1(393-421)
(TREATMENT AREA)		P	1(428-456)	1(442-470)	0	0	0
ABDOMINAL DISTENSION		P	5(246-540)	2(316-556)	8(316-555)	6(351-549)	6(386-549)
UNEMPTY		P	2(421-505)	2(302-386)	1(401)	1(116-120)	2(175-415)
URINE STAINS		P	18(274-549)	15(274-548)	14(302-553)	12(155-511)	19(266-556)

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 0.05 %, 4 is 0.10 %, 5 is 0.50 %

Grades: P = present, 1 = mild, 2 = moderate, 3 = severe.
 Numbers represent the number of animals exhibiting the finding at least once during the study.
 Parenthetical numbers "()" represent earliest to latest day a finding of the specified grade was observed.

TABLE 2 (Continued)
 TRIBUTYLENE GLYCOL DIACRYLATE (TRIGDA): CHRONIC DERMAL
 STAGSAY IN C3H/HEMIZO MALE MICE
 SUMMARY OF CLINICAL OBSERVATIONS

CATEGORY FINDING (LOCATION)	GROUP:	MALES					
		GRADE	1 (DAYS)	2 (DAYS)	3 (DAYS)	4 (DAYS)	5 (DAYS)
ROOF							
COLD EXTREMITIES (LEGS-ALL)	P		3(308-543)	5(23-548)	1 (333)	4(399-541)	4(234-527)
PALLOR (LEGS-ALL)	P		1 (494)	0	0	3(359-541)	2(234-372)
HUNCHED POSTURE	P		4(311-554)	0	2(401-514)	2(519-521)	5(175-544)
UROGENITAL DISCHARGE, RED	P		0	0	0	0	1 (442)
RECTAL PROLAPSE	P		1 (120)	1 (141)	2(99-267)	0	0
TRAUMATIZED (NOSE)	P		0	1 (23)	0	0	0
UROGENITAL AREA WITNESS	P		11(246-547)	8(302-548)	6(331-526)	3(483-541)	9(175-498)
HEAD TILT	P		3(456-555)	1(533-549)	3(274-554)	2(316-550)	1 (415)
BLUE CUTIS (ABDOMEN)	P		5	3	3	2	6
(ENTIRE BODY)	P		3(421-494)	2(463-540)	3(428-555)	2(505-540)	6(435-549)
CARDIO-PULMONARY LABORED RESPIRATION	P		2(532-543)	1(505-514)	0	0	0
	P		3(494-543)	6(23-548)	0	4(359-516)	4(371-527)

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 0.05 %, 4 is 0.10 %, 5 is 0.50 %

Grades: P = present, 1 = mild, 2 = moderate, 3 = severe.
 Numbers represent the number of animals exhibiting the finding at least once during the study.
 Parenthetical numbers "()" represent earliest to latest day a finding of the specified grade was observed.

TABLE 2 (Continued)
 TRIETHYLENE GLYCOL DIACRYLATE (TRIGDA): CHRONIC DERMAL
 BIOASSAY IN C3H/HEMISP MALE MICE
 SUMMARY OF CLINICAL OBSERVATIONS

MALES

CATEGORY FINDING (LOCATION)	GROUP:	GRADE (DAYS)	1 (DAYS)	2 (DAYS)	3 (DAYS)	4 (DAYS)	5 (DAYS)
CARDIO-PULMONARY							
GASPING		P	0	0	0	1 (351)	0
RAPID RESPIRATION		P	1 (505)	0	0	0	0
SLOW RESPIRATION		P	1 (422)	0	0	1 (519)	1 (-96)
EYES/NOSE/MOUSE							
OPACITY (EYE-LEFT)		P	4 (456-550)	0	0	0	0
(EYE-RIGHT)		P	1 (428-550)	0	0	0	0
OCULAR DISCHARGE (EYE-LEFT)		P	1 (463-533)	0	0	2 (521)	0
(EYE-RIGHT)		P	0	0	0	1 (351)	0
SWOLLEN PERIOCCULAR TISSUE							
(EYE-LEFT)		P	1 (456-491)	0	0	0	1
(EYE-RIGHT)		P	0	0	0	0	1 (556)

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 0.05%, 4 is 0.20%, 5 is 0.50%

Grades: P = present, 1 = mild, 2 = moderate, 3 = severe.
 Numbers represent the number of animals exhibiting the finding at least once during the study.
 Parenthetical numbers "()" represent earliest to latest day a finding of the specified grade was observed.

TABLE 2 (Continued)
 TRISTYRENE GLYCOL DIACRYLATE (TRIGDA); CHRONIC DERMAL
 BIOASSAY IN C3H/HEMISD MALE MICE
 SUMMARY OF CLINICAL OBSERVATIONS

CATEGORIES FINDING (LOCATION)	GROUP:	MALES				
		1 (DAYS)	2 (DAYS)	3 (DAYS)	4 (DAYS)	5 (DAYS)
SKIN/HAIR/NOSE PERIOPICULAR ENCRUSTATION (EYE-LEFT)	P	3 1(498-547)	0	0	0	0
(EYE-RIGHT)	P	2(498-542)	0	0	0	0
ALPHANOSPASH (EYE-LEFT)	P	2 1(498-547)	0	0	0	0
(EYE-RIGHT)	P	1 (494)	0	0	0	0
ORAL/DERMAL PERIORAL WITNESS	P	0	0	0	1 (351)	0
PERIORAL ENCRUSTATION	P	0	1 (23)	0	0	0
SKIN ALOPECIA (ARROW)	P	16 2(36-134)	20 2(50-176)	31 1(127-141)	24 1(29-113)	13 1(36-120)
(CHEST)	P	13(22-554)	15(8-556)	24(22-556)	21(29-556)	13(29-555)
(GENITAL)	P	0	1 (470)	0	1 (470)	0

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 0.05%, 4 is 0.10%, 5 is 0.50%

Grades: P = present, 1 = mild, 2 = moderate, 3 = severe.
 Numbers represent the number of animals exhibiting the finding at least once during the study.
 Parenthetical numbers {} represent earliest to latest day a finding of the specified grade was observed.

TABLE 2 (Continued)
 TRIETHYLENE GLYCOL DIACRYLATE (TREGDA); CHRONIC DERMAL
 BIOASSAY IN C3H/HEMISD MALE MICE
 SUMMARY OF CLINICAL OBSERVATIONS

MALES

CATEGORY FINDING (LOCATION)	GROUP	GRADE (DAYS)	1 (DAYS)	2 (DAYS)	3 (DAYS)	4 (DAYS)	5 (DAYS)
SKIN	ALOPECIA (CONTINUED)						
	(LEG-FRONT-BOTH)	P	0	0	1 (29)	0	0
	(LEG-FORE-LEFT)	P	0	1 (29)	0	0	0
	(LEG-FORE-RIGHT)	P	1 (92)	0	0	0	0
	(MULTIPLE AREAS-NOS)	P	12(78-556)	13(29-555)	17(64-556)	7(78-556)	7(78-556)
	ERYTHEMA (TREATMENT AREA)	P	0	0	1(540-555)	0	4(428-540)
	EXFOLIATION/DESCAMATION (CHEST)	P	19	25	46	61	68
	(TREATMENT AREA)	P	0	0	0	1(498-505)	1 (505)
	(TREATMENT AREA)	P	19(127-555)	25(127-556)	46(22-556)	61(15-556)	68(8-556)
		1	0	0	1 (463)	1 (540)	15(134-553)
EXCORIATED (ABDOMEN)	P	12	14	18	13	11	
	P	0	0	1(288-316)	0	0	
	P	0	1 (555)	3(331-549)	0	0	
(GENITAL)	P	4(379-556)	1 (556)	3(379-555)	1 (491)	0	

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 0.05 %, 4 is 0.10 %, 5 is 0.50 %

Grades: P = present, 1 = mild, 2 = moderate, 3 = severe.
 Numbers represent the number of animals exhibiting the finding at least once during the study.
 Parenthetical numbers "()" represent earliest to latest day of finding of the specified grade was observed.

TABLE 2 (Continued)
 TRINITROFLUORENE GLYCOL DIACRYLATE (TRFDGA); CHRONIC DERMAL
 BIOASSAY IN C3H/HEBRED MALE RICE
 SUMMARY OF CLINICAL OBSERVATIONS

CATEGORY FINDING (LOCATION)	GROUP	MALES				
		GRADE (DAYS)	1 (DAYS)	2 (DAYS)	3 (DAYS)	5 (DAYS)
ENLARGED (CONFINED) (HEAD)	P	0	0	0	0	1 (555)
(INGUINAL-RIGHT)	P	0	0	1 (379)	0	0
(MULTIPLE AREAS-NOB)	P	0	0	2(323-548)	0	0
(SIDE-LEFT)	P	0	0	1 (519)	0	0
(TREATMENT AREA)	P	8(386-556)	12(50-554)	15(50-556)	13(414-556)	10(407-548)
CRUST						
(GENITAL)	P	5	4	6	3	2
(NECK)	P	2(309-372)	1(281-344)	1 (281)	2(302-344)	2(281-358)
(SIDE-RIGHT)	P	0	1 (470)	1(456-463)	0	0
(SHOULDER-LEFT)	P	0	0	1(407-435)	0	0
(TREATMENT AREA)	P	0	0	1 (484)	0	0
OPEN SORE (WET)	P	3(197-554)	2(155-197)	3(155-295)	1 (127)	0
		3	2	3	2	3

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 0.05 %, 4 is 0.10 %, 5 is 0.50 %

Grades: P = present, 1 = mild, 2 = moderate, 3 = severe.
 Numbers represent the number of animals exhibiting the finding at least once during the study.
 Parenthetical numbers "()" represent earliest to latest day a finding of the specified grade was observed.

TABLE 2 (Continued)
 DIETHYLENE GLYCOL DIACRYLATE (TREGDA): CHRONIC DERMAL
 BIOASSAY IN C3H/HEMISP MALE MICE
 SUMMARY OF CLINICAL OBSERVATIONS

CATEGORY FINDING (LOCATION)	GROUP:	MALES				
		GRADE (DAYS)	2 (DAYS)	3 (DAYS)	4 (DAYS)	5 (DAYS)
SKIN OPEN SCARS (WET) (CONTINUED) (CHEST)	P	1(540-554)	0	0	0	1 (540)
	P	2(302-498)	1(302-344)	1(85-190)	2(190-302)	1(43-120)
	P	0	0	1 (442)	0	0
	P	0	0	1(442-449)	0	0
	P	0	1 (553)	0	0	0
(SHOULDER-LEFT) (TREATMENT AREA)	F	0	0	0	0	1 (274)
	P	24	17	23	17	7
UPPER (DRY) (BACK)	P	0	0	2(99-556)	0	0
	P	1(498-512)	0	2(351-505)	2(456-540)	1(526-553)
(EAR-LEFT)	P	0	0	0	0	1 (512)
(EAR-RIGHT)	P	0	0	0	0	1 (555)
(GENITAL)	P	6(400-505)	4(414-555)	4(64-463)	7(106-548)	2(120-555)

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 0.05%, 4 is 0.1%, 5 is 0.50%

Grades: P = Prurient, 1 = mild, 2 = moderate, 3 = severe.
 Numbers represent the number of animals exhibiting the finding at least once during the study.
 Parenthetical numbers "()" represent earliest to latest day a finding of the specified grade was observed.

TABLE 2 (Continued)
 TRIETHYLENE GLYCOL DIACRYLATE (TRIGDA); CHRONIC DERMAL
 BIOASSAY IN C3H/HEMISP MALE MICE
 SUMMARY OF CLINICAL OBSERVATIONS

MALES

CATEGORY FINDING (LOCATION)	GROUP:	1 CRUDE (DAYS)	2 (DAYS)	3 (DAYS)	4 (DAYS)	5 (DAYS)
SKIN ULCER (DRY) (CONTINUED) (MUSCIPLE AREAS-NOB)	P	1(526-554)	0	1(351-456)	0	0
	P	3(407-498)	1(470)	0	1(462-449)	0
	P	0	0	1(407-435)	0	0
	P	0	0	1(491)	0	1(498)
	P	17(155-519)	13(99-519)	18(106-554)	13(99-505)	3(106-491)
PUSTULE (ORBITAL)	P	1(43-64)	0	1	0	0
	P	0	0	0	0	0
	P	0	0	1(484)	0	0
SCALDS MASS(ES) PRESENT	P	1(463-556)	2(477-548)	1(470-477)	1(505-512)	0
	P	9(0-549)	10(43-449)	5(15-540)	9(0-512)	4(3-540)
OTHER CLIPPING INJURY (TREATMENT AREA)	P	9(0-549)	10(43-449)	5(15-540)	9(0-512)	4(3-540)
	P	9(0-549)	10(43-449)	5(15-540)	9(0-512)	4(3-540)

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 0.05%, 4 is 0.10%, 5 is 0.50%

Grades: P = present, 1 = mild, 2 = moderate, 3 = severe.
 Numbers represent the number of animals exhibiting the finding at least once during the study.
 Parenthetical numbers "()" represent earliest to latest day a finding of the specified grade was observed.

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TABLE 3
 TRIPHENYLENE GLYCOL DIACRYLATE (TRGDGA): CHRONIC DEBILITATING
 BIOASSAY IN C3H/HEBRED MALE MICE
 SUMMARY OF BODY WEIGHT (GRAMS)

TRGDGA MALES						
GROUP: &	0.0 ^a	0.0 ^b	0.05	0.10	0.50	
WEEK 0						
MEAN	25.2	25.2	25.1	25.0	24.9	
S.D.	1.18	0.96	1.07	1.18	0.96	
N	70	70	70	70	70	
WEEK 1						
MEAN	26.5	26.8	26.5	26.6	26.4	
S.D.	1.18	1.06	1.12	1.24	0.92	
N	70	70	70	70	70	
WEEK 2						
MEAN	28.1	28.3	27.9	28.0	28.1	
S.D.	1.20	1.22	1.09	1.37	1.10	
N	70	70	70	70	70	
WEEK 3						
MEAN	28.7	28.8	28.6	28.3	28.5	
S.D.	1.21	1.12	1.29	1.39	1.20	
N	70	70	70		70	
WEEK 4						
MEAN	29.7	29.7	29.6	29.1	29.4	
S.D.	1.24	1.21	1.23	1.46	1.32	
N	65	64	65	65	65	
WEEK 5						
MEAN	30.1	29.8	30.0	30.0	30.1	
S.D.	1.29	1.25	1.25	1.57	1.71	
N	65	64	65	65	65	
WEEK 6						
MEAN	30.7	30.7	30.9	31.0	30.8	
S.D.	1.42	1.19	1.46	1.55	1.36	
N	65	64	65	65	65	
WEEK 7						
MEAN	31.2	31.2	31.3	31.3	31.2	
S.D.	1.59	1.28	1.51	1.60	1.30	
N	65	64	65	65	65	
WEEK 8						
MEAN	31.4	31.8	31.7	31.6	31.2	
S.D.	1.74	1.44	1.42	1.61	1.43	
N	65	64	65	65	65	
WEEK 9						
MEAN	31.5	31.7	32.0	31.5	31.4	
S.D.	1.76	1.46	1.47	1.64	1.55	
N	65	64	65	65	65	
WEEK 10						
MEAN	31.9	31.9	31.9	31.4	31.6	
S.D.	2.01	1.43	1.60	1.73	1.60	
N	65	64	65	65	65	
WEEK 11						
MEAN	31.8	32.0	32.2	31.5	31.8	
S.D.	1.99	1.69	1.72	1.82	1.71	
N	65	64	65	65	65	
WEEK 12						
MEAN	32.1	31.6	32.1	31.7	31.8	
S.D.	1.76	1.41	1.57	1.80	1.81	
N	65	64	65	65	65	
WEEK 16						
MEAN	32.6	32.6	32.5	32.3	32.2	
S.D.	1.83	1.58	1.93	2.04	1.85	
N	60	59	60	60	59	

^a None significantly different from control group
^b untreated control group
^c vehicle treated control group

TABLE 2 (continued)
 TRIMETHYLENE GLYCOL DIACRYLATE (TRIGDA): CHRONIC DERMAL
 STORAGE IN C57BL/6J MALE MICE
 SUMMARY OF BODY WEIGHT (GRAMS)

		TRIGDA MALES				
GROUP: 0	0.0 ^a	0.0 ^b	0.05	0.10	0.50	
WEEK 20						
MEAN	32.4	32.3	32.5	32.0	31.7	
S.D.	1.60	1.64	1.74	1.97	1.89	
N	60	59	60	59	59	
WEEK 24						
MEAN	32.5	32.7	32.5	32.1	31.8	
S.D.	1.70	1.70	1.79	1.99	1.70	
N	60	59	60	59	59	
WEEK 28						
MEAN	32.9	33.0	33.0	32.0 ^{ad}	32.2 ^{ac}	
S.D.	1.71	1.73	1.81	1.98	1.76	
N	60	59	60	59	58	
WEEK 32						
MEAN	33.5	33.8	33.3	33.0	33.2	
S.D.	1.89	1.81	1.88	2.26	1.81	
N	60	59	60	59	58	
WEEK 36						
MEAN	33.9	33.8	34.0	33.2	33.3	
S.D.	1.94	1.97	2.18	2.15	1.86	
N	60	59	60	59	57	
WEEK 40						
MEAN	33.6	34.0	33.6	33.2 ^c	33.0 ^{ad}	
S.D.	2.04	2.04	1.83	2.07	1.83	
N	60	59	59	59	56	
WEEK 44						
MEAN	33.3	33.6	33.7	33.3	33.1	
S.D.	2.05	2.10	1.96	2.32	1.78	
N	60	59	59	59	56	
WEEK 48						
MEAN	33.7	34.2	33.6	33.6	33.6	
S.D.	2.07	2.35	2.06	2.47	1.91	
N	59	59	57	59	55	
WEEK 52						
MEAN	34.4	34.5	34.4	33.5	33.6	
S.D.	2.15	2.65	2.12	2.44	2.25	
N	54	55	52	54	51	
WEEK 56						
MEAN	34.5	34.5	34.4	34.0	33.9	
S.D.	2.25	2.66	2.04	2.54	2.16	
N	52	55	52	54	50	
WEEK 60						
MEAN	34.3	34.2	34.4	33.4	33.6	
S.D.	2.24	2.29	1.86	2.46	1.98	
N	52	54	51	53	49	
WEEK 64						
MEAN	34.3	34.6	34.4	33.6	33.7	
S.D.	2.12	1.99	1.93	2.85	2.19	
N	50	52	50	52	49	
WEEK 68						
MEAN	34.0	34.1	34.6	33.4	33.1 ^c	
S.D.	2.17	2.16	2.10	2.16	2.28	
N	50	51	50	50	45	
WEEK 72						
MEAN	33.8	34.7	34.5	33.6	33.7	
S.D.	2.64	2.21	2.04	2.34	1.92	
N	47	48	48	47	43	

^a Significantly different from the untreated control group (p<.05)
^b Significantly different from the vehicle treated control group (p<.05)
^c Significantly different from the vehicle treated control group (p<.01)
¹ untreated control group
² vehicle treated control group

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TABLE 3 (continued):
 TRIETHYLENE GLYCOL DIACRYLATE (TREGDA): CHRONIC NEURAL
 BIOSCOPY IN C57BL/6J MALE MICE
 SUMMARY OF BODY WEIGHT (GRAMS)

		TREGDA MALES				
GROUP: 6	0.0 ¹	0.0 ²	0.05	0.10	0.50	
WEEK 76						
MEAN	33.6	34.2	34.0	33.6	33.3	
S.D.	2.74	2.36	2.27	2.28	1.94	
N	44	43	45	44	40	
WEEK 78						
MEAN	33.7	34.4	33.8	33.6	33.0	
S.D.	2.42	2.84	2.28	2.28	1.74	
N	35	35	39	36	34	

None significantly different from control group
¹ untreated control group
² vehicle treated control group

0039

TABLE 4
 TRIS(2-HYDROXYETHYL)AMMONIUM METHACRYLATE (TREGDA): CHRONIC DERMAL
 BIOASSAY IN C57BL/6J MICE
 SUMMARY OF BODY WEIGHT GAIN (GRAMS)

GROUP: 8	TREGDA MALES				
	0.0 ^a	0.0 ^b	0.05	0.10	0.50
WEEK 0 TO 1					
MEAN	1.3	1.6 ^b	1.4	1.6 ^b	1.5
S.D.	0.41	0.39	0.75	0.51	0.50
N	70	70	70	70	70
WEEK 0 TO 2					
MEAN	2.9	3.1 ^a	2.7 ^d	3.0	3.1 ^a
S.D.	0.55	0.61	0.62	0.61	0.61
N	70	70	70	70	70
WEEK 0 TO 3					
MEAN	3.5	3.6	3.5	3.3	3.5
S.D.	0.62	0.60	0.78	0.76	0.72
N	70	70	70	70	70
WEEK 0 TO 4					
MEAN	4.5	4.4	4.5	4.1 ^{bc}	4.5
S.D.	0.72	0.62	0.75	0.80	0.90
N	65	64	65	65	65
WEEK 0 TO 5					
MEAN	4.9	4.6	4.9	5.0 ^c	5.2 ^d
S.D.	0.83	0.69	0.82	0.93	1.19
N	65	64	65	65	65
WEEK 0 TO 6					
MEAN	5.5	5.4	5.7 ^c	6.0 ^{bd}	5.8 ^{ad}
S.D.	0.87	0.74	0.99	0.89	0.91
N	65	64	65	65	65
WEEK 0 TO 7					
MEAN	6.0	5.9	6.1	6.3	6.2
S.D.	1.00	0.87	1.09	0.96	0.85
N	65	64	65	65	65
WEEK 0 TO 8					
MEAN	6.2	6.6	6.6	6.6	6.3
S.D.	1.35	0.98	1.02	0.94	1.01
N	65	64	65	65	65
WEEK 0 TO 9					
MEAN	6.3	6.5	6.9 ^{bc}	6.5	6.5
S.D.	1.32	0.99	1.05	1.05	1.14
N	65	64	65	65	65
WEEK 0 TO 10					
MEAN	6.7	6.6	6.8	6.4	6.6
S.D.	1.57	0.98	1.12	1.06	1.15
N	65	64	65	65	65
WEEK 0 TO 11					
MEAN	6.6	6.6	7.1	6.5	6.8
S.D.	1.55	1.27	1.38	1.19	1.37
N	65	64	65	65	65
WEEK 0 TO 12					
MEAN	6.9	6.4	7.0	6.7	6.9
S.D.	1.26	1.11	1.21	1.19	1.39
N	65	64	65	65	65
WEEK 0 TO 16					
MEAN	7.3	7.3	7.4	7.4	7.1
S.D.	1.32	1.17	1.64	1.61	1.52
N	60	59	60	60	59
WEEK 0 TO 20					
MEAN	7.1	7.0	7.3	7.1	6.6
S.D.	1.11	1.30	1.34	1.43	1.60
N	60	59	60	59	59

^a Significantly different from the untreated control group (p<.05)
^b Significantly different from the untreated control group (p<.01)
^c Significantly different from the vehicle treated control group (p<.05)
^d Significantly different from the vehicle treated control group (p<.01)
¹ untreated control group
² vehicle treated control group

0040

TABLE 4 (continued)
 TRIETHYLENE GLYCOL DIACRYLATE (TREGDA): CHRONIC DERMAL
 BIOASSAY IN C3H/HEWED MALE MICE
 SUMMARY OF BODY WEIGHT GAIN (GRAMS)

TREGDA MALES						
GROUP: t	0.0 ¹	0.0 ²	0.05	0.10	0.50	
WEEK 0 TO 24						
MEAN	7.2	7.4	7.4	7.1	6.8	
S.D.	1.21	1.35	1.36	1.42	1.38	
N	60	59	60	59	59	
WEEK 0 TO 28						
MEAN	7.7	7.7	7.9	7.1 ^{ac}	7.1 ^{ac}	
S.D.	1.21	1.38	1.35	1.38	1.46	
N	60	59	60	59	58	
WEEK 0 TO 32						
MEAN	8.2	8.6	8.2	8.1	8.1	
S.D.	1.36	1.55	1.33	1.74	1.45	
N	60	59	60	59	58	
WEEK 0 TO 36						
MEAN	8.6	8.5	8.9	8.3	8.2	
S.D.	1.27	1.65	1.72	1.62	1.50	
N	60	59	60	59	57	
WEEK 0 TO 40						
MEAN	8.6	8.8	8.5	8.3	8.0	
S.D.	1.45	1.73	1.42	1.66	1.43	
N	60	59	59	59	56	
WEEK 0 TO 44						
MEAN	8.1	8.3	8.6	8.4	8.0	
S.D.	1.63	1.84	1.60	1.84	1.49	
N	60	59	59	59	56	
WEEK 0 TO 48						
MEAN	8.4	9.0	8.5	8.7	8.5	
S.D.	1.58	2.06	1.73	1.97	1.68	
N	59	59	57	59	55	
WEEK 0 TO 52						
MEAN	9.2	9.1	9.2	8.5	8.6	
S.D.	1.54	2.46	1.82	1.88	1.99	
N	54	55	52	54	51	
WEEK 0 TO 56						
MEAN	9.3	9.2	9.2	9.0	8.9	
S.D.	1.64	2.41	1.76	1.97	1.89	
N	52	55	52	54	50	
WEEK 0 TO 60						
MEAN	9.1	8.9	9.2	8.4	8.5	
S.D.	1.71	1.89	1.66	1.96	1.76	
N	52	54	51	53	49	
WEEK 0 TO 64						
MEAN	9.2	9.3	9.1	8.6	8.7	
S.D.	1.51	1.76	1.73	2.27	1.97	
N	50	52	50	52	49	
WEEK 0 TO 68						
MEAN	8.8	8.8	9.3	8.4	8.2	
S.D.	1.51	1.88	1.84	1.62	1.88	
N	50	51	50	50	45	
WEEK 0 TO 72						
MEAN	8.7	9.3	9.3	8.6	8.7	
S.D.	1.94	1.98	1.84	1.88	1.59	
N	47	48	48	47	43	
WEEK 0 TO 76						
MEAN	8.4	8.8	8.8	8.6	8.3	
S.D.	2.25	2.18	2.06	1.86	1.65	
N	44	43	45	44	40	

^a Significantly different from the untreated control group (p<.05)
^c Significantly different from the vehicle treated control group (p<.05)
¹ untreated control group
² vehicle treated control group

0047

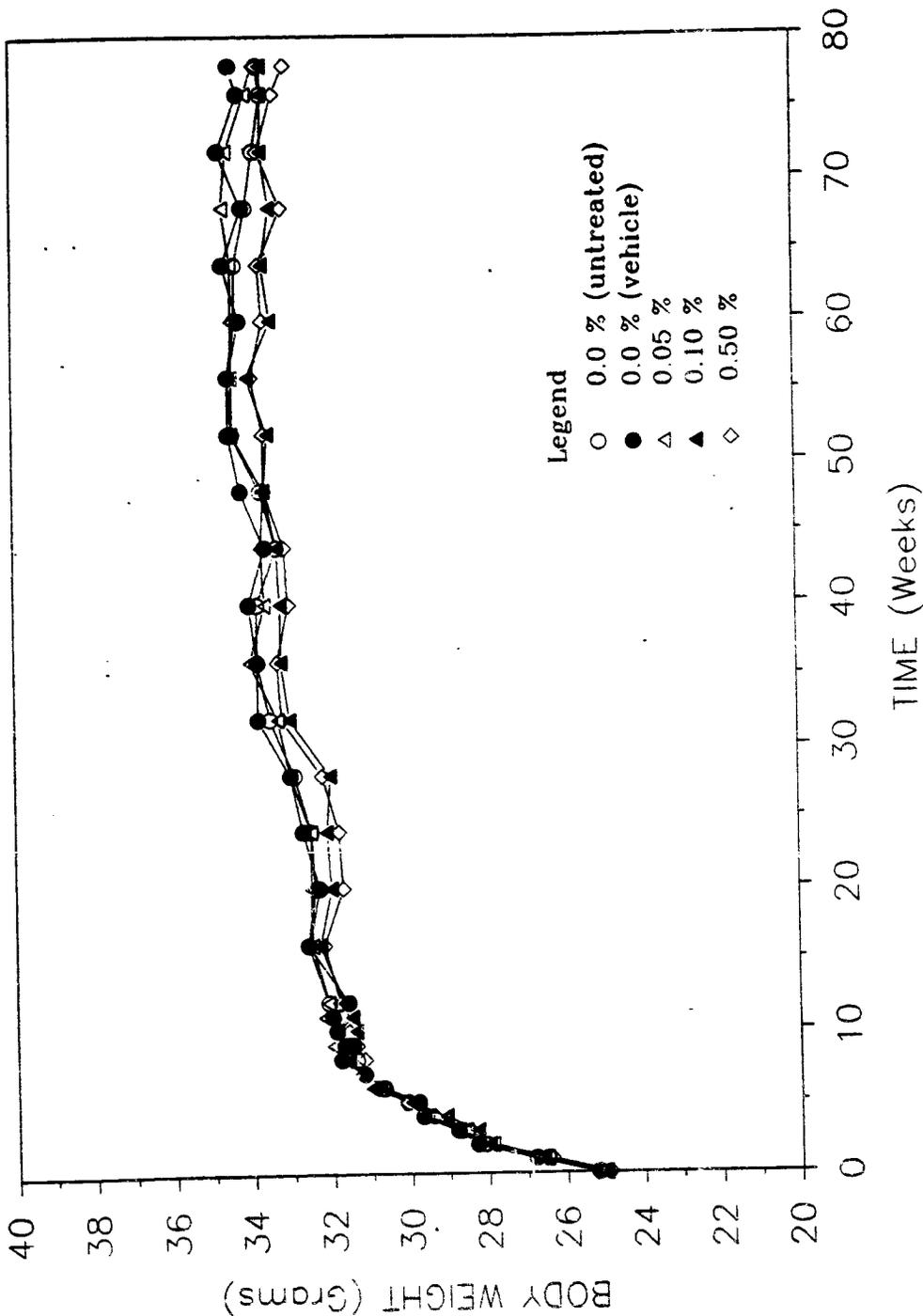
TABLE 4 (continued)
 TRINITROBENZENE GLYCOL DIACRYLATE (TRBGDA): CHRONIC DERMAL
 BIOASSAY IN C57BL/6J MALE MICE
 SUMMARY OF BODY WEIGHT GAIN (GRAMS)

TRBGDA MALES					
GROUP: 1	0.0 ^a	0.0 ^b	0.05	0.10	0.50
WEEK 0 TO 78					
MEAN	8.6	9.1	8.7	8.5	8.1
S.D.	1.98	2.55	2.00	1.81	1.56
N	35	35	39	36	34

^a None significantly different from control group
^b untreated control group
^c vehicle treated control group

0048

FIGURE 2
 TRIETHYLENE GLYCOL DIACRYLATE (TREGDA): CHRONIC DERMAL
 BICASSAY IN C3H/H3NHSD MALE MICE
 GRAPH OF MEAN BODY WEIGHT VERSUS TIME
 MALES



**TRIS(2-HYDROXYETHYL)AMMONIUM METHACRYLATE (THREGDA): CHRONIC DERMAL
 IRRITATION IN C57BL/6J MICE
 SUMMARY OF HEMATOLOGY
 WEEK 52**

		THREGDA MALES				
GROUP:	0	0.0 ¹	0.05	0.10	0.50	
ERYTHROCYTES (10⁶/μl)						
MEAN	7.72	8.07	7.42	7.76	7.55	
S.D.	0.343	0.750	0.344	0.114	0.621	
N	5	5	5	5	5	
HEMOGLOBIN (g/dl)						
MEAN	13.3	14.1	13.2	13.8	13.3	
S.D.	0.56	0.82	0.49	0.33	0.71	
N	5	5	5	5	5	
HEMATOCRIT (%)						
MEAN	38.8	41.3	38.6	39.4	38.4	
S.D.	1.56	2.83	1.48	1.03	2.58	
N	5	5	5	5	5	
MEAN CORPUSCULAR VOLUME (μm³)						
MEAN	50.	51.	52.	51.	51.	
S.D.	1.1	1.2	0.8	1.0	0.8	
N	5	5	5	5	5	
MEAN CORPUSCULAR HEMOGLOBIN (pg)						
MEAN	17.2	17.5	17.8	17.8	17.6	
S.D.	0.60	0.59	0.22	0.17	0.65	
N	5	5	5	5	5	
MEAN CORPUSCULAR HEMOGLOBIN CONCENTRATION (g/dl)						
MEAN	34.3	34.2	34.2	35.0	34.7	
S.D.	0.68	0.52	0.37	0.54	0.77	
N	5	5	5	5	5	
PLATELETS (10³/μl)						
MEAN	713.	847.	800.	723.	829.	
S.D.	240.7	327.3	92.7	23.1	78.5	
N	5	5	5	5	5	
LEUCOCYTES (10³/μl)						
MEAN	6.1	5.9	4.9	4.9	5.6	
S.D.	1.56	0.63	0.16	0.74	1.03	
N	5	5	5	5	5	
SEGMENTED NEUTROPHILS (10³/μl)						
MEAN	2.15	1.96			1.53	
S.D.	0.962	0.883			0.648	
N	5	5			5	
LYMPHOCYTES (10³/μl)						
MEAN	3.66	3.73			3.83	
S.D.	0.824	0.828			0.862	
N	5	5			5	
MONOCYTES (10³/μl)						
MEAN	0.14	0.09			0.16	
S.D.	0.176	0.069			0.126	
N	5	5			5	

None significantly different from control group
¹ untreated control group
² vehicle treated control group

0 0 4) 4

TABLE 3 (CONTINUED)
 TRIETHYLENE GLYCOL DIACRYLATE (TREGDA): CHRONIC DERMAL
 BIOASSAY IN C3H/HEWESD MALE MICE
 SUMMARY OF HEMATOLOGY
 WEEK 52

TREGDA MALES					
GROUP: ♀	0.0 ¹	0.0 ²	0.05	0.10	0.50
BASOPHILS (10³/μl)					
MEAN	0.00	0.00			0.00
S.D.	3.000	0.000			0.000
N	5	5			5
EOSINOPHILS (10³/μl)					
MEAN	0.17	0.07			0.07
S.D.	0.075	0.076			0.064
N	5	5			5
BANDED NEUTROPHILS (10³/μl)					
MEAN	0.	0.			0.
S.D.	0.0	0.0			0.0
N	5	5			5
LARGE MONOCYTES (10³/μl)					
MEAN	0.	0.			0.
S.D.	0.0	0.0			0.0
N	5	5			5
IMMATURE GRANULOCYTES (10³/μl)					
MEAN	0.	0.			0.
S.D.	0.0	0.0			0.0
N	5	5			5
NUCLEATED RBCs (cells/100 WBCs)					
MEAN	0.	0.			0.
S.D.	0.0	0.0			0.0
N	5	5			5

None significantly different from control group
¹ untreated control group
² vehicle treated control group

0045

TABLE 6
HEMATOLOGICAL PARAMETERS (TRIGDA): CHRONIC DEXAMETHASONE
SIGNIFICANT IN CSM/TREATED MALE MICE
SUMMARY OF HEMATOLOGY
WEEK 79

		TRIGDA MALES				
GROUP: 1	0.0 ¹	0.0 ²	0.05	0.10	0.50	
ERYTHROCYTES (10⁶/μl)						
MEAN	7.42	8.16	7.38	8.48	7.91	
S.D.	1.229	1.083	1.012	1.081	0.328	
N	5	5	5	5	5	
HEMOGLOBIN (g/dl)						
MEAN	12.6	13.7	12.8	14.2	13.8	
S.D.	2.02	0.86	0.89	1.60	0.52	
N	5	5	5	5	5	
HEMATOCRIT (%)						
MEAN	38.5	41.1	38.7	42.5	40.5	
S.D.	3.84	3.88	1.49	4.70	1.31	
N	5	5	5	5	5	
MEAN CORPUSCULAR VOLUME (μm³)						
MEAN	53.	51.	53.	50.	51.	
S.D.	4.7	2.3	6.2	0.8	1.1	
N	5	5	5	5	5	
MEAN CORPUSCULAR HEMOGLOBIN (pg)						
MEAN	17.0	16.9	17.5	16.7	17.5	
S.D.	0.46	1.22	1.53	0.44	0.33	
N	5	5	5	5	5	
MEAN CORPUSCULAR HEMOGLOBIN CONCENTRATION (g/dl)						
MEAN	32.6	33.4	32.9	33.3	34.1	
S.D.	2.20	1.14	1.09	0.80	0.46	
N	5	5	5	5	5	
PLATELETS (10³/μl)						
MEAN	833.	831.	990.	716.	773.	
S.D.	94.4	248.5	260.0	78.3	22.4	
N	5	5	5	5	5	
LEUCOCYTES (10³/μl)						
MEAN	6.3	5.8	6.6	5.3	5.9	
S.D.	3.32	0.39	2.37	1.43	1.56	
N	5	5	5	5	5	
SEGMENTED NEUTROPHILS (10³/μl)						
MEAN	3.82	3.02			2.68	
S.D.	3.427	1.108			0.894	
N	5	5			5	
LYMPHOCYTES (10³/μl)						
MEAN	2.35	2.60			3.08	
S.D.	0.828	0.829			1.035	
N	5	5			5	
MONOCYTES (10³/μl)						
MEAN	0.09	0.12			0.08	
S.D.	0.102	0.212			0.093	
N	5	5			5	

None significantly different from control group
¹ untreated control group
² vehicle treated control group

0046

TABLE 6 (continued)
 TRIMETHYLENE GLYCOL DIACRYLATE (TREGDA): CHRONIC DERMAL
 BIOASSAY IN C57/BL6JEDD MALE MICE
 SUMMARY OF HEMATOLOGY
 WEEK 79

TREGDA MALES					
GROUP: ♀	0.0 ¹	0.0 ²	0.05	0.10	0.50
EOSINOPHILS (10³/μl)					
MEAN	0.00	0.00			0.00
S.D.	0.000	0.000			0.000
N	5	5			5
EOSINOPHILS (10³/μl)					
MEAN	0.02	0.02			0.11
S.D.	0.040	0.048			0.096
N	5	5			5
BANDED NEUTROPHILS (10³/μl)					
MEAN	0.	0.			0.
S.D.	0.0	0.0			0.0
N	5	5			5
LARGE MONOCYTES (10³/μl)					
MEAN	0.	0.			0.
S.D.	0.0	0.0			0.0
N	5	5			5
IMMATURE GRANULOCYTES (10³/μl)					
MEAN	0.	0.			0.
S.D.	0.0	0.0			0.0
N	5	5			5
NUCLEATED RBCs (cells/100 WBCs)					
MEAN	0.	0.			0.
S.D.	0.0	0.0			0.0
N	5	5			5

None significantly different from control group
¹ untreated control group
² vehicle treated control group

0047

TABLE 7
 TRIETHYLENE GLYCOL DIACRYLATE (TRIGDA): CHRONIC DERMAL
 IRRITATION IN C3H/HEWED MALE MICE
 SUMMARY OF CLINICAL CHEMISTRY
 WEEK 52

GROUP: #	TRIGDA MALES				
	0.0 ^a	0.0 ^a	0.05	0.10	0.50
GLUCOSE (g/l)					
MEAN	1.02	1.63	1.79	1.89	1.74
S.D.	0.231	0.357	0.187	0.211	0.196
N	5	5	5	5	5
UREA NITROGEN (mg/l)					
MEAN	322.	310.	290.	272. ^{ac}	405.
S.D.	33.0	22.9	15.1	9.5	204.7
N	5	5	5	5	5
CREATININE (mg/l)					
MEAN	5.	6.	5.	5.	7.
S.D.	0.5	0.4	0.8	0.5	3.9
N	5	5	5	5	5
TOTAL PROTEIN (g/l)					
MEAN	58.	62.	56.	56.	56.
S.D.	3.2	11.3	1.6	3.3	3.9
N	5	5	5	5	5
ALBUMIN (g/l)					
MEAN	32.	36.	32.	32.	32.
S.D.	2.6	7.1	1.8	1.9	3.6
N	5	5	5	5	5
TOTAL BILIRUBIN (mg/l)					
MEAN	3.	3.	3.	3.	3.
S.D.	0.5	0.9	0.0	0.8	0.7
N	5	5	5	5	5
CALCIUM (mg/l)					
MEAN	99.	101.	96.	97.	104.
S.D.	8.0	10.8	6.6	8.8	12.6
N	5	5	5	5	5
INORGANIC PHOSPHORUS (mg/l)					
MEAN	72.	69.	71.	64.	78.
S.D.	6.8	10.5	10.5	12.7	28.7
N	5	5	5	5	5
SODIUM (mmol/l)					
MEAN	160.	160.	159.	159.	166.
S.D.	7.7	5.8	6.8	6.5	14.1
N	5	5	5	5	5
POTASSIUM (mmol/l)					
MEAN	7.1	6.5	6.2	6.2	6.2
S.D.	0.42	0.64	0.60	0.75	0.31
N	5	5	5	5	5
CHLORIDE (mmol/l)					
MEAN	124.	124.	124.	124.	126.
S.D.	6.7	4.0	4.8	4.9	7.6
N	5	5	5	5	5
ASPARTATE AMINOTRANSFERASE (IU/l)					
MEAN	46.	55.	49.	54.	47.
S.D.	4.9	21.6	8.9	10.1	8.6
N	5	5	5	5	5
ALANINE AMINOTRANSFERASE (IU/l)					
MEAN	58.	71.	46.	73.	56.
S.D.	25.9	49.1	15.9	38.6	31.5
N	5	5	5	5	5

^a Significantly different from the untreated control group (p<.05)
^c Significantly different from the vehicle treated control group (p<.05)
^a untreated control group
^c vehicle treated control group

0048

TABLE 7 (continued)
 TRIETHYLENE GLYCOL DIACRYLATE (TREGDA): CHRONIC DERMAL
 BIOASSAY IN C3H/HEBESD MALE MICE
 SUMMARY OF CLINICAL CHEMISTRY
 WEEK 52

		TREGDA MALES				
GROUP: %	0.0 ¹	0.0 ²	0.05	0.10	0.50	
γ-Glutamyl Transferase (IU/l)						
MEAN	3.	3.	4.	3.	3.	
S.D.	0.5	0.5	0.5	0.5	0.4	
N	5	5	5	5	5	
Creatine Kinase (IU/l)						
MEAN	52.	144.	98.	85.	58.	
S.D.	15.6	175.3	65.5	118.1	63.2	
N	5	5	5	5	5	
Alkaline Phosphatase (IU/l)						
MEAN	51.	46.	45.	47.	50.	
S.D.	8.5	5.0	7.3	7.4	6.0	
N	5	5	5	5	5	
Cholesterol (g/l)						
MEAN	1.68	1.99	1.70	1.66	1.84	
S.D.	0.064	0.466	0.111	0.125	0.361	
N	5	5	5	5	5	

None significantly different from control group
¹ untreated control group
² vehicle treated control group

0049

TABLE 8
 TRIBENYLAMINE GLYCOL DIACRYLATE (TRBGDA): CHRONIC DERMAL
 BIOASSAY IN C57BL/6J MALE MICE
 SUMMARY OF CLINICAL CHEMISTRY
 WEEK 79

GROUP: %	TRBGDA MALES				
	0.0 ^a	0.0 ^a	0.05	0.10	0.50
GLUCOSE (g/l)					
MEAN	1.84	1.68	1.51	1.60	1.76
S.D.	0.261	0.323	0.390	0.156	0.095
N	5	5	5	5	5
UREA NITROGEN (mg/l)					
MEAN	379.	337.	305. ^a	305. ^a	285. ^b
S.D.	55.2	50.2	49.1	31.5	50.1
N	5	5	5	5	5
CREATININE (mg/l)					
MEAN	6.	6.	5.	5.	5.
S.D.	0.5	0.5	0.7	0.4	0.8
N	5	5	5	5	5
TOTAL PROTEIN (g/l)					
MEAN	66.	67.	59.	61.	58.
S.D.	11.9	19.5	3.4	4.8	5.1
N	5	5	5	5	5
ALBUMIN (g/l)					
MEAN	36.	37.	32.	33.	33.
S.D.	7.1	9.3	3.4	2.3	2.2
N	5	5	5	5	5
TOTAL BILIRUBIN (mg/l)					
MEAN	5.	4.	5.	4.	3.
S.D.	3.0	2.5	5.1	1.8	0.8
N	5	5	5	5	5
CALCIUM (mg/l)					
MEAN	93.	95.	89.	92.	90.
S.D.	7.5	8.3	2.3	4.0	2.1
N	5	5	5	5	5
INORGANIC PHOSPHORUS (mg/l)					
MEAN	67.	70.	62.	64.	68.
S.D.	4.4	11.8	8.7	5.2	4.3
N	5	5	5	5	5
SODIUM (mmol/l)					
MEAN	157.	155.	156.	156.	156.
S.D.	2.2	1.9	3.1	1.5	1.8
N	5	5	5	5	5
POTASSIUM (mmol/l)					
MEAN	6.0	5.9	5.9	5.9	5.9
S.D.	0.46	0.58	0.83	0.16	0.65
N	5	5	5	5	5
CHLORIDE (mmol/l)					
MEAN	121.	121.	120.	120.	121.
S.D.	2.0	2.5	3.1	1.8	1.7
N	5	5	5	5	5
ASPARTATE AMINOTRANSFERASE (IU/l)					
MEAN	69.	123.	133.	100.	60.
S.D.	22.7	132.2	161.0	63.9	13.7
N	5	5	5	5	5
ALANINE AMINOTRANSFERASE (IU/l)					
MEAN	57.	86.	51.	64.	49.
S.D.	37.1	114.5	30.5	39.7	18.7
N	5	5	5	5	5

^a Significantly different from the untreated control group (p<.05)
^b Significantly different from the untreated control group (p<.01)
^c untreated control group
^d vehicle treated control group

00058

TABLE 8 (continued)
 TRIETHYLENE GLYCOL DIACRYLATE (TEGDA): CHRONIC DERMAL
 BIOASSAY IN C57BL/6J¹ MALE MICE
 SUMMARY OF CLINICAL CHEMISTRY
 WEEK 7²

GROUP: 8	TEGDA MALES				
	0.0 ³	0.0 ³	0.05	0.10	0.50
γ-Glutamyl Transferase (IU/l)					
MEAN	4.	3.	3.	3.	3.
S.D.	0.5	0.7	0.4	0.7	0.7
N	5	5	5	5	5
Creatine Kinase (IU/l)					
MEAN	272.	302.	252.	143.	169.
S.D.	370.3	187.8	145.4	93.5	144.1
N	5	5	5	5	5
Alkaline Phosphatase (IU/l)					
MEAN	47.	104.	57.	85.	47.
S.D.	6.3	112.7	22.3	64.5	5.8
N	5	5	5	5	5
Cholesterol (g/l)					
MEAN	2.09	2.48	1.51	1.71	1.63
S.D.	0.456	1.137	0.288	0.455	0.297
N	5	5	5	5	5

* None significantly different from control group
¹ untreated control group
² vehicle treated control group

0-11-5-1

TABLE 9
 TRIBUTYLENE GLYCOL DIMETHACRYLATE (TRBDMA): CHRONIC DERMAL
 BIOASSAY IN C57BL/6J MALE MICE

SUMMARY OF EPIDERMAL CELL PROLIFERATION

(n = 5 except where noted)

	MALE				
	Q1 ¹	Q1 ²	0.05g	0.10g	0.50g
Week 4	22.5 ± 2.99	20.6 ± 3.84	25.2 ± 10.03	30.2 ± 10.24	59.6 ± 10.20 ^{bd}
Week 13	21.8 ± 7.26	18.8 ± 4.35	25.4 ± 7.00	22.9 ± 5.02	50.1 ± 12.21 ^{bd}
Week 52	31.9 ± 9.61	30.4 ± 3.27 ³	28.7 ± 14.21 ³	34.1 ± 4.12 ³	63.1 ± 11.63 ^{bd}
Week 78	25.8 ± 8.09	24.4 ± 4.99	22.9 ± 10.04	38.9 ± 11.39 ^{bc}	53.9 ± 7.95 ^{bd}

¹untreated control group

²vehicle treated control group

³n = 4 due to mortality in these dose groups

Units = % of labeled cells

^asignificantly different from the untreated control group (p < 0.05)

^bsignificantly different from the untreated control group (p < 0.01)

^csignificantly different from the vehicle control group (p < 0.05)

^dsignificantly different from the vehicle control group (p < 0.01)

0052

TABLE 10
 TRIMETHYLENE GLYCOL DIACRYLATE (TREGDA): CHRONIC DERMAL
 BIOASSAY IN C57BL/6J MALE MICE
 SUMMARY OF ORGAN WEIGHTS (GRAMS)
 ANIMALS SACRIFICED AT WEEK 78

		TREGDA MALES				
GROUP: %	0.0 ^a	0.0 ^b	0.05	0.10	0.50	
FINAL BODY WEIGHT						
MEAN	33.6	34.4	33.7	33.3	33.7	
S.D.	2.19	2.37	2.26	2.13	1.86	
N	35	34	39	36	34	
LIVER						
MEAN	2.137	2.825 ^a	2.379	2.135 ^c	2.069 ^d	
S.D.	0.8339	1.5729	1.1693	0.6125	0.6158	
N	40	39	44	41	39	
KIDNEYS						
MEAN	0.840	0.824	0.846	0.817	0.837	
S.D.	0.0859	0.0974	0.0991	0.0945	0.0806	
N	40	39	44	41	39	
SPLEEN						
MEAN	0.108	0.110	0.101	0.096	0.099	
S.D.	0.0873	0.0568	0.0478	0.0369	0.0474	
N	40	39	44	41	39	
BRAIN						
MEAN	0.466	0.465	0.468	0.464	0.461	
S.D.	0.0213	0.0206	0.0237	0.0220	0.0201	
N	40	39	44	41	39	
TESTES						
MEAN	0.073	0.075	0.071	0.069	0.077	
S.D.	0.0184	0.0235	0.0225	0.0233	0.0222	
N	40	39	44	41	39	

^a Significantly different from the untreated control group (p<.05)
^c Significantly different from the vehicle treated control group (p<.05)
^d Significantly different from the vehicle treated control group (p<.01)

¹ untreated control group
² vehicle treated control group

Note: Organ weights were obtained for all the animals sacrificed at Week 78. However, final body weights were not measured for the animals implanted with the osmotic pumps (5 animals/group).

0053

TABLE 11
 TRIS(ETHYLENE GLYCOL) DIACRYLATE (TEGDMA): OSMOTIC DERMAL
 RELEASE IN C3H/HEMISP MALE MICE
 SUMMARY OF ORGAN WEIGHTS AS % OF FINAL BODY WEIGHT
 ANIMALS SACRIFICED AT WEEK 78

GROUP:	TEGDMA MALES				
	0.0 ¹	0.0 ²	0.05	0.10	0.50
LIVER					
MEAN	6.224	7.954 ^a	6.698	6.249 ^c	6.035 ^c
S.D.	2.5625	4.1206	2.7357	2.2746	1.9059
N	35	34	39	36	34
KIDNEYS					
MEAN	2.478	2.400	2.506	2.438	2.463
S.D.	0.1728	0.2616	0.2110	0.2356	0.1815
N	35	34	39	36	34
SPLLEN					
MEAN	0.327	0.300	0.290	0.284	0.291
S.D.	0.2780	0.1047	0.1255	0.1003	0.1404
N	35	34	39	36	34
BRAIN					
MEAN	1.388	1.355	1.398	1.399	1.389
S.D.	0.0579	0.0994	0.1198	0.1058	0.0718
N	35	34	39	36	34
TESTES					
MEAN	0.216	0.216	0.210	0.201	0.224
S.D.	0.0623	0.0713	0.0704	0.0667	0.0649
N	35	34	39	36	34

^a Significantly different from the untreated control group (p<.05)
^c Significantly different from the vehicle treated control group (p<.05)
¹ untreated control group
² vehicle treated control group

Note: Organ weights were obtained for all the animals sacrificed at Week 78. However, final body weights were not measured for the animals implanted with the osmotic pumps (5 animals/group).

0054

TABLE 12
 TRISTHYLENE GLYCOL DIACRYLATE (TREGDA): CHRONIC DERMAL
 BIOASSAY IN C3H/HEMISD MALE MICE
 SUMMARY OF ORGAN WEIGHTS AS % OF BRAIN WEIGHT
 ANIMALS SACRIFICED AT WEEK 78

		TREGDA MALES				
GROUP: %	0.0 ^a	0.0 ^a	0.05	0.10	0.50	
LIVER						
MEAN	462.219	610.383 ^a	517.161	464.189 ^c	444.082 ^d	
S.D.	192.8142	346.8361	261.6523	195.3923	135.4853	
N	40	39	44	41	39	
KIDNEYS						
MEAN	180.344	177.262	180.900	176.043	179.247	
S.D.	15.8924	20.1283	20.7945	19.6257	15.9054	
N	40	39	44	41	39	
SPLEEN						
MEAN	23.374	23.729	21.784	20.979	21.386	
S.D.	18.8293	12.0520	11.1277	8.7382	10.4163	
N	40	39	44	41	39	
TESTES						
MEAN	15.696	16.033	15.259	15.014	16.452	
S.D.	4.0124	4.7422	4.8805	5.2126	4.7810	
N	40	39	44	41	39	

^a Significantly different from the untreated control group (p<.05)
^c Significantly different from the vehicle treated control group (p<.05)
^d Significantly different from the vehicle treated control group (p<.01)
^a untreated control group
^c vehicle treated control group

Note: Organ weights were obtained for all the animals sacrificed at Week 78. However, final body weights were not measured for the animals implanted with the osmotic pumps (5 animals/group).

0055

TABLE 13
 TRINITYLENE GLYCOL DIACRYLATE (TRNDA): CHRONIC DERMAL
 STASSAY IN C57/BL6ND MALE MICE
 SUMMARY OF NECROPSY OBSERVATIONS

ANIMALS SACRIFICED AT WEEK 4
 MALES

	GROUP:	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP		70	70	70	70	70
NUMBER OF ANIMALS SACRIFICED		5	5	5	5	5
ADIPOSE TISSUE HEMORRHAGE		0	0	0	0	1
STOMACH DIVERTICULUM		1	0	0	0	0
SKIN, TREATED EXFOLIATION		0	0	0	3	3
KIDNEYS DILATED PELVIS		1	0	0	0	0

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 0.05%, 4 is 0.10%, 5 is 0.50%

00055

TABLE 14
 TRIETHYLENE GLYCOL DIACRYLATE (TEGDMA): CHRONIC DERMAL
 BIOASSAY IN C3H/HEBISD MALE MICE
 SUMMARY OF NECROPSY OBSERVATIONS

ANIMALS SACRIFICED AT WEEK 13
 MALES

	GROUP:	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP		70	70	70	70	70
NUMBER OF ANIMALS SACRIFICED		5	5	5	5	5
SKIN, TREATED						
EXFOLIATION		0	0	0	0	1
SKIN						
ALOPECIA		0	0	1	1	0
KIDNEYS						
DILATED PELVIS		2	2	0	3	4
GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 0.05%, 4 is 0.10%, 5 is 0.50%						

TABLE 15
 TRISTYRENE GLYCOL DIACRYLATE (TREGDA): CHRONIC DERMAL
 BIOASSAY IN C57BL/6J MALE MICE
 SUMMARY OF NECROPSY OBSERVATIONS

ANIMALS SACRIFICED AT WEEK 52
 MALES

	GROUP:	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP		70	70	70	70	70
NUMBER OF ANIMALS SACRIFICED		5	4	4	4	4
PERITONEAL CAV						
HEMORRHAGE		0	0	0	1	0
LIVER						
COLOR CHANGE, FOCAL/MULTIFOCAL MASS		1	0	3	0	0
COLOR CHANGE, DIFFUSE MODULE		1	1	1	2	1
		0	1	0	0	0
		0	0	1	1	2
GALLBLADDER						
SIZE DECREASE		1	0	0	0	0
ADRENAL GL						
COLOR CHANGE, FOCAL/MULTIFOCAL		2	4	3	2	4
SKIN, TREATED						
EXFOLIATION		0	0	0	1	2
SKIN						
ALOPECIA		1	0	1	2	0
SPLEEN						
SIZE INCREASE		0	0	0	1	0
LYMPH ND, MES						
COLOR CHANGE, DIFFUSE		1	0	2	0	0
CYST		2	1	0	1	0
COLOR CHANGE, FOCAL/MULTIFOCAL		0	0	1	0	0
THYMIC REGION						
COLOR CHANGE, FOCAL/MULTIFOCAL		1	0	0	0	0
LUNGS						
COLOR CHANGE, FOCAL/MULTIFOCAL		2	0	1	0	0
COLOR CHANGE, DIFFUSE		0	1	0	0	0
KIDNEYS						
DILATED PELVIS		1	3	0	3	2
CONTENTS ABNORMAL		0	0	0	1	0
SIZE INCREASE		0	1	0	2	2
SHAPE/CONTOUR CHANGE		1	0	0	0	0

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 0.05%, 4 is 0.10%, 5 is 0.50%

00518

TABLE 16
 TRIETHYLENE GLYCOL DIACRYLATE (TEGDMA): CHRONIC DERMAL
 BIOASSAY IN C58/HEBRED MALE MICE
 SUMMARY OF NECROPSY OBSERVATIONS

ANIMALS SACRIFICED AT WEEK 78
 MALES

	GROUP:				
	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP	70	70	70	70	70
NUMBER OF ANIMALS SACRIFICED	40	39	44	41	39
TOTAL BODY					
STAINED	1	0	1	0	4
CLIPPING INJURY	1	0	0	0	0
ADIPOSE TISSUE					
NODULE	0	0	0	1	0
HEART					
SIZE INCREASE	1	0	1	3	1
COLOR CHANGE, FOCAL/MULTIFOCAL	0	0	1	1	1
CONSISTENCY CHANGE	0	0	0	0	1
DILATATION/DISTENTION	0	0	0	0	1
SALIVARY GL					
EDEMA	0	0	0	1	0
STOMACH					
DIVERTICULUM	0	0	0	0	1
COLOR CHANGE, FOCAL/MULTIFOCAL	0	0	0	0	1
CONTENTS ABNORMAL	0	1	0	0	0
GASEOUS	0	0	1	0	0
LIVER					
COLOR CHANGE, FOCAL/MULTIFOCAL	9	5	8	9	10
MASS	19	26	19	20	13
COLOR CHANGE, DIFFUSE	1	0	0	0	1
NODULE	7	10	8	8	4
ANOMALY	0	0	0	2	1
ADHESION	0	0	0	0	1
SURF. CH. CHANGE	0	0	2	1	1
CYST	0	1	0	0	1
GALLBLADDER					
SIZE DECREASE	0	1	0	0	0
SIZE INCREASE	0	0	2	0	1
COLON					
GASEOUS	0	0	0	0	1
RECTUM					
NODULE	0	0	0	0	1
THYROID GL					
SIZE INCREASE	0	0	1	0	0
SIZE DECREASE	1	1	0	0	0
COLOR CHANGE, FOCAL/MULTIFOCAL	1	0	0	0	0
ADRENAL GL					
COLOR CHANGE, FOCAL/MULTIFOCAL	33	31	38	39	33
SIZE INCREASE	1	2	2	4	1
COLOR CHANGE, DIFFUSE	1	1	0	0	0
CYST	3	2	2	1	3
MASS	1	0	0	1	0

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 0.05%, 4 is 0.10%, 5 is 0.50%

TABLE 16 (Continued)
 TRIETHYLENE GLYCOL DIACRYLATE (TRIGDA): CHRONIC DERMAL
 BIOASSAY IN C57BL/6J MALE MICE
 SUMMARY OF NECROPSY OBSERVATIONS

ANIMALS SACRIFICED AT WEEK 78
 MALES

	GROUP:	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP		70	70	70	70	70
NUMBER OF ANIMALS SACRIFICED		40	39	44	41	39
SKIN, TREATED						
EXFOLIATION		6	10	18	21	39
EROSION		2	4	4	1	0
ERYTHEMA		0	0	1	0	1
ULCERATED		0	1	2	0	0
CRUST/SCAB/SCALE		1	0	0	0	0
SKIN						
CRUST/SCAB/SCALE		1	0	0	0	0
ALOPECIA		12	14	20	14	12
EROSION		1	2	2	0	1
ABSCESS		5	5	7	4	13
ULCERATED		1	0	0	0	3
HEMORRHAGE		0	0	0	1	0
COLOR CHANGE, DIFFUSE		0	0	1	0	0
PREPUTIAL GLAND, SIZE INCREASE		2	1	0	1	0
SWOLLEN		0	0	0	0	1
SUBCUTIS						
MASS		1	0	0	0	0
SPLLEN						
SIZE DECREASE		4	2	0	2	4
SIZE INCREASE		2	9	5	3	1
SWOLLEN		1	0	0	1	1
SHAPE/CONTOUR CHANGE		0	0	0	1	1
COLOR CHANGE, FOCAL/MULTIFOCAL		2	1	0	0	0
LYMPH ND, S-MAN						
COLOR CHANGE, DIFFUSE		1	0	0	0	0
LYMPH ND, MES						
COLOR CHANGE, DIFFUSE		0	1	2	1	2
CYST		3	4	2	1	4
COLOR CHANGE, FOCAL/MULTIFOCAL		7	5	7	8	9
LYMPH ND, OTHER						
SIZE INCREASE		2	0	0	1	0
COLOR CHANGE, DIFFUSE		1	0	0	1	0
THYMIC REGION						
MASS		0	0	0	1	0
BONE/JOINT						
NODULE		0	0	0	1	0
BONE, STERNUM						
COLOR CHANGE, FOCAL/MULTIFOCAL		1	0	0	1	0
BONE MARROW						
COLOR CHANGE, DIFFUSE		1	0	0	0	0
SKELETAL MUSCLE						
ATROPHY		0	0	1	0	0

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 0.05%, 4 is 0.10%, 5 is 0.50%

TABLE 16 (Continued)
 TRIETHYLENE GLYCOL DIACRYLATE (TEGDA): CHRONIC DERMAL
 BIOASSAY IN C3H/HEBRED MALE MICE
 SUMMARY OF MICROPSY OBSERVATIONS

ANIMALS SACRIFICED AT WEEK 78
 MALES

	GROUP:	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP		70	70	70	70	70
NUMBER OF ANIMALS SACRIFICED		40	39	44	41	39
BRAIN						
MENINGEAL HEMORRHAGE		0	0	0	1	0
COLOR CHANGE, FOCAL/MULTIFOVAL		6	0	0	1	0
EYE						
OPACITY		3	0	0	0	0
HARDERIAN GL						
SIZE DECREASE		3	3	3	2	4
TESTES						
SIZE DECREASE		32	26	37	32	30
CONSISTENCY CHANGE		2	2	4	6	5
COLOR CHANGE, DIFFUSE		1	1	3	1	2
COLOR CHANGE, FOCAL/MULTIFOVAL		2	4	1	1	0
EPIDIDYMIDES						
SIZE DECREASE		1	1	0	1	0
COLOR CHANGE, FOCAL/MULTIFOVAL		0	0	0	1	0
SEMINAL VESICLE						
SIZE DECREASE		2	2	0	0	1
SIZE INCREASE		1	0	1	0	3
COLOR CHANGE, FOCAL/MULTIFOVAL		0	1	1	0	0
COLOR CHANGE, DIFFUSE		1	1	0	0	1
PROSTATE						
SIZE DECREASE		1	0	0	0	0
PENIS						
SWOLLEN		0	0	1	1	1
PARAPHIMOSIS		2	9	3	3	3
LUNGS						
COLOR CHANGE, FOCAL/MULTIFOVAL		2	3	5	1	1
COLOR CHANGE, DIFFUSE		1	5	3	0	1
HYPERINFLATION		0	2	2	0	0
MODULE		2	3	2	1	3
MASS		1	0	0	0	0
KIDNEYS						
DILATED PELVIS		12	7	11	11	9
CONTENTS ABNORMAL		1	0	1	1	0
COLOR CHANGE, FOCAL/MULTIFOVAL		5	4	3	5	1
COLOR CHANGE, DIFFUSE		0	1	0	0	0
SIZE INCREASE		1	1	2	2	0
SIZE DECREASE		0	1	0	0	0
SHAPE/CONTOUR CHANGE		0	1	0	0	0
SURFACE CHANGE		1	0	0	0	0
CYST		1	1	0	0	0
DEPRESSION/INDENTATION		3	5	2	3	3
URETER						
DILATATION/DISTENTION		2	3	3	3	4

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 0.05%, 4 is 0.10%, 5 is 0.50%

TABLE 16 (Continued)
 TRISTYLLINE GLYCOL DIACRYLATE (TRIGDA): CHRONIC DERMAL
 BIOASSAY IN C3H/HEMISP MALE MICE
 SUMMARY OF NECROPSY OBSERVATIONS

ANIMALS SACRIFICED AT WEEK 78
 MALES

	GROUP:	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP		70	70	70	70	70
NUMBER OF ANIMALS SACRIFICED		40	39	44	41	39
URINARY BLADDER						
DILATATION/DISTENTION		6	5	3	5	4
CONTENTS ABNORMAL		0	1	0	0	0
THICKER THAN NORMAL		0	1	0	0	0

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 0.05%, 4 is 0.10%, 5 is 0.50%

0062

TABLE 17
 TRIS(2-HYDROXYETHYL)AMMONIUM METHACRYLATE (TRIS(2-HEMA)): CHRONIC DERMAL
 BIOASSAY IN C3H/HEMISP MALE MICE
 SUMMARY OF NECROPSY OBSERVATIONS

ALL ANIMALS FOUND DEAD/SACRIFICED MORIBUND
 MALES

GROUP:	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP	70	70	70	70	70
NUMBER OF ANIMALS FOUND DEAD/SACRIFICED MORIBUND	15	17	12	15	17
TOTAL BODY					
POSTMORTEM CHANGE	2	6	4	4	7
EMACIATION	5	6	1	5	3
STAINED	6	3	4	8	5
CLIPPING INJURY	1	0	0	0	0
UNWEIGHT	2	0	1	1	0
PARALYSIS	1	0	0	0	0
ADIPOSE TISSUE					
CONSISTENCY CHANGE	0	0	1	0	0
PERITONEAL CAV					
HEMORRHAGE	2	2	0	3	0
FLUID	1	0	1	0	0
THORACIC CAV					
FLUID	0	1	1	1	0
HEMORRHAGE	1	0	0	0	0
HEART					
SIZE INCREASE	1	4	0	1	3
COLOR CHANGE, FOCAL/MULTIFOCAL	1	3	0	1	1
CONSISTENCY CHANGE	0	2	0	1	0
SALIVARY GL					
EDEMA	1	0	0	0	0
ESOPHAGUS					
DILATATION/DISTENTION	0	1	0	0	1
STOMACH					
COLOR CHANGE, FOCAL/MULTIFOCAL	3	3	3	1	0
CONTENTS ABNORMAL	1	4	2	1	1
HEMORRHAGE	1	1	0	0	0
LIVER					
COLOR CHANGE, FOCAL/MULTIFOCAL	7	2	2	3	4
MASS	10	13	7	12	7
COLOR CHANGE, DIFFUSE	1	1	0	3	0
SIZE DECREASE	1	2	1	0	0
SIZE INCREASE	1	0	0	1	0
ABNORMAL	0	2	0	2	0
ADHESION	0	1	0	0	0
GALLBLADDER					
SIZE DECREASE	1	3	1	2	3
UNIDENTIFIABLE	0	0	3	0	1
CONTENTS ABNORMAL	2	0	1	1	0
DUODENUM					
ADHESION	0	0	1	0	0
MASS	1	0	0	0	0
DILATATION/DISTENTION	0	1	0	0	0

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 0.05%, 4 is 0.10%, 5 is 0.50%

00068

TABLE 17 (Continued)
 TRIETHYLENE GLYCOL DIACRYLATE (TRGDGA): CHRONIC DERMAL
 BIOASSAY IN C57BL/6J MALE MICE
 SUMMARY OF NECROPSY OBSERVATIONS

ALL ANIMALS FOUND DEAD/SACRIFICED MORIBUND
 MALES

	GROUP:	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP		70	70	70	70	70
NUMBER OF ANIMALS FOUND DEAD/SACRIFICED MORIBUND		15	17	12	15	17
JEJUNUM						
CONTENTS ABNORMAL		1	0	0	0	0
MASS		0	0	0	1	0
CECUM						
ADHESION		1	0	0	0	0
DILATATION/DISTENTION		0	0	0	1	0
THICKER THAN NORMAL		0	0	0	1	0
COLON						
DIVERTICULUM		0	0	1	0	0
RECTUM						
PROLAPSE		0	0	1	0	0
PITUITARY						
SWOLLEN		2	0	0	0	0
COLOR CHANGE, DIFFUSE		1	2	1	0	0
THYROID GL						
SIZE INCREASE		0	1	1	0	1
ADRENAL GL						
POSTMORTEM CHANGE		0	1	1	0	0
COLOR CHANGE, FOCAL/MULTIFOCAL		11	10	7	12	6
SIZE INCREASE		1	2	0	0	0
COLOR CHANGE, DIFFUSE		1	0	0	0	0
SKIN, TREATED						
EXFOLIATION		4	4	6	7	15
EXCORIATION		1	0	0	1	1
MASS		0	1	0	0	0
SKIN						
CRACK/SCAB/SCALE		1	3	0	0	0
ALOPECIA		3	5	7	5	2
EXCORIATION		0	0	1	0	0
ABSCESS		3	3	1	2	0
MOULE		0	0	0	0	1
ULCERATED		0	1	0	1	0
HEAD						
TRAUMATIZED		0	1	0	0	0
HEMORRHAGE		1	0	0	0	0
SPLLEN						
SIZE DECREASE		2	5	2	3	3
SIZE INCREASE		2	3	2	5	3
SWOLLEN		3	1	1	3	1
LYMPH ND, S-MAN						
COLOR CHANGE, DIFFUSE		0	0	1	0	0
LYMPH ND, MED						
SIZE DECREASE		0	1	0	0	0
GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 0.05%, 4 is 0.10%, 5 is 0.50%						

00064

TABLE 17 (Continued)
 TRIETHYLENE GLYCOL DIACRYLATE (TEGDMA): CHRONIC DERMAL
 BIOASSAY IN C3H/HEBRED MALE MICE
 SUMMARY OF NECROPSY OBSERVATIONS

ALL ANIMALS FOUND DEAD/SACRIFICED MORIBUND
 MALES

	GROUP:				
	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP	70	70	70	70	70
NUMBER OF ANIMALS FOUND DEAD/SACRIFICED MORIBUND	15	17	12	15	17
LYMPH NO. MES					
COLOR CHANGE, DIFFUSE	0	0	0	1	0
COLOR CHANGE, FOCAL/MULTIFOCAL	2	0	0	0	0
POSTMORTEM CHANGE	0	0	1	0	0
SIZE DECREASE	3	2	1	0	3
MASS	1	0	0	0	0
SIZE INCREASE	0	0	0	1	0
LYMPH NO. REN					
SIZE INCREASE	0	1	0	0	0
LYMPH NO. OTHER					
SIZE INCREASE	0	1	0	3	0
THYMIC REGION					
MASS	0	0	1	0	0
BONE, STERNUM					
COLOR CHANGE, FOCAL/MULTIFOCAL	0	0	0	0	1
NODULE	0	1	0	1	2
SKELTAL MUSCLE					
ATROPHY	2	1	1	2	3
MASS	1	0	0	0	0
BRAIN					
HEMORRHAGE	3	2	1	0	1
CONSISTENCY CHANGE	0	0	1	1	1
POSTMORTEM CHANGE	0	1	1	0	1
MEMBRANAL HEMORRHAGE	0	2	1	0	0
COLOR CHANGE, FOCAL/MULTIFOCAL	0	1	0	0	0
EYE					
OPACITY	1	0	0	0	0
PAROTIDIAN GL					
SIZE DECREASE	2	1	0	0	0
COLOR CHANGE, DIFFUSE	0	0	1	0	0
TESTES					
SIZE DECREASE	9	15	2	11	9
CONSISTENCY CHANGE	2	2	1	0	1
COLOR CHANGE, DIFFUSE	2	0	0	0	1
EPIDIDYMIDES					
SIZE DECREASE	2	2	0	0	2
SEMINAL VESICLE					
SIZE DECREASE	3	5	0	1	4
SIZE INCREASE	0	1	0	1	1
ABSCISS	0	1	0	0	0
PENIS					
SWOLLEN	1	0	0	0	2

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 0.05%, 4 is 0.10%, 5 is 0.50%

TABLE 17 (Continued)
 TRIBUTYLENE GLYCOL DIACRYLATE (TRIGDA): CHRONIC DERMAL
 EXPOSURE IN C58/WHISED MALE MICE
 SUMMARY OF NECROPSY OBSERVATIONS

ALL ANIMALS FOUND DEAD/SACRIFICED MORIBUND
 MALES

	GROUP:	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP		70	70	70	70	70
NUMBER OF ANIMALS FOUND DEAD/SACRIFICED MORIBUND		15	17	12	15	17
FEMIS (CONTINUED)						
PARAFFINOSIS		5	11	6	7	4
ULCERATED		1	4	4	3	1
CONTENTS ABNORMAL		0	2	0	0	0
TRACHEA						
CONTENTS ABNORMAL		0	1	0	0	0
LUNGS						
COLOR CHANGE, FOCAL/MULTIFOCAL		2	5	3	2	3
COLOR CHANGE, DIFFUSE		5	6	5	6	5
HYPERINFLATION		1	0	1	2	2
NODULE		1	1	0	0	1
MASS		0	0	0	1	0
TRAUMATIZED		1	0	0	0	0
CONSISTENCY CHANGE		0	0	0	1	0
KIDNEYS						
DILATED PELVIS		6	11	3	2	4
NODULE		1	1	1	0	2
CONTENTS ABNORMAL		1	4	1	3	3
COLOR CHANGE, FOCAL/MULTIFOCAL		3	4	1	4	2
COLOR CHANGE, DIFFUSE		0	2	2	3	1
SIZE INCREASE		4	5	2	3	2
SIZE DECREASE		1	5	1	2	3
ADHESION		0	1	1	0	1
SHAPE/CONTOUR CHANGE		0	1	0	1	1
GRANULAR		0	3	0	0	2
SURFACE CHANGE		1	0	0	0	1
CYST		0	1	0	1	0
URTER						
DILATATION/DISTENTION		2	4	1	3	3
CONTENTS ABNORMAL		1	1	0	1	0
URINARY BLADDER						
CALCULUS		0	1	0	1	2
HEMORRHAGE		0	0	1	0	0
CYST		1	0	0	0	0
DILATATION/DISTENTION		2	3	0	1	2
CONTENTS ABNORMAL		1	3	1	1	0
THICKER THAN NORMAL		0	2	0	1	0

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 0.05%, 4 is 0.10%, 5 is 0.50%

0066

TABLE 19
 TRIETHYLENE GLYCOL DIACRYLATE (TRIGDA): CHRONIC DERMAL
 BIOASSAY IN C3H/HEBESD MALE MICE
 SUMMARY OF NECROPSY OBSERVATIONS

DATA FOR ALL ANIMALS ON STUDY
 MALES

	GROUP:	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP		70	70	70	70	70
NUMBER OF ANIMALS		70	70	70	70	70
TOTAL BODY						
POSTMORTEM CHANGE		2	6	4	4	7
EMACIATION		5	6	1	5	3
STAINED		7	3	5	8	9
CLIPPING INJURY		2	0	0	0	0
UNSCRYPT		2	0	1	1	0
PARALYSIS		1	0	0	0	0
ADIPOSE TISSUE						
HEMORRHAGE		0	0	0	0	1
CONSISTENCY CHANGE		0	0	1	0	0
MODULE		0	0	0	1	0
PERITONEAL CAV						
HEMORRHAGE		2	2	0	4	0
FLUID		1	0	1	0	0
THORACIC CAV						
FLUID		0	1	1	1	0
HEMORRHAGE		1	0	0	0	0
HEART						
SIZE INCREASE		2	4	1	4	4
COLOR CHANGE, FOCAL/MULTIFOCAL		1	3	1	2	2
CONSISTENCY CHANGE		0	2	0	1	1
DILATATION/DISTENTION		0	0	0	0	1
SALIVARY GL						
EDEMA		1	0	0	1	0
ESOPHAGUS						
DILATATION/DISTENTION		0	1	0	0	1
STOMACH						
DIVERTICULUM		1	0	0	0	1
COLOR CHANGE, FOCAL/MULTIFOCAL		3	3	3	1	1
CONTENT'S ABNORMAL		1	5	2	1	1
HEMORRHAGE		1	1	0	0	0
GASTOUS		0	0	1	0	0
LIVER						
COLOR CHANGE, FOCAL/MULTIFOCAL		17	7	13	12	14
MASS		30	40	27	34	21
COLOR CHANGE, DIFFUSE		2	2	0	3	1
MODULE		7	10	9	9	6
SIZE DECREASE		1	2	1	0	0
SIZE INCREASE		1	0	0	1	0
ABNORMAL		0	2	0	4	1
ADHESION		0	1	0	0	1
SURFACE CHANGE		0	0	2	1	1
CYST		0	1	0	0	1
GALLBLADDER						
SIZE DECREASE		2	4	1	2	3

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 0.05%, 4 is 0.10%, 5 is 0.50%

TABLE 18 (Continued)
 TRIETHYLENE GLYCOL DIACRYLATE (TRGD): CHRONIC DERMAL
 BIOASSAY IN C57BL/6J MALE MICE
 SUMMARY OF NECROPSY OBSERVATIONS

DATA FOR ALL ANIMALS ON STUDY
 MALES

	GROUP:	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP		70	70	70	70	70
NUMBER OF ANIMALS		70	70	70	70	70
GALLBLADDER (CONTINUED)						
UNIDENTIFIABLE		0	0	3	0	1
CONTENTS ABNORMAL		2	0	1	1	0
SIZE INCREASE		0	0	2	0	1
DUODENUM						
ADHESION		0	0	1	0	0
MASS		1	0	0	0	0
DILATATION/DISTENTION		0	1	0	0	0
JEJUNUM						
CONTENTS ABNORMAL		1	0	0	0	0
MASS		0	0	0	1	0
CECUM						
ADHESION		1	0	0	0	0
DILATATION/DISTENTION		0	0	0	1	0
THICKER THAN NORMAL		0	0	0	1	0
COLON						
DIVERTICULUM		0	0	1	0	0
GASBOUS		0	0	0	0	1
RECTUM						
PROLAPSE		0	0	1	0	0
MODULE		0	0	0	0	1
PITUITARY						
SWOLLEN		2	0	0	0	0
COLOR CHANGE, DIFFUSE		1	2	1	0	0
THYROID GL						
SIZE INCREASE		0	1	2	0	1
SIZE DECREASE		1	1	0	0	0
COLOR CHANGE, FOCAL/MULTIFOCAL		1	0	0	0	0
ADRENAL GL						
POSTMORTEM CHANGE		0	1	1	0	0
COLOR CHANGE, FOCAL/MULTIFOCAL		46	45	48	53	43
SIZE INCREASE		2	4	2	4	1
COLOR CHANGE, DIFFUSE		2	1	0	0	0
CYST		3	2	2	1	3
MASS		1	0	0	1	0
SKIN, TREATED						
EXFOLIATION		10	14	24	32	60
EXCORIATION		3	4	4	2	1
MASS		0	1	0	0	0
ERYTHEMA		0	0	1	0	1
ULCERATED		0	1	2	0	0
CRUST/SCAB/SCALE		1	0	0	0	0
SKIN						
CRUST/SCAB/SCALE		2	3	0	0	0

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 0.05%, 4 is 0.10%, 5 is 0.50%

0068

TABLE 18 (Continued)
 TRIETHYLENE GLYCOL DIACRYLATE (TEGDMA): CHRONIC DERMAL
 BIOASSAY IN C3H/HEMISD MALE MICE
 SUMMARY OF NECROPSY OBSERVATIONS

DATA FOR ALL ANIMALS ON STUDY
 MALES

	GROUP:	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP		70	70	70	70	70
NUMBER OF ANIMALS		70	70	70	70	70
SKIN (CONTINUED)		16	19	29	22	14
ALOPECIA		1	2	3	0	1
EXCORIATION		8	8	8	6	13
ABSCESS		0	0	0	0	1
MODULE		1	1	0	1	3
ULCERATED		0	0	0	1	0
HEMORRHAGE		0	0	1	0	0
COLOR CHANGE, DIFFUSE		2	1	0	1	0
PREPUTIAL GLAND, SIZE INCREASE		0	0	0	0	1
SWOLLEN						
SUBCUTIS		1	0	0	0	0
MASS						
HEAD		0	1	0	0	0
TRAUMATIZED		1	0	0	0	0
HEMORRHAGE						
SPLEEN		6	7	2	5	7
SIZE DECREASE		4	12	7	9	4
SIZE INCREASE		4	1	1	4	2
SWOLLEN		0	0	0	1	1
SHAPE, CONTOUR CHANGE		2	1	0	0	0
COLOR CHANGE, FOCAL/MULTIFOVAL						
LYMPH ND, S-MAN		1	0	1	0	0
COLOR CHANGE, DIFFUSE						
LYMPH ND, MED		0	1	0	0	0
SIZE DECREASE						
LYMPH ND, MES		1	1	4	2	2
COLOR CHANGE, DIFFUSE		5	5	2	2	4
CYST		9	5	8	8	9
COLOR CHANGE, FOCAL/MULTIFOVAL		0	0	1	0	0
POSTMORTEM CHANGE		3	2	1	0	3
SIZE DECREASE		1	0	0	0	0
MASS		0	0	0	1	0
SIZE INCREASE						
LYMPH ND, REN		0	1	0	0	0
SIZE INCREASE						
LYMPH ND, OTHER		2	1	0	4	0
SIZE INCREASE		1	0	0	1	0
COLOR CHANGE, DIFFUSE						
THYMIC REGION		1	0	0	0	0
COLOR CHANGE, FOCAL/MULTIFOVAL		0	0	1	1	0
MASS						
BONE/JOINT		0	0	0	1	0
MODULE						

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 0.05%, 4 is 0.10%, 5 is 0.50%

0059

TABLE 18 (Continued)
 TRIPHENYLENE GLYCOL DIACRYLATE (TRIGDA): CHRONIC DERMAL
 BIOASSAY IN C57/BL6J6 MALE MICE
 SUMMARY OF NECROPSY OBSERVATIONS

DATA FOR ALL ANIMALS ON STUDY
 MALES

	GROUP:				
	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP	70	70	70	70	70
NUMBER OF ANIMALS	70	70	70	70	70
BONE, STERNUM					
COLOR CHANGE, FOCAL/MULTIFOCAL	1	0	0	1	1
NODULE	0	1	0	1	2
BONE MARROW					
COLOR CHANGE, DIFFUSE	1	0	0	0	0
SKELTAL MUSCLE					
ATROPHY	2	1	2	2	3
MASS	1	0	0	0	0
BRAIN					
HEMORRHAGE	3	2	1	0	1
CONSISTENCY CHANGE	0	0	1	1	1
POSTMORTEM CHANGE	0	1	1	0	1
MEMINGEAL HEMORRHAGE	0	2	1	1	0
COLOR CHANGE, FOCAL/MULTIFOCAL	0	1	0	1	0
EYE					
OPACITY	4	0	0	0	0
THYROID GL					
SIZE DECREASE	5	4	3	2	4
COLOR CHANGE, DIFFUSE	0	0	1	0	0
TESTES					
SIZE DECREASE	41	41	39	43	39
CONSISTENCY CHANGE	4	4	5	6	6
COLOR CHANGE, DIFFUSE	3	1	3	1	3
COLOR CHANGE, FOCAL/MULTIFOCAL	2	4	1	1	0
EPIDIDYMIDES					
SIZE DECREASE	3	3	0	1	2
COLOR CHANGE, FOCAL/MULTIFOCAL	0	0	0	1	0
SEMINAL VESICLE					
SIZE DECREASE	3	7	0	1	5
SIZE INCREASE	1	1	1	1	4
ABSCESS	0	1	0	0	0
COLOR CHANGE, FOCAL/MULTIFOCAL	0	1	1	0	0
COLOR CHANGE, DIFFUSE	1	1	0	0	1
PROSTATE					
SIZE DECREASE	1	0	0	0	0
PENIS					
SWOLLEN	1	0	1	1	3
PARAPHIMOSIS	7	20	9	10	7
ULCERATED	1	4	4	3	1
CONTENTS ABNORMAL	0	2	0	0	0
TRACHEA					
CONTENTS ABNORMAL	0	1	0	0	0

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 0.05%, 4 is 0.10%, 5 is 0.50%

TABLE 18 (Continued)
 TRIETHYLENE GLYCOL DIACRYLATE (TRGDGA): CHRONIC DERMAL
 BIOASSAY IN C3H/HEBRED MALE MICE
 SUMMARY OF NECROPSY OBSERVATIONS

DATA FOR ALL ANIMALS ON STUDY
 MALES

	GROUP:				
	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP	70	70	70	70	70
NUMBER OF ANIMALS	70	70	70	70	70
LUNGS					
COLOR CHANGE, FOCAL/MULTIFOCAL	6	8	9	3	4
COLOR CHANGE, DIFFUSE	6	12	8	6	6
HYPERINFLATION	1	2	3	2	2
NOOULE	3	4	2	1	4
MASS	1	0	0	1	0
TRAUMATIZED	1	0	0	0	0
CONSISTENCY CHANGE	0	0	0	1	0
KIDNEYS					
DILATED PELVIS	22	23	14	19	19
NOOULE	1	1	1	0	2
CONTENTS ABNORMAL	2	4	2	5	3
COLOR CHANGE, FOCAL/MULTIFOCAL	8	8	4	9	3
COLOR CHANGE, DIFFUSE	0	3	2	3	1
SIZE INCREASE	5	7	4	7	4
SIZE DECREASE	1	6	1	2	3
ADHESION	0	1	1	0	1
SHAPE/CONTOUR CHANGE	1	2	0	1	1
GRANULAR	0	3	0	0	2
SURFACE CHANGE	2	0	0	0	1
CYST	1	2	0	1	0
DEPRESSION/INDENTATION	3	5	2	3	3
URETER					
DILATATION/DISTENTION	4	7	4	6	7
CONTENTS ABNORMAL	1	1	0	1	0
URINARY BLADDER					
CALCULUS	0	1	0	1	2
HEMORRHAGE	0	0	1	0	0
CYST	1	0	0	0	0
DILATATION/DISTENTION	8	8	3	6	6
CONTENTS ABNORMAL	1	4	1	1	0
THICKER THAN NORMAL	0	3	0	1	0

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 0.05%, 4 is 0.10%, 5 is 0.50%

TABLE 19
 TRISHTYLENE GLYCOL DIACRYLATE (TRISDA): CHRONIC DERMAL
 BIOASSAY IN C57BL/6J MALE MICE
 SUMMARY OF MICROSCOPIC DIAGNOSES

ANIMALS SACRIFICED AT WEEK 78
 MALES

	GROUP:				
	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP	70	70	70	70	70
NUMBER OF ANIMALS SACRIFICED	40	39	44	41	39
ADIPOSE TISSUE					
TOTAL NUMBER EXAMINED	0	0	0	1	0
OB LIPOMA	-	-	-	1	-
MESENTERY/OM'TU.					
TOTAL NUMBER EXAMINED	0	0	0	0	1
PERIART/ITIS/ARTERITIS	-	-	-	-	1
MINERALIZATION	-	-	-	-	1
PERITONITIS	-	-	-	-	1
PERITONEUM					
TOTAL NUMBER EXAMINED	0	0	0	2	0
PERITONITIS	-	-	-	2	-
HEART					
TOTAL NUMBER EXAMINED	40	39	2	4	39
EXAMINED, UNREMARKABLE	10	12	0	0	10
ATRIAL THROMBOSIS	0	0	1	2	1
MYOCARDIAL MINERALIZATION	18	25	1	3	21
MYOCARDIAL DEGENERATION/FIBROSIS	30	15 ^b	1	3	24
OR HEMANGIOSARCOMA	0	1	0	0	0
AORTA					
TOTAL NUMBER EXAMINED	40	39	0	0	39
EXAMINED, UNREMARKABLE	40	38	-	-	38
MINERALIZATION	0	1	-	-	1
VASCULATURE					
TOTAL NUMBER EXAMINED	2	1	0	0	1
MINERALIZATION	2	1	-	-	1
SALIVARY GL.					
TOTAL NUMBER EXAMINED	40	39	0	1	39
EXAMINED, UNREMARKABLE	29	23	-	0	20
MINERALIZATION	1	0	-	0	1
LYMPHOCYTIC INFILTRATES	11	16	-	0	15
SIALOADENITIS	1	0	-	1	1
FIBROSIS	0	1	-	0	0
MYELOID INFILTRATES	1	0	-	0	0
HYPERPLASIA	0	0	-	0	1
DUCT HYPERPLASIA	0	0	-	0	3
ESOPHAGUS					
TOTAL NUMBER EXAMINED	40	39	0	0	39
EXAMINED, UNREMARKABLE	40	39	-	-	39

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 0.05%, 4 is 0.10%, 5 is 0.50%

§ = NEOPLASM, B = BENIGN, M = MALIGNANT
^b Significantly different from CONTROL group 1 (p < .01)

TABLE 19 (Continued)
 TRIETHYLENE GLYCOL DIACRYLATE (TEGDMA): CHRONIC DERMAL
 BIOASSAY IN C3H/HEBRED MALE MICE
 SUMMARY OF MICROSCOPIC DIAGNOSES

ANIMALS SACRIFICED AT WEEK 78
 MALES

GROUP:	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP	70	70	70	70	70
NUMBER OF ANIMALS SACRIFICED	40	39	44	41	39
STOMACH					
TOTAL NUMBER EXAMINED	40	39	44	41	39
EXAMINED, UNREMARKABLE	30	35	38	34	34
GLAND ECTASIA	2	3	2	2	4
GASTRITIS	10	3	3 ^a	3 ^a	4
ULCER/ULCERATION	0	0	1	2	0
LIVER					
TOTAL NUMBER EXAMINED	40	39	44	41	39
EXAMINED, UNREMARKABLE	10	9	20	10	15
ANOMALOUS LOBULATION	0	5 ^a	0 ^c	2	3
EXTRAMEDULLARY HEMATOPOIESIS	1	0	0	0	0
PELIOSIS/TELANGIECTASIS	0	1	0	0	0
PIGMENT GRANULOMA(S)	0	0	0	1	0
HEMOSIDEROSIS	0	0	0	0	3
MINERALIZATION	1	2	0	0	1
HEPATITIS	0	0	1	0	0
HEPATIC ABSCESS(ES)	0	1	0	0	0
ADHESION(S)	0	0	0	0	1
HEPATOCELLULAR NECROSIS	2	2	2	0	3
BILIARY CYST(S)	0	0	0	0	1
HEPATOCELLULAR HYPERPLASIA	8	5	4	2 ^a	6
#B HEPATOCELLULAR ADENOMA	22	19	16	23	12 ^a
#B HEPATOCELLULAR ADENOMA WITH CARCINOMA IN SITU	0	1	0	0	0
#M HEPATOCELLULAR CARCINOMA	6	13	10	8	5
#M HEMANGIOSARCOMA	1	1	0	1	1
GALLBLADDER					
TOTAL NUMBER EXAMINED	37	34	2	0	38
EXAMINED, UNREMARKABLE	37	30	1	-	34
MISSING	3	5	0	-	1
DILATION	0	3	1	-	4
CYSTIC GLAND ECTASIA	0	1	0	-	0
PANCREAS					
TOTAL NUMBER EXAMINED	40	39	1	0	39
EXAMINED, UNREMARKABLE	40	39	1	-	38
HEMOSIDEROSIS	0	0	0	-	1
DUODENUM					
TOTAL NUMBER EXAMINED	40	39	0	0	39
EXAMINED, UNREMARKABLE	40	39	-	-	39
JEJUNUM					
TOTAL NUMBER EXAMINED	40	39	0	0	39
EXAMINED, UNREMARKABLE	40	39	-	-	39

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 0.05%, 4 is 0.10%, 5 is 0.50%

= NEOPLASM, B = BENIGN, M = MALIGNANT
^a Significantly different from CONTROL group 1 (p < .05)
^c Significantly different from CONTROL group 2 (p < .05)

TABLE 19 (Continued)
 TRIPHENYLENE GLYCOL DIACRYLATE (TRIGDA): CHRONIC DERMAL
 BIOASSAY IN C3H/HEWED MALE MICE
 SUMMARY OF MICROSCOPIC DIAGNOSES

ANIMALS SACRIFICED AT WEEK 78
 MALES

	GROUP:				
	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP	70	70	70	70	70
NUMBER OF ANIMALS SACRIFICED	40	39	44	41	39
ILEUM					
TOTAL NUMBER EXAMINED	40	39	0	0	39
EXAMINED, UNREMARKABLE	40	39	-	-	39
CECUM					
TOTAL NUMBER EXAMINED	40	39	0	0	39
EXAMINED, UNREMARKABLE	40	39	-	-	39
COLON					
TOTAL NUMBER EXAMINED	40	39	0	0	39
EXAMINED, UNREMARKABLE	39	39	-	-	38
MUCOSAL FIBROSIS	1	0	-	-	0
LYMPHOID HYPERPLASIA	0	0	-	-	1
RECTUM					
TOTAL NUMBER EXAMINED	40	39	0	0	39
EXAMINED, UNREMARKABLE	39	39	-	-	38
PROCTITIS	1	0	-	-	0
SM ROUND CELL CARCINOMA	0	0	-	-	1
PITUITARY					
TOTAL NUMBER EXAMINED	40	39	0	0	39
EXAMINED, UNREMARKABLE	37	35	-	-	39
CYST(S)	1	1	-	-	0
CYSTIC RATHKE'S CLEFT	2	3	-	-	0
THYROID GL					
TOTAL NUMBER EXAMINED	40	39	1	0	39
EXAMINED, UNREMARKABLE	13	14	0	-	12
THYROIDGLAND DUCT CYST	17	5b	0	-	2b
MINERALIZATION	0	0	0	-	1
COLLOID MINERALIZATION	2	0	0	-	0
COLLOID CRYSTALLIZATION	8	10	0	-	6
THYROIDITIS	1	0	0	-	1
GRANULOMATOUS THYROIDITIS	1	0	0	-	0
FOLLICULAR ECTASIA	4	6	1	-	7
FOLLICULAR CELL HYPERPLASIA/HYPERTROPHY	11	17	1	-	18
FB FOLLICULAR CELL ADENOMA	3	6	1	-	7
PARATHYROID GL					
TOTAL NUMBER EXAMINED	23	15	0	0	18
EXAMINED, UNREMARKABLE	23	15	-	-	18
MISSING	17	24	-	-	21

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 0.05%, 4 is 0.10%, 5 is 0.50%

b = NEOPLASM, B = BENIGN, M = MALIGNANT
 § Significantly different from CONTROL group 1 (p < .01)

0074

TABLE 19 (Continued)
 TRIETHYLENE GLYCOL DIACRYLATE (TEGDMA): CHRONIC DERMAL
 BIOASSAY IN C3H/HEWED MALE MICE
 SUMMARY OF MICROSCOPIC DIAGNOSES

ANIMALS SACRIFICED AT WEEK 78
 MALES

	GROUP:	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP		70	70	70	70	70
NUMBER OF ANIMALS SACRIFICED		40	39	44	41	39
ADRENAL GL						
TOTAL NUMBER EXAMINED		40	39	39	39	39
EXAMINED, UNREMARKABLE		1	0	0	0	0
VASCULAR ECTASIA		0	0	0	0	1
HEMOSIDEROSIS		0	0	0	1	0
CORTICAL CYST		6	5	3	6	2
CORTICAL CEROID DEGENERATION		28	29	30	30	31
CORTICAL CELL HYPERPLASIA		0	1	0	0	1
SPINDLE CELL HYPERPLASIA		39	39	38	39	39
NODULAR CORTICAL CELL HYPERPLASIA		35	38	35	39	36
SB ADENOMA		0	0	0	1	2
SKIN, TREATED						
TOTAL NUMBER EXAMINED		40	39	44	41	39
EXAMINED, UNREMARKABLE		27	14	21	4	0
EPIDERMAL SPONGIOSIS		0	0	0	0	2
ACANTHOSIS		6	9	14	32 ^{bd}	39 ^{bd}
HYPERKERATOSIS/PARA KERATOSIS		2	5	3	1 ^{bc}	39 ^{bd}
DERMATITIS		5	7	6	8	39 ^{bd}
INTRACORNEAL PUSTULE FORMATION		2	1	1	8 ^c	14 ^{bd}
SUBEPIDERMAL CLEFT/BULLA FORMATION		1	0	0	0	4
PIGMENTARY INCONTINENCE		0	0	0	0	39 ^{bd}
SUPERFICIAL EPIDERMAL NECROLYSIS		0	0	0	0	14 ^{bd}
BASAL ZONE EPIDERMAL NECROLYSIS		0	0	0	0	13 ^{bd}
FULL THICKNESS EPIDERMAL NECROLYSIS		0	0	0	0	1
ULCER/ULCERATION		0	2	2	1	3
MINERALIZATION		0	0	0	0	1
ADMEKAL ATROPHY		4	16 ^b	11	23 ^b	4 ^d
DERMAL FIBROSIS		1	1	1	2	3 ^{bd}
SKIN						
TOTAL NUMBER EXAMINED		40	39	43	41	39
EXAMINED, UNREMARKABLE		30	27	23	25	18
MISSING		0	0	1	0	0
ACANTHOSIS		3	5	6	5	8
VASCULAR ECTASIA		1	0	0	0	0
DERMATITIS		3	4	4	2	0
ULCER/ULCERATION		1	1	1	0	3
MINERALIZATION		0	0	1	1	0
CLITORAL/PREPUTIAL GLAND ABSCESS		0	1	1	3	7 ^b
CLITORAL/PREPUTIAL GLAND ADENITIS		6	4	10	6	7
CLITORAL/PREPUTIAL GLAND DUCT ECTASIA		0	8 ^b	7 ^a	5	9 ^b
ADMEKAL ATROPHY		3	2	9	10 ^c	7
SUBCUTIS						
TOTAL NUMBER EXAMINED		2	1	2	3	0

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 0.05%, 4 is 0.10%, 5 is 0.50%

‡ = NEOPLASM, B = BENIGN
^a Significantly different from CONTROL group 1 (p < .05)
^b Significantly different from CONTROL group 1 (p < .01)
^c Significantly different from CONTROL group 2 (p < .05)
^d Significantly different from CONTROL group 2 (p < .01)

TABLE 19 (Continued)
 TRIS(1-HYDROXYETHYL)AMMONIUM METHACRYLATE (TRISDMA): CHRONIC DERMAL
 BIOASSAY IN C57BL/6J MALE MICE
 SUMMARY OF MICROSCOPIC DIAGNOSES

ANIMALS SACRIFICED AT WEEK 70
 MALES

GROUP:	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP	70	70	70	70	70
NUMBER OF ANIMALS SACRIFICED	40	39	44	41	39
SUBCUTIS (CONTINUED)					
MINERALIZATION	1	0	0	0	-
PANICULITIS (UNDER TREATED SKIN)	0	1	2	3	-
SM HEMANGIOSARCOMA	1	0	0	0	-
SPLEEN					
TOTAL NUMBER EXAMINED	40	39	43	41	39
EXAMINED, UNREMARKABLE	28	23	33	21	29
EXTRAMEDULLARY HEMATOPOIESIS	7	15 ^a	10	17 ^a	6 ^c
SPLEENITIS	0	0	0	1	0
HEMOSIDEROSIS	1	0	0	0	1
CONGESTION	1	0	0	0	0
SINUSOID ECTASIA	0	0	0	2	1
FIBROSIS, CAPSULE	0	0	0	0	1
LYMPHOID HYPERPLASIA	2	2	0	0	2
SM MYELOSARCOMA	1	0	0	0	0
SM HEMANGIOSARCOMA	1	0	0	0	1
LYMPH NO, S-MAN					
TOTAL NUMBER EXAMINED	38	39	0	0	37
EXAMINED, UNREMARKABLE	32	36	-	-	28
MISSING	2	0	-	-	2
HEMOSIDEROSIS	4	1	-	-	8 ^c
SINUS HISTIOCYTOSIS	1	2	-	-	2
LYMPHOID HYPERPLASIA	1	0	-	-	0
EXTRAMEDULLARY HEMATOPOIESIS	1	0	-	-	0
LYMPH NO, MED					
TOTAL NUMBER EXAMINED	1	1	0	0	0
SINUS ERITROCYTOSIS	0	1	-	-	-
PIGMENT GRANULOMA(S)	1	0	-	-	-
LYMPH NO, MES					
TOTAL NUMBER EXAMINED	39	39	11	10	39
EXAMINED, UNREMARKABLE	17	22	0	0	18
MISSING	1	0	0	0	0
CYSTIC LYMPHATIC ECTASIA	7	8	5	3	8
SINUS ERITROCYTOSIS	6	4	7	8	7
HEMOSIDEROSIS	1	1	1	0	0
SINUS HISTIOCYTOSIS	1	1	3	0	2
PROTEIN DEPOSIT(S)	0	0	1	0	0
PIGMENT GRANULOMA(S)	12	7	3	1	10
EXTRAMEDULLARY HEMATOPOIESIS	0	0	0	1	0
SM MYELOSARCOMA	1	0	0	0	0
LYMPH NO, OTHER					
TOTAL NUMBER EXAMINED	2	0	0	1	0

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 0.05%, 4 is 0.10%, 5 is 0.50%

§ = NEOPLASM, M = MALIGNANT

^a Significantly different from CONTROL group 1 (p < .05)

^c Significantly different from CONTROL group 2 (p < .05)

0076

TABLE 19 (Continued)
 TRIETHYLENE GLYCOL DIACRYLATE (TEGDMA): CHRONIC DERMAL
 BIOASSAY IN C3H/HEBISD MALE MICE
 SUMMARY OF MICROSCOPIC DIAGNOSES

ANIMALS SACRIFICED AT WEEK 78
 MALES

	GROUP:	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP		70	70	70	70	70
NUMBER OF ANIMALS SACRIFICED		40	39	44	41	39
LYMPH ND, OTHER (CONTINUED)						
§M MYELOSARCOMA		1	-	-	0	-
§M HEMANGIOSARCOMA		1	-	-	1	-
THYMIC REGION						
TOTAL NUMBER EXAMINED		40	39	0	1	39
EXAMINED, UNREMARKABLE		30	33	-	0	27
THYMIC TISSUE NOT PRESENT		7	6	-	0	8
VASCULAR ECTASIA		0	0	-	0	-
INFLAMMATION, GRANULOMATOUS		0	0	-	1	0
EPITHELIAL CYST(S)		2	0	-	1	3
§M LYMPHOSARCOMA		0	0	-	1	0
§M MYELOSARCOMA		1	0	-	0	0
BONE/JOINT						
TOTAL NUMBER EXAMINED		40	39	0	1	39
EXAMINED, UNREMARKABLE		40	39	-	1	39
BONE, STERNUM						
TOTAL NUMBER EXAMINED		40	39	0	2	39
EXAMINED, UNREMARKABLE		28	32	-	2	24
CARTILAGE DEGENERATION		12	7	-	0	15
BONE, FEMUR						
TOTAL NUMBER EXAMINED		40	39	0	0	39
EXAMINED, UNREMARKABLE		40	39	-	-	39
BONE MARROW						
TOTAL NUMBER EXAMINED		40	39	0	0	39
EXAMINED, UNREMARKABLE		38	39	-	-	39
HYPERPLASIA		1	0	-	-	0
§M HEMANGIOSARCOMA		1	0	-	-	0
SKELETAL MUSCLE						
TOTAL NUMBER EXAMINED		40	39	1	0	39
EXAMINED, UNREMARKABLE		38	39	0	-	36
MINERALIZATION		0	0	0	-	3
ATROPHY		2	0	1	-	0
BRAIN						
TOTAL NUMBER EXAMINED		40	39	0	1	39
EXAMINED, UNREMARKABLE		3	6	-	0	10
MINERALIZATION		36	32	-	1	27 ^a

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 0.05%, 4 is 0.10%, 5 is 0.50%

§ = NEOPLASM, M = MALIGNANT

^a Significantly different from CONTROL group 1 (p < .05)

TABLE 19 (Continued)
 TRIETHYLENE GLYCOL SEACRYLATE (TEGDA): CHRONIC DERMAL
 BIOASSAY IN C57/BL6J MALE MICE
 SUMMARY OF MICROSCOPIC DIAGNOSES

ANIMALS SACRIFICED AT WEEK 78
 MALES

	GROUP:				
	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP	70	70	70	70	70
NUMBER OF ANIMALS SACRIFICED	40	39	44	41	39
BRAIN (CONTINUED)					
ENCEPHALOMALACIA	3	2	-	1	3
CORTICAL INFARCT	1	0	-	0	0
MEINGITIS	0	1	-	0	0
ENCEPHALITIS	1	0	-	0	2
NEUROFIL VACUOLATION	3	3	-	0	8
NEURON LOSS	1	0	-	0	0
GLIOSIS	0	0	-	0	1
SPINAL CORD					
TOTAL NUMBER EXAMINED	40	39	0	0	39
EXAMINED, UNREMARKABLE	38	24	-	-	25
VACUOLATION	1	1	-	-	2
MYELIN SHEATH SWELLING	1	15 ^b	-	-	12 ^b
NERVE FIBER DEGENERATION	0	1	-	-	0
NERVE, SCIATIC					
TOTAL NUMBER EXAMINED	40	39	0	0	39
EXAMINED, UNREMARKABLE	38	36	-	-	36
MYELIN SHEATH SWELLING	0	2	-	-	1
MYELIN DEGENERATION	2	1	-	-	3
EYE					
TOTAL NUMBER EXAMINED	40	39	0	0	39
OPTIC NEURITIS	0	1	-	-	0
CORNEAL MINERALIZATION	13	8	-	-	8
KERATITIS	1	0	-	-	0
CATARACT	1	0	-	-	0
RETINAL ATROPHY	40	39	-	-	39
ATROPHY, OCULAR MUSCLES	0	3	-	-	1
PHENISIS BULBI	1	0	-	-	0
MANDIBULAR GL					
TOTAL NUMBER EXAMINED	40	39	3	2	39
EXAMINED, UNREMARKABLE	36	36	1	2	33
LYMPHOCYTIC INFILTRATES	1	0	0	0	2
ADENITIS	2	2	1	0	4
ECTASIA	0	0	1	0	2
FIBROSIS	0	1	0	0	2
MINERALIZATION	1	0	0	0	0
FB ADHESION	1	0	0	0	0
TESTES					
TOTAL NUMBER EXAMINED	40	39	38	33	39
CYST(S)	0	0	0	0	1

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 0.05%, 4 is 0.10%, 5 is 0.50%

^b = NEOPLASM, B = LESION
^b Significantly different from CONTROL group 1 (p < .01)

TABLE 19 (Continued)
 TRISTYRENE GLYCOL DIACRYLATE (TRIGDA): CHRONIC DERMAL
 BIOASSAY IN C3H/HEBESD MALE MICE
 SUMMARY OF MICROSCOPIC DIAGNOSES

ANIMALS SACRIFICED AT WEEK 78
 MALES

	GROUP:	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP		70	70	70	70	70
NUMBER OF ANIMALS SACRIFICED		40	39	44	41	39
TESTES (CONTINUED)						
MINERALIZATION		38	38	38	33	37
SEMIFEROUS TUBULAR ATROPHY		39	39	38	33	39
ORCHITIS		1	1	0	0	1
INTERSTITIAL CELL HYPERPLASIA		0	1	0	0	0
EPIDIDYMIDES						
TOTAL NUMBER EXAMINED		40	39	0	2	39
EXAMINED, UNREMARKABLE		37	39	-	1	39
MINERALIZATION		3	0	-	0	0
OR HEMANGIOSARCOMA		0	0	-	1	0
SEMINAL VESICLE						
TOTAL NUMBER EXAMINED		40	39	2	0	39
EXAMINED, UNREMARKABLE		37	32	0	-	36
ECTASIA		1	1	1	-	2
SEMINAL VESICULITIS		2	5	1	-	1
MINERALIZATION		0	0	0	-	1
ATROPHY		1	3	0	-	1
FIBROSIS		0	1	0	-	0
PROSTATE						
TOTAL NUMBER EXAMINED		40	39	0	0	39
EXAMINED, UNREMARKABLE		36	34	-	-	39
PROSTATITIS		3	5	-	-	0
OR ADENOMA		1	0	-	-	0
PENIS						
TOTAL NUMBER EXAMINED		2	9	4	-	3
EXAMINED, UNREMARKABLE		1	2	0	0	0
COLLIGULAR CYST(S)		0	0	0	1	0
CONGESTION		0	2	0	0	1
BALANITIS		1	6	4	2	2
POSTHITIS		0	0	0	1	0
BALANOPOSTHITIS		0	0	0	1	0
ULCER/ULCERATION		0	1	2	1	1
TRACHEA						
TOTAL NUMBER EXAMINED		40	39	0	0	39
EXAMINED, UNREMARKABLE		40	39	-	-	39
LUNGS						
TOTAL NUMBER EXAMINED		40	39	44	41	39
EXAMINED, UNREMARKABLE		18	2	12	5	6
CONGESTION		11	18	21	22 ^a	19

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 0.05%, 4 is 0.10%, 5 is 0.50%

‡ = NEOPLASM, B = BENIGN, M = MALIGNANT
^a Significantly different from CONTROL group 1 (p < .05)

TABLE 19 (Continued)
 TRIS(ETHYLENE GLYCOL) DIACRYLATE (TEGDA): CHRONIC DERMAL
 BIOASSAY IN C57BL/6J MALE MICE
 SUMMARY OF MICROSCOPIC DIAGNOSES

ANIMALS SACRIFICED AT WEEK 78
 MALES

GROUP:	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP	70	70	70	70	70
NUMBER OF ANIMALS SACRIFICED	40	39	44	41	39
LUNGS (CONTINUED)					
ALVEOLAR PROTEIN DEPOSITS	0	0	2	0	0
ALVEOLAR HISTIOCYTOSIS	1	0	3	4	2
HEMORRHAGE	1	2	1	1	0
MINERALIZATION	11	26 ^b	20	27 ^b	24 ^b
LUNGWOUND INFILTRATES	0	1	0	0	0
INTERSTITIAL PNEUMONITIS	0	1	1	3	1
INTERSTITIAL FIBROSIS	0	0	1	1	1
BRONCHIOALVEOLAR CELL HYPERPLASIA	0	1	0	0	0
68 ADENOMA	4	3	3	0	2
69 CARCINOMA	0	0	0	1	0
69 MYELOsarcoma	1	0	0	0	0
69 HEPATOMA, METASTATIC	0	1	1	1	3
KIDNEYS					
TOTAL NUMBER EXAMINED	40	39	44	41	39
CYST(S)	4	4	3	5	1
HYDRONEPHROSIS	18	24	20	28 ^a	27 ^a
INTRAPELVIC HEMORRHAGE	0	0	0	0	1
INFARCTIC	3	0	4	7 ^c	0
MINERALIZATION	36	38	43	40	37
HEMOSIDEROSIS	0	0	0	1	0
PYELITIS	4	0	2	3	2
PYELONEPHRITIS	7	4	3	2	1
TUBULAR NEPHRITIS	1	0	0	0	0
TUBULAR DILATION	1	3	0	0	1
CORTICAL ATROPHY	1	0	0	0	0
TUBULAR PIGMENTATION	0	0	1	3	1
TUBULAR PROTEINOSIS	12	13	17	20	19
GLOMERULOCYCLINOSIS	1	3	2	2	0
NEPHRITIS, INTERSTITIAL	5	2	3	5	2
FIBROSIS, INTERSTITIAL	7	5	0 ^{bc}	6	10
DILATED HYPERPLASTIC TUBULES	18	19	22	27	21
URETER					
TOTAL NUMBER EXAMINED	2	3	2	3	3
EXAMINED, UNREMARKABLE	0	0	1	0	1
MISSING	0	0	0	0	1
ECTASIA	2	3	1	3	2
URETERITIS	0	1	0	0	0
PERIURETERITIS	0	0	0	0	1
HYPERPLASIA	0	-	0	0	-
URINARY BLADDER					
TOTAL NUMBER EXAMINED	40	39	3	5	39
EXAMINED, UNREMARKABLE	33	31	2	1	28

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 0.05%, 4 is 0.10%, 5 is 0.50%

§ = NEOPLASM, B = BENIGN, M = MALIGNANT
^a Significantly different from CONTROL group 1 (p < .05)
^b Significantly different from CONTROL group 1 (p < .01)
^c Significantly different from CONTROL group 2 (p < .05)

TABLE 19 (Continued)
 TRIETHYLENE GLYCOL DIACRYLATE (TEGDMA): CHRONIC DERMAL
 IRRITATION ASSAY IN C57BL/6J MALE MICE
 SUMMARY OF MICROSCOPIC DIAGNOSES

ANIMALS SACRIFICED AT WEEK 78
 MALES

	GROUP:	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP		70	70	70	70	70
NUMBER OF ANIMALS SACRIFICED		40	39	44	41	39
URINARY BLADDER (CONTINUED)						
ECTASIA		1	1	1	4	4
LYMPHOCYTIC INFILTRATE(S)		4	5	0	1	9
CYSTITIS		1	3	0	0	1
TRANSITIONAL CELL HYPERPLASIA		1	0	0	0	0

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 0.05%, 4 is 0.10%, 5 is 0.50%

None significantly different from control group

TABLE 20
 TRIETHYLENE GLYCOL DIACRYLATE (TEGDA): CHRONIC DERMAL
 BIOASSAY IN C57BL/6J MALE MICE
 SUMMARY OF MICROSCOPIC DIAGNOSES BY GRADE (SKIN, TREATED)

ANIMALS SACRIFICED AT WEEK 78
 MALES

GROUP:	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP	70	70	70	70	70
NUMBER OF ANIMALS SACRIFICED	40	39	44	41	39
SKIN, TREATED					
TOTAL NUMBER EXAMINED	40	39	44	41	39
EXAMINED, UNREMARKABLE	27	14	21	4	0
EPIDERMAL SPONGIOSIS					
MINIMAL	0	0	0	0	2
ACANTHOSIS	0	9	14	32bd	39bd
MINIMAL	2	6	6	14	0
MILD	1	1	6	15	0
MODERATE	3	1	1	3	13
MARKED	0	1	1	0	19
SEVERE	0	0	0	0	7
HYPERKERATOSIS/PARAHERATOSIS					
MINIMAL	2	5	3	14bc	39bd
MILD	0	5	1	11	2
MODERATE	2	0	2	3	22
MARKED	0	0	0	0	14
SEVERE	0	0	0	0	1
DERMATITIS					
MINIMAL	5	7	6	8	39bd
MILD	0	1	2	4	4
MODERATE	4	4	4	3	34
SEVERE	1	2	0	1	1
INTRACORNEAL PUSTULE FORMATION					
MINIMAL	2	1	1	8c	14bd
MILD	0	0	0	6	2
MODERATE	2	1	1	2	11
SEVERE	0	0	0	0	1
SUBEPIDERMAL CLEFT/BULLA FORMATION					
MINIMAL	1	0	0	0	4
MILD	0	0	0	0	3
MODERATE	1	0	0	0	1

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 0.05%, 4 is 0.10%, 5 is 0.50%

^b Significantly different from CONTROL group 1 (p < .01)

^c Significantly different from CONTROL group 2 (p < .05)

^d Significantly different from CONTROL group 2 (p < .01)

TABLE 20 (Continued)
 TRIETHYLENE GLYCOL DIACRYLATE (TEGDA): CHRONIC DERMAL
 BIOASSAY IN C3H/HEBESD MALE MICE
 SUMMARY OF MICROSCOPIC DIAGNOSES BY GRADE (SKIN, TREATED)

ANIMALS SACRIFICED AT WEEK 78
 MALES

GROUP:	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP	70	70	70	70	70
NUMBER OF ANIMALS SACRIFICED	40	39	44	41	39
SKIN, TREATED (CONTINUED)					
PIGMENTARY INCONTINENCE	0	0	0	0	39 ^b
MINIMAL	0	0	0	0	3
MILD	0	0	0	0	33
MODERATE	0	0	0	0	3
SUPERFICIAL EPIDERMAL NECROLYSIS	0	0	0	0	14 ^b
MINIMAL	0	0	0	0	3
MILD	0	0	0	0	8
MODERATE	0	0	0	0	3
BASAL ZONE EPIDERMAL NECROLYSIS	9	0	0	0	13 ^b
MINIMAL	0	0	0	0	4
MILD	0	0	0	0	9
FULL THICKNESS EPIDERMAL NECROLYSIS	0	0	0	0	1
MINIMAL	0	0	0	0	1
ULCER/ULCERATION	0	2	2	1	3
MINIMAL	0	0	0	1	2
MILD	0	0	1	0	1
MODERATE	0	2	1	0	0
MINERALIZATION	0	0	0	0	1
MINIMAL	0	0	0	0	1
ADRENAL ATROPHY	4	16 ^b	11	23 ^b	42
MINIMAL	1	9	3	14	2
MILD	3	7	7	9	2
MODERATE	0	0	1	0	0
DERMAL FIBROSIS	1	1	1	2	37 ^b
MINIMAL	0	0	0	2	0
MILD	1	0	0	0	24
MODERATE	0	0	0	0	13
MARKED	0	1	1	0	0

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 0.05%, 4 is 0.10%, 5 is 0.50%

^b Significantly different from CONTROL group 1 (p < .01)

^d Significantly different from CONTROL group 2 (p < .01)

0-0-8-3

TABLE 21
 TRIS(2-ETHYLHEXYL) GLYCOL DIACRYLATE (TEGDMA): CHRONIC DERMAL
 BIOASSAY IN C3H/HEMISP MALE MICE
 SUMMARY OF MICROSCOPIC DIAGNOSES BY GRADE (SPINAL CORD)

ANIMALS SACRIFICED AT WEEK 78
 MALES

	GROUP:	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP		70	70	70	70	70
NUMBER OF ANIMALS SACRIFICED		40	39	44	41	39
SPINAL CORD						
TOTAL NUMBER EXAMINED		40	39	0	0	39
EXAMINED, UNREMARKABLE		38	24	-	-	25
VACUOLATION						
MINIMAL		1	1	-	-	2
MILD		0	1	-	-	2
NERVE SHEATH SWELLING						
MINIMAL		1	15 ^b	-	-	12 ^b
MILD		0	0	-	-	1
NERVE FIBER DEGENERATION						
MINIMAL		0	1	-	-	0
		0	1	-	-	0

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 0.05%, 4 is 0.10%, 5 is 0.50%

^b Significantly different from CONTROL group 1 (p < .01)

0084

TABLE 22
 TRIETHYLENE GLYCOL DIACRYLATE (TEDSA): CHRONIC DERMAL
 BIOASSAY IN C57/BL6J MALE MICE
 SUMMARY OF MICROSCOPIC DIAGNOSES BY GRADE (KIDNEYS)

ANIMALS SACRIFICED AT WEEK 78
 MALES

GROUP:	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP	70	70	70	70	70
NUMBER OF ANIMALS SACRIFICED	40	39	44	41	39
KIDNEYS					
TOTAL NUMBER EXAMINED	40	39	44	41	39
CYST(S)	4	4	3	5	1
MINIMAL	1	1	1	1	1
MILD	2	3	2	4	0
MODERATE	1	0	0	0	0
HYDRONEPHROSIS	18	26	20	28 ^a	27 ^a
MINIMAL	0	2	0	1	1
MILD	14	21	16	24	22
MODERATE	4	0	3	2	4
MARKED	0	1	1	1	0
INTRAPELVIC HEMORRHAGE	0	0	0	0	1
MODERATE	0	0	0	0	1
INFARCTION	3	0	4	1 ^c	0
MILD	2	0	4	6	0
MODERATE	1	0	0	1	0
MINERALIZATION	36	38	43	40	37
MINIMAL	21	29	34	32	35
MILD	15	8	8	7	1
MODERATE	0	1	1	1	1
HEMOSIDEROSIS	0	0	0	1	0
MILD	0	0	0	1	0
PYELITIS	4	0	2	3	2
MILD	4	0	1	2	1
MODERATE	0	0	1	1	1
PYELONEPHRITIS	7	4	3	2	1
MILD	5	2	3	0	1
MODERATE	2	1	0	2	0
MARKED	0	1	0	0	0

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 0.05%, 4 is 0.10%, 5 is 0.50%

^a Significantly different from CONTROL group 1 (p < .05)

^c Significantly different from CONTROL group 2 (p < .05)

1085

TABLE 22 (Continued)
 TRIS(2-HYDROXYETHYL)AMMONIUM METHACRYLATE (TRIS): CHRONIC DERMAL
 BIOASSAY IN C57BL/6J MALE MICE
 SUMMARY OF MICROSCOPIC DIAGNOSES BY GRADE (KIDNEYS)

ANIMALS SACRIFICED AT WEEK 70
 MALES

GROUP:	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP	70	70	70	70	70
NUMBER OF ANIMALS SACRIFICED	40	39	44	41	39
KIDNEYS (CONTINUED)					
TUBULAR NEPHRITIS	1	0	0	0	0
MINIMAL	1	0	0	0	0
TUBULAR DILATION	1	3	0	0	1
MINIMAL	1	2	0	0	0
MILD	0	1	0	0	1
CORTICAL ATROPHY	1	0	0	0	0
MILD	1	0	0	0	0
TUBULAR PIGMENTATION	0	0	1	3	1
MILD	0	0	1	3	0
MODERATE	0	0	0	0	1
TUBULAR PROTEINOSIS	12	13	17	20	19
MINIMAL	11	13	15	20	17
MILD	1	0	2	0	2
GLOMERULOSCLEROSIS	1	3	2	2	0
MINIMAL	0	2	0	0	0
MILD	1	1	2	2	0
NEPHRITIS, INTERSTITIAL	5	2	3	5	2
MINIMAL	0	2	3	3	2
MILD	5	0	0	1	0
MODERATE	0	0	0	1	0
FIBROSIS, INTERSTITIAL	7	5	0 ^{b,c}	6	10
MINIMAL	4	1	0	2	4
MILD	3	4	0	4	6
DILATED HYPERPLASTIC TUBULES	18	19	22	27	21
MINIMAL	12	16	17	25	19
MILD	6	3	5	2	2

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 0.05%, 4 is 0.10%, 5 is 0.50%

^b significantly different from CONTROL group 1 (p < .01)

^c significantly different from CONTROL group 2 (p < .05)

0086

TABLE 23
 TRIETHYLENE GLYCOL DIACRYLATE (TEGDA): CHRONIC DERMAL
 BIOASSAY IN C3H/HEBRED MALE MICE
 SUMMARY OF MICROSCOPIC DIAGNOSES

ALL ANIMALS FOUND DEAD/SACRIFICED MORIBUND
 MALES

	GROUP:				
	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP	70	70	70	70	70
NUMBER OF ANIMALS FOUND DEAD/SACRIFICED MORIBUND	15	17	12	15	17
ADIPOSE TISSUE					
TOTAL NUMBER EXAMINED	0	0	1	0	0
HEMORRHAGE	-	-	1	-	-
PERITONEUM					
TOTAL NUMBER EXAMINED	0	0	1	0	0
PERITONITIS	-	-	1	-	-
HEART					
TOTAL NUMBER EXAMINED	15	17	1	1	17
EXAMINED, UNREMARKABLE	3	4	0	0	2
ATRIAL THROMBOSIS	3	3	1	1	3
NECROSIS	1	0	0	0	0
MYOCARDIAL MINERALIZATION	3	8	0	1	13
MYOFIBER VACUOLATION	1	0	0	0	0
MYOCARDIAL DEGENERATION/FIBROSIS	7	11	0	1	13
MYOCARDITIS	2	1	0	0	1
EPICARDITIS	1	0	0	0	0
ENDOCARDITIS	3	0	0	0	0
AORTA					
TOTAL NUMBER EXAMINED	15	17	0	0	17
EXAMINED, UNREMARKABLE	15	17	-	-	17
VASCULATURE					
TOTAL NUMBER EXAMINED	0	1	0	1	0
MINERALIZATION	-	1	-	0	-
INTRAVASCULAR THROMBOSIS	-	0	-	1	-
SALIVARY GL					
TOTAL NUMBER EXAMINED	15	17	1	0	17
EXAMINED, UNREMARKABLE	15	13	1	-	13
LYMPHOCTIC INFILTRATES	0	3	0	-	3
SIALOADENITIS	0	1	0	-	0
DUCT HYPERPLASIA	0	0	0	-	1
ESOPHAGUS					
TOTAL NUMBER EXAMINED	15	17	0	0	17
EXAMINED, UNREMARKABLE	15	16	-	-	16
DILATION	0	1	-	-	1
STOMACH					
TOTAL NUMBER EXAMINED	15	17	11	15	15
EXAMINED, UNREMARKABLE	14	13	9	14	13
TOO AUTOLYZED TO EVALUATE	0	0	1	0	1
MISSING	0	0	0	0	1

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 0.05%, 4 is 0.10%, 5 is 0.50%

0087

TABLE 23 (Continued)
 TRIS(2-HYDROXYETHYL)GLYCOL DIACRYLATE (TRIGDA): CHRONIC DERMAL
 BIOASSAY IN C57BL/6J MALE MICE
 SUMMARY OF MICROSCOPIC DIAGNOSES

ALL ANIMALS FOUND DEAD/SACRIFICED MORIBUND
 MALES

GROUP:	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP	70	70	70	70	70
NUMBER OF ANIMALS FOUND DEAD/SACRIFICED MORIBUND	15	17	12	15	17
STOMACH (CONTINUED)					
DIVERTICULUM	0	2	0	0	0
GLAND ECTASIA	0	0	0	0	1
MINERALIZATION	0	0	1	0	0
EDEMA	0	0	0	0	1
GASTRITIS	1	1	0	0	0
ULCER/ULCERATION	1	1	1	1	0
LIVER					
TOTAL NUMBER EXAMINED	15	17	12	15	17
EXAMINED, UNREMARKABLE	1	4	4	2	9
ANOMALOUS LOBULATION	0	1	0	1	0
CONGESTION	0	0	0	1	0
PELIOSIS/TELANGIECTASIS	1	0	0	0	0
MINERALIZATION	2	0	1	0	0
HEPATIC ABSCESS(ES)	0	0	1	0	0
ADHESION(S)	0	1	1	0	0
HEPATOCELLULAR NECROSIS	6	2	3	3	0
HEPATOCELLULAR HYPERTROPHY	1	0	0	0	0
HEPATOCELLULAR HYPERPLASIA	1	0	2	0	1
#B HEPATOCELLULAR ADENOMA	4	2	2	3	2
#B HEPATOCELLULAR ADENOMA WITH CARCINOMA IN SITU	0	0	0	1	0
#M HEPATOCELLULAR CARCINOMA	8	12	6	10	6
#M HEMANGIOSARCOMA	1	0	0	0	0
GALLBLADDER					
TOTAL NUMBER EXAMINED	12	12	1	1	10
EXAMINED, UNREMARKABLE	8	12	1	1	8
TOO AUTOLYSED TO EVALUATE	2	4	0	0	1
MISSING	1	1	0	1	6
DILATION	3	0	0	0	2
IMPREGATED SECRETION	1	0	0	0	0
CHOLECYSTITIS	1	0	0	0	0
PANCREAS					
TOTAL NUMBER EXAMINED	15	17	1	0	17
EXAMINED, UNREMARKABLE	14	17	1	-	17
ACINAR ATROPHY	1	0	0	-	0
DUODENUM					
TOTAL NUMBER EXAMINED	15	10	1	0	11
EXAMINED, UNREMARKABLE	14	10	1	-	11
TOO AUTOLYSED TO EVALUATE	0	7	0	-	6
ENTERITIS	1	0	0	-	0
JEJUNUM					
TOTAL NUMBER EXAMINED	13	7	0	1	10
EXAMINED, UNREMARKABLE	13	7	-	0	10
TOO AUTOLYSED TO EVALUATE	2	10	-	0	7

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 0.05%, 4 is 0.10%, 5 is 0.50%

= NEOPLASM, B = BENIGN, M = MALIGNANT

TABLE 23 (Continued)
 TRIETHYLENE GLYCOL DIACRYLATE (TRIGDA): CHRONIC DERMAL
 BIOASSAY IN C3H/HEBRED MALE MICE
 SUMMARY OF MICROSCOPIC DIAGNOSES

ALL ANIMALS FOUND DEAD/SACRIFICED MORIBUND
 MALES

GROUP:	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP	70	70	70	70	70
NUMBER OF ANIMALS FOUND DEAD/SACRIFICED MORIBUND	15	17	12	15	17
JEJUNUM (CONTINUED)					
#M LYMPHOSARCOMA	0	0	-	1	0
ILEUM					
TOTAL NUMBER EXAMINED	15	11	0	0	9
EXAMINED, UNREMARKABLE	15	11	-	-	9
TOO AUTOLYZED TO EVALUATE	0	6	-	-	8
CECUM					
TOTAL NUMBER EXAMINED	14	9	0	1	10
EXAMINED, UNREMARKABLE	14	9	-	0	10
TOO AUTOLYZED TO EVALUATE	1	8	-	0	7
TYPHILITIS	0	0	-	1	0
COLON					
TOTAL NUMBER EXAMINED	15	16	1	0	14
EXAMINED, UNREMARKABLE	15	16	0	-	14
TOO AUTOLYZED TO EVALUATE	0	1	0	-	2
MISSING	0	0	0	-	1
COLITIS	0	0	1	-	0
MUCOSAL HYPERTROPHY	0	0	1	-	0
RECTUM					
TOTAL NUMBER EXAMINED	15	16	1	0	16
EXAMINED, UNREMARKABLE	15	16	1	-	16
TOO AUTOLYZED TO EVALUATE	0	1	0	-	1
PITUITARY					
TOTAL NUMBER EXAMINED	15	17	1	0	16
EXAMINED, UNREMARKABLE	15	13	0	-	15
MISSING	0	0	0	-	1
CYST(S)	0	0	0	-	0
CYSTIC RATHKE'S CLEFT	0	2	0	-	1
CONGESTION	0	0	1	-	0
HEMORRHAGE	0	1	0	-	0
THYROID GL					
TOTAL NUMBER EXAMINED	15	17	1	0	17
EXAMINED, UNREMARKABLE	7	11	0	-	12
THYROGLOSSAL DUCT CYST	4	1	0	-	0
COLLOID CRYSTALLIZATION	3	5	0	-	0
FOLLICULAR ECTASIA	1	1	1	-	5
FOLLICULAR CELL HYPERPLASIA/HYPERTROPHY	2	1	0	-	0
#B FOLLICULAR CELL ADENOMA	0	1	0	-	0
PARATHYROID GL					
TOTAL NUMBER EXAMINED	5	8	0	0	3
EXAMINED, UNREMARKABLE	5	8	-	-	3
MISSING	10	9	-	-	14

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 0.05%, 4 is 0.10%, 5 is 0.50%

= NEOPLASM, B = BENIGN, M = MALIGNANT

TABLE 23 (Continued)
 TRIS(2-ETHYLHEXYL) GLYCOL DIACRYLATE (TEGDMA): CHRONIC DERMAL
 ELOASSAY IN C3H/HEBRED MALE MICE
 SUMMARY OF MICROSCOPIC DIAGNOSES

ALL ANIMALS FOUND DEAD/SACRIFICED MORIBUND
 MALES

	GROUP:	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP		70	70	70	70	70
NUMBER OF ANIMALS FOUND DEAD/SACRIFICED MORIBUND		15	17	12	15	17
ADRENAL GL						
TOTAL NUMBER EXAMINED		15	17	7	12	17
EXAMINED, UNREMARKABLE		0	3	0	0	2
CONGESTION		0	0	0	1	0
BACTERIAL INCUBATION		0	0	1	0	0
HEMORRHAGE		1	0	0	0	0
CORTICAL CYST		1	0	1	1	1
CORTICAL CELL VACUOLIZATION		1	0	0	0	0
CORTICAL CEROID DEGENERATION		11	11	3	8	6
MINERALIZATION		0	0	0	0	1
CORTICAL CELL HYPERPLASIA		2	0	0	0	0
SPINDLE CELL HYPERPLASIA		15	14	7	11	15
MODULAR CORTICAL CELL HYPERPLASIA		11	13	6	10	10
IN LYMPHOSARCOMA		0	0	0	1	0
SKIN, TREATED						
TOTAL NUMBER EXAMINED		15	17	12	15	17
EXAMINED, UNREMARKABLE		8	5	3	0	0
EPIDERMAL SPONGIOSIS		0	0	0	0	1
ACANTHOSIS		2	1	3	9	16
HYPERKERATOSIS/PARAKERATOSIS		1	6	3	8	17
DERMATITIS		3	0	2	0	16
INTRADERMAL PUSTULE FORMATION		1	0	4	5	5
SUBEPIDERMAL CLEFT/BULLA FORMATION		0	0	0	0	2
PIGMENTARY INCONTINENCE		0	0	0	0	16
SUPERFICIAL EPIDERMAL NECROLYSIS		0	0	0	0	6
BASAL ZONE EPIDERMAL NECROLYSIS		0	0	0	0	6
FULL THICKNESS EPIDERMAL NECROLYSIS		0	0	0	0	2
ULCER/ULCERATION		0	0	0	0	1
ADRENAL ATROPHY		4	10	8	14	4
DERMAL FIBROSIS		0	0	0	0	15
IN HEMANGIOSARCOMA		0	1	0	0	0
SKIN						
TOTAL NUMBER EXAMINED		15	17	12	15	17
EXAMINED, UNREMARKABLE		8	9	6	9	8
ACANTHOSIS		2	3	2	0	1
HYPERKERATOSIS/PARAKERATOSIS		0	1	0	0	0
DERMATITIS		4	4	3	1	2
INTRADERMAL MELANIN DEPOSITS		0	0	1	0	0
ULCER/ULCERATION		1	1	0	1	0
MINERALIZATION		0	0	1	0	0
CLITORAL/PREPUTIAL GLAND ABSCESS		2	1	0	1	0
CLITORAL/PREPUTIAL GLAND ADENITIS		1	3	1	1	1
CLITORAL/PREPUTIAL GLAND DUCT ECTASIA		1	3	0	2	1
ADRENAL GLAND ECTASIA		0	0	1	0	0
ADRENAL ATROPHY		1	5	3	5	5
EPIDERMAL CYST		0	0	0	0	1

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 0.05%, 4 is 0.10%, 5 is 0.50%

0 = NEOPLASM, N = MALIGNANT

0 0 9 0

TABLE 23 (Continued)
 TRIETHYLENE GLYCOL DIACRYLATE (TRIGDA): CHRONIC DERMAL
 BIOASSAY IN C3H/HEBRED MALE MICE
 SUMMARY OF MICROSCOPIC DIAGNOSES

ALL ANIMALS FOUND DEAD/SACRIFICED MORIBUND
 MALES

	GROUP:				
	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP	70	70	70	70	70
NUMBER OF ANIMALS FOUND DEAD/SACRIFICED MORIBUND	15	17	12	15	17
SUBCUTIS					
TOTAL NUMBER EXAMINED	0	1	1	1	0
FOLLICULITIS (UNDER TREATED SKIN)	-	0	0	1	-
FOLLICULITIS (UNDER UNTREATED SKIN)	-	1	1	0	-
HEAD					
TOTAL NUMBER EXAMINED	1	1	0	0	0
CONGESTION	1	0	-	-	-
HEMORRHAGE	0	1	-	-	-
SPLEEN					
TOTAL NUMBER EXAMINED	15	17	11	14	17
EXAMINED, UNREMARKABLE	2	6	3	2	3
TOO AUTOLYZED TO EVALUATE	0	0	1	0	0
EXTRAMEDULLARY HEMATOPOIESIS	12	9	8	12	11
SPLENITIS	1	0	1	1	0
HEMOSIDEROSIS	2	3	0	0	1
CONGESTION	1	0	0	1	0
LYMPHOID DEPLETION	1	3	0	0	5
LYMPH ND, S-NAN					
TOTAL NUMBER EXAMINED	14	16	1	0	16
EXAMINED, UNREMARKABLE	10	11	0	-	14
MISSING	1	1	0	-	1
SINUS ERYTHROCYTOSIS	0	1	0	-	0
HEMOSIDEROSIS	4	5	1	-	2
SINUS HISTIOCYTOSIS	2	2	0	-	0
PIGMENT GRANULOMA(S)	0	1	0	-	0
LYMPH ND, MED					
TOTAL NUMBER EXAMINED	3	3	0	0	0
SINUS ERYTHROCYTOSIS	1	2	-	-	-
HEMOSIDEROSIS	2	0	-	-	-
SINUS HISTIOCYTOSIS	1	2	-	-	-
LYMPH ND, MES					
TOTAL NUMBER EXAMINED	15	15	1	2	13
EXAMINED, UNREMARKABLE	5	6	0	0	3
TOO AUTOLYZED TO EVALUATE	0	1	1	0	4
MISSING	0	1	0	0	0
CYSTIC LYMPHATIC ECTASIA	3	1	0	0	2
SINUS ERYTHROCYTOSIS	3	2	1	1	1
HEMORRHAGE	1	0	0	0	1
HEMOSIDEROSIS	1	2	0	0	2
SINUS HISTIOCYTOSIS	5	4	1	1	6

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 0.05%, 4 is 0.10%, 5 is 0.50%

TABLE 23 (Continued)
 TRIBUTYLENE GLYCOL DIACRYLATE (TBGDA): CHRONIC DERMAL
 BIOASSAY IN C57BL/6J MALE MICE
 SUMMARY OF MICROSCOPIC DIAGNOSES

ALL ANIMALS FOUND DEAD/SACRIFICED MORIBUND
 MALES

GROUP:	1	2	3	4	5
NUMBER OF ANIMALS IN DCS GROUP	70	70	70	70	70
NUMBER OF ANIMALS FOUND DEAD/SACRIFICED MORIBUND	15	17	12	15	17
LYMPH ND, NER (CONTINUED)					
PIGMENT GRANULOMA(S)	5	3	1	0	2
LYMPHOID ATROPHY	0	1	0	0	1
SM LYMPHOSARCOMA	0	0	0	1	0
LYMPH ND, REN					
TOTAL NUMBER EXAMINED	0	1	0	0	0
SINUS HISTIOCYTOSIS	-	1	-	-	-
LYMPHOID HYPERPLASIA	-	1	-	-	-
LYMPH ND, OTHER					
TOTAL NUMBER EXAMINED	0	1	0	3	0
SINUS HISTIOCYTOSIS	-	1	-	2	-
LYMPHADENITIS	-	0	-	1	-
LYMPHOID HYPERPLASIA	-	1	-	2	-
SM LYMPHOSARCOMA	-	0	-	1	-
THYMIC REGION					
TOTAL NUMBER EXAMINED	15	17	1	0	16
EXAMINED, UNREMARKABLE	8	10	1	-	7
MISSING	0	0	0	-	1
THYMIC TISSUE NOT PRESENT	4	6	0	-	9
PIGMENT GRANULOMA(S)	0	1	0	-	0
INFLAMMATION, GRANULOMATOUS	1	0	0	-	0
LYMPHATIC ECTASIA	3	0	0	-	0
BONE/JOINT					
TOTAL NUMBER EXAMINED	15	17	0	0	17
EXAMINED, UNREMARKABLE	15	17	-	-	17
BONE, STERNUM					
TOTAL NUMBER EXAMINED	15	17	0	1	17
EXAMINED, UNREMARKABLE	10	13	-	0	11
CARTILAGE DEGENERATION	5	4	-	1	6
BONE, FIBUR					
TOTAL NUMBER EXAMINED	15	17	0	0	17
EXAMINED, UNREMARKABLE	15	17	-	-	17
BONE MARROW					
TOTAL NUMBER EXAMINED	15	17	0	0	17
EXAMINED, UNREMARKABLE	12	15	-	-	13
HEMOsiderosis	0	1	-	-	0
INFARCTION	1	0	-	-	0

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 0.05%, 4 is 0.10%, 5 is 0.50%

g = NEOPLASIA, M = MALIGNANT

00042

TABLE 23 (Continued)
 TRIETHYLENE GLYCOL DIACRYLATE (TEGDA): CHRONIC DERMAL
 BIOASSAY IN C3H/HEBRED MALE MICE
 SUMMARY OF MICROSCOPIC DIAGNOSES

ALL ANIMALS FOUND DEAD/SACRIFICED MORIBUND
 MALES

	GROUP:				
	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP	70	70	70	70	70
NUMBER OF ANIMALS FOUND DEAD/SACRIFICED MORIBUND	15	17	12	15	17
BONE MARROW (CONTINUED)					
MYELITIS	1	0	-	-	0
MYELOFIBROSIS	1	0	-	-	0
HYPERPLASIA	2	0	-	-	3
GRANULOCYTIC CELL HYPERPLASIA	0	1	-	-	1
SKELETAL MUSCLE					
TOTAL NUMBER EXAMINED	15	17	1	2	17
EXAMINED, UNREMARKABLE	7	13	0	0	15
ABSCCESS	1	0	0	0	0
ATROPHY	7	4	1	2	2
BRAIN					
TOTAL NUMBER EXAMINED	15	17	2	1	17
EXAMINED, UNREMARKABLE	3	4	0	1	3
SQUAMOUS CYST	0	0	1	0	0
BRAIN HEMORRHAGE	0	3	0	0	0
MINERALIZATION	10	11	2	0	13
ENCEPHALOMALACIA	2	3	1	0	3
MEINGITIS	0	0	0	0	1
ENCEPHALITIS	2	0	0	0	1
NEUROFIL VACUOLATION	2	0	0	0	1
NEURON LOSS	1	0	0	0	0
GLIOSIS	0	1	0	0	0
SPINAL CORD					
TOTAL NUMBER EXAMINED	15	17	0	0	17
EXAMINED, UNREMARKABLE	15	16	-	-	16
HEMORRHAGE	0	1	-	-	0
MYELITIS	0	0	-	-	1
NERVE, SCIATIC					
TOTAL NUMBER EXAMINED	15	17	0	0	17
EXAMINED, UNREMARKABLE	13	15	-	-	16
MYELIN SHEATH SWELLING	0	1	-	-	0
MYELIN DEGENERATION	2	1	-	-	1
NERVE, OTHER					
TOTAL NUMBER EXAMINED	0	1	0	0	0
VACUOLATION	-	1	-	-	-
EYS					
TOTAL NUMBER EXAMINED	15	16	0	0	16
TOO AUTOLYZED TO EVALUATE	0	1	-	-	1
OPTIC NEURITIS	0	0	-	-	1

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 0.05%, 4 is 0.10%, 5 is 0.50%

0093

TABLE 23 (Continued)
 TRIETHYLENE GLYCOL DIACRYLATE (TREGDA): CHRONIC DERMAL
 BIOASSAY IN C3H/HEHSD MALE MICE
 SUMMARY OF MICROSCOPIC DIAGNOSES

ALL ANIMALS FOUND DEAD/SACRIFICED MORIBUND
 MALES

	GROUP:	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP		70	70	70	70	70
NUMBER OF ANIMALS FOUND DEAD/SACRIFICED MORIBUND		15	17	12	15	17
EYE (CONTINUED)						
OPTIC NERVE DEMYELINATION/MALACIA		0	0	-	-	1
CORNEAL MINERALIZATION		8	3	-	-	8
KERATITIS		1	1	-	-	0
CATARACT		2	3	-	-	1
RETINAL ATROPHY		14	16	-	-	15
PHACOPHTHALMITIS		1	0	-	-	0
ATROPHY, OCULAR MUSCLES		0	1	-	-	0
PAROTID GL						
TOTAL NUMBER EXAMINED		15	17	1	0	17
EXAMINED, UNREMARKABLE		13	16	0	-	12
IMPASSATED SECRETION		0	0	1	-	0
LYMPHOCYTIC INFILTRATES		0	0	0	-	2
ADENITIS		1	1	0	-	1
ECTASIA		0	0	0	-	2
FIBROSIS		1	0	0	-	1
TESTES						
TOTAL NUMBER EXAMINED		15	17	3	11	17
EXAMINED, UNREMARKABLE		3	2	0	0	5
INFARCTION		1	0	0	0	0
MINERALIZATION		10	12	3	11	9
SEMINEFEROUS TUBULAR ATROPHY		12	15	3	11	12
ORCHITIS		1	0	0	0	1
EPIDIDYMIDES						
TOTAL NUMBER EXAMINED		15	17	0	0	17
EXAMINED, UNREMARKABLE		15	17	-	-	15
EPIDIDYMITIS		0	0	-	-	2
SEMINAL VESICLE						
TOTAL NUMBER EXAMINED		15	16	0	2	17
EXAMINED, UNREMARKABLE		9	10	-	0	6
MISSING		0	1	-	0	0
ECTASIA		0	1	-	1	3
SEMINAL VESICULITIS		5	5	-	1	7
MINERALIZATION		1	1	-	0	0
ATROPHY		2	4	-	0	5
HYPERPLASIA		0	0	-	0	2
COAGULATING GL						
TOTAL NUMBER EXAMINED		0	1	0	1	0
ADENITIS		-	1	-	1	-
PROSTATE						
TOTAL NUMBER EXAMINED		15	14	0	0	17
EXAMINED, UNREMARKABLE		10	11	-	-	11
MISSING		0	3	-	-	0

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 0.05%, 4 is 0.10%, 5 is 0.50%

0099

TABLE 23 (Continued)
 TRIETHYLENE GLYCOL DIACRYLATE (TREGDA): CHRONIC DERMAL
 BIOASSAY IN C3H/HEMISD MALE MICE
 SUMMARY OF MICROSCOPIC DIAGNOSES

ALL ANIMALS FOUND DEAD/SACRIFICED MORIBUND
 MALES

GROUP:	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP	70	70	70	70	70
NUMBER OF ANIMALS FOUND DEAD/SACRIFICED MORIBUND	15	17	12	15	17
PROSTATE (CONTINUED)					
MINERALIZATION	2	0	-	-	0
PROSTATITIS	4	3	-	-	6
PENIS					
TOTAL NUMBER EXAMINED	6	11	6	7	6
EXAMINED, UNREMARKABLE	1	1	0	0	0
FOLLICULAR CYST(S)	0	0	1	2	0
CONGESTION	1	3	1	0	2
BALANITIS	4	3	3	4	5
POSTHITIS	0	3	0	0	0
BALANOPOSTHITIS	1	1	1	2	0
ULCER/ULCERATION	1	4	5	4	2
TRACHEA					
TOTAL NUMBER EXAMINED	15	17	9	0	17
EXAMINED, UNREMARKABLE	15	17	-	-	17
LUNGS					
TOTAL NUMBER EXAMINED	15	17	12	15	17
EXAMINED, UNREMARKABLE	4	0	1	0	0
CONGESTION	10	14	10	10	14
ALVEOLAR PROTEIN DEPOSITS	0	1	1	2	1
ALVEOLAR HISTIOCYTOSIS	4	6	1	3	5
VASCULAR THROMBOSIS	0	0	1	2	0
HEMORRHAGE	3	5	1	4	3
MINERALIZATION	3	7	4	4	3
LYMPHOID INFILTRATES	0	0	0	0	1
BRONCHOPNEUMONIA	0	1	0	0	1
INTERSTITIAL PNEUMONITIS	1	3	0	0	0
INTERSTITIAL FIBROSIS	0	1	9	2	1
*B ADENOMA	1	0	0	0	1
*M HEPATOMA, METASTATIC	1	3	1	1	1
KIDNEYS					
TOTAL NUMBER EXAMINED	15	17	12	15	17
EXAMINED, UNREMARKABLE	0	1	0	0	0
CYST(S)	1	2	0	1	1
HYDRONEPHROSIS	8	13	4	7	10
BACTERIAL EMBOLIZATION	0	0	2	1	1
INFARCTION	1	0	1	2	1
PAPILLARY NECROSIS	1	1	1	3	3
MINERALIZATION	11	12	10	13	13
HEMOSIDEROSIS	0	1	0	0	0
PYELITIS	0	1	0	0	1
PYELONEPHRITIS	3	7	4	5	7
NEPHRITIS, PURULENT	0	1	0	0	0

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 0.05%, 4 is 0.10%, 5 is 0.50%

* = NEOPLASM, B = BENIGN, M = MALIGNANT

00095

TABLE 23 (Continued)
 TRIETHYLENE GLYCOL DIACRYLATE (TREGDA): CHRONIC DERMAL
 BIOASSAY IN C3H/HEMISD MALE MICE
 SUMMARY OF MICROSCOPIC DIAGNOSTICS

ALL ANIMALS FOUND DEAD/SACRIFICED MORIBUND
 MALES

GROUP:	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP	70	70	70	70	70
NUMBER OF ANIMALS FOUND DEAD/SACRIFICED MORIBUND	15	17	12	15	17
EYE (CONTINUED)					
OPTIC NERVE DEMYELINATION/MALACIA	0	0	-	-	1
CORNEAL MINERALIZATION	8	3	-	-	8
KERATITIS	1	1	-	-	0
CATARACT	2	3	-	-	1
RETINAL ATROPHY	14	16	-	-	15
PHACOPHTHALMITIS	1	0	-	-	0
ATROPHY, OCULAR MUSCLES	0	1	-	-	0
MANDIBULAR GL					
TOTAL NUMBER EXAMINED	15	17	1	0	17
EXAMINED, UNREMARKABLE	13	16	0	-	12
INSPISSATED SECRETION	0	0	1	-	0
LYMPHOCTIC INFILTRATES	0	0	0	-	2
ADENITIS	1	1	0	-	1
ECTASIA	0	0	0	-	2
FIBROSIS	1	0	0	-	1
TESTES					
TOTAL NUMBER EXAMINED	15	17	3	11	17
EXAMINED, UNREMARKABLE	3	2	0	0	5
INFARCTION	1	0	0	0	0
MINERALIZATION	10	12	3	11	9
SEMINIFEROUS TUBULAR ATROPHY	12	15	3	11	12
ORCHITIS	1	0	0	0	1
EPIDIDYMIDES					
TOTAL NUMBER EXAMINED	15	17	0	0	17
EXAMINED, UNREMARKABLE	15	17	-	-	15
EPIDIDYMITIS	0	0	-	-	2
SEMINAL VESICLE					
TOTAL NUMBER EXAMINED	15	16	0	2	17
EXAMINED, UNREMARKABLE	9	10	-	0	6
MYOSITIS	0	1	-	0	0
ECTASIA	0	1	-	1	3
SEMINAL VESICULITIS	5	5	-	1	7
MINERALIZATION	1	1	-	0	0
ATROPHY	2	4	-	0	5
HYPERPLASIA	0	0	-	0	2
COAGULATING GL					
TOTAL NUMBER EXAMINED	0	1	0	1	0
ADENITIS	-	1	-	1	-
PROSTATE					
TOTAL NUMBER EXAMINED	15	14	0	0	17
EXAMINED, UNREMARKABLE	10	11	-	-	11
MISSING	0	3	-	-	0

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 0.05%, 4 is 0.10%, 5 is 0.50%

00099

TABLE 23 (Continued)
 TRIETHYLENE GLYCOL DIACRYLATE (TREGDA): CHRONIC DERMAL
 IRRITATION IN C3H/HEMISD MALE MICE
 SUMMARY OF MICROSCOPIC DIAGNOSES

ALL ANIMALS FOUND DEAD/SACRIFICED MORIBUND
 MALES

	GROUP:	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP		70	70	70	70	70
NUMBER OF ANIMALS FOUND DEAD/SACRIFICED MORIBUND		15	17	12	15	17
PROSTATE (CONTINUED)						
MINERALIZATION		1	0	-	-	0
PROSTATITIS		4	3	-	-	6
PENIS						
TOTAL NUMBER EXAMINED		6	11	6	7	6
EXAMINED, UNREMARKABLE		1	1	0	0	0
FOLLICULAR CYST(S)		0	0	1	2	0
CONGESTION		1	3	1	0	2
BALANITIS		4	3	3	4	5
POSTHITIS		0	3	0	0	0
BALANOPOSTHITIS		1	1	1	2	0
ULCER/ULCERATION		1	4	5	4	2
TRACHEA						
TOTAL NUMBER EXAMINED		15	17	9	0	17
EXAMINED, UNREMARKABLE		15	17	-	-	17
LUNGS						
TOTAL NUMBER EXAMINED		15	17	12	15	17
EXAMINED, UNREMARKABLE		4	0	1	0	0
CONGESTION		10	14	10	10	14
ALVEOLAR PROTEIN DEPOSITS		0	1	1	2	1
ALVEOLAR HISTIOCYTOSIS		4	6	1	3	5
VASCULAR THROMBOSIS		0	0	1	2	0
HEMORRHAGE		3	5	1	4	3
MINERALIZATION		3	7	4	4	3
LYMPHOID INFILTRATES		0	0	0	0	1
BRONCHOPNEUMONIA		0	1	0	0	1
INTERSTITIAL PNEUMONITIS		1	3	0	0	0
INTERSTITIAL FIBROSIS		0	1	0	2	1
#F ADENOMA		1	0	0	0	1
#M HEPATOMA, METASTATIC		1	3	1	1	1
KIDNEYS						
TOTAL NUMBER EXAMINED		15	17	12	15	17
EXAMINED, UNREMARKABLE		0	1	0	0	0
CYST(S)		1	2	0	1	1
HYDRONEPHROSIS		8	13	4	7	10
BACTERIAL EMBOLIZATION		0	0	2	1	1
INFARCTION		1	0	1	2	1
PAPILLARY NECROSIS		1	1	1	3	3
MINERALIZATION		11	12	10	13	13
HEMOSIDEROSIS		0	1	0	0	0
PYELITIS		0	1	0	0	1
PELONEPHRITIS		3	7	4	5	7
NEPHRITIS, PURULENT		0	1	0	0	0

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 0.05%, 4 is 0.10%, 5 is 0.50%

= NEPLASIA, B = BENIGN, M = MALIGNANT

0095

TABLE 23 (Continued)
 TRISTYLENE GLYCOL DIACRYLATE (TREGDA): CHRONIC DERMAL
 BIOASSAY IN C3H/HEBESD MALE MICE
 SUMMARY OF MICROSCOPIC DIAGNOSES

ALL ANIMALS FOUND DEAD/SACRIFICED MORIBUND
 MALES

	GROUP:	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP		70	70	70	70	70
NUMBER OF ANIMALS FOUND DEAD/SACRIFICED MORIBUND		15	17	12	15	17
KIDNEYS (CONTINUED)						
ADHESION(S)		0	0	1	0	1
TUBULAR DILATION		0	1	0	0	2
TUBULAR PIGMENTATION		2	0	0	3	0
TUBULAR PROTEINOSIS		6	7	4	8	9
GLOMERULONEPHRITIS		1	0	0	0	0
GLOMERULOSCLEROSIS		2	3	2	2	2
NEPHRITIS, INTERSTITIAL		1	1	3	0	2
FIBROSIS, INTERSTITIAL		1	4	0	1	3
DILATED HYPERPLASTIC TUBULES		4	4	3	2	3
LIVER						
TOTAL NUMBER EXAMINED		2	3	1	3	3
TOO AUTOLYZED TO EVALUATE		0	1	0	0	0
ECTASIA		1	2	1	1	3
URETERITIS		1	2	1	2	0
URINARY BLADDER						
TOTAL NUMBER EXAMINED		15	14	2	3	15
EXAMINED, UNREMARKABLE		9	6	0	1	8
TOO AUTOLYZED TO EVALUATE		0	2	0	0	1
MISSING		0	1	0	0	1
ECTASIA		3	1	1	1	1
DIVERTICULUM		1	0	0	0	0
LYMPHOCYTIC INFILTRATE(S)		0	2	0	0	1
CYSTITIS		3	6	1	1	5
URETHRA						
TOTAL NUMBER EXAMINED		1	1	1	0	1
INTRALUMINAL PROTEIN COAGULUM		1	1	0	-	0
URETERITIS		0	0	1	-	1
CAUSE OF DEATH						
TOTAL NUMBER EXAMINED		15	17	0	0	17
UNDETERMINED		1	1	-	-	2
TRAUMA		1	1	-	-	0
CHRONIC RENAL DISEASE		0	2	-	-	0
PYELONEPHRITIS		2	2	-	-	6
ENDOCARDITIS		3	0	-	-	0
ENCEPHALITIS		0	0	-	-	1
ENCEPHALOMALACIA		0	0	-	-	2
ATRIAL THROMBOSIS/CONGESTIVE HEART FAILURE		0	1	-	-	1
HEPATOCELLULAR ADENOMA		1	0	-	-	0
HEPATOCELLULAR CARCINOMA		7	10	-	-	5

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 0.25%, 4 is 0.10%, 5 is 0.50%

TABLE 24
 TRINITYLENE GLYCOL DIACRYLATE (TREGD_m): CARCINOGENESIS SKIN
 PAINTING STUDY IN C3H/HEBND MALE MICE
 SUMMARY OF NEOPLASTIC MICROSCOPIC DIAGNOSES

DATA FOR ALL ANIMALS ON STUDY
 MALES

	GROUP:	1	2	3	4	5
NUMBER OF ANIMALS IN LCSE GROUP		70	70	70	70	70
NUMBER OF ANIMALS		70	70	70	70	70
ADIPOSE TISSUE						
TOTAL NUMBER EXAMINED		0	0	1	1	0
§B LIPOMA		-	-	0	1	-
MESENTERY/OMENTUM						
TOTAL NUMBER EXAMINED		0	0	0	0	1
PERITONEUM						
TOTAL NUMBER EXAMINED		0	0	1	2	0
HEART						
TOTAL NUMBER EXAMINED		55	56	3	5	56
EXAMINED, UNREMARKABLE		1	16	0	0	12
§M HEMANGIOSARCOMA		0	1	0	0	0
AORTA						
TOTAL NUMBER EXAMINED		55	56	0	0	56
EXAMINED, UNREMARKABLE		55	57	-	-	53
VASCULATURE						
TOTAL NUMBER EXAMINED		2	2	0	1	1
SALIVARY GL						
TOTAL NUMBER EXAMINED		55	56	1	1	56
EXAMINED, UNREMARKABLE		44	36	1	0	33
ESOPHAGUS						
TOTAL NUMBER EXAMINED		55	56	0	0	56
EXAMINED, UNREMARKABLE		55	55	-	-	55
STOMACH						
TOTAL NUMBER EXAMINED		55	56	54	56	54
EXAMINED, UNREMARKABLE		44	48	46	48	47
TOO AUTOLYZED TO EVALUATE		0	0	1	0	1
MISSING		0	0	0	0	1
LIVER						
TOTAL NUMBER EXAMINED		55	56	56	56	56
EXAMINED, UNREMARKABLE		11	13	24	12	24
§B HEPATOCELLULAR ADENOMA		26	21	18	26	14a

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 0.05%, 4 is 0.10%, 5 is 0.50%

§ = NEOPLASM, B = BENIGN, M = MALIGNANT
 a Significantly different from CONTROL group 1 (p < .05)

TABLE 24 (Continued)
 TRIMETHYLENE GLYCOL DIACRYLATE (TRIGDA): CARCINOGENESIS SKIN
 PAINTING STUDY IN C3H/HEBESD MALE MICE
 SUMMARY OF NEOPLASTIC MICROSCOPIC DIAGNOSES

DATA FOR ALL ANIMALS ON STUDY
 MALES

GROUP:	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP	70	70	70	70	70
NUMBER OF ANIMALS	70	70	70	70	70
LIVER (CONTINUED)					
ON HEPATOCELLULAR ADENOMA WITH CARCINOMA IN SITU	0	1	0	1	0
ON HEPATOCELLULAR CARCINOMA	14	25 ^a	16	18	11 ^d
ON HEMANGIOSARCOMA	2	1	0	1	1
GALLBLADDER					
TOTAL NUMBER EXAMINED	49	46	3	1	48
EXAMINED, UNREMARKABLE	45	42	2	1	42
TOO AUTOLYZED TO EVALUATE	2	4	0	0	1
MISSING	4	6	0	1	7
PANCREAS					
TOTAL NUMBER EXAMINED	55	56	2	0	56
EXAMINED, UNREMARKABLE	54	56	2	-	55
DUODENUM					
TOTAL NUMBER EXAMINED	55	49	1	0	50
EXAMINED, UNREMARKABLE	54	49	1	-	50
TOO AUTOLYZED TO EVALUATE	0	7	0	-	3
JEJUNUM					
TOTAL NUMBER EXAMINED	53	46	0	1	49
EXAMINED, UNREMARKABLE	53	46	-	0	49
TOO AUTOLYZED TO EVALUATE	2	10	-	0	7
ON LYMPHOSARCOMA	0	0	-	1	0
ILEUM					
TOTAL NUMBER EXAMINED	55	50	0	0	48
EXAMINED, UNREMARKABLE	55	50	-	-	48
TOO AUTOLYZED TO EVALUATE	0	6	-	-	8
CECUM					
TOTAL NUMBER EXAMINED	54	48	0	1	49
EXAMINED, UNREMARKABLE	54	48	-	0	49
TOO AUTOLYZED TO EVALUATE	1	9	-	0	7
COLON					
TOTAL NUMBER EXAMINED	55	55	1	0	53
EXAMINED, UNREMARKABLE	54	55	0	-	52
TOO AUTOLYZED TO EVALUATE	0	1	0	-	2
MISSING	0	0	0	-	1
RECTUM					
TOTAL NUMBER EXAMINED	55	55	1	0	55
EXAMINED, UNREMARKABLE	54	55	1	-	54
TOO AUTOLYZED TO EVALUATE	0	1	0	-	1

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 0.05%, 4 is 0.10%, 5 is 0.50%

§ = NEOPLASM, B = BENIGN, M = MALIGNANT
^a Significantly different from CONTROL group 1 (p < .05)
^d Significantly different from CONTROL group 2 (p < .01)

TABLE 24 (Continued)
 TRIETHYLENE GLYCOL DIACRYLATE (TREGDA): CARCINOGENESIS SKIN
 PAINTING STUDY IN C3H/HEMISD MALE MICE
 SUMMARY OF NEOPLASTIC MICROSCOPIC DIAGNOSES

DATA FOR ALL ANIMALS ON STUDY
 MALES

	GROUP:	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP		70	70	70	70	70
NUMBER OF ANIMALS		70	70	70	70	70
RECTUM (CONTINUED)						
#M ROUND CELL CARCINOMA		0	0	0	-	1
PITUITARY						
TOTAL NUMBER EXAMINED		55	56	1	0	55
EXAMINED, UNREMARKABLE		52	48	0	-	54
MISSING		0	0	0	-	1
THYROID GL						
TOTAL NUMBER EXAMINED		55	56	2	0	56
EXAMINED, UNREMARKABLE		20	25	0	-	24
#E FOLLICULAR CELL ADENOMA		3	7	1	-	7
PARATHYROID GL						
TOTAL NUMBER EXAMINED		28	23	0	0	21
EXAMINED, UNREMARKABLE		28	23	-	-	21
MISSING		27	33	-	-	35
ADRENAL GL						
TOTAL NUMBER EXAMINED		55	56	46	51	56
EXAMINED, UNREMARKABLE		1	3	0	0	2
#E ADENOMA		0	0	0	1	2
#M LYMPHOSARCOMA		0	0	0	1	0
SKIN, TREATED						
TOTAL NUMBER EXAMINED		55	56	56	56	56
EXAMINED, UNREMARKABLE		35	19	24	4	0
#M HEMANGIOSARCOMA		0	1	0	0	0
SKIN						
TOTAL NUMBER EXAMINED		55	56	55	56	56
EXAMINED, UNREMARKABLE		38	36	29	34	26
MISSING		0	0	1	0	0
SUBCUTIS						
TOTAL NUMBER EXAMINED		2	2	3	4	0
#M HEMANGIOSARCOMA		1	0	0	0	-
HEAD						
TOTAL NUMBER EXAMINED		1	1	0	0	0
SPLEEN						
TOTAL NUMBER EXAMINED		55	56	54	55	56
EXAMINED, UNREMARKABLE		30	29	36	23	32
TOO AUTOLYZED TO EVALUATE		0	0	1	0	0

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 0.05%, 4 is 0.10%, 5 is 0.50%

= NEOPLASM, E = BENIGN, M = MALIGNANT
 None significantly different from control group

TABLE 24 (Continued)
 TRIS(2-HYDROXYETHYL)AMMONIUM METHACRYLATE (TRIS(2-HAEMA)): CARCINOGENESIS SKIN
 PAINTING STUDY IN C3H/HEPESD MALE MICE
 SUMMARY OF NEOPLASTIC MICROSCOPIC DIAGNOSES

DATA FOR ALL ANIMALS ON STUDY
 MALES

	GROUP:				
	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP	70	70	70	70	70
NUMBER OF ANIMALS	70	70	70	70	70
SPLEEN (CONTINUED)					
#N NYELOSARCOMA	1	0	0	0	0
#N HEMANGIOSARCOMA	1	0	0	0	1
LYMPH ND, S-MAN					
TOTAL NUMBER EXAMINED	52	55	1	0	53
EXAMINED, UNREMARKABLE	42	47	0	-	42
MISSING	3	1	0	-	3
LYMPH ND, MED					
TOTAL NUMBER EXAMINED	4	4	0	0	0
LYMPH ND, RES					
TOTAL NUMBER EXAMINED	54	54	12	12	52
EXAMINED, UNREMARKABLE	22	26	0	0	21
TOO AUTOLYZED TO EVALUATE	0	1	1	0	4
MISSING	1	1	0	0	0
#N LYMPHOSARCOMA	0	0	0	1	0
#N NYELOSARCOMA	1	0	0	0	0
LYMPH ND, REN					
TOTAL NUMBER EXAMINED	0	1	0	0	0
LYMPH ND, OTHER					
TOTAL NUMBER EXAMINED	2	1	0	4	0
#N LYMPHOSARCOMA	0	0	-	1	-
#N NYELOSARCOMA	1	0	-	0	-
#N HEMANGIOSARCOMA	1	0	-	1	-
THYMIC REGION					
TOTAL NUMBER EXAMINED	55	56	1	1	55
EXAMINED, UNREMARKABLE	38	43	1	0	34
MISSING	0	0	0	0	1
#N LYMPHOSARCOMA	0	0	0	1	0
#N NYELOSARCOMA	1	0	0	0	0
BONE/JOINT					
TOTAL NUMBER EXAMINED	55	56	0	1	56
EXAMINED, UNREMARKABLE	55	56	-	1	56
BONE, STERNUM					
TOTAL NUMBER EXAMINED	55	56	0	3	56
EXAMINED, UNREMARKABLE	38	45	-	2	35

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 0.05%, 4 is 0.10%, 5 is 0.50%

= NEOPLASM, N = MALIGNANT
 None significantly different from control group

TABLE 24 (Continued)
 TRIETHYLENE GLYCOL DIACRYLATE (TREGDA): CARCINOGENESIS SKIN
 PAINTING STUDY IN C3H/HEMISD MALE MICE
 SUMMARY OF NEOPLASTIC MICROSCOPIC DIAGNOSIS

DATA FOR ALL ANIMALS ON STUDY
 MALES

	GROUP:	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP		70	70	70	70	70
NUMBER OF ANIMALS		70	70	70	70	70
BONE, FEMUR						
TOTAL NUMBER EXAMINED		55	56	0	0	56
EXAMINED, UNREMARKABLE		55	56	-	-	56
BONE MARROW						
TOTAL NUMBER EXAMINED		55	56	0	0	56
EXAMINED, UNREMARKABLE		0	54	-	-	52
§M HEMANGIOSARCOMA		1	0	-	-	0
SKELETAL MUSCLE						
TOTAL NUMBER EXAMINED		55	56	2	2	56
EXAMINED, UNREMARKABLE		45	52	0	0	51
BRAIN						
TOTAL NUMBER EXAMINED		55	56	2	2	56
EXAMINED, UNREMARKABLE		6	10	0	1	13
SPINAL CORD						
TOTAL NUMBER EXAMINED		55	56	0	0	56
EXAMINED, UNREMARKABLE		53	40	-	-	41
NERVE, SCIATIC						
TOTAL NUMBER EXAMINED		55	56	0	0	56
EXAMINED, UNREMARKABLE		51	51	-	-	52
NERVE, OTHER						
TOTAL NUMBER EXAMINED		0	1	0	0	0
EYE						
TOTAL NUMBER EXAMINED		55	55	0	0	55
TOO AUTOLYZED TO EVALUATE		0	1	-	-	1
HARDERIAN GL						
TOTAL NUMBER EXAMINED		55	56	4	2	56
EXAMINED, UNREMARKABLE		49	52	1	2	45
§B ADENOMA		1	0	0	0	0
TESTES						
TOTAL NUMBER EXAMINED		55	56	41	44	56
EXAMINED, UNREMARKABLE		3	2	0	0	5
EPIDIDYMEDES						
TOTAL NUMBER EXAMINED		55	56	0	2	56
EXAMINED, UNREMARKABLE		52	56	-	1	54

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 0.05%, 4 is 0.10%, 5 is 0.50%

§ = NEOPLASM, B = BENIGN, M = MALIGNANT
 None significantly different from control group

TABLE 24 (Continued)
 TRIMETHYLENE GLYCOL DIACRYLATE (TMGDA): CARCINOGENESIS SKIN
 PAINTING STUDY IN C3H/HEBESD MALE MICE
 SUMMARY OF NEOPLASTIC MICROSCOPIC DIAGNOSES

DATA FOR ALL ANIMALS ON STUDY
 MALES

	GROUP:				
	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP	70	70	70	70	70
NUMBER OF ANIMALS	70	70	70	70	70
EPIDIDYMIDES (CONTINUED)					
#M HEMANGIOSARCOMA	0	0	-	1	0
SEMINAL VESICLE					
TOTAL NUMBER EXAMINED	55	55	2	2	55
EXAMINED, UNREMARKABLE	46	42	0	0	42
MISSING	0	1	0	0	0
COAGULATING GL					
TOTAL NUMBER EXAMINED	0	1	0	1	0
PROSTATE					
TOTAL NUMBER EXAMINED	55	53	0	0	56
EXAMINED, UNREMARKABLE	46	45	-	-	50
MISSING	0	3	-	-	0
#B ADENOMA	1	0	-	-	0
PENIS					
TOTAL NUMBER EXAMINED	8	20	10	11	9
EXAMINED, UNREMARKABLE	2	3	0	0	0
TRACHEA					
TOTAL NUMBER EXAMINED	55	56	0	0	56
EXAMINED, UNREMARKABLE	55	56	-	-	56
LUNGS					
TOTAL NUMBER EXAMINED	55	56	56	56	56
EXAMINED, UNREMARKABLE	22	2	13	5	6
#B ADENOMA	5	3	3	0a	3
#M CARCINOMA	0	0	0	1	0
#M MYELOSARCOMA	1	0	0	0	0
#M HEPATOMA, METASTATIC	1	4	2	2	4
KIDNEYS					
TOTAL NUMBER EXAMINED	55	56	56	56	56
EXAMINED, UNREMARKABLE	0	1	0	0	0
URETER					
TOTAL NUMBER EXAMINED	4	6	3	6	6
EXAMINED, UNREMARKABLE	0	0	1	0	1
TOO AUTOLYZED TO EVALUATE	0	1	0	0	0
MISSING	0	0	0	0	1

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 0.05%, 4 is 0.10%, 5 is 0.50%

a = NEOPLASM, B = BENIGN, M = MALIGNANT
 * Significantly different from CONTROL group 1 (p < .05)

TABLE 24 (Continued)
 TRISTYLENE GLYCOL DIACRYLATE (TREGDA): CARCINOGENESIS SKIN
 PAINTING STUDY IN C3H/HEMISD MALE MICE
 SUMMARY OF HISTOPATHOLOGIC MICROSCOPIC DIAGNOSES

DATA FOR ALL ANIMALS ON STUDY
 MALES

	GROUP:	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP		70	70	70	70	70
NUMBER OF ANIMALS		70	70	70	70	70
URINARY BLADDER						
TOTAL NUMBER EXAMINED		55	53	5	8	54
EXAMINED, UNREMARKABLE		42	37	2	2	36
TOO AUTOLYZED TO EVALUATE		0	2	0	0	1
MISSING		0	1	0	0	1
URETHRA						
TOTAL NUMBER EXAMINED		1	1	1	0	1

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 0.05%, 4 is 0.10%, 5 is 0.50%

None significantly different from control group

FMOD_RPT:MHTDAC.T24/CM, 061295

**Triethylene Glycol Diacrylate (TREGDA): Chronic Dermal
Bioassay in C3H/HeNHSd Male Mice**

QUALITY ASSURANCE UNIT INSPECTION SUMMARY

<u>Inspection Date(s)</u>	<u>Inspection Type</u>	<u>Date QAU Report Issued To</u>	
		<u>Stud</u>	<u>Instructor Management</u>
10-15-92	PROTOCOL	10-16-92	10-19-92
11-20-92	EVENT-DOSING	11-20-92	03-04-93
12-07-92	EVENT-OSMOTIC PUMP IMPLANTS	12-07-92	03-04-93
12-23-92	PROTOCOL AMENDMENT #1	01-08-93	01-12-93
02-09-93	EVENT-SACRIFICE	02-12-93	03-04-93
	INTERIM		
04-26-93	PROTOCOL AMENDMENT #2	04-26-93	04-30-93
05-12-93	EVENT-SACRIFICE	05-13-93	09-10-93
	6-MONTH SENTINEL		
06-16-93	EVENT-CLIPPING	08-17-93	09-10-93
11-09-93	EVENT-SACRIFICE	11-16-93	12-01-93
	SATELLITE MICE		
11-10-93	PROTOCOL AMENDMENT #3	11-15-93	12-13-93
01-11-94	PROTOCOL AMENDMENT #4	01-11-94	01-17-94
05-12-94	EVENT-SACRIFICE	05-12-94	05-23-94
	FINAL		
06-09-94	PROTOCOL AMENDMENT #5	06-09-94	06-15-94
04-10-95 to 04-11-95	PROTOCOL AMENDMENT #6	04-11-95	04-17-95
05-09-95 to 05-18-95	ANALYTICAL CHEMISTRY DATA, REPORT	05-19-95	08-23-95
06-09-95 to 06-22-95	CLINICAL PATHOLOGY DATA, REPORT	06-22-95	08-23-95
06-22-95 to 08-06-95	RAW DATA, REPORT	08-06-95	08-23-95
07-07-95 to 07-21-95	ANATOMIC PATHOLOGY DATA, REPORT	07-21-95	08-23-95
08-22-95	PROTOCOL AMENDMENT #7	08-22-95	08-22-95
08-22-95	ARCHIVES	08-22-95	08-23-95

James H. Coleman
James H. Coleman, B.S.
Representative, Quality Assurance Unit

8-23-95
Date

Triethylene Glycol Diacrylate (TREGDA): Chronic Dermal
Bioassay in C3H/HeNHsd Male Mice

Analytical Chemistry Report

(42 Pages)