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September 13, 1995

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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"

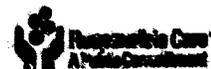
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These reports do not include confidential information.

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

Sincerely,

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STUDY TITLE

Triethylene Glycol Dimethacrylate (TREGDMA): Chronic Dermal
Bioassay in C3H/HeNHsd Male Mice

TEST SUBSTANCE

Triethylene Glycol Dimethacrylate (TREGDMA)

DATA REQUIREMENT

Not Applicable

AUTHORS

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STUDY COMPLETION DATE

August 24, 1995

PERFORMING LABORATORY

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LABORATORY PROJECT ID

92N1168B

SPONSOR

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

CMA REFERENCE NUMBER

SAM-6.0-BIO-BRRC

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Triethylene Glycol Dimethacrylate (TREGDMA): Chronic Dermal
Bioassay in C3H/HeNHsd 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 TREGDMA dosing are presented in this report. The results and conclusions of the TREGDA dosing are included in BRRC Report 92N1168A.

This study consisted of 3 TREGDMA 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 5, 25, and 50% TREGDMA 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 TREGDA 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). 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.

Cutaneous treatment of male mice with TREGDMA did not result in any treatment-related changes in hematology, clinical chemistry, mean absolute body weights, or body weight gain. The mid and high dose groups had decreased survival as compared to both control groups but only the mean survival time of the high dose group was statistically significantly different from the control groups. 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 an increased cell turnover rate that was very similar in the mid and high dose groups. The increase was greatest at the 4 and 13 Week measurement intervals and tended to be less pronounced at the 52 and 78 Week measurement intervals. Microscopic examination at 78 Weeks again indicated very similar chronic cutaneous irritation changes at the site of treatment in the mid and high dose groups. 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.

There were no microscopic lesions in the mid and/or high dose groups that were considered to result in an increased incidence of mortality. Therefore, the statistically significantly increased size of the kidneys (observed as increased mean absolute and relative organ weights) in the mid and high dose groups at the terminal sacrifice was the only finding in these groups, other than the chronic skin irritation. Microscopic evaluation of the kidneys did not reveal a cause of the increased size of the kidneys. The chronic cutaneous irritation observed in this study was not considered to be sufficiently severe to result in increased mortality in these groups. There were no other microscopic lesions in the mid and high dose groups that were considered to result in an increased incidence of mortality. Therefore, a cause for the increased mortality in the mid and high dose groups was not identified.

Based upon observations made during the in-life phase of the study that were recorded in the raw data as well as in photographs taken of some animals on this study, oral consumption of the TREGDMA was likely to have occurred in, at least, the high dose group. The effect of this inadvertent route of exposure on the kidney weights and decreased survival is unknown but must be considered.

Under the conditions of this study, the No-Observed-Adverse-Effect Level (NOAEL) for TREGDMA was considered to be 5%. Furthermore, under the conditions of this study, there was no indication of carcinogenicity of TREGDMA at any dose level.

OBJECTIVE

The objective of this study was to evaluate the chronic toxicity and carcinogenic potential of triethylene glycol dimethacrylate (TREGDMA) 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 (BRRC Report 54-538 and 54-554) were conducted with TREGDA and TREGDMA at BRRC. 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 on body weight were observed in either study.

The clinical signs observed for the TREGDMA-treated animals included exfoliation (present in all mice), color change and eschar formation (present in 2 mice in the 25% group), ulceration (seen in several mice in the 25% group), and erythema (present in 1 mouse in the 25% 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) were utilized except for the change from box to hanging feeders. TREGDMA-treated animals had exfoliation during the study and at necropsy for the 50 and 100% groups. Microscopic changes primarily consisted of dermatitis, intracorneal pustule formation, acanthosis, and hyperkeratosis. A No-Observed-Effect Level (NOEL) was not established for TREGDMA even though the highest concentration (100%) did not result in epidermal necrosis or ulceration; other microscopic changes (dermatitis and acanthosis) were observed even at the lowest concentration (25%).

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 BRRC 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 BIRC 14-day studies. Both agents also produced very significant increases in cell proliferation in basal epithelium. TREGDMA produced dose-related increases in the LI that were up to 14-fold higher than the acetone control. The effects were generally more pronounced after 14 days of dosing than after 7 days. 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 (BIRC Report 91N0017) was conducted with TREGDA and TREGDMA at BIRC. 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 μl for 13 weeks (90 days). An additional 10 mice were treated topically with 50 μl 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. Dose-related increases in both absolute and relative weights of livers of mice treated with 50 or 100% TREGDMA were observed. There were no confirmatory microscopic diagnoses; therefore, the etiology and biological significance, if any, is unknown. 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 TREGDMA-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 basal 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

Two 1-gallon bottles of TREGDMA (CAS Registry No. 109-16-0), Lot No. 85674, were received on February 21, 1991 from Polysciences Inc., Warrington, PA, and assigned BRRC Sample Number 54-43 A and B. The test substance was a clear liquid and was stored refrigerated at approximately 4°C. Related correspondence from the supplier stated the purity of the test substance to be approximately 95%. Samples of the test substance were periodically shipped to the GLP Analytical Skill Center at the UCC South Charleston, WV, Technical Center for compositional analysis which included analysis of the hydroquinone (polymerization inhibitor) concentration. Analyses of these samples by the Skill Center indicated that the concentration of inhibitor or composition of the test substance 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 3 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 22.1 to 28.3 g for TREGDMA animals.

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.

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	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.

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

Dosing solutions were prepared by adding the appropriate amount of TREGDMA (ml) to a 25 ml volumetric flask, then diluting to volume with acetone. 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.

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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 50 μ l/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 test solutions were prepared to assess the homogeneity and stability. Homogeneity (duplicate samples each from the top, middle, and bottom of the mixing vessel) was determined for the 5, 25, and 50% solutions. Stability was evaluated by determining the test substance concentration in triplicate samples (6 samples used for Day 7) from the 5 and 50% 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 TREGDMA 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 $\pm 10\%$ of nominal; the difference between duplicate analyses did not exceed 15%; and individual analyses were within $\pm 15\%$ 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 (MCHC)
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 incurrent infectious diseases. None were found. An additional sentinel sacrifice was performed to evaluate for the PVM virus on April 19, 1995. 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 5 μ , 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, testis, 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, s iatic
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

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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 TREGDA 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 5 and 50% solutions ranged from 100.9 to 105.7 and 100.1 to 105.9% of nominal, respectively. These results indicated that TREGDMA 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 TREGDMA in the 5, 25, and 50% solutions were 105.7 (\pm 0.7), 100.4 (\pm 0.9), and 101.6 (\pm 0.6)% of nominal, respectively. The coefficients of variation of the percent of nominal for the 5, 25, and 50% solutions were 0.7, 0.9, and 0.6%, respectively. These results show that the solutions were uniformly prepared.

The mean measured concentrations of the 5, 25, and 50% solutions ranged from 94.4 to 106.2% of nominal for the 6 periods of analysis. TREGDMA 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 and untreated control groups. The survival rates over the study period (including those sacrificed moribund but excluding accidental and procedural deaths) were 74, 70, 70, 62, and 49% for the untreated control, vehicle treated control, low, mid, and high dose groups, respectively. Life-table analyses (Kaplan-Meier, 1958) indicated that the survival of the high dose group was statistically significantly decreased as compared to both control groups. While both the survival rate and the mean survival time for the mid dose group was lower than either control group, the mean survival time was not statistically significantly different from either control group.

Treatment-related clinical signs of toxicity were generally limited to local signs of irritation at the site of treatment, although statistical analyses were not performed for 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 TREGDMA-treatment groups as compared to both control groups. Exfoliation was first observed on Day 8 in the high dose group and by Day 29 was observed in all TREGDMA-treated groups (exfoliation was not observed in either control group until Day 127). Exfoliation was observed in all but 3 animals from the mid dose group and all animals from the high dose group. The summary table (Table 2) indicates that the number of animals observed with exfoliation was increased in the low dose group as well as the mid and high dose groups. The incidence of this finding in the low dose group was considered to be biologically significant only in the latter stages of the study as indicated by the following table of randomly selected study periods:

Study Days	Number of animals with Exfoliation				
	Untreated	Vehicle	5g	25g	50g
35-42	0	0	1	22	49
210-215	0	0	2	6	17
350-355	2	2	7	4	10
440-445	0	1	7	13	17
546-550	3	4	21	24	25

Two animals from the mid dose group and 7 animals from the high dose group were observed with exfoliation of a grade of 1 (compared to "P" for present) while none of the low dose group or 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.

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The number of animals observed with one or several non-specific signs including emaciated body, dehydration, abdominal distention, cold extremities, or labored respiration was generally increased in the high dose group. These findings are frequently observed in animals prior to death and, therefore, the increased incidence of these findings was attributed to the increased mortality in this dose group.

In addition to routine observations for clinical signs of toxicity other documentation during the in-life portion of this study suggested that oral consumption of the TREGDMA was likely to have occurred in the high dose group and possibly in the mid and low dose groups because the fur surrounding the treatment site became contaminated with the test substance. These observations were recorded in the raw data and photographs of representative animals taken periodically throughout the study. The contamination gradually became more noticeable from Monday to Friday (days of dosing) and improved over the weekend (animals were not dosed over the weekend). Therefore, it is assumed that the normal preening behavior of the animals resulted in oral consumption of the test substance (an examination of the inside of the caging for some of these animals did not indicate that the test substance was rubbing off onto the cage). The possible effects of this inadvertent route of exposure must be taken into account in the evaluation of the results of this 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 (Lamminuusta 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.

The mean measured rate of epidermal basal cell proliferation of the mid and high dose groups was consistently increased as compared to both control groups throughout the study. While the rate of epidermal cell proliferation was slightly higher in the high dose group than the mid dose group at all measurement intervals except at Week 4, the differences between these dose groups were most likely not biologically significant. At the Week 4 and 13 measurement intervals, the rate of cell proliferation for both of these groups was approximately 65 to 127% increased over the control groups. However, at the Week 52 and 78 measurement intervals the rate of cell proliferation for these groups was approximately 25 to 60% increased over the control groups. Therefore, the proliferative response of the skin to TREGDMA decreased as the animals aged. The cause or biological significance of this change in proliferative response was unknown. There were no biologically significant differences in the rate of epidermal basal cell proliferation between the control groups and the low dose group of TREGDMA-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 26. 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 (to brain) liver weights of the vehicle treated control group as compared to the untreated control and low 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.

Both the mean absolute and relative weight of the kidneys were statistically significantly increased in the mid (8 to 12%) and high (14 to 19%) dose groups as compared to both control groups.

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 TREGDMA. At Week 52 (mid and high dose groups) and 78 (high dose group), there was also a numerical increase in the number of animals with grossly enlarged kidneys. There were no other biologically significant, treatment-related necropsy findings observed in any dose group. 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 minimal 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 TREGDMA 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 mid and high dose groups with both control groups indicated TREGDMA-related changes only in the skin. The diagnosis and incidence of lesions in the mid and high dose groups were similar and were indicative of chronic cutaneous irritation/inflammation. The lesions, primarily graded as minimal to mild, included acanthosis, hyperkeratosis/parakeratosis, and dermatitis. There were no biologically significant indications of chronic inflammation at the treatment site in the low dose group.

Microscopic diagnoses did not reveal a cause for either the increased kidney weights or decreased survival in the mid and high dose groups. While dilated hyperplastic tubules of the kidney was statistically significantly increased in the high dose group as compared to both control groups, the lesion was graded as minimal for most affected animals and was not, therefore, considered to be biologically significant. In high dose group animals that died or were sacrificed in a moribund condition, there was a slightly increased frequency of mineralization in several organs as well as increased frequency of alveolar histiocytosis as compared to both controls. Neither of these lesions were considered to be responsible for the increased mortality in the high dose group. Finally, there were no biologically significant differences between groups in the frequencies of kidney lesions in animals that died or were sacrificed in a moribund condition. Therefore, a cause for the decreased survival in the high dose group was not identified.

CONCLUSIONS

Cutaneous treatment of C3H/HeNHsd male mice with 50 μ l of 5, 25, or 50% of TREGDMA in acetone 5 days/week for at least 78 weeks did not result in any treatment-related changes in hematology, clinical chemistry, mean absolute body weights, or body weight gain. The mid and high dose groups had slightly decreased survival as compared to both control groups but only the mean survival time of the high dose group was statistically significantly different from the control groups. 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 an increased cell turnover rate that was very similar in the mid and high dose groups. The increase was greatest at the 4 and 13 Week measurement intervals and tended to be less pronounced at the 52 and 78 Week measurement intervals. Microscopic examination at 78 Weeks again indicated very similar chronic cutaneous irritation changes at the site of treatment in the mid and high dose groups. 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.

There were no microscopic lesions in the mid and/or high dose groups that were considered to result in an increased incidence of mortality. Therefore, the statistically significantly increased size of the kidneys (observed as increased mean absolute and relative organ weights) in the mid and high dose groups at the terminal sacrifice was the only finding in these groups, other than the chronic skin irritation, that was considered to be biologically significant. However, microscopic diagnoses of the kidneys did not reveal a cause of the increased size of the kidneys. An increased incidence of dilated hyperplastic tubules of the kidney in animals sacrificed at Week 78 was not considered to be biologically significant. The chronic cutaneous irritation observed in this study was not considered to be sufficiently severe to result in increased mortality in these groups. Therefore, while a cause for the increased mortality in the mid and high dose groups was not identified, the increased kidney weights may have been related to the mortality observed in this study.

Based upon observations made during the in-life phase of the study that were recorded in the raw data as well as in photographs taken of some animals on this study, oral consumption of the TREGDMA was likely to have occurred in, at least, the high dose group. The effect of this inadvertent route of exposure on the kidney weights and decreased survival is unknown but must be considered.

Under the conditions of this study, the No-Observed-Adverse-Effect Level (NOAEL) for TREGDMA was considered to be 5%. Furthermore, under the conditions of this study, there was no indication of carcinogenicity of TREGDMA at any dose level.

REVIEW AND APPROVAL

Study Director:

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

Director:

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

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 Consultant: R. H. Garman

Additional personnel are listed in the raw data.

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TABLE 1
TRISTYRENE GLYCOL DIMETHACRYLATE (TRGDMA): CHRONIC DERMAL
BIOASSAY IN C57BL/6J MALE MICE

SUMMARY OF MORTALITY

	MALE				
	DOSE LEVEL				
	0¹	0²	1.0g	25.0g	50.0g
Total Number of Animals	70	70	70	70	70
Number Sacrificed (Week 4)	5	5	5	5	5
Number Sacrificed (Week 13)	5	5	5	5	5
Number Sacrificed (Week 52)	5	4	4	4	5
Number Sacrificed (Week 70)	40	39	39	34	27
Number Found Dead	8	14	12	13	14
Number Sacrificed Moribund	6	3	5	8	14
Number Accidental	1	0	0	0	0
Number Procedural	0	0	0	1	0
Mean Survival Time (Days)	535	532	526	503	508 ^{abc}

Statistical analysis was performed on the mean survival time for all groups compared individually to the control groups using the Kaplan-Meier method.

^aStatistically significant to the untreated control group by the Breslow statistic for equality of survival curves (p < 0.05).

^bStatistically significant to the untreated control group by the Mantel-Cox statistic for equality of survival curves (p < 0.01).

^cStatistically significant to the vehicle control group by Breslow and Mantel-Cox statistics for equality of survival curves (p < 0.05).

¹untreated control group

²vehicle treated control group

0 7 3 2

FIGURE 1
TRIETHYLENE GLYCOL DIMETHACRYLATE (TREGDMA): CHRONIC DERMAL BIOASSAY IN
C3H/HeNsd MALE MICE
SURVIVAL CURVES

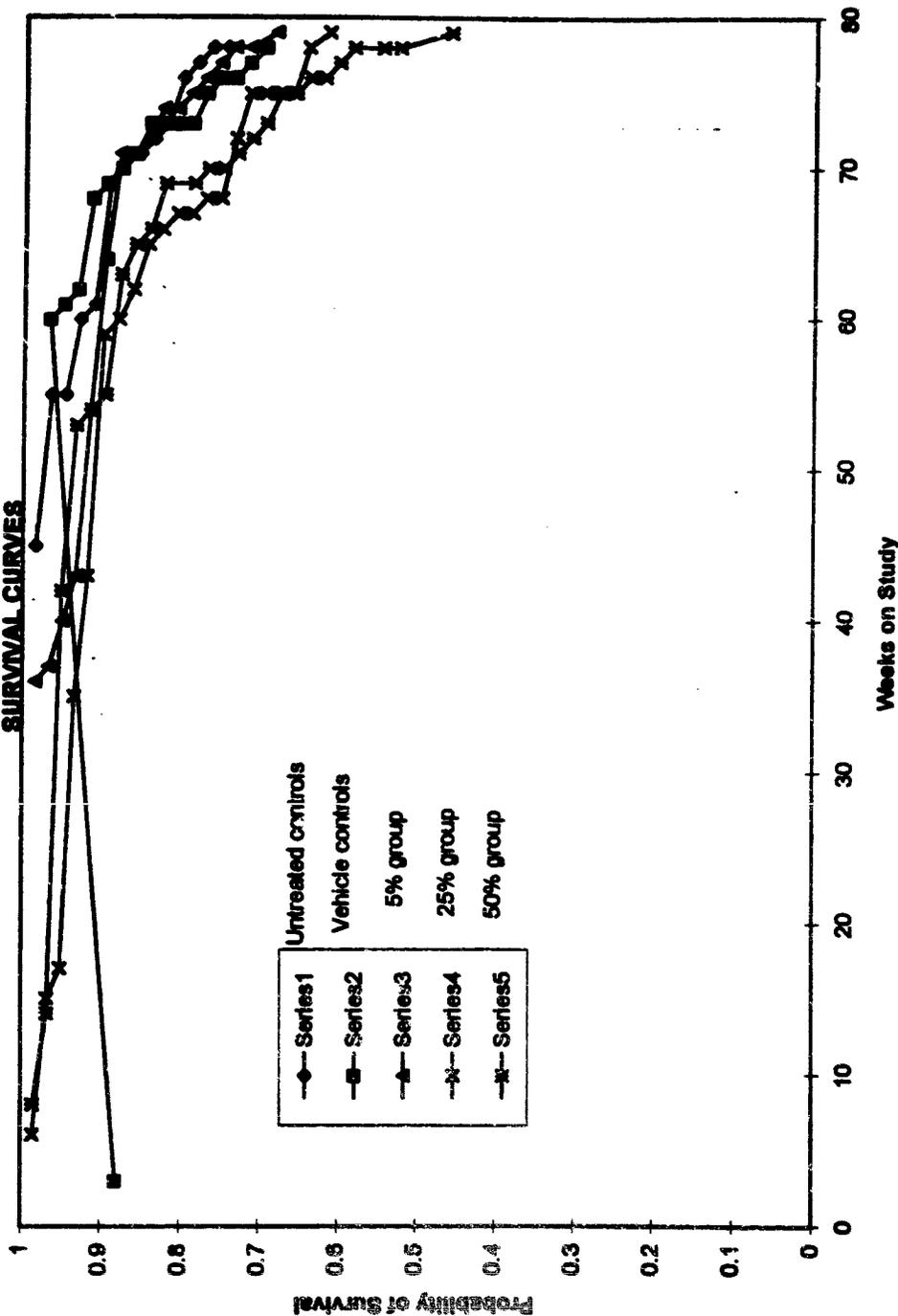


TABLE 2
 TRIFLUOROMETHYL GLYCOL DIMETHACRYLATE (TFGDMA): CHRONIC DERMAL
 BIOASSAY IN C3H/HEMISP MALE MICE
 SUMMARY OF CLINICAL OBSERVATIONS

CATEGORY FINDING (LOCATION)	GROUP:	MALES				
		1 GRADE: (DAYS)	2 (DAYS)	3 (DAYS)	4 (DAYS)	5 (DAYS)
NEURON/CNS						
HYPOACTIVE						
PARALYSIS (LEG-HIND-BOTH)	P	7(308-543)	2(23-494)	4(203-539)	6(415-550)	6(95-551)
PARALYSIS (LEG-HIND-LEFT)	P	1(507-542)	0	0	0	0
ATAXIA	P	1(494)	0	0	0	0
TREMOR	P	2(539-543)	0	0	0	4(403-543)
MELICOPTRING	P	2(311-543)	2(494-548)	2(252-516)	6(415-550)	1(523-524)
CIRCLING	P	3(311-555)	1(533-549)	3(442-548)	3(415-555)	0
PROSTRATION	P	0	0	0	1(456)	0
	P	0	2(437-548)	4(500-548)	2(464-525)	9(54-551)
NOSE						
PRURITIC	P	1(388)	6(356-548)	5(247-548)	6(429-550)	10(295-551)
DEHYDRATED	P	9(71-543)	8(239-514)	8(197-548)	12(99-543)	17(53-551)
SWELLING (ABDOMEN)	P	52 39(302-556)	54 25(246-556)	53 29(337-556)	54 30(267-556)	53 39(106-556)

GROUP LEGEND: 1 is 0 (UNTREATED), 2 is 06 (VEHICLES), 3 is 5.0 v, 4 is 25.0 v, 5 is 50.0 v
 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)
 TRIPHENYLENE GLYCOL DIMETHACRYLATE (TRIGONA); CHRONIC DERMAL
 BIOASSAY IN C3H/HEMISP MALE MICE
 SUMMARY OF CLINICAL OBSERVATIONS

CATEGORY FINDING (LOCATION)	GROUP:	MALES				
		1 GRADE (DAYS)	2 (DAYS)	3 (DAYS)	4 (DAYS)	5 (DAYS)
BODY SWELLING (CONTINUED) (CHEST) (EAR-RIGHT) (FACE) (GENITAL) (HEAD) (INGUINAL-LEFT) (INGUINAL-RIGHT) (NECK) (PENIS) (SCROTUM) (SIDE-BOTH)	P	0	0	0	0	1(512-547)
	P	0	0	1(295-553)	0	0
	P	0	0	0	1(113-120)	1(344-386)
	P	44(78-555)	44(8-556)	44(9-555)	43(211-556)	41(57-555)
	P	0	0	1(246-252)	1 (122)	0
	P	3(351-404)	0	0	5(106-393)	8(106-505)
	P	1 (491)	1 (302)	2(344-548)	0	3(148-337)
	P	0	0	1(505-512)	0	0
	P	7(323-555)	20(239-555)	14(197-556)	14(351-556)	17(190-551)
	P	0	0	0	0	1(372-547)
	P	0	0	0	2(491-533)	1(133-134)
	P	0	0	0	0	1 (480)

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 5.0%, 4 is 25.0%, 5 is 50.0%

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)
 TRIFLUOROMETHYL DINITROCHLORIDE (TRICERNA); CHRONIC DERMAL
 RIGOR IN C3H/WHIMED MALE MICE
 SUMMARY OF CLINICAL OBSERVATIONS

CATEGORY FINDING (LOCATION)	GROUP:	GRADE	DAYS					
			1	2	3	4	5	
			(DAYS)	(DAYS)	(DAYS)	(DAYS)	(DAYS)	
BODY								
	SWELLING (CONFINED) (SIDE-LEFT)	P	4(494-540)	1(519-526)	3(225-548)	7(155-548)	1(379-435)	
	(SIDE-RIGHT)	P	0	4(463-540)	2(253-533)	3(281-533)	4(106-435)	
	(SHOULDER-LEFT)	P	0	1(519-533)	1(540)	0	0	
	(SHOULDER-RIGHT)	P	0	1(442-456)	0	0	0	
	(TREATMENT AREA)	P	1(428-456)	1(442-470)	1(533-549)	2(456-549)	0	
	ABDOMINAL DISTENSION	P	5(246-540)	12(316-556)	6(379-554)	9(414-555)	14(95-554)	
	UNEWEIGHT	P	2(421-505)	2(302-386)	1(435)	1(428)	4(294-491)	
	URINE STAINING	P	18(274-549)	15(274-548)	18(78-556)	22(316-556)	16(71-553)	
	COLD EXTREMITIES (LEGS-ALL)	P	3(388-543)	5(23-548)	6(500-548)	7(421-550)	9(295-551)	
FALLOR (ENTIRE BODY)	P	1	0	0	2	3	1	
	P	0	0	0	2(421-500)	0	1(294)	
	P	1(494)	0	0	1(428-435)	3(428-526)	0	

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 5.0%, 4 is 25.0%, 5 is 50.0%

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)
 TRITHYLENE GLYCOL DIMETHACRYLATE (TRIEDMA); CHRONIC DERMAL
 BIOASSAY IN C3H/HEMISD MALE MICE
 SUMMARY OF CLINICAL OBSERVATIONS

CATEGORY FINDING (LOCATION)	GROUP:	MALES					
		1 GRADE (DAYS)	2 (DAYS)	3 (DAYS)	4 (DAYS)	5 (DAYS)	
BODY	FALLOR (CONTINUED) (PAWS-ALL)	P 0	0	0	0	1 (525)	0
	HUNCHER POSTURE	P 4(311-554)	0	0	3(255-491)	4(525-543)	3(491-550)
	UROGENITAL DISCHARGE, RED	P 0	0	0	0	0	2(463-480)
	RECTAL PROLAPSE	P 1 (120)	1 (141)	1 (141)	2(120-518)	2(64- 71)	0
	TRAUMATIZED (HOSE)	P 0	1 (23)	0	0	0	0
	UROGENITAL AREA WETNESS	P 11(246-547)	8(302-548)	7(291-547)	10(281-550)	9(53-551)	
	HEAD TILT	P 3(456-555)	1(533-549)	3(442-548)	4(302-555)	0	
	BLUE CUTIS (ABDOMEN)	P 5 3(421-494)	2(463-540)	1 (526)	4(428-526)	7(428-540)	
	(ENTIRE BODY)	P 2(532-543)	1(505-514)	0	1 (421)	1 (543)	
	CARDIO-PULMONARY LABORED RESPIRATION	P 3(494-543)	6(23-548)	6(247-548)	8(421-550)	11(95-543)	

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 5.0%, 4 is 25.0%, 5 is 50.0%

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 DIMETHACRYLATE (TRIGEMA); CHRONIC DERMAL
 BIOASSAY IN CBN/FINISHED KULS MICE
 SUMMARY OF CLINICAL OBSERVATIONS

MALES

CATEGORY FINDING (LOCATION)	GROUP:	GRADE (DAYS)					5 (DAYS)
		1 (DAYS)	2 (DAYS)	3 (DAYS)	4 (DAYS)	(DAYS)	
CARDIO-PULMONARY							
RAPID RESPIRATION	P	1 (505)	0	0	0	0	0
SLOW RESPIRATION	P	1 (422)	0	0	5 (283-539)	3 (501-513)	6 (386-533)
ETES/TEES/NOSES							
CORNEAL ULCERATION (EYE-LEFT)	P	0	0	0	0	1 (113-120)	1
(EYE-RIGHT)	P	0	0	0	0	0	1 (379-386)
OPACITY (EYE-LEFT)	P	4 (456-550)	0	0	0	0	1 (463-540)
(EYE-RIGHT)	P	1 (428-550)	0	0	0	0	0
LACRIMATION (EYE-RIGHT)	P	0	0	0	0	0	1 (366-372)
OCULAR DISCHARGE (EYE-LEFT)	P	1 (463-533)	0	0	1 (225-252)	0	3
(EYE-RIGHT)	P	0	0	0	0	0	0
SWOLLEN PERIOCCULAR TISSUE	P	0	0	0	0	0	3 (386-550)
		1	0	0	1	0	1

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLES), 3 is 5.0%, 4 is 25.0%, 5 is 50.0%

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)
 TRIMETHYLENE GLYCOL DIMETHACRYLATE (TREGDMA): CHRONIC DERMAL
 BIOASSAY IN C3H/334MSD MALE MICE
 SUMMARY OF CLINICAL OBSERVATIONS

MALES

CATEGORY FINDING (LOCATION)	GROUP	1 GRADE (DAYS)	2 (DAYS)	3 (DAYS)	4 (DAYS)	5 (DAYS)
EYES/NARS/NOSE SWOLLEN PERIOCLAR TISSUE (CONTINUED)						
	(EYE-LEFT)	P 1(456-491)	0	0	1(232-246)	0
(EYE-RIGHT)	P 0	0	0	0	0	1(344-372)
PERIOCLAR ENCRUSTATION						
	(EYE-LEFT)	P 3 1(498-547)	0	0	0	0
(EYE-RIGHT)	P 2(498-542)	0	0	0	0	1 (379)
ELEPHANTSPASH						
	(EYE-BOTH)	P 2	0	0	0	0
(EYE-LEFT)	P 0	0	0	0	0	2
(EYE-RIGHT)	P 1(498-547)	0	0	0	0	1 (499)
ENCRIETA	P 1 (494)	0	0	0	0	0
LOOSE FECES	P 0	0	0	0	0	1 (480)
ORAL/DENTAL OVERGROWN INCISORS	P 0	0	0	0	1(36-155)	0

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 5.0%, 4 is 25.0%, 5 is 50.0%

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)
 TRIFLUOROMETHYL DIMETHACRYLATE (TRIFLOMA): CHRONIC DERMAL
 BIOASSAY IN C3H/HEMISP MALE MICE
 SUMMARY OF CLINICAL OBSERVATIONS

CATEGORY FINDING (LOCATION)	GROUP	GRADE (DAYS)				
		1	2	3	4	5
		(DAYS)	(DAYS)	(DAYS)	(DAYS)	(DAYS)
ORAL/DERMAL						
PERIORAL EXCORIATION	F	0	1 (23)	0	0	0
SKIN						
ALOPECIA (ABDOMEN)	F	18 2(36-134)	20 2(50-176)	25 2(64- 85)	25 1(64-218)	25 1 (176)
(CHEST)	F	13(22-554)	15(0-556)	21(36-556)	24(29-553)	21(57-554)
(FACE)	F	0	0	0	0	1 (148)
(GENITAL)	F	0	1 (470)	1(393-477)	1(428-435)	1 (512)
(LEG-FORE-LEFT)	F	0	1 (29)	0	0	0
(LEG-FORE-RIGHT)	F	1 (92)	0	0	0	0
(MULTIPLE AREAS-NOS)	F	12(78-556)	13(29-555)	12(43-555)	8(43-556)	7(71-555)
(TREATMENT AREA)	F	0	0	1(295-309)	0	2 (449)
EXCORIATED (CHEST)	F	12	14	18	6	6
	F	0	1 (555)	0	0	1(470-519)

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 5.0%, 4 is 25.0%, 5 is 50.0%

Grades: 0 = 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 DIMETHACRYLATE (TREGDMA); CHRONIC DERMAL
 BIOASSAY IN C3H/H1HSD MALE MICE
 SUMMARY OF CLINICAL OBSERVATIONS

MALES

CATEGORY FINDING (LOCATION)	GROUP:	1 GRADE (DAYS)	2 (DAYS)	3 (DAYS)	4 (DAYS)	5 (DAYS)
EXCORIATED (CONTINUED) (GENITAL)	P	4(379-556)	1(556)	1(490-505)	1(555)	0
	P	0	0	2(484-491)	0	0
	P	0	0	1(15)	0	0
	P	8(386-556)	12(50-554)	15(92-533)	5(420-463)	5(400-512)
	P	5	4	8	4	4
CRUST (CHEST)	P	0	0	1(148-162)	0	1(366-372)
	P	0	0	1(295-553)	0	0
(EAR-RIGHT)	P	2(309-372)	1(281-344)	2(274-302)	2(246-302)	1(43)
	P	0	1(470)	1(141)	0	0
(GENITAL)	P	0	0	1(197-218)	0	0
	P	3(197-554)	2(155-197)	3(71-484)	2(99-519)	2(22-106)
(NECK)	P	0	0	0	0	0
	P	0	0	0	0	1(491-553)
(SIDE-RIGHT)	P	0	0	0	0	0
	P	0	0	0	0	0
(TREATMENT AREA)	P	0	0	0	0	0
	P	0	0	0	0	0
PAPULE (TREATMENT AREA)	P	0	0	0	0	0
	P	0	0	0	0	0

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 5.0%, 4 is 25.0%, 5 is 50.0%

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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21
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26

TABLE 2 (Continued)
 TRIMETHOPRIM GLYCOL DIMETHACRYLATE (TRIMDMA): CHRONIC DERMAL
 BIOASSAY IN C3H/HEMISD MALE MICE
 SUMMARY OF CLINICAL OBSERVATIONS

CATEGORY FINDING (LOCATION)	GROUP:	MALES				
		1 GRADE (DAYS)	2 (DAYS)	3 (DAYS)	4 (DAYS)	5 (DAYS)
PIMPLE (GENITAL)	P	1 (43-64)	0	0	0	0
	P	0	0	0	1 (122)	0
NECROSIS (EYE-LEFT)	P	19	25	53	67	70
	P	0	0	0	0	1 (533-549)
EXFOLIATION/DESCAMATION (CHEST)	P	0	0	1 (526)	0	0
	P	0	0	0	0	0
(MULTIPLE AREAS-ROB)	P	19 (127-555)	25 (127-556)	53 (29-556)	67 (15-556)	70 (9-556)
	1	0	0	0	2 (470-555)	7 (306-550)
(TREATMENT AREA)	P	24	17	32	16	15
	P	0	0	1 (549)	0	0
ULCER (DRY) (ARUS)	P	1 (498-512)	0	2 (169-547)	2 (512-556)	1 (379-540)
	P	6 (400-505)	4 (414-555)	8 (106-533)	5 (337-449)	8 (344-554)
(CHEST)	P	0	0	1 (449-456)	0	0
	P	1 (526-554)	0	1 (477-491)	0	1 (456-463)
(GENITAL)	P	0	0	0	0	0
	P	0	0	0	0	0
(LEG-HIND-RIGHT)	P	0	0	0	0	0
	P	0	0	0	0	0
(MULTIPLE AREAS-ROB)	P	0	0	0	0	0
	P	0	0	0	0	0

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 5.0%, 4 is 25.0%, 5 is 50.0%

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 DIMETHACRYLATE (TRIGDMA); CHRONIC DERMAL
 BIOASSAY IN C3H/HEMISD MALE MICE
 SUMMARY OF CLINICAL OBSERVATIONS

CATEGORY FINDING (LOCATION)	GROUP	GRADE (DAYS)					5 (DAYS)
		1	2	3	4		
MALES							
SKIN							
ULCER (DRY) (CONTINUED)							
(NECK)	P	3(407-498)	1(470)	2(498-533)	1(344)	0	0
(SIDE-RIGHT)	P	0	0	1(211-255)	0	0	0
(TREATMENT AREA)	P	17(155-519)	13(99-519)	25(127-526)	10(99-540)	0(127-442)	0
ESCHAR (SCAB) (TAIL)	P	0	0	1(22)	0	0	0
OPEN SORE (NET)							
(APUS)	P	3	2	4	1(456-477)	0	0
(CHEST)	P	1(540-554)	0	1(155-162)	0	0	0
(GENITAL)	P	2(302-498)	1(302-344)	1(358)	1(498)	0	0
(SIDE-RIGHT)	P	0	0	1(197-204)	0	0	0
(SHOULDER-LEFT)	P	0	1(553)	0	0	0	0
DISCOLORATION (TREATMENT AREA)	P	0	0	1(253-281)	0	1(491-553)	0
HAIRS							
HAIR(S) PRESENT	P	1(463-556)	2(477-548)	1(176-190)	0	1(512-555)	0

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 5.0%, 4 is 25.0%, 5 is 50.0%

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)
TRIFLUETHYLENE GLYCOL DIMETHACRYLATE (TFGDMA); CHRONIC DERMAL
BIODASSAY IN C3H/HEMISP MALE MICE
SUMMARY OF CLINICAL OBSERVATIONS

CARTON FINDING (LOCATION)	GROUP:	DAYS					
		1	2	3	4	5	
		CRUDE	(DAYS)	(DAYS)	(DAYS)	(DAYS)	(DAYS)
CLIPPING INJURY (TREATMENT AREA)	P	9(0-549)	10(43-449)	7(232-526)	2(93-162)	0	

MALES

GROUP LEAD: 1 is 0% (UNTREATED), 2 is 0% (VEHICLES), 3 is 5.0 %, 4 is 25.0 %, 5 is 50.0 %

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
 TRIMETHYLENE GLYCOL DIMETHACRYLATE (TREGDMA): CHRONIC DERMAL
 BIOASSAY IN C3H/HEBRED MALE MICE
 SUMMARY OF BODY WEIGHT (GRAMS)

TREGDMA MALES						
GROUP: $\frac{t}{s}$	0.0 ^a	0.0 ^a	5.0	25.0	50.0	
WEEK 0						
MEAN	25.2	25.2	25.4	25.0	24.9	
S.D.	1.18	0.96	1.09	1.07	1.15	
N	70	70	70	70	70	
WEEK 1						
MEAN	26.5	26.8	26.6	26.3	26.4	
S.D.	1.18	1.06	1.15	1.08	1.10	
N	70	70	70	70	70	
WEEK 2						
MEAN	28.1	28.3	27.7 ^d	27.3 ^{bd}	27.5 ^{bd}	
S.D.	1.20	1.22	1.18	1.22	1.28	
N	70	70	70	70	70	
WEEK 3						
MEAN	28.7	28.8	28.7	28.6	28.5	
S.D.	1.21	1.12	1.33	1.16	1.35	
N	70	70	70	70	70	
WEEK 4						
MEAN	29.7	29.7	29.7	29.4	29.4	
S.D.	1.24	1.21	1.44	1.23	1.31	
N	65	64	65	65	65	
WEEK 5						
MEAN	30.1	29.8	30.3	30.4	30.2	
S.D.	1.29	1.25	1.81	1.20	1.37	
N	65	64	65	65	65	
WEEK 6						
MEAN	30.7	30.7	30.8	30.8	30.7	
S.D.	1.42	1.19	1.52	1.33	1.42	
N	65	64	65	64	65	
WEEK 7						
MEAN	31.2	31.2	31.1	31.5	30.8	
S.D.	1.59	1.28	1.56	1.42	1.58	
N	65	64	65	64	65	
WEEK 8						
MEAN	31.4	31.8	31.4	31.7	31.0 ^d	
S.D.	1.74	1.44	1.61	1.82	1.61	
N	65	64	65	64	64	
WEEK 9						
MEAN	31.5	31.7	31.2	31.7	31.2	
S.D.	1.76	1.46	1.59	1.61	1.68	
N	65	64	65	64	64	
WEEK 10						
MEAN	31.9	31.9	31.8	32.1	32.0	
S.D.	2.01	1.43	1.65	1.59	1.79	
N	65	64	65	64	64	
WEEK 11						
MEAN	31.8	32.0	32.0	32.3	32.1	
S.D.	1.99	1.69	1.76	1.59	1.69	
N	65	64	65	64	64	
WEEK 12						
MEAN	32.1	31.6	32.6 ^d	32.7 ^{ad}	32.2	
S.D.	1.76	1.41	1.79	1.77	1.64	
N	65	64	65	64	64	
WEEK 16						
MEAN	32.6	32.6	31.8 ^{bd}	32.6	32.3	
S.D.	1.83	1.58	1.67	1.82	1.56	
N	60	59	60	58	58	

^a Significantly different from the untreated control group (p<.05)
^b Significantly different from the untreated control group (p<.01)
^d 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)
 TRISBETHANE GLUCOSIDIMETHACRYLATE (TRIGEMA): CHRONIC DERMAL
 BIOASSAY IN C57BL/6J MALE MICE
 SUMMARY OF BODY WEIGHT (GRAMS)

GROUP:	TRIGEMA MALES				
	0.0 ^a	0.0 ^b	5.0	25.0	50.0
WEEK 20					
MEAN	32.4	32.3	31.8	32.6	32.3
S.D.	1.60	1.64	1.65	1.73	1.64
N	60	59	60	57	58
WEEK 24					
MEAN	32.5	32.7	31.8 ^{cd}	32.5	32.5
S.D.	1.70	1.70	1.48	1.69	1.71
N	60	59	60	57	58
WEEK 28					
MEAN	32.9	33.0	32.7	32.7	32.9
S.D.	1.71	1.73	1.85	1.63	1.75
N	60	59	60	57	58
WEEK 32					
MEAN	33.5	33.8	32.9 ^d	33.6	33.7
S.D.	1.89	1.81	1.71	1.82	1.84
N	60	59	60	57	58
WEEK 36					
MEAN	33.8	33.8	33.8	34.0	33.8
S.D.	1.94	1.57	2.04	1.82	1.88
N	60	59	59	56	58
WEEK 40					
MEAN	33.8	34.0	33.6	34.2	33.3
S.D.	2.04	2.04	1.77	1.96	1.94
N	60	59	58	56	58
WEEK 44					
MEAN	33.3	33.6	34.1	33.9	33.6
S.D.	2.05	2.10	1.84	1.82	2.12
N	60	59	56	55	57
WEEK 48					
MEAN	33.7	34.2	33.9	34.8 ^b	33.8
S.D.	2.07	2.35	1.97	2.20	2.38
N	59	59	56	55	57
WEEK 52					
MEAN	34.4	34.5	34.7	34.9	34.2
S.D.	2.15	2.65	1.93	2.17	2.18
N	54	55	52	51	52
WEEK 56					
MEAN	34.5	34.5	34.8	34.7	34.0
S.D.	2.25	2.66	2.00	2.24	1.85
N	52	55	51	50	49
WEEK 60					
MEAN	34.3	34.2	34.3	34.0	34.3
S.D.	2.24	2.29	2.31	2.31	1.88
N	52	54	51	49	49
WEEK 64					
MEAN	34.3	34.6	34.0	34.3	34.0
S.D.	2.12	1.99	2.02	1.86	1.88
N	50	52	51	47	48
WEEK 68					
MEAN	34.0	34.1	34.1	34.5	34.0
S.D.	2.17	2.16	2.31	1.86	2.23
N	50	51	50	4	46
WEEK 72					
MEAN	33.8	34.7	33.7	34.6	34.0
S.D.	2.64	2.21	2.33	1.84	1.95
N	47	48	48	40	39

^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<.01)
^d untreated control group
^e vehicle treated control group

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TABLE 3 (continued)
 TRIETHYLENE GLYCOL DIMETHACRYLATE (TRIGDMA): CHRONIC DERMAL
 BIOASSAY IN C57/BL6/MSH MALE MICE
 SUMMARY OF BODY WEIGHT (GRAMS)

GROUP: 0	TRIGDMA MALES				
	0.0 ¹	0.0 ²	5.0	25.0	50.0
WEEK 76					
MEAN	33.6	34.2	33.9	34.3	33.9
S.D.	2.74	2.36	1.77	2.16	2.13
N	44	43	44	36	35
WEEK 78					
MEAN	33.7	34.4	33.3	33.7	33.5
S.D.	2.42	2.84	2.32	2.23	2.46
N	35	35	36	30	24

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

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

GROUP: 0	TRISOMA MALES				
	0.0 ^a	0.0 ^a	5.0	25.0	50.0
WEEK 0 TO 1					
MEAN	1.3	1.6 ^b	1.2 ^d	1.2 ^d	1.5 ^a
S.D.	0.41	0.39	0.53	0.64	0.48
N	70	70	70	70	70
WEEK 0 TO 2					
MEAN	2.9	3.1 ^a	2.3 ^{bd}	2.3 ^{bd}	2.5 ^{bd}
S.D.	0.55	0.61	0.71	0.85	0.62
N	70	70	70	70	70
WEEK 0 TO 3					
MEAN	3.5	3.6	3.3	3.5	3.6
S.D.	0.62	0.60	0.83	0.71	0.73
N	70	70	70	70	70
WEEK 0 TO 4					
MEAN	4.5	4.4	4.3	4.4	4.5
S.D.	0.72	0.62	1.03	0.84	0.79
N	65	64	65	65	65
WEEK 0 TO 5					
MEAN	4.9	4.6 ^a	4.9	5.4 ^{bd}	5.3 ^{bd}
S.D.	0.83	0.69	1.44	0.88	0.90
N	65	64	65	65	65
WEEK 0 TO 6					
MEAN	5.5	5.4	5.4	5.8 ^c	5.8 ^c
S.D.	0.87	0.74	1.10	0.95	0.77
N	65	64	65	64	65
WEEK 0 TO 7					
MEAN	6.0	5.9	5.6 ^a	6.5 ^{ad}	5.8
S.D.	1.00	0.87	1.08	1.23	1.01
N	65	64	65	64	65
WEEK 0 TO 8					
MEAN	6.2	6.6	5.9 ^d	6.7 ^b	6.1 ^c
S.D.	1.35	0.98	1.19	1.56	1.09
N	65	64	65	64	64
WEEK 0 TO 9					
MEAN	6.3	6.5	5.8 ^{ad}	6.7	6.3
S.D.	1.32	0.99	1.14	1.17	1.10
N	65	64	65	64	64
WEEK 0 TO 10					
MEAN	6.7	6.6	6.3	7.1 ^c	7.1 ^{ac}
S.D.	1.57	0.98	1.21	1.14	1.22
N	65	64	65	64	64
WEEK 0 TO 11					
MEAN	6.6	6.8	6.5	7.3 ^{bc}	7.1 ^a
S.D.	1.55	1.27	1.33	1.11	1.08
N	65	64	65	64	64
WEEK 0 TO 12					
MEAN	6.9	6.4 ^a	7.1 ^d	7.7 ^{bd}	7.3 ^d
S.D.	1.26	1.11	1.34	1.38	1.06
N	65	64	65	64	64
WEEK 0 TO 16					
MEAN	7.3	7.3	6.2 ^{bd}	7.6	7.4
S.D.	1.32	1.17	1.33	1.42	1.06
N	60	59	60	58	58
WEEK 0 TO 20					
MEAN	7.1	7.0	6.3 ^{bd}	7.5 ^c	7.4
S.D.	1.11	1.30	1.35	1.34	1.18
N	60	59	60	57	58

^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)
^u untreated control group
^v vehicle treated control group

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TABLE 4 (continued)
 TRISTHYLENE GLYCOL DIMETHACRYLATE (TRGDMA): CHRONIC DERMAL
 BIOASSAY IN C3H/HEMISP MALE MICE
 SUMMARY OF BODY WEIGHT GAIN (GRAMS)

TRGDMA MALES						
GROUP: 6	0.0 ^a	0.0 ^a	5.0	25.0	50.0	
WEEK 0 TO 24						
MEAN	7.2	7.4	6.2 ^{bd}	7.4	7.6	
S.D.	1.21	1.35	1.20	1.34	1.10	
N	60	59	60	57	58	
WEEK 0 TO 28						
MEAN	7.7	7.7	7.2 ^c	7.6	8.0	
S.D.	1.21	1.38	1.56	1.33	1.31	
N	60	59	60	57	58	
WEEK 0 TO 32						
MEAN	8.2	8.6	7.4 ^{bd}	8.5	8.8 ^a	
S.D.	1.36	1.55	1.35	1.38	1.35	
N	60	59	60	57	58	
WEEK 0 TO 36						
MEAN	8.6	8.5	8.3	8.9	8.9	
S.D.	1.27	1.65	1.61	1.42	1.27	
N	60	59	59	56	58	
WEEK 0 TO 40						
MEAN	8.6	8.8	8.1 ^c	9.1 ^a	8.4	
S.D.	1.45	1.73	1.15	1.54	1.35	
N	60	59	58	56	58	
WEEK 0 TO 44						
MEAN	8.1	8.3	8.6	8.9	8.7	
S.D.	1.63	1.84	1.31	1.45	1.44	
N	60	59	56	55	57	
WEEK 0 TO 48						
MEAN	8.4	9.0	8.3	9.8 ^{bc}	8.8	
S.D.	1.58	2.06	1.50	1.77	1.74	
N	59	59	56	55	57	
WEEK 0 TO 52						
MEAN	9.2	9.1	9.1	9.8	9.2	
S.D.	1.54	2.46	1.46	1.70	1.66	
N	54	55	52	51	52	
WEEK 0 TO 56						
MEAN	9.3	9.2	9.2	9.6	9.0	
S.D.	1.64	2.41	1.55	1.77	1.39	
N	52	55	51	50	49	
WEEK 0 TO 60						
MEAN	9.1	8.9	8.7	8.9	9.4	
S.D.	1.71	1.89	1.79	1.96	1.54	
N	52	54	51	49	49	
WEEK 0 TO 64						
MEAN	9.2	9.3	8.4 ^{ad}	9.2	9.1	
S.D.	1.51	1.76	1.65	1.42	1.58	
N	50	52	51	47	48	
WEEK 0 TO 68						
MEAN	8.8	8.8	8.5	9.4	9.1	
S.D.	1.51	1.88	1.82	1.45	2.04	
N	50	51	50	41	46	
WEEK 0 TO 72						
MEAN	8.7	9.3	8.1 ^d	9.4	9.2	
S.D.	1.94	1.98	2.10	1.53	1.59	
N	47	48	48	40	39	
WEEK 0 TO 76						
MEAN	8.4	8.8	8.3	9.1	9.1	
S.D.	2.25	2.18	1.57	1.79	1.82	
N	44	43	44	36	35	

^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

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

GROUP: 0	TREATMENT MALES				
	0.0 ^a	0.0 ^b	3.0	25.0	50.0
WEEK 0 TO 78					
MEAN	0.6	3.1	7.8	0.4	0.7
S.D.	1.98	2.55	2.14	1.95	1.91
N	35	35	36	30	24

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

0 7 5 0

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

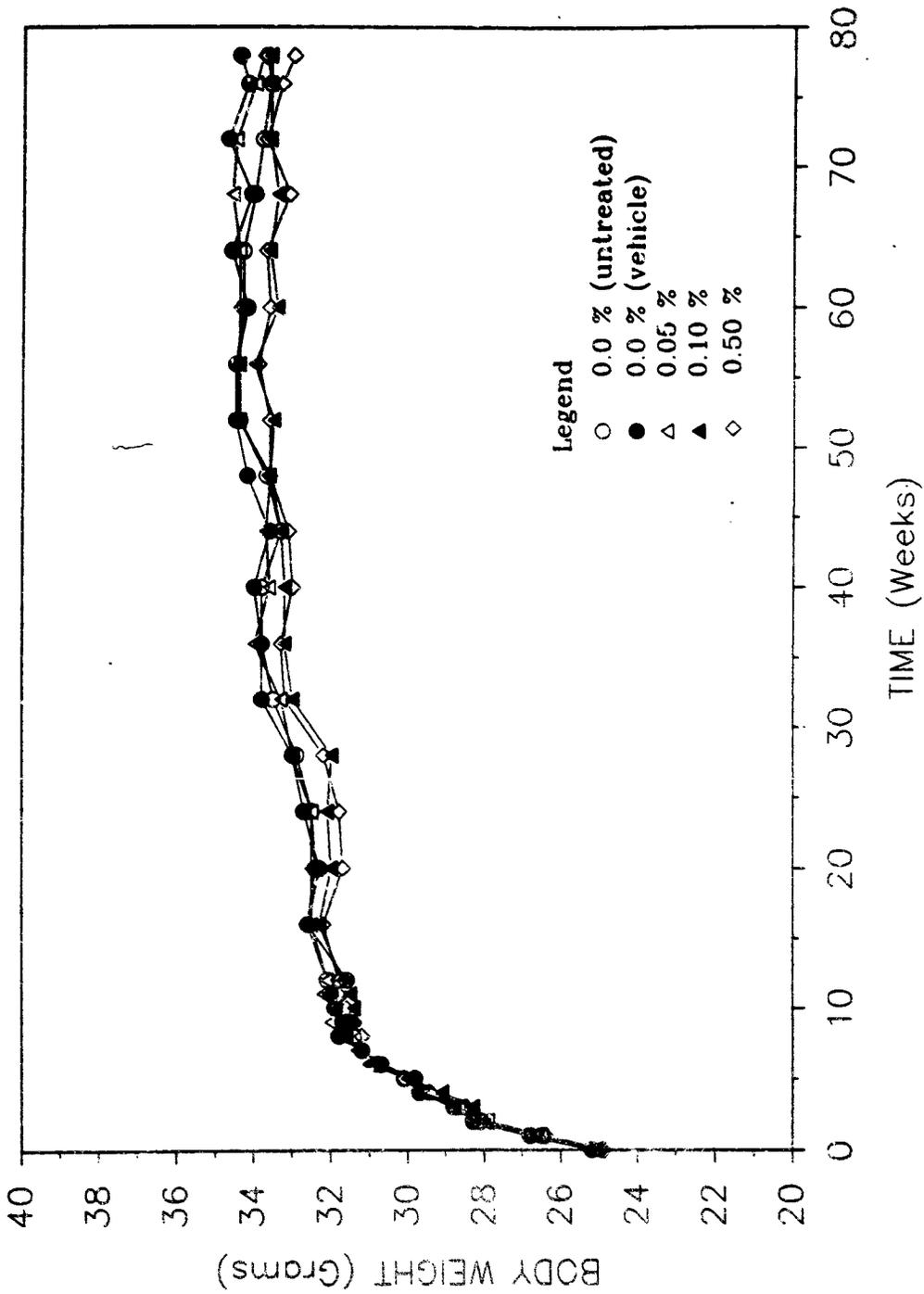


TABLE 5
 TRINITYLENE GLYCOL DICHAZYLATE (TRIGEMA): CHRONIC DERMAL
 BIOASSAY IN C57/BL6J MALE MICE
 SUMMARY OF HEMATOLOGY
 WEEK 52

TRIGEMA MALES						
GROUP: 0	0.0 ^a	0.0 ^a	3.0	25.0	50.0	
ERYTHROCYTES (10⁶/μl)						
MEAN	7.72	8.07	7.41	7.33	7.40	
S.D.	0.343	0.750	0.264	0.277	0.392	
N	5	5	5	5	5	
HEMOGLOBIN (g/dL)						
MEAN	13.3	14.1	13.3	12.8	13.3	
S.D.	0.86	0.82	0.40	0.58	0.95	
N	5	5	5	5	5	
HEMATOCRIT (%)						
MEAN	38.8	41.3	38.3 ^c	37.1 ^d	38.6 ^c	
S.D.	1.56	2.83	1.42	1.05	2.29	
N	5	5	5	5	5	
MEAN CORPUSCULAR VOLUME (μm³)						
MEAN	50.	51.	52.	50.	52.	
S.D.	1.1	1.2	0.5	2.4	1.4	
N	5	5	5	5	5	
MEAN CORPUSCULAR HEMOGLOBIN (pg)						
MEAN	17.2	17.5	17.9	17.5	18.0	
S.D.	0.60	0.59	0.16	0.95	0.49	
N	5	5	5	5	5	
MEAN CORPUSCULAR HEMOGLOBIN CONCENTRATION (g/dL)						
MEAN	34.3	34.2	34.6	34.5	34.5	
S.D.	0.68	0.52	0.36	0.62	0.55	
N	5	5	5	5	5	
PLATELETS (10³/μl)						
MEAN	713.	847.	686.	749.	740.	
S.D.	240.7	327.3	75.6	125.2	168.2	
N	5	5	5	5	5	
LEUCOCYTES (10³/μl)						
MEAN	6.1	5.9	5.8	5.7	6.1	
S.D.	1.56	0.63	1.09	0.97	1.30	
N	5	5	5	5	5	
SEGMENTED NEUTROPHILS (10³/μl)						
MEAN	2.15	1.96			1.82	
S.D.	0.962	0.883			0.605	
N	5	5			5	
LYMPHOCYTES (10³/μl)						
MEAN	3.66	3.73			4.09	
S.D.	0.824	0.828			0.769	
N	5	5			5	
MONOCYTES (10³/μl)						
MEAN	0.14	0.09			0.09	
S.D.	0.176	0.069			0.080	
N	5	5			5	

^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

^b vehicle treated control group

0752

TABLE 5 (continued)
 TRIETHYLENE GLYCOL DIBENZOYLATE (TREGDMA): CHRONIC DERMAL
 BIOASSAY IN C3H/HEMISD MALE MICE
 SUMMARY OF HEMATOLOGY
 WEEK 52

TREGDMA MALES						
GROUP: 1	0.0 ¹	0.0 ²	5.0	25.0	50.0	
BASOPHILS (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	0.17	0.07			0.13	
S.D.	0.075	0.076			0.098	
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

0 7 5 3

TABLE 6
 TRINITYLENE GLYCOL DIMETHACRYLATE (TRGDMA): CHRONIC DERMAL
 BIOASSAY IN C57BL/6J MALE MICE
 SUMMARY OF HEMATOLOGY
 WEEK 79

		TRGDMA MALES				
GROUP: 1	0.0 ^a	0.0 ^a	5.0	25.0	50.0	
ERYTHROCYTES (10⁶/μl)						
MEAN	7.42	8.16	8.90	8.18	8.21	
S.D.	1.229	1.083	1.916	0.578	1.443	
N	5	5	5	5	5	
HEMOGLOBIN (g/dl)						
MEAN	12.6	13.7	14.6	13.9	13.7	
S.D.	1.92	0.86	3.42	0.93	2.31	
N	5	5	5	5	5	
HEMATOCRIT (%)						
MEAN	40.8	41.1	45.9	41.8	42.2	
S.D.	3.84	3.88	11.70	3.31	8.21	
N	5	5	5	5	5	
MEAN CORPUSCULAR VOLUME (μm³)						
MEAN	53.	51.	51.	51.	51.	
S.D.	4.7	2.3	3.4	0.8	1.7	
N	5	5	5	5	5	
MEAN CORPUSCULAR HEMOGLOBIN (pg)						
MEAN	17.0	16.9	16.3	17.0	16.7	
S.D.	0.46	1.22	1.23	0.49	0.78	
N	5	5	5	5	5	
MEAN CORPUSCULAR HEMOGLOBIN CONCENTRATION (g/dl)						
MEAN	32.6	33.4	31.9	33.2	32.6	
S.D.	2.20	1.14	1.19	0.63	1.22	
N	5	5	5	5	5	
PLATELETS (10³/μl)						
MEAN	833.	831.	800.	782.	732.	
S.L.	94.4	248.5	437.6	147.3	220.3	
N	5	5	5	5	5	
LEUCOCYTES (10³/μl)						
MEAN	6.3	5.8	4.6	5.8	6.2	
S.D.	3.32	0.39	1.24	1.53	1.60	
N	5	5	5	5	5	
SEGMENTED NEUTROPHILS (10³/μl)						
MEAN	3.02	3.02			2.93	
S.D.	3.427	1.108			1.157	
N	5	5			5	
LYMPHOCYTES (10³/μl)						
MEAN	2.35	2.60			2.98	
S.D.	0.828	0.829			0.411	
N	5	5			5	
MONOCYTES (10³/μl)						
MEAN	0.09	0.12			0.14	
S.D.	0.102	0.212			0.174	
N	5	5			5	

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

0754

TABLE 6 (continued)
 TRIETHYLENE GLYCOL DIMETHACRYLATE (TRIGDMA): CHRONIC DERMAL
 BIOASSAY IN C3H/HEBRED MALE MICE
 SUMMARY OF HEMATOLOGY
 WEEK 79

		TRIGDMA MALES			
GROUP: %	0.0 ¹	0.0 ²	5.0	25.0	50.0
BASOPHILS (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			0.12
S.D.	0.040	0.048			0.091
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

0 7 5 5

TABLE 7
TRIS(2-HYDROXYETHYL)AMMONIUM METHACRYLATE (TRISDMA); CHRONIC DERMAL
BIASSAY IN C57BL/6J MALE MICE
SUMMARY OF CLINICAL CHEMISTRY
WEEK 52

TRISDMA MALES						
GROUP: ^a	0.0 ^b	0.0 ^c	5.0	25.0	50.0	
GLUCOSE (g/l)						
MEAN	1.62	1.63	1.70	1.75	1.69	
S.D.	0.231	0.357	0.362	0.143	0.374	
N	5	5	5	5	5	
UREA NITROGEN (mg/l)						
MEAN	322.	310.	278.	306.	310.	
S.D.	33.0	22.9	34.9	41.4	50.8	
N	5	5	5	5	5	
CREATININE (mg/l)						
MEAN	5.	6.	6.	6.	6.	
S.D.	0.5	0.4	0.5	0.8	0.5	
N	5	5	5	5	5	
TOTAL PROTEIN (g/l)						
MEAN	58.	62.	58.	62.	62.	
S.D.	3.2	11.3	3.3	10.1	8.7	
N	5	5	5	5	5	
ALBUMIN (g/l)						
MEAN	32.	36.	34.	35.	34.	
S.D.	2.6	7.1	2.0	5.5	4.4	
N	5	5	5	5	5	
TOTAL BILIRUBIN (mg/l)						
MEAN	3.	3.	3.	3.	4.	
S.D.	0.5	0.9	0.5	1.1	2.2	
N	5	5	5	5	5	
CALCIUM (mg/l)						
MEAN	99.	101.	104.	105.	104.	
S.D.	8.0	10.8	9.6	14.9	13.3	
N	5	5	5	5	5	
INORGANIC PHOSPHORUS (mg/l)						
MEAN	72.	69.	70.	72.	69.	
S.D.	6.8	10.5	7.5	16.7	15.8	
N	5	5	5	5	5	
SODIUM (mmol/l)						
MEAN	160.	160.	161.	160.	173.	
S.D.	7.7	5.8	4.8	6.1	22.3	
N	5	5	5	5	5	
POTASSIUM (mmol/l)						
MEAN	7.1	6.5	7.1	7.1	7.1	
S.D.	0.42	0.64	0.72	1.37	1.11	
N	5	5	5	5	5	
CHLORIDE (mmol/l)						
MEAN	124.	124.	126.	124.	132.	
S.D.	6.7	4.0	3.6	4.5	16.7	
N	5	5	5	5	5	
ASPARTATE AMINOTRANSFERASE (IU/l)						
MEAN	46.	55.	62.	62.	66.	
S.D.	4.9	21.6	12.6	13.5	16.1	
N	5	5	5	5	4	
ALANINE AMINOTRANSFERASE (IU/l)						
MEAN	58.	71.	84.	88.	249.	
S.D.	25.9	49.1	31.5	67.3	321.6	
N	5	5	5	5	5	

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

0755

TABLE 7 (continued)
 TRIS(ETHYLENE GLYCOL) DIMETHACRYLATE (TREGDMA): CHRONIC DERMAL
 BIOASSAY IN C3H/HEMISP MALE MICE
 SUMMARY OF CLINICAL CHEMISTRY
 WEEK 52

TREGDMA MALES						
GROUP: 1	0.0 ¹	0.0 ²	5.0	25.0	50.0	
γ-GLUTAMYL TRANSFERASE (IU/l)						
MEAN	3.	3.	3.	3.	3.	
S.D.	0.5	0.5	0.4	0.4	0.5	
N	5	5	5	5	5	
CREATINE KINASE (IU/l)						
MEAN	52.	144.	212.	81.	84.	
S.D.	15.6	175.3	187.1	97.8	101.1	
N	5	5	5	5	5	
ALKALINE PHOSPHATASE (IU/l)						
MEAN	51.	46.	52.	74.	216.	
S.D.	8.5	5.0	1.0	69.5	370.3	
N	5	5	5	5	5	
CHOLESTEROL (g/l)						
MEAN	1.68	1.99	1.86	2.07	2.28	
S.D.	0.064	0.466	0.165	0.707	1.142	
N	5	5	5	5	5	

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

TABLE 8
**TRIS(2-HYDROXYETHYL)AMMONIUM METHACRYLATE (TREGDMA): CHRONIC DERMAL
 BIOASSAY IN C57BL/6J MALE MICE**
 SUMMARY OF CLINICAL CHEMISTRY
 WEEK 79

TREGDMA MALES						
GROUP: 6	0.0 ^a	0.0 ^b	5.0	25.0	50.0	
GLUCOSE (g/l)						
MEAN	1.84	1.68	1.74	1.56	1.76	
S.D.	0.261	0.323	0.683	0.376	0.118	
N	5	5	5	5	5	
UREA NITROGEN (mg/l)						
MEAN	379.	337.	319.	296.	331.	
S.D.	55.2	50.2	18.9	25.8	40.6	
N	5	5	5	5	5	
CREATININE (mg/l)						
MEAN	6.	6.	5.	5.	5.	
S.D.	0.5	0.5	0.9	0.7	0.5	
N	5	5	5	5	5	
TOTAL PROTEIN (g/l)						
MEAN	66.	67.	63.	59.	63.	
S.D.	11.9	19.5	6.9	1.6	10.0	
N	5	5	5	5	5	
ALBUMIN (g/l)						
MEAN	36.	37.	34.	33.	35.	
S.D.	7.1	9.3	2.7	0.8	5.0	
N	5	5	5	5	5	
TOTAL BILIRUBIN (mg/l)						
MEAN	5.	4.	3.	5.	3.	
S.D.	3.0	2.5	0.9	5.6	0.9	
N	5	5	5	5	5	
CALCIUM (mg/l)						
MEAN	93.	95.	92.	89.	92.	
S.D.	7.5	8.3	5.9	3.0	4.3	
N	5	5	5	5	5	
INORGANIC PHOSPHORUS (mg/l)						
MEAN	67.	70.	66.	69.	76.	
S.D.	4.4	11.8	6.5	3.9	6.9	
N	5	5	5	5	5	
SODIUM (mmol/l)						
MEAN	157.	155.	156.	156.	156.	
S.D.	2.2	1.9	2.3	3.6	1.4	
N	5	5	5	5	5	
POTASSIUM (mmol/l)						
MEAN	6.0	5.9	6.1	6.2	6.4	
S.D.	0.46	0.58	0.69	0.67	0.35	
N	5	5	5	5	5	
CHLORIDE (mmol/l)						
MEAN	121.	121.	120.	120.	119.	
S.D.	2.0	2.5	3.0	3.8	1.3	
N	5	5	5	5	5	
ASPARTATE AMINOTRANSFERASE (IU/l)						
MEAN	69.	123.	83.	259.	52.	
S.D.	22.7	132.2	68.9	461.2	2.5	
N	5	5	5	5	5	
ALANINE AMINOTRANSFERASE (IU/l)						
MEAN	57.	86.	141.	113.	89.	
S.D.	37.1	114.5	241.1	181.4	37.6	
N	5	5	5	5	5	

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

0758

TABLE 8 (continued)
 TRIETHYLENE GLYCOL DIMETHACRYLATE (TREGDMA): CHRONIC DERMAL
 BIOASSAY IN C3H/HEBISD MALE MICE
 SUMMARY OF CLINICAL CHEMISTRY
 WEEK 79

TREGDMA MALES						
GROUP: 4	0.0 ¹	0.0 ²	5.0	25.0	50.0	
γ-GLUTAMYL TRANSFERASE (IU/l)						
MEAN	4.	3.	3.	3.	3.	
S.D.	0.5	0.7	0.5	1.1	0.4	
N	5	5	5	5	5	
CREATINE KINASE (IU/l)						
MEAN	272.	202.	149.	163.	111.	
S.D.	370.3	187.8	70.2	155.1	154.7	
N	5	5	5	5	5	
ALKALINE PHOSPHATASE (IU/l)						
MEAN	47.	104.	87.	74.	63.	
S.D.	6.3	122.7	76.2	63.5	17.9	
N	5	5	5	5	5	
CHOLESTEROL (g/l)						
MEAN	2.09	2.48	1.97	1.44	1.98	
S.D.	0.456	1.137	0.334	0.399	0.594	
N	5	5	5	5	5	

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

01159

TABLE 9
 TRIMETHYLENE GLYCOL DIMETHACRYLATE (TRGDMA): CHRONIC DERMAL
 BIOASSAY IN C3H/HEMISP MALE MICE

SUMMARY OF EPIDERMAL CELL PROLIFERATION

(n = 5 except where noted)

	DOSE LEVEL				
	0g ¹	0g ²	5g	25g	50g
Week 4	22.5 ± 2.99	20.6 ± 3.84	24.0 ± 8.20	40.5 ± 11.39 ^{ac}	37.2 ± 7.5 ^{bd}
Week 13	21.8 ± 7.26	18.8 ± 4.35	20.2 ± 5.10	36.5 ± 4.97 ^{bd}	42.6 ± 9.39 ^{bd}
Week 52	31.9 ± 9.61	30.4 ± 3.27 ³	29.5 ± 8.55 ³	40.4 ± 17.25 ³	48.5 ± 16.8
Week 78	25.8 ± 8.09	24.4 ± 4.99	29.2 ± 7.41	32.2 ± 8.24	34.0 ± 3.63

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)

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

TREGDMA MALES						
GROUP: 0	0.0 ¹	0.0 ²	5.0	25.0	50.0	
FINAL BODY WEIGHT						
MEAN	33.6	34.4	33.3	33.7	34.0	
S.D.	2.19	2.37	2.58	2.33	1.81	
N	35	34	34	29	22	
LIVER						
MEAN	2.137	2.825 ^a	2.156 ^c	2.508	2.176 ^c	
S.D.	0.8339	1.5729	0.8164	1.2109	0.5577	
N	40	39	39	34	27	
KIDNEYS						
MEAN	0.840	0.824	0.824	0.905 ^{hd}	0.982 ^{bd}	
S.D.	0.0859	0.0974	0.1035	0.1115	0.1146	
N	40	39	39	34	27	
SPLEEN						
MEAN	0.108	0.110	0.097	0.110	0.096	
S.D.	0.0873	0.0568	0.0293	0.0372	0.0285	
N	40	39	39	34	27	
BRAIN						
MEAN	0.466	0.465	0.470	0.463	0.469	
S.D.	0.0213	0.0206	0.0194	0.0273	0.0238	
N	40	39	39	34	27	
TESTES						
MEAN	0.073	0.075	0.073	0.072	0.078	
S.D.	0.0184	0.0235	0.0205	0.0298	0.0244	
N	40	39	39	34	27	

- ^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

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).

TABLE 11
 TRIS(2-ETHYLHEXYL) GLYCOL DIMETHACRYLATE (TRIGDMA): CHRONIC DERMAL
 BIOASSAY IN C57BL/6J MALE MICE
 SUMMARY OF ORGAN WEIGHTS AS % OF FINAL BODY WEIGHT
 ANIMALS SACRIFICED AT WEEK 78

GROUP: %	TRIGDMA MALES				
	0.0 ^a	0.0 ^a	5.0	25.0	50.0
LIVER					
MEAN	6.224	7.954	6.663	7.427	6.453
S.D.	2.5625	4.1206	2.9509	3.8147	1.8545
N	35	34	34	29	22
KIDNEYS					
MEAN	2.478	2.400	2.471	2.697 ^{bd}	2.819 ^{bd}
S.D.	0.1728	0.2616	0.2335	0.2363	0.2525
N	35	34	34	29	22
SPLEEN					
MEAN	0.327	0.300	0.286	0.330	0.280
S.D.	0.2780	0.1047	0.0844	0.1228	0.0930
N	35	34	34	29	22
BRAIN					
MEAN	1.388	1.355	1.420	1.388	1.377
S.D.	0.0579	0.0994	0.1207	0.0938	0.0724
N	35	34	34	29	22
TESTES					
MEAN	0.216	0.216	0.214	0.198	0.217
S.D.	0.0623	0.0713	0.0616	0.0634	0.0698
N	35	34	34	29	22

^b Significantly different from the untreated control group (p<.01)
^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).

TABLE 12
 TRINITYLENE GLYCOL DIMETHACRYLATE (TRIGDMA): CHRONIC DERMAL
 BIOASSAY IN C3H/HEBRED MALE MICE
 SUMMARY OF ORGAN WEIGHTS AS % OF BRAIN WEIGHT
 ANIMALS SACRIFICED AT WEEK 78

GROUP: 9	TRIGDMA MALES				
	0.0 ^a	0.0 ^a	5.0	25.0	50.0
LIVER					
MEAN	462.219	610.383 ^a	461.028 ^c	550.344	466.312 ^c
S.D.	192.8142	346.8361	184.3794	288.4533	129.2553
N	40	39	39	34	27
KIDNEYS					
MEAN	180.344	177.262	175.254	195.441 ^{bd}	209.308 ^{bd}
S.D.	15.8924	20.1283	21.0745	19.9878	21.6326
N	40	39	39	3	27
SPLEEN					
MEAN	23.374	23.729	20.627	24.043	20.666
S.D.	18.8293	12.0520	6.5022	8.7862	6.4279
N	40	39	39	34	27
TESTES					
MEAN	15.696	16.033	15.397	15.766	16.711
S.D.	4.0124	4.7422	4.1635	7.0103	5.2103
N	40	39	39	34	27

^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)
^a untreated control group
^b 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).

TABLE 13
 TRICHTHYLENE GLYCOL DINITRATE (TRICOMA): CHRONIC DERMAL
 BIOASSAY IN C57BL/6J 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
STOMACH						
DIVERTICULUM		1	0	0	0	0
SKIN, TREATED						
EXFOLIATION		0	0	0	5	5
LIVER						
COLOR CHANGE, FOCAL/MULTIFOCAL		0	0	0	0	1
KIDNEYS						
DILATED PELVIS		1	0	1	1	1
GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 5.0%, 4 is 25.0%, 5 is 50.0%						

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TABLE 14
 TRIMETHYLENE GLYCOL DIMETHACRYLATE (TREGDMA): CHRONIC DERMAL
 BIOASSAY IN C57BL/6J 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
STOMACH						
DIVERTICULUM		0	0	0	0	1
SKIN, TREATED						
EXFOLIATION		0	0	0	3	1
ECCHORINATION		0	0	1	0	0
SKIN						
EXFOLIATION		0	0	0	0	1
KIDNEYS						
DILATED PELVIS		2	2	1	1	0
GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 5.0 %, 4 is 25.0 %, 5 is 50.0 %						

TABLE 15
 POLYETHYLENE GLYCOL DIMETHACRYLATE (TREGDMA): 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	5
LIVER						
MASS		1	1	2	1	1
COLOR CHANGE, FOCAL/MULTIFOCAL		1	0	1	0	1
COLOR CHANGE, DIFFUSE		0	1	0	0	0
GALLBLADDER						
SIZE DECREASE		1	0	0	1	0
ADRENAL GL						
COLOR CHANGE, FOCAL/MULTIFOCAL		2	4	3	4	3
SKIN, TREATED						
EXFOLIATION		0	0	1	1	1
SKIN						
EXFOLIATION		0	0	1	0	0
ALOPECIA		1	0	1	1	0
SPLEEN						
SIZE INCREASE		0	0	0	0	1
LYMPH ND, MES						
COLOR CHANGE, DIFFUSE		1	0	0	0	1
CYST		2	1	0	1	1
THYMIC REGION						
COLOR CHANGE, FOCAL/MULTIFOCAL		1	0	0	0	0
PENIS						
ULCERATED		0	0	1	0	0
LUNGS						
COLOR CHANGE, FOCAL/MULTIFOCAL		2	0	0	1	1
COLOR CHANGE, DIFFUSE		0	1	0	0	1
KIDNEYS						
DILATED PELVIS		1	3	0	1	2
SHAPE/CONTOUR CHANGE		1	0	0	0	0
CONTENTS ABNORMAL		0	0	0	1	1
SIZE INCREASE		0	1	0	3	4
GRANULAR		0	0	0	0	1

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 5.0%, 4 is 25.0%, 5 is 50.0%

TABLE 16
 TRISTYRENE GLYCOL DIMETHACRYLATE (TRGDMA): CHRONIC DERMAL
 BIOASSAY IN C3H/HEWSD MALE MICE
 SUMMARY OF NECROPSY OBSERVATIONS

ANIMALS SACRIFICED AT WEEK 79
 MALES

GROUP:	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP	70	70	70	70	70
NUMBER OF ANIMALS SACRIFICED	40	39	39	34	27
TOTAL BODY					
EMACIATION	0	0	1	0	0
STAINED	1	0	4	5	0
CLIPPING INJURY	1	0	0	0	0
ADIPOSE TISSUE					
NODULE	0	0	0	0	1
PERITONEAL CAV					
HEMORRHAGE	0	0	0	0	1
THORACIC CAV					
FLUID	0	0	1	0	0
HEART					
COLOR CHANGE, FOCAL/MULTIFOCA	0	0	0	0	3
SIZE INCREASE	1	0	1	2	1
CONSISTENCY CHANGE	1	0	0	0	2
STOMACH					
DIVERTICULUM	0	0	1	0	0
CONTENTS ABNORMAL	0	1	1	0	0
MASS	0	0	0	1	0
LIVER					
MASS	19	26	16	22	14
COLOR CHANGE, FOCAL/MULTIFOCA	9	5	6	6	9
COLOR CHANGE, DIFFUSE	1	0	0	0	0
ADHESION	0	0	2	0	0
MODULE	7	10	8	6	5
ANOMALY	0	0	1	4	1
CYST	0	1	0	0	0
SURFACE CHANGE	0	0	1	0	0
GALLBLADDER					
SIZE DECREASE	0	1	0	0	0
SIZE INCREASE	0	0	0	2	0
UNIDENTIFIABLE	0	0	1	1	0
CECUM					
MASS	0	0	1	0	0
THYROID GL					
SIZE INCREASE	0	0	0	0	2
SIZE DECREASE	1	1	0	0	0
COLOR CHANGE, FOCAL/MULTIFOCA	1	0	0	0	0
ADRENAL GL					
COLOR CHANGE, FOCAL/MULTIFOCA	33	31	34	26	25
SIZE INCREASE	1	2	2	0	1
COLOR CHANGE, DIFFUSE	1	1	0	0	0
CYST	3	2	1	3	2
MASS	1	0	0	1	1

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 5.0%, 4 is 25.0%, 5 is 50.0%

TABLE 13 (Continued)
 TRIS(2-ETHYLHEXYL) GLYCOL DIMETHACRYLATE (TREGDMA); CHRONIC DERMAL
 BIOASSAY IN C57BL/6JF1HED 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	39	34	27
SKIN, TREATED						
EXFOLIATION		6	10	17	23	23
EXCORIATION		2	4	0	0	0
ULCERATED		0	1	0	0	0
CRUST/SCAB/SCALE		1	0	0	0	0
COLOR CHANGE, FOCAL/MULTIFOVAL		0	0	0	0	1
SKIN						
CRUST/SCAB/SCALE			0	0	0	0
ALOPECIA		12	14	14	14	13
SWOLLEN		0	0	1	0	0
ABCESS		5	5	6	8	10
EXCORIATION		1	2	0	0	0
ULCERATED		1	0	0	3	1
MEIBOMIAN GLAND, SIZE INCREASE		2	1	0	1	0
SUBCUTIS						
MASS		1	0	0	0	0
EARS						
MODULE		0	0	1	0	0
SPLEEN						
SIZE INCREASE		2	9	2	0	3
COLOR CHANGE, FOCAL/MULTIFOVAL		2	1	0	0	1
SWOLLEN		1	0	1	1	0
SIZE DECREASE		4	2	1	0	1
LYMPH ND, S-MEM						
SIZE INCREASE		0	0	0	0	1
COLOR CHANGE, DIFFUSE		1	0	0	0	0
COLOR CHANGE, FOCAL/MULTIFOVAL		0	0	0	0	1
LYMPH ND, MED						
COLOR CHANGE, DIFFUSE		0	1	3	5	1
CYST		3	4	0	0	3
COLOR CHANGE, FOCAL/MULTIFOVAL		7	5	3	8	5
SIZE INCREASE		0	0	0	1	2
LYMPH ND, OTHER						
SIZE INCREASE		2	0	0	0	0
COLOR CHANGE, DIFFUSE		1	0	0	0	0
ABCESS		0	0	0	0	1
BONE, STERNUM						
COLOR CHANGE, FOCAL/MULTIFOVAL		1	0	0	0	0
BONE MARROW						
COLOR CHANGE, DIFFUSE		1	0	0	0	0
BRAIN						
HEMORRHAGE		0	0	0	1	0
EYE						
OPACITY		3	0	0	0	0
GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLES), 3 is 5.0%, 4 is 25.0%, 5 is 50.0%						

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TABLE 16 (Continued)
 TRIETHYLENE GLYCOL DIMETHACRYLATE (TRAGEDMA): CHRONIC DERMAL
 EXPOSURE IN C58/HEDDED MALE MICE
 SUMMARY OF NECROPSY OBSERVATIONS

ANIMALS SACRIFICED AT WEEK 76
 MALES

GROUP:	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP	70	70	70	70	70
NUMBER OF ANIMALS SACRIFICED	40	39	39	34	27
ETC.(CONTINUED)					
SIZE DECREASE	0	0	0	0	1
PANCREAS GL					
SIZE DECREASE	3	3	6	2	3
COLOR CHANGE, DIFFUSE	0	0	0	1	0
COLOR CHANGE, FOCAL/MULTIFOCAL	0	0	0	0	1
TESTES					
SIZE DECREASE	32	26	27	30	22
CONSISTENCY CHANGE	2	2	6	4	3
COLOR CHANGE, DIFFUSE	1	1	1	1	2
COLOR CHANGE, FOCAL/MULTIFOCAL	2	4	1	1	0
MASS	0	0	0	1	1
EPIDIDYMIDES					
SIZE DECREASE	1	1	1	2	2
SEMINAL VESICLE					
SIZE INCREASE	1	0	1	0	0
SIZE DECREASE	2	2	3	1	0
COLOR CHANGE, FOCAL/MULTIFOCAL	0	1	0	0	0
COLOR CHANGE, DIFFUSE	1	1	1	0	0
PROSTATE					
SIZE DECREASE	1	0	0	0	0
PENIS					
PARAPHIMOSIS	2	9	4	4	0
SCULLER	0	0	1	1	0
LUNGS					
COLOR CHANGE, FOCAL/MULTIFOCAL	2	3	2	2	1
COLOR CHANGE, DIFFUSE	1	5	3	5	1
HYPERINFLATED	0	0	0	1	0
HYPERINFLATION	0	2	0	0	0
NOOULE	2	3	2	1	0
MASS	1	0	0	2	0
KIDNEYS					
DILATED PELVIS	12	7	8	5	7
SHAPE/CONTOUR CHANGE	0	1	1	2	1
COLOR CHANGE, FOCAL/MULTIFOCAL	5	4	8	4	5
CONTENTS ABNORMAL	1	0	1	0	1
SIZE INCREASE	1	1	0	2	6
SIZE DECREASE	0	1	2	0	2
SURFACE CHANGE	1	0	1	0	0
COLOR CHANGE, DIFFUSE	0	1	0	0	1
CYST	1	1	0	3	2
DEPRESSION/INDENTATION	3	5	4	0	2
URETER					
DILATATION/DISTENTION	2	3	2	1	2

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 5.0%, 4 is 25.0%, 5 is 50.0%

TABLE 16 (Continued)
 TRISTYRENE GLYCOL DIMETHACRYLATE (TRIGDMA): 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	39	34	27
URINARY BLADDER						
DILATATION/DISTENTION		6	5	4	1	2
CONTENTS ABNORMAL		0	1	0	0	0
THICKER THAN NORMAL		0	1	1	1	0
DIVERTICULUM		0	0	0	0	1

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 5.0%, 4 is 25.0%, 5 is 50.0%

TABLE 17
 TRIETHYLENE GLYCOL DIMETHACRYLATE (TEGDMA): CHRONIC DERMAL
 IRRITATION 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	17	22	28
TOTAL BODY					
POSTMORTEM CHANGE	2	6	5	4	7
EMACIATION	5	6	2	5	10
STAINED	4	3	3	6	4
UNWEIGHT	2	0	0	1	6
SWOLLEN	0	0	0	0	1
CLIPPING INJURY	1	0	0	0	0
PARALYSIS	1	0	0	0	0
PERITONEAL CAV					
HEMORRHAGE	2	2	2	1	4
FLUID	1	0	1	2	1
THORACIC CAV					
FLUID	0	1	0	2	3
HEMORRHAGE	1	0	0	0	0
HEART					
CYST	0	0	1	0	0
COLOR CHANGE, FOCAL/MULTIFOCAL	1	3	0	1	2
SIZE INCREASE	1	4	4	3	4
CONSISTENCY CHANGE	0	2	0	0	1
SALIVARY GL					
EDEMA	0	0	0	0	0
SIZE DECREASE	0	0	0	1	0
ESOPHAGUS					
DILATATION/DISTENTION	0	1	0	0	0
STOMACH					
COLOR CHANGE, FOCAL/MULTIFOCAL	3	3	1	1	4
CONTENTS ABNORMAL	1	4	2	4	5
HEMORRHAGE	1	1	0	0	0
COLOR CHANGE, DIFFUSE	0	0	1	1	0
LIVER					
MASS	10	13	8	15	11
COLOR CHANGE, FOCAL/MULTIFOCAL	7	2	4	5	8
COLOR CHANGE, DIFFUSE	1	1	0	1	1
ADHESION	0	1	3	0	1
SIZE INCREASE	1	0	1	1	0
MOULD	0	0	2	0	1
SIZE DECREASE	1	2	0	0	0
ABNORMAL	0	2	0	1	2
CYST	0	0	1	0	0
SHAPE/CONTOUR CHANGE	0	0	0	1	0
SWOLLEN	0	0	0	0	1
SURFACE CHANGE	0	0	2	0	0
GALLBLADDER					
SIZE DECREASE	1	3	0	1	1
CONTENTS ABNORMAL	2	0	1	1	1

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 5.0%, 4 is 25.0%, 5 is 50.0%

TABLE 17 (Continued)
 TRIETHYLENE GLYCOL DIMETHACRYLATE (TRIGOMA): CHRONIC DERMAL
 STIMULATION 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	17	22	28
GALLBLADDER (CONTINUED)						
SIZE INCREASE		0	0	0	1	2
UNIDENTIFIABLE		0	0	2	0	0
PANCREAS						
CONSISTENCY CHANGE		0	0	0	1	0
DUODENUM						
MASS		1	0	0	0	0
DILATATION/DISTENSION		0	1	1	0	0
CONTENTS ABNORMAL		0	0	1	0	0
JEJUNUM						
ULCERATION		0	0	1	0	0
CONTENTS ABNORMAL		1	0	0	0	0
ILEUM						
GASPOUS		0	0	0	0	1
CECUM						
ADHESION		1	0	0	0	0
COLOR CHANGE, DIFFUSE		0	0	1	0	0
COLON						
GASPOUS		0	0	0	0	1
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	0	1	1
THYROID GL						
SIZE INCREASE		0	1	0	0	0
ADRENAL GL						
COLOR CHANGE, FOCAL/MULTIFOCAL		11	10	9	16	15
POSTMORTEM CHANGE		0	1	0	0	0
SIZE INCREASE		1	2	3	0	0
COLOR CHANGE, DIFFUSE		1	0	0	0	0
CYST		0	0	0	0	1
MASS		0	0	1	0	0
SIZE DECREASE		0	0	0	1	0
SKIN, TREATED						
EXFOLIATION		4	4	9	12	23
INDURATION		1	0	0	0	0
MASS		0	1	0	0	0
ABSCESS		0	0	0	1	0
SKIN						
CRUST/SCAB/SCALE		1	3	0	0	0

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 5.0%, 4 is 25.0%, 5 is 50.0%

TABLE 17 (Continued)
 TRIS(ETHYLENE GLYCOL DIMETHACRYLATE (TRIGDMA): CHRONIC DERMAL
 BIOASSAY IN C3H/HEBISD MALE MICE
 SUMMARY OF NECROPSY OBSERVATIONS

ALL ANIMALS FOUND DEAD/SACRIFICED MORIBUND
 MALES

	GROUP:	1	2	3	4	5
<hr/>						
NUMBER OF ANIMALS IN DOSE GROUP		70	70	70	70	70
NUMBER OF ANIMALS FOUND DEAD/SACRIFICED MORIBUND		15	17	17	22	28
<hr/>						
SKIN (CONTINUED)						
EXFOLIATION		0	0	0	1	0
ALOPECIA		3	1	10	9	6
SWOLLEN		0	0	1	0	0
ABSCESS		3	3	2	1	5
ULCERATED		0	1	2	0	2
HEAD						
TRAUMATIZED		0	1	0	0	0
MASS		3	2	1	1	0
HEMORRHAGE		1	0	0	0	0
TAIL						
NECROTIC		0	0	0	0	2
SPLEEN						
SIZE INCREASE		2	3	6	8	7
COLOR CHANGE, FOCAL/MULTIFOVAL		0	0	1	0	0
SWOLLEN		3	1	3	0	1
SIZE DECREASE		2	5	0	3	2
LYMPH ND, S-NAN						
SIZE INCREASE		0	0	0	1	0
LYMPH ND, MED						
SIZE DECREASE		0	1	0	0	0
LYMPH ND, MES						
COLOR CHANGE, DIFFUSE		0	0	1	0	2
CYST		0	0	1	1	0
SIZE DECREASE		3	2	3	2	4
COLOR CHANGE, FOCAL/MULTIFOVAL		2	0	0	2	0
MASS		1	0	0	0	0
SIZE INCREASE		0	0	0	1	0
LYMPH ND, REN						
SIZE INCREASE		0	1	0	0	0
LYMPH ND, OTHER						
SIZE INCREASE		0	1	0	0	0
THYMIC REGION						
SIZE DECREASE		0	0	0	1	0
BONE, STERNUM						
MODULE		0	1	1	1	1
SKELETAL MUSCLE						
ATROPHY		2	1	1	3	3
MASS		1	0	0	0	0
BRAIN						
HEMORRHAGE		3	2	1	3	3

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 5.0%, 4 is 25.0%, 5 is 50.0%

TABLE 17 (Continued)
 TRIMETHYLENE GLYCOL DIMETHACRYLATE (TRIGEMA): CHRONIC DERMAL
 BIOASSAY IN C3H/HEBRO 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	17	22	28
BRAIN (CONTINUED)					
CONSISTENCY CHANGE	0	0	0	0	1
DEPRESSION/INDENTATION	0	0	0	0	1
POSTMORTEM CHANGE	0	1	0	0	0
NEUTRICAL HEMORRHAGE	0	0	0	0	0
COLOR CHANGE, FOCAL/MULTIFOCAL	0	1	0	0	0
EYE					
PROTUSED	0	0	0	1	0
NECROTIC	0	0	0	1	0
SURFACE CHANGE	0	0	0	0	1
OPACITY	1	0	0	0	1
MEDULLARY GL.					
ABSCESS	0	0	0	0	1
SIZE DECREASE	2	1	2	2	2
COLOR CHANGE, DIFFUSE	0	0	0	0	1
TESTES					
SIZE DECREASE	9	15	11	13	15
CONSISTENCY CHANGE	2	2	1	3	2
COLOR CHANGE, DIFFUSE	2	0	0	1	0
ABSCESS	0	0	0	1	0
EPIDIDYMIDES					
SIZE DECREASE	2	2	0	1	1
COLOR CHANGE, FOCAL/MULTIFOCAL	0	0	1	1	0
SEMINAL VESICLE					
SIZE INCREASE	0	1	1	0	0
SIZE DECREASE	1	5	2	2	2
ABSCESS	0	1	0	0	0
COLOR CHANGE, DIFFUSE	0	0	0	0	1
PROSTATE					
SIZE DECREASE	0	0	0	1	0
PENIS					
PARAPHIMOSIS	5	11	6	6	11
ULCERATED	1	4	2	1	4
SWOLLEN	1	0	1	0	3
CONTENTS ABNORMAL	0	2	0	0	0
TRACHEA					
CONTENTS ABNORMAL	0	1	0	1	0
LUNGS					
COLOR CHANGE, FOCAL/MULTIFOCAL	2	0	0	4	7
COLOR CHANGE, DIFFUSE	5	0	10	11	10
HYPERINFLATED	0	0	0	2	2
HYPERINFLATION	1	0	0	0	0
NODULE	1	1	0	3	3
MASS	0	0	0	0	1

GROUP LEGEND: 1 is 0% (CONTROL), 2 is 0.5%, 3 is 5.0%, 4 is 25.0%, 5 is 50.0%

TABLE 17 (Continued)
 TRIETHYLENE GLYCOL DIMETHACRYLATE (TRIGDMA): CHRONIC DERMAL
 BIOASSAY IN C3H/HEMISD 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	17	22	26
LUNGS (CONTINUED)						
TRAUMATIZED		1	0	0	0	0
KIDNEYS						
DILATED PELVIS		6	11	5	5	7
SHAPE/CONTOUR CHANGE		0	1	2	4	0
COLOR CHANGE, FOCAL/MULTIFOCAL		3	4	2	6	3
MODULE		1	1	3	1	2
CONTENTS ABNORMAL		1	4	0	3	2
SIZE INCREASE		4	5	3	3	2
SIZE DECREASE		2	5	3	2	1
SURFACE CHANGE		1	0	1	0	1
GRANULAR		0	3	0	1	1
COLOR CHANGE, DIFFUSE		0	2	1	1	1
ADHESION		0	1	1	0	0
CYST		0	1	0	0	1
URETER						
DILATATION/DISTENTION		2	4	2	4	2
CONTENTS ABNORMAL		1	1	0	0	0
URINARY BLADDER						
CALCULUS		0	1	0	1	1
CYST		1	0	0	0	0
SIZE INCREASE		0	0	1	1	2
DILATATION/DISTENTION		2	3	3	1	1
CONTENTS ABNORMAL		1	3	3	0	0
THICKER THAN NORMAL		0	2	1	0	0
POLYP		0	0	0	0	1

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 5.0%, 4 is 25.0%, 5 is 50.0%

TABLE 18
 TRIETHYLENE GLYCOL DIMETHACRYLATE (TRIGDMA): 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
TOTAL BODY					
PC-PORTION CHANGE	2	6	5	4	7
ERUPTION	5	6	3	5	10
STAINED	7	3	7	11	4
ULCER	2	0	0	1	8
SWOLLEN	0	0	0	0	1
CLIPPING INJURY	2	0	0	0	0
PARALYSIS	1	0	0	0	0
ADIPOSE TISSUE					
NODULE	0	0	0	0	1
PERITONEAL CAV					
HEMORRHAGE	2	2	2	1	5
FLUID	1	0	1	2	1
THORACIC CAV					
FLUID	0	1	1	2	3
HEMORRHAGE	1	0	0	0	0
HEART					
CYST	0	0	1	0	0
COLOR CHANGE, FOCAL/MULTIFOCAL	1	3	0	1	5
SIZE INCREASE	2	4	5	5	5
CONSISTENCY CHANGE	0	2	0	0	2
SALIVARY GL					
EDEMA	1	0	0	0	0
SIZE DECREASE	0	0	0	1	0
ESOPHAGUS					
DILATATION/DISTENTION	0	1	0	0	0
STOMACH					
DIVERTICULUM	1	0	1	0	1
COLOR CHANGE, FOCAL/MULTIFOCAL	3	3	1	1	4
CONTENTS ABNORMAL	1	5	3	4	5
HEMORRHAGE	1	1	0	0	0
COLOR CHANGE, DIFFUSE	0	0	1	1	0
MASS	0	0	0	1	0
LIVER					
MASS	30	40	26	38	35
COLOR CHANGE, FOCAL/MULTIFOCAL	17	7	11	11	18
COLOR CHANGE, DIFFUSE	2	2	0	1	1
ADENOMA	0	1	5	0	1
SIZE INCREASE	1	0	1	1	0
NODULE	7	10	10	6	6
SIZE INCREASE	1	2	0	0	0
ABNORMAL	0	2	1	5	3
CYST	0	1	1	0	0
SHAPE/CONTOUR CHANGE	0	0	0	1	0
SWOLLEN	0	0	0	0	1

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 5.0%, 4 is 25.0%, 5 is 50.0%

TABLE 18 (Continued)
 TRIETHYLENE GLYCOL DIMETHACRYLATE (TREGDMA): 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
LIVER (CONTINUED)					
SURFACE CHANGE	0	0	3	0	0
GALL BLADDER					
SIZE DECREASE	2	4	0	2	1
CONTENTS ABNORMAL	2	0	1	1	1
SIZE INCREASE	0	0	0	3	2
UNIDENTIFIABLE	0	0	5	1	0
PANCREAS					
CONSISTENCY CHANGE	0	0	0	1	0
DUODENUM					
MASS	1	0	0	0	0
DILATATION/DISTENSION	0	1	1	0	0
CONTENTS ABNORMAL	0	0	1	0	0
JEJUNUM					
ADHESION	0	0	1	0	0
CONTENTS ABNORMAL	1	0	0	0	0
ILEUM					
CASEOUS	0	0	0	0	1
CECUM					
ADHESION	1	0	0	0	0
COLOR CHANGE, DIFFUSE	0	0	1	0	0
MASS	0	0	1	0	0
COLON					
CASEOUS	0	0	0	0	1
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	0	1	1
THYROID GL					
SIZE INCREASE	0	1	0	0	2
SIZE DECREASE	1	1	0	0	0
COLOR CHANGE, FOCAL/MULTIFOCAL	1	0	0	0	0
ADRENAL GL					
COLOR CHANGE, FOCAL/MULTIFOCAL	46	45	46	46	43
POSTMORTEM CHANGE	0	1	0	0	0
SIZE INCREASE	2	4	5	0	1
COLOR CHANGE, DIFFUSE	2	1	0	0	0
CYST	3	2	2	3	3
MASS	1	0	1	1	1
SIZE DECREASE	0	0	0	1	0

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 5.0%, 4 is 25.0%, 5 is 50.0%

TABLE 18 (Continued)
 TRIFLYLENE GLYCOL DIMETHACRYLATE (TRFDGMA): CHRONIC DERMAL
 BIOASSAY IN C3H/HEWSD 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, TREATED					
EXFOLIATION	10	14	27	44	52
RECOILIATION	3	4	1	0	0
MASS	0	1	0	0	0
ULCERATED	0	1	0	0	0
CRUST/SCAB/SCALE	1	0	0	0	0
ABSCESS	0	0	0	1	0
COLOR CHANGE, FOCAL/MULTIFOCAL	0	0	0	0	1
SKIN					
CRUST/SCAB/SCALE	2	3	0	0	0
EXFOLIATION	0	0	1	1	1
ALOPECIA	16	19	25	24	19
SWOLLEN	0	0	2	0	0
ABSCESS	8	8	8	9	15
RECOILIATION	1	2	0	0	0
ULCERATED	1	1	2	3	3
PREPUTIAL GLAND, SIZE INCREASE	2	1	0	1	0
SUPPURTIS					
MASS	1	0	0	0	0
HEAD					
TRAUMATIZED	0	1	0	0	0
MASS	0	0	1	1	0
HEMORRHAGE	1	0	0	0	0
EARS					
MODULE	0	0	1	0	0
TAIL					
NECROTIC	0	0	0	0	2
SPLEEN					
SIZE INCREASE	4	12	8	14	11
COLOR CHANGE, FOCAL/MULTIFOCAL	2	1	1	0	1
SWOLLEN	4	1	4	1	1
SIZE DECREASE	6	7	1	3	3
LYMPH ND, S-MAN					
SIZE INCREASE	0	0	0	1	1
COLOR CHANGE, DIFFUSE	1	0	0	0	0
COLOR CHANGE, FOCAL/MULTIFOCAL	0	0	0	0	1
LYMPH ND, MED					
SIZE DECREASE	0	1	0	0	0
LYMPH ND, MBS					
COLOR CHANGE, DIFFUSE	1	1	4	5	4
CYST	5	5	1	2	4
SIZE DECREASE	3	2	3	2	4
COLOR CHANGE, FOCAL/MULTIFOCAL	9	5	3	10	5
MASS	1	0	0	0	0

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 5.0%, 4 is 25.0%, 5 is 50.0%

TABLE 18 (Continued)
 TRIETHYLENE GLYCOL DIMETHACRYLATE (TRIGEMA): CHRONIC DERMAL
 BIOASSAY IN C57BL/6J 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
LYMPH ND, MES (CONTINUED)						
SIZE INCREASE		0	0	0	2	2
LYMPH ND, REN						
SIZE INCREASE		0	1	0	0	0
LYMPH ND, OTHER						
SIZE INCREASE		2	1	0	0	0
COLOR CHANGE, DIFFUSE		1	0	0	0	0
ABSCESS		0	0	0	0	1
THYMIC SPLENIC						
SIZE INCREASE		0	0	0	1	0
COLOR CHANGE, FOCAL/MULTIFOCAL		1	0	0	0	0
BONE, STERNUM						
COLOR CHANGE, FOCAL/MULTIFOCAL		1	0	0	0	0
MODULE		0	0	0	0	0
BONE MARROW						
COLOR CHANGE, DIFFUSE		1	0	0	0	0
SKELETAL MUSCLE						
ATROPHY		2	1	1	3	3
WISS		1	0	0	0	0
BRAIN						
HEMORRHAGE		3	2	1	4	3
CONSISTENCY CHANGE		0	0	0	0	1
DEPRESSION/INDENTATION		0	0	0	0	1
POSTMORTEM CHANGE		0	1	0	0	0
MEMBRANE HEMORRHAGE		0	2	0	0	0
COLOR CHANGE, FOCAL/MULTIFOCAL		0	1	0	0	0
EYE						
PROPTOSIS		0	0	0	1	0
NECROTIC		0	0	0	1	0
SURFACE CHANGE		0	0	0	0	1
CAPACITY		4	0	0	0	1
SIZE DECREASE		0	0	0	0	1
PAROTID GL						
ABSCESS		0	0	0	0	1
SIZE DECREASE		5	4	6	4	5
COLOR CHANGE, DIFFUSE		0	0	0	1	1
COLOR CHANGE, FOCAL/MULTIFOCAL		0	0	0	0	1
TESTES						
SIZE DECREASE		41	41	38	43	37
CONSISTENCY CHANGE		4	4	7	7	5
COLOR CHANGE, DIFFUSE		3	1	1	2	2
COLOR CHANGE, FOCAL/MULTIFOCAL		2	4	1	1	0
ABSCESS		0	0	0	1	0

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 5.0%, 4 is 25.0%, 5 is 50.0%

0 7 3 9

TABLE 18 (Continued)
 TRIETHYLENE GLYCOL DIMETHACRYLATE (TREGDMA): CHRONIC DERMAL
 BIOASSAY IN C3H/HENED 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
TESTES (CONTINUED)						
MASS		0	0	0	1	1
EPIDIDYMIDES						
SIZE DECREASE		3	3	1	3	3
COLOR CHANGE, FOCAL/MULTIFOCAL		0	0	1	1	0
SEMINAL VESICLE						
SIZE INCREASE		1	1	2	0	0
SIZE DECREASE		3	7	5	3	2
ABSCISS		0	1	0	0	0
COLOR CHANGE, FOCAL/MULTIFOCAL		0	1	0	0	0
COLOR CHANGE, DIFFUSE		1	1	1	0	1
PROSTATE						
SIZE DECREASE		1	0	0	1	0
PENIS						
PARAPHIMOSIS		7	20	10	10	11
ULCERATED		1	4	3	1	4
SWOLLEN		1	0	2	1	3
CONTENTS ABNORMAL		0	2	0	0	0
TRACHEA						
CONTENTS ABNORMAL		0	1	0	1	0
LUNGS						
COLOR CHANGE, FOCAL/MULTIFOCAL		6	8	2	8	10
COLOR CHANGE, DIFFUSE		6	12	13	16	12
HYPERINFLATED		0	0	0	3	2
HYPERINFLATION		1	2	0	0	0
NODULE		3	4	2	4	3
MASS		1	0	0	2	1
GRAINATED		1	0	0	0	0
KIDNEYS						
DILATED PELVIS		22	23	15	13	17
SHAPE/CONTOUR CHANGE		1	2	3	6	1
COLOR CHANGE, FOCAL/MULTIFOCAL		8	8	10	10	8
NODULE		1	1	0	1	2
CONTENTS ABNORMAL		2	4	1	4	4
SIZE INCREASE		5	7	3	8	12
SIZE DECREASE		1	6	5	2	3
SURFACE CHANGE		2	0	2	0	1
GRANULAR		0	3	0	1	2
COLOR CHANGE, DIFFUSE		0	3	1	1	2
ADHESION		0	1	1	0	0
CYST		1	2	0	3	3
DEPRESSION/INDENTATION		3	5	4	0	2
URETER						
DILATATION/DISTENSION		4	7	4	5	4
CONTENTS ABNORMAL		1	1	0	0	0

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 5.0%, 4 is 25.0%, 5 is 50.0%

TABLE 18 (Continued)
 TRIETHYLENE GLYCOL DIMETHACRYLATE (TRISOL): CERAMIC DERMAL
 BIOASSAY IN C3H/HEWED MARY MICE
 SUMMARY OF NECROPSY OBSERVATIONS

DATA FOR ALL ANIMALS OF BOTH SEXES

	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						
CALCULUS		0	1	0	1	1
CYST		1	0	0	0	0
SIZE INCREASE		0	0	1	1	2
DILATATION/DISTENTION		8	6	7	2	3
CONTENTS ABNORMAL		1	4	3	0	0
THICKER THAN NORMAL		0	3	2	1	0
POLYP		0	0	0	0	1
DIVERTICULUM		0	0	0	0	1

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 5.0%, 4 is 25.0%, 5 is 50.0%

TABLE 19
 TRIS(1,3-DIPHENYLISOPROPYL) CARBODIIMIDE (T-807DMA): CHRONIC DERMAL
 BIOASSAY IN C3H/HEMISP MALE MICE
 SUMMARY OF HISTOPATHOLOGIC DIAGNOSES
 ANIMALS SACRIFICED AT WEEK 76
 MALES

GROUP:	1	2	3	4	5
NUMBER OF ANIMALS BY DOSE GROUP	70	70	70	70	70
NUMBER OF ANIMALS SACRIFICED	40	39	39	34	27
ADIPOSE TISSUE					
TOTAL NUMBER EXAMINED	0	0	0	0	1
AS LIPOMA	-	-	-	-	1
HEART					
TOTAL NUMBER EXAMINED	40	39	1	2	27
EXAMINED, UNREMARKABLE	10	12	0	0	6
ATRIAL FIBROSIS	0	0	1	1	1
MYOCARDIAL MINERALIZATION	18	25	0	1	18
MYOCARDIAL DEGENERATION/FIBROSIS	30	15b	0	2	16
ENDOCARDITIS	0	0	0	1	0
OR HEMANGIOsarcoma	0	1	0	0	0
AORTA					
TOTAL NUMBER EXAMINED	40	39	0	0	27
EXAMINED, UNREMARKABLE	40	38	-	-	26
MINERALIZATION	0	1	-	-	1
VASCULATURE					
TOTAL NUMBER EXAMINED	2	1	0	0	1
MINERALIZATION	2	1	-	-	1
SPLEEN					
TOTAL NUMBER EXAMINED	40	39	0	0	27
EXAMINED, UNREMARKABLE	29	23	-	-	19
MINERALIZATION	1	0	-	-	0
LYMPHOID CELL INFILTRATES	11	16	-	-	6
SPLEENITIS	1	0	-	-	2
FIBROSIS	0	1	-	-	1
HYPERPLASIA	1	0	-	-	0
DUPLICATE HYPERPLASIA	0	0	-	-	2
ESOPHAGUS					
TOTAL NUMBER EXAMINED	40	39	0	0	27
EXAMINED, UNREMARKABLE	40	39	-	-	27
STOMACH					
TOTAL NUMBER EXAMINED	40	39	38	34	27
EXAMINED, UNREMARKABLE	30	35	32	27	22
MISSING	0	0	1	0	0
GLAND HYPERPLASIA	2	3	3	2	4
ULCERATIVE LESIONS	0	0	0	1	0
MINERALIZATION	0	0	0	1	1

GROUP LEGEND: 1 is 0% (CONTROL), 2 is 0% (VEHICLE), 3 is 5.0%, 4 is 25.0%, 5 is 50.0%

b = BENIGN, l = LESION, M = MALIGNANT
 Significantly different from CONTROL group 1 (p < .01)

TABLE 19 (Continued)
 TRIETHYLENE GLYCOL DIMETHACRYLATE (TRIGDMA): CHRONIC DERMAL
 BIOASSAY IN C3H/HEBND 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	39	34	27
STOMACH (CONTINUED)					
EDEMA	0	0	0	1	0
GASTRITIS	10	3	4	3	1a
LIVER					
TOTAL NUMBER EXAMINED	40	39	39	34	27
EXAMINED, UNREMARKABLE	10	9	15	4	8
ANOMALOUS LOBULATION	0	5a	2	2	1
EXTRAMEDULLARY HEMATOPOIESIS	1	0	0	0	0
FELIOSIS/TELANGIECTASIS	0	1	0	0	1
HEPATOCELLULAR VACUOLATION	0	0	0	0	1
MINERALIZATION	1	2	0	0	0
MONONUCLEAR CELL INFILTRATE(S)	0	0	0	0	1
HEPATIC ABSCESS(ES)	0	1	0	0	0
ADHESION(S)	0	0	1	0	0
HEPATOCELLULAR NECROSIS	2	2	2	1	0
HEPATOCELLULAR HYPERPLASIA	8	5	9	6	3
#B HEPATOCELLULAR ADENOMA	22	19	17	21	15
#B HEPATOCELLULAR ADENOMA WITH CARCINOMA IN SITU	0	1	0	0	0
#M HEPATOCELLULAR CARCINOMA	6	13	7	11	4
#M HEMANGIOSARCOMA	1	1	3	2	0
GALLBLADDER					
TOTAL NUMBER EXAMINED	37	34	0	2	25
EXAMINED, UNREMARKABLE	37	30	-	0	25
MISSING	3	5	-	0	2
DILATION	0	3	-	2	0
CYSTIC GLAND ECTASIA	0	1	-	0	0
PANCREAS					
TOTAL NUMBER EXAMINED	40	39	0	0	27
EXAMINED, UNREMARKABLE	40	39	-	-	27
DUODENUM					
TOTAL NUMBER EXAMINED	40	39	0	0	27
EXAMINED, UNREMARKABLE	40	39	-	-	27
JEJUNUM					
TOTAL NUMBER EXAMINED	40	39	0	0	27
EXAMINED, UNREMARKABLE	40	39	-	-	27
ILEUM					
TOTAL NUMBER EXAMINED	40	39	0	0	27
EXAMINED, UNREMARKABLE	40	39	-	-	26

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 5.0%, 4 is 25.0%, 5 is 50.0%

= NEOPLASM, B = BENIGN, M = MALIGNANT

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

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TABLE 19 (Continued)
 TRIBUTYL-SWE GLYCOL DIMETHACRYLATE (TRPGDMA): 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	39	34	27
ILEUM (CONTINUED)					
LYMPHOID HYPERPLASIA	0	0	-	-	1
CECUM					
TOTAL NUMBER EXAMINED	40	39	1	0	27
EXAMINED, UNREMARKABLE	40	39	0	-	27
ABSCESSES	0	0	1	-	0
COLON					
TOTAL NUMBER EXAMINED	40	39	0	0	27
EXAMINED, UNREMARKABLE	39	39	-	-	27
MUCOSAL FIBROSIS	1	0	-	-	0
RECTUM					
TOTAL NUMBER EXAMINED	40	39	0	0	27
EXAMINED, UNREMARKABLE	39	39	-	-	25
EDEMA	0	0	-	-	1
PROCTITIS	1	0	-	-	2
PITUITARY					
TOTAL NUMBER EXAMINED	40	39	0	0	27
EXAMINED, UNREMARKABLE	37	35	-	-	24
CYST(S)	1	1	-	-	0
CYSTIC RATHKE'S CLEFT	2	3	-	-	3
THYROID GL					
TOTAL NUMBER EXAMINED	40	39	0	0	27
EXAMINED, UNREMARKABLE	13	14	-	-	6
THYROGLOSSAL DUCT CYST	17	5 ^b	-	-	10 ^c
COLLOID MINERALIZATION	2	0	-	-	0
COLLOID CRYSTALLIZATION	8	10	-	-	6
THYROIDITIS	1	0	-	-	0
GRANULOMATOUS THYROIDITIS	1	0	-	-	0
FOLLICULAR ECTASIA	4	6	-	-	4
FOLLICULAR CELL HYPERPLASIA/HYPERTROPHY	11	17	-	-	6 ^c
SB FOLLICULAR CELL ADENOMA	3	6	-	-	2
PARATHYROID GL					
TOTAL NUMBER EXAMINED	23	15	0	0	7
EXAMINED, UNREMARKABLE	23	15	-	-	7
MISSING	17	24	-	-	20
ADRENAL GL					
TOTAL NUMBER EXAMINED	40	39	34	27	27
EXAMINED, UNREMARKABLE	1	0	0	0	0

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 5.0%, 4 is 25.0%, 5 is 50.0%

^a = NEOPLASIA, ^b = BENIGN

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

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

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TABLE 19 (Continued)
 TRIETHYLENE GLYCOL DIMETHACRYLATE (TREGEMA): CHRONIC DERMAL
 BIOASSAY IN C3H/HEBESD MALE MICE
 SUMMARY OF MICROSCOPIC DIAGNOSES

ANIMALS SACRIFICED AT WEEK 79
 MALES

GROUP:	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP	70	70	70	70	70
NUMBER OF ANIMALS SACRIFICED	40	39	39	34	27
ADRENAL GL (CONTINUED)					
HEMORRHAGE	0	0	0	0	1
CORTICAL CYST	6	5	7	3	3
CORTICAL CERCID DEGENERATION	28	29	25	17	24
FIBROSIS	0	0	0	0	1
CORTICAL CELL HYPERPLASIA	0	1	0	0	0
SPINDLE CELL HYPERPLASIA	39	37	34	26	27
MODULAR CORTICAL CELL HYPERPLASIA	35	38	34	27	27
#B ADENOMA	0	0	0	2	0
#M PHEOCHROMOCYTOMA	0	0	0	1	0
SKIN, TREATED					
TOTAL NUMBER EXAMINED	40	39	39	34	27
EXAMINED, UNREMARKABLE	27	14	17	4	0
ACANTHOSIS	6	9	9	20bd	26bd
HYPERKERATOSIS/PARAKERATOSIS	2	5	10a	22bd	22bd
DERMATITIS	5	7	5	7	13bc
INTRACORNEAL PUSTULE FORMATION	2	1	3	3	2
SUBEPIDERMAL CLEFT/BULLA FORMATION	1	0	0	1	2
PIGMENTARY INCONTINENCE	0	0	2	0	0
SUPERFICIAL EPIDERMAL NECROLYSIS	0	0	0	1	0
PARASAL ZONE EPIDERMAL NECROLYSIS	0	0	0	1	0
ULCER/ULCERATION	0	2	0	0	1
APPEXIAL ATROPHY	4	16b	13a	11a	13b
DERMAL FIBROSIS	1	1	1	0	0
SKIN					
TOTAL NUMBER EXAMINED	40	39	39	34	27
EXAMINED, UNREMARKABLE	20	27	19	16	11
ACANTHOSIS	3	5	9	8	6
HYPERKERATOSIS/PARAKERATOSIS	0	0	3	1	0
VASCULAR ECTASIA	1	0	0	0	0
DERMATITIS	3	4	3	4	3
ULCER/ULCERATION	1	1	0	2	0
MINERALIZATION	0	0	1	0	0
CLITORAL/PREPUITAL GLAND ABSCESS	0	1	5a	8bc	5bc
CLITORAL/PREPUITAL GLAND ADENITIS	5	4	7	4	8
CLITORAL/PREPUITAL GLAND DUCT ECTASIA	0	8b	8b	5a	10b
APPEXIAL ATROPHY	3	2	8	5	6
SUBCUTIS					
TOTAL NUMBER EXAMINED	2	1	2	3	0
MINERALIZATION	1	0	0	0	-
PARNICULITIS (UNDER TREATED SKIN)	0	1	0	2	-

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 5.0 %, 4 is 25.0 %, 5 is 50.0 %

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

TABLE 19 (Continued)
 TRIFETHYLENE GLYCOL DIMETHACRYLATE (TFEDMA): CHRONIC DERMAL
 BIOASSAY IN C3H/HEMISP 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	39	34	27
SUBCUTIS (CONTINUED)					
DERMATITIS (UNDER UNTREATED SKIN)					
IN HEMANGIOSARCOMA	0	0	2	1	-
	1	0	0	0	-
BARS					
TOTAL NUMBER EXAMINED					
IN HEMANGIOSARCOMA	0	0	1	0	0
	-	-	1	-	-
SPLEEN					
TOTAL NUMBER EXAMINED					
EXAMINED, UNREMARKABLE	40	39	39	34	27
	28	23	28	20	20
EXTRAMEDULLARY HEMATOPOIESIS					
HEMOSIDEROSIS	7	15 ^a	10	13	7
CONGESTION	1	0	0	0	0
LYMPHOID HYPERPLASIA	1	0	0	0	0
IN MYELOSARCOMA	2	2	1	2	0
IN HEMANGIOSARCOMA	1	0	0	0	0
	1	0	0	0	0
LYMPH NO. S-MAN					
TOTAL NUMBER EXAMINED					
EXAMINED, UNREMARKABLE	38	39	0	0	27
MISSING	32	36	-	-	19
	2	0	-	-	0
HEMOSIDEROSIS					
SINUS HISTIOCYTOSIS	4	1	-	-	8 ^d
LYMPHOID HYPERPLASIA	1	2	-	-	3
EXTRAMEDULLARY HEMATOPOIESIS	1	0	-	-	0
	1	0	-	-	0
LYMPH NO. MED					
TOTAL NUMBER EXAMINED					
SINUS ERITHROCYTOSIS	1	1	0	0	0
PIGMENT GRANULOMA(S)	0	1	-	-	-
	1	0	-	-	-
LYMPH NO. MES					
TOTAL NUMBER EXAMINED					
EXAMINED, UNREMARKABLE	39	39	6	13	27
MISSING	17	22	0	0	12
	1	0	0	0	0
CYSTIC LYMPHATIC ECTASIA					
SINUS ERITHROCYTOSIS	7	8	1	5	9
HEMORRHAGE	6	4	3	8	8
HEMOSIDEROSIS	0	0	0	0	1
SINUS HISTIOCYTOSIS	1	1	2	1	2
PIGMENT GRANULOMA(S)	1	1	2	0	0
LYMPHOID ATROPHY	12	7	3	4	4
EXTRAMEDULLARY HEMATOPOIESIS	0	0	0	0	1
	6	0	0	1	0

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 5.0 %, 4 is 25.0 %, 5 is 50.0 %

g = NEOPLASM, N = MALIGNANT

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

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

TABLE 19 (Continued)
 TRIETHYLENE GLYCOL DIMETHACRYLATE (TREGDMA): 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	39	34	27
LYMPH NO, MES (CONTINUED)					
#N MYELOSARCOMA	1	0	0	0	0
LYMPH NO, OTHER					
TOTAL NUMBER EXAMINED	2	0	0	0	
SINUS HISTIOCYTOSIS	0	-	-	-	1
LYMPHADENITIS	0	-	-	-	1
#N MYELOSARCOMA	1	-	-	-	0
#N HEMANGIOSARCOMA	1	-	-	-	0
THYMIC REGION					
TOTAL NUMBER EXAMINED	40	39	0	0	27
EXAMINED, UNREMARKABLE	30	33	-	-	21
THYMIC TISSUE NOT PRESENT	7	6	-	-	6
KYTHELIAL CYST(S)	2	0	-	-	0
#N MYELOSARCOMA	1	0	-	-	0
BONE/JOINT					
TOTAL NUMBER EXAMINED	40	39	0	0	27
EXAMINED, UNREMARKABLE	40	39	-	-	27
BONE, STERNUM					
TOTAL NUMBER EXAMINED	40	39	0	0	27
EXAMINED, UNREMARKABLE	28	32	-	-	21
CARTILAGE DEGENERATION	12	7	-	-	6
BONE, FEMUR					
TOTAL NUMBER EXAMINED	40	39	0	0	27
EXAMINED, UNREMARKABLE	40	39	-	-	27
BONE MARROW					
TOTAL NUMBER EXAMINED	40	39	0	0	27
EXAMINED, UNREMARKABLE	38	39	-	-	27
HYPERPLASIA	1	0	-	-	0
#N HEMANGIOSARCOMA	1	0	-	-	0
SKELETAL MUSCLE					
TOTAL NUMBER EXAMINED	40	39	0	0	27
EXAMINED, UNREMARKABLE	38	39	-	-	26
ATROPHY	2	0	-	-	1
BRAIN					
TOTAL NUMBER EXAMINED	40	39	0	1	27
EXAMINED, UNREMARKABLE	3	6	-	0	5

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 5.0%, 4 is 25.0%, 5 is 50.0%

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

TABLE 19 (Continued)
 TRIMETHYLENE GLYCOL DIMETHACRYLATE (TREGOMA): 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	39	34	27
BRAIN (CONTINUED)					
MINERALIZATION	36	32	-	1	22
ENCEPHALOMALACIA	3	2	-	0	3
CORTICAL INFARCT	1	0	-	0	0
MEINGITIS	0	1	-	0	0
ENCEPHALITIS	1	0	-	0	1
NEURONIL VACUOLATION	3	3	-	0	3
NEURON LOSS	1	0	-	0	0
SPINAL CORD					
TOTAL NUMBER EXAMINED	40	39	0	0	27
EXAMINED, UNREMARKABLE	38	24	-	-	23
VACUOLATION	1	1	-	-	0
MYELIN SHEATH SWELLING	1	15 ^b	-	-	4
NERVE FIBER DEGENERATION	0	1	-	-	0
NERVE, SCIATIC					
TOTAL NUMBER EXAMINED	40	39	0	0	27
EXAMINED, UNREMARKABLE	38	36	-	-	27
MYELIN SHEATH SWELLING	0	2	-	-	0
MYELIN DEGENERATION	2	1	-	-	0
EYE					
TOTAL NUMBER EXAMINED	40	39	0	0	27
OPTIC NEURITIS	0	1	-	-	0
CORNEAL MINERALIZATION	13	8	-	-	14 ^c
KERATITIS	1	0	-	-	1
CATARACT	1	0	-	-	1
RETINAL ATROPHY	40	39	-	-	26
ATROPHY, OCULAR MUSCLES	0	3	-	-	0
PHIMOSIS BULBI	1	0	-	-	1
MANDIBULAR GL					
TOTAL NUMBER EXAMINED	40	39	6	2	27
EXAMINED, UNREMARKABLE	35	36	1	0	21
MISSING	0	0	0	1	0
LYMPHOCTIC INFILTRATES	1	0	0	0	1
ADENITIS	2	2	3	1	1
ECTASIA	0	0	0	0	3
FIBROSIS	0	1	3	0	1
ATROPHY	0	0	3	2	0
MINERALIZATION	1	0	0	0	0
SB ADENOMA	1	0	0	0	2
TESTES					
TOTAL NUMBER EXAMINED	40	39	32	31	27

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 5.0 %, 4 is 25.0 %, 5 is 50.0 %

^a = NEOFLAM, ^b = BENIGN

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

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

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TABLE 19 (Continued)
 TRIETHYLENE GLYCOL DIMETHACRYLATE (TREGMD): CHRONIC DERMAL
 BIOASSAY IN C3H/HEMISD 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	39	34	27
TESTES (CONTINUED)					
MINERALIZATION					
SEMIPERIOUS TUBULAR ATROPHY	38	38	30	28	25
ORCHITIS	39	39	32	31	26
INTERSTITIAL CELL HYPERPLASIA	1	1	0	0	0
SM HEMANGIOSARCOMA	0	1	0	0	0
	0	0	0	1	0
EPIDIDYMIDES					
TOTAL NUMBER EXAMINED					
EXAMINED, UNREMARKABLE	40	39	6	2	27
	37	39	-	2	27
MINERALIZATION					
	3	0	-	0	0
SEMINAL VESICLE					
TOTAL NUMBER EXAMINED					
EXAMINED, UNREMARKABLE	40	39	4	1	27
	37	32	0	0	25
ECTASIA					
SEMINAL VESICULITIS	1	1	1	0	0
ATROPHY	2	5	2	0	2
FIBROSIS	1	3	3	1	1
	0	1	0	0	0
PROSTATE					
TOTAL NUMBER EXAMINED					
EXAMINED, UNREMARKABLE	40	39	0	0	26
MISSING	36	34	-	-	25
	0	0	-	-	1
PROSTATITIS					
SM ADENOMA	3	5	-	-	1
	1	0	-	-	0
PENIS					
TOTAL NUMBER EXAMINED					
EXAMINED, UNREMARKABLE	2	9	5	5	1
	1	2	3	2	0
FOLLICULAR CYST(S)					
CONGESTION	0	0	1	0	0
BALANITIS	0	2	1	2	0
ULCER/ULCERATION	1	6	0	2	1
	0	1	0	0	0
TRACHEA					
TOTAL NUMBER EXAMINED					
EXAMINED, UNREMARKABLE	40	39	0	0	27
	40	39	-	-	27
LUNGS					
TOTAL NUMBER EXAMINED					
EXAMINED, UNREMARKABLE	40	39	39	34	27
	18	2	9	13	13
CONGESTION					
ALVEOLAR PROTEIN DEPOSITS	11	18	14	12	28
	0	0	0	0	1

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 5.0%, 4 is 25.0%, 5 is 50.0%

= NEOPLASM, B = BENIGN, M = MALIGNANT
 † Significantly different from CONTROL group 2 (p < .01)

TABLE 19 (Continued)
 TRIETHYLENE GLYCOL DIMETHACRYLATE (TARGEMA): CHRONIC DERMAL
 BIOASSAY IN C57/BL6JED MALE MICE
 SUMMARY OF MICROSCOPIC DIAGNOSES

ANIMALS SACRIFICED AT WEEK 78
 MALES

GROUP:	1	2	3	4	5
SUMMER OF ANIMALS IN DOSE GROUP	70	70	70	70	70
NUMBER OF ANIMALS SACRIFICED	40	39	39	34	27
LUNGS (CONTINUED)					
ALVEOLAR HYSTIOCYTOSIS	1	0	3	6ad	4c
ATELECTASIS	0	0	1	1	0
HEMORRHAGE	1	2	2	0	1
MINERALIZATION	11	26b	20a	11d	7d
PERIVASCULAR INFILTRATE(S)	0	0	0	0	1
LYMPHOID INFILTRATES	0	1	0	2	0
INTERSTITIAL PNEUMONITIS	0	1	1	2	3
BRONCHIOALVEOLAR CELL HYPERPLASIA	0	1	1	1	0
68 ADENOMA	4	3	3	3	1
69 MYXIOSARCOMA	1	0	0	0	0
69 HEPATOMA, METASTATIC	0	1	1	3	1
KIDNEYS					
TOTAL NUMBER EXAMINED	40	39	39	34	27
CYST(S)	4	4	6	2	6
HYDRONEPHROSIS	18	24	23	20	12
INTRAPELVIC HEMORRHAGE	0	0	2	0	0
INFARCTION	3	0	2	1	1
PAPILLARY NECROSIS	0	0	1	0	0
MINERALIZATION	36	38	38	33	25
PIELITIS	4	0	6c	3	4c
PIELONEPHRITIS	7	4	2	1	3
TUBULAR NEPHRITIS	1	0	0	0	0
TUBULAR DILATION	1	3	2	7a	3
CORTICAL ATROPHY	1	0	4	4c	0
TUBULAR PIGMENTATION	0	0	0	0	1
TUBULAR PROTEINOSIS	12	13	8	7	8
GLOMERULOSCLEROSIS	1	3	0	1	0
DILATED GLOMERULUS SPACE(S)	0	0	0	0	1
NEPHRITIS, INTERSTITIAL	5	2	3	0	1
FIBROSIS, INTERSTITIAL	7	5	10	3	4
DILATED HYPERPLASTIC TUBULES	18	19	17	13	20ac
68 TUBULAR CELL ADENOMA	0	0	0	1	0
URETER					
TOTAL NUMBER EXAMINED	2	3	2	0	2
ECTASIA	2	3	2	-	2
URETERITIS	0	1	0	-	0
HYPERPLASIA	0	1	0	-	0
URINARY BLADDER					
TOTAL NUMBER EXAMINED	40	39	5	1	27
EXAMINED, UNREMARKABLE	33	31	0	0	18

GROUP LEGEND: 1 is 0% (UNTRATED), 2 is 0% (VEHICLE), 3 is 5.0%, 4 is 25.0%, 5 is 50.0%

- 6 = 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)
- d Significantly different from CONTROL group 2 (p < .01)

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TABLE 19 (Continued)
 TRIETHYLENE GLYCOL DIMETHACRYLATE (TEDDMA): CHRONIC DERMAL
 BIOASSAY IN C3H/HEMISD 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	39	34	27
URINARY BLADDER (CONTINUED)						
ECTASIA		1	1	4	1	1
DIVERTICULUM		0	0	0	0	1
LYMPHOCYTIC INFILTRATE(S)		4	6	3	1	7
CYSTITIS		1	3	1	0	1
TRANSITIONAL CELL HYPERPLASIA		1	0	1	0	0

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 5.0%, 4 is 25.0%, 5 is 50.0%

None significantly different from control group

TABLE 20
 TRISTYLENE GLYCOL DIMETHACRYLATE (TRIGDMA): CHRONIC DERMAL
 BIOASSAY IN C57/BL6J8D 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	39	34	27
SKIN, TREATED					
TOTAL NUMBER EXAMINED	40	39	39	34	27
EXAMINED, UNREMARKABLE	27	14	17	4	0
ACANTHOOSIS	6	9	9	29bd	26bd
MINIMAL	2	6	6	4	3
MILD	1	1	3	23	19
MODERATE	3	1	0	2	4
MARKED	0	1	0	0	0
HYPERKERATOSIS/PARAKERATOSIS	2	5	10a	22bd	22bd
MINIMAL	0	5	10	17	17
MILD	2	0	0	5	5
DERMATITIS	5	7	5	7	13bc
MINIMAL	0	1	5	6	10
MILD	4	4	0	0	3
MODERATE	1	2	0	1	0
INTRACORNEAL PUSTULE FORMATION	2	1	3	3	2
MINIMAL	0	0	3	1	1
MILD	2	1	0	2	1
SUBEPIDERMAL CLEFT/PULLA FORMATION	1	0	0	1	2
MINIMAL	0	0	0	1	1
MILD	0	0	0	0	1
MODERATE	1	0	0	0	0
PIGMENTARY INCONTINENCE	0	0	2	0	0
MINIMAL	0	0	2	0	0
SUPERFICIAL EPIDERMAL NECROLYSIS	0	0	0	1	0
MILD	0	0	0	1	0

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 5.0%, 4 is 25.0%, 5 is 50.0%

- 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 20 (Continued)
 TRIETHYLENE GLYCOL DIMETHACRYLATE (TRISOMA): CHRONIC DERMAL
 BIOASSAY IN C3H/HEMISE 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	39	34	27
SKIN, TREATED (CONTINUED)					
BASAL SOME EPIDERMAL NECROLYSIS	0	0	0	1	0
MILD	0	0	0	1	0
ULCER/ULCERATION	0	2	0	0	1
MILD	0	0	0	0	1
MODERATE	0	2	0	0	0
ADDERMAL ATROPHY	4	16 ^b	13 ^a	11 ^a	13 ^b
MINIMAL	1	9	4	6	6
MILD	3	7	9	5	7
DERMAL FIBROSIS	1	1	1	0	0
MILD	1	0	1	0	0
MARKED	0	1	0	0	0

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 5.0 %, 4 is 25.0 %, 5 is 50.0 %

^a Significantly different from CONTROL group 1 (p < .05)
^b Significantly different from CONTROL group 1 (p < .01)

0 7 9 3

TABLE 21
 TRIPHENYLENE GLYCOL DIMETHACRYLATE (TADGMA): CHRONIC DERMAL
 EXPOSURE IN C57BL/6J MALE MICE
 SUMMARY OF MICROSCOPIC DIAGNOSES BY GRADE (LUNGS)

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	39	34	27
LUNGS					
TOTAL NUMBER EXAMINED	40	39	39	34	27
EXAMINED, UNREMARKABLE	18	2	9	13	13
CONGESTION	11	18	14	12	22
MILD	4	12	11	5	2
MODERATE	7	5	3	5	0
MARKED	0	1	0	2	0
ALVEOLAR PROTEIN DEPOSIT	0	0	0	0	1
MILD	0	0	0	0	1
ALVEOLAR HISTIOCYTOSIS	1	0	3	6 ^a	4 ^c
MINIMAL	1	0	0	0	1
MILD	0	0	2	5	3
MODERATE	0	0	1	1	0
ATELECTASIS	0	0	1	1	0
MILD	0	0	1	1	0
HEMORRHAGE	1	2	2	0	1
MINIMAL	0	0	1	0	0
MILD	1	1	1	0	1
MARKED	0	1	0	0	0
MINERALIZATION	11	26 ^b	20 ^a	11 ^d	7 ^d
MINIMAL	11	26	20	11	7
PERIVASCULAR INFILTRATE(S)	0	0	0	0	1
MILD	0	0	0	0	1
Lymphoid Infiltrates	9	1	0	2	0
MINIMAL	0	1	0	2	0

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 5.0%, 4 is 25.0%, 5 is 50.0%

- ^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)

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TABLE 21 (Continued)
 TRIETHYLENE GLYCOL DIMETHACRYLATE (TRIGDMA): CHRONIC DERMAL
 BIOASSAY IN C3H/HEMISD MALE MICE
 SUMMARY OF MICROSCOPIC DIAGNOSES BY GRADE (LUNGS)

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	39	34	27
LUNGS (CONTINUED)						
INTERSTITIAL PNEUMONITIS						
		0	1	1	2	3
MINIMAL						
		0	0	0	0	1
MILD						
		0	1	1	2	2
PNEUMONIALVOLAR CELL HYPERPLASIA						
		0	1	1	1	0
MILD						
		0	1	1	0	0
MODERATE						
		0	0	0	1	0
SB ADENOMA						
		4	3	3	3	1
MILD						
		2	2	2	1	1
MODERATE						
		1	0	1	1	0
MARKED						
		1	1	0	1	0
SM MYELOSARCOMA						
		1	0	0	0	0
MILD						
		1	0	0	0	0
SM HEPATOMA, METASTATIC						
		0	1	1	3	1
MINIMAL						
		0	1	0	2	1
MILD						
		0	0	1	0	0
MODERATE						
		0	0	0	1	0

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 5.0%, 4 is 25.0%, 5 is 50.0%

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

TABLE 22
 TRIPHENYLENE GLYCOL DIMETHACRYLATE (TADGDM): CHRONIC DERMAL
 NICASSAY IN C57BL/6J 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	39	34	27
KIDNEYS					
TOTAL NUMBER EXAMINED	40	39	39	34	27
CYST(S)	4	4	6	2	6
MINIMAL	1	1	2	1	2
MILD	2	3	4	1	4
MODERATE	1	0	0	0	0
HEMORRHAGES	18	24	23	20	12
MINIMAL	0	2	4	1	0
MILD	14	21	15	18	9
MODERATE	4	0	4	1	3
MARKED	0	1	0	0	0
INTRAPELVIC HEMORRHAGE	0	0	2	0	0
MINIMAL	0	0	1	0	0
MILD	0	0	1	0	0
INFARCTION	3	0	2	1	1
MILD	2	0	0	1	0
MODERATE	1	0	2	0	1
PAPILLARY NECROSIS	0	0	1	0	0
MODERATE	0	0	1	0	0
MINERALIZATION	36	38	38	33	25
MINIMAL	21	29	27	26	24
MILD	15	8	9	3	1
MODERATE	0	1	2	2	0
PHLEBITIS	4	0	6c	3	4c
MINIMAL	0	0	1	0	0
MILD	4	0	4	2	4
MODERATE	0	0	1	1	0

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 5.0 %, 4 is 25.0 %, 5 is 50.0 %

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

TABLE 22 (Continued)
 TRIMETHYLENE GLYCOL DIMETHACRYLATE (TRISOMA): CHRONIC DERMAL
 BIOASSAY IN C3H/HEWED 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	39	34	27
KIDNEYS (CONTINUED)						
PYELONEPHRITIS		7	4	2	1	3
MILD		5	2	1	1	2
MODERATE		2	1	0	0	0
MARKED		0	1	1	0	1
TUBULAR NEPHRITIS		1	0	0	0	0
MINIMAL		1	0	0	0	0
TUBULAR DILATION		1	3	2	7a	3
MINIMAL		1	2	1	7	2
MILD		0	1	1	0	1
CORTICAL ATROPHY		1	0	4	4c	0
MINIMAL		0	0	0	1	0
MILD		1	0	2	1	0
MODERATE		0	0	2	2	0
TUBULAR PIGMENTATION		0	0	0	0	1
MILD		0	0	0	0	1
TUBULAR PROTEINOSIS		12	13	8	7	8
MINIMAL		11	13	8	6	7
MILD		1	0	0	1	1
GLOMERULOCYCLEROSIS		1	3	0	1	0
MINIMAL		0	2	0	1	0
MILD		1	1	0	0	0
DILATED GLOMERULAR SPACE(S)		0	0	0	0	1
MINIMAL		0	0	0	0	1
NEPHRITIS, INTERSTITIAL		5	2	3	0	1
MINIMAL			2	2	0	0
MILD		5	0	1	0	1

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 5.0%, 4 is 25.0%, 5 is 50.0%

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

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

TABLE 22 (Continued)
 TRIFLYLURE GLYCOL DIMETHACRYLATE (TFGDMA): 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	39	34	27
KIDNEYS (CONTINUED)					
FIBROSIS, INTERSTITIAL	7	5	10	3	4
MINIMAL	4	1	4	0	1
MILD	3	4	5	3	3
MARKED	0	0	1	0	0
ISOLATED HYPERPLASTIC TUBULES	18	19	17	13	20 ^a
MINIMAL	12	16	14	10	12
MILD	6	3	2	3	8
MODERATE	0	0	1	0	0
CB TUBULAR CELL ADENOMA	0	0	0	1	0
MINIMAL	0	0	0	1	0

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 5.0%, 4 is 25.0%, 5 is 50.0%

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

TABLE 23
 TRIETHYLENE GLYCOL DIMETHACRYLATE (TRIGEMA): 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	17	22	28
ADIPOSE TISSUE					
TOTAL NUMBER EXAMINED	0	0	0	1	0
# M HEMANGIOSARCOMA	-	-	-	1	-
PERITONEUM					
TOTAL NUMBER EXAMINED	0	0	1	0	0
PERITONITIS	-	-	1	-	-
HEART					
TOTAL NUMBER EXAMINED	15	17	5	4	28
EXAMINED, UNREMARKABLE	3	4	0	1	3
ATRIAL THROMBOSIS	3	3	3	1	9
VENTRICULAR THROMBOSIS	0	0	0	0	1
NECROSIS	1	0	0	0	1
MYOCARDIAL MINERALIZATION	3	8	1	1	19
MYOFIBER VACUOLATION	1	0	0	0	0
MYOCARDIAL DEGENERATION/FIBROSIS	7	11	4	1	21
MYOCARDITIS	2	1	0	0	1
EPICARDITIS	1	0	0	0	0
ENDOCARDITIS	3	0	0	0	2
# M HEMANGIOSARCOMA	0	0	1	1	2
AORTA					
TOTAL NUMBER EXAMINED	15	17	0	0	27
EXAMINED, UNREMARKABLE	15	17	-	-	26
MISSING	0	0	-	-	1
MINERALIZATION	0	0	-	-	1
VASCULATURE					
TOTAL NUMBER EXAMINED	0	1	0	0	1
MINERALIZATION	-	1	-	-	0
BACTERIAL EMBOLIZATION	-	0	-	-	1
SALIVARY GL					
TOTAL NUMBER EXAMINED	15	17	0	2	28
EXAMINED, UNREMARKABLE	15	13	-	1	23
LEUCOCYTTIC INFILTRATES	0	3	-	0	2
SIALOADENITIS	0	1	-	1	1
FIBROSIS	0	0	-	1	1
ATROPHY	0	0	-	0	1
HYPERPLASIA	0	0	-	1	0
DUCT HYPERPLASIA	0	0	-	1	1
ESOPHAGUS					
TOTAL NUMBER EXAMINED	15	17	0	0	28
EXAMINED, UNREMARKABLE	15	16	-	-	28

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 5.0%, 4 is 25.0%, 5 is 50.0%

= NEOPLASIA, M = MALIGNANT

TABLE 23 (Continued)
 TRIBUTYLENE GLYCOL DIBENZOYLATE (TRIGEMA): 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	17	22	28
ESOPHAGUS (CONTINUED)					
DILATION	0	1	-	-	0
STOMACH					
TOTAL NUMBER EXAMINED	15	17	16	22	28
EXAMINED, UNREMARKABLE	14	13	14	21	21
TOO AUTOLYZED TO EVALUATE	0	0	1	0	0
DIVERTICULUM	0	2	0	0	0
GLAND ECTASIA	0	0	1	1	3
GASTRITIS	1	1	1	0	0
ULCEL-/ULCERATION	1	1	0	0	4
LIVER					
TOTAL NUMBER EXAMINED	15	17	17	22	28
EXAMINED, UNREMARKABLE	1	4	5	4	5
ANOMALOUS LOBULATION	0	1	0	0	1
CYST(S)	0	0	1	0	0
CONGESTION	0	0	0	1	0
FELIOSIS/TELANGIECTASIS	1	0	0	0	0
MINERALIZATION	2	0	2	0	0
HEPATITIS	0	0	0	0	1
HEPATIC ABSCESS(ES)	0	0	1	0	0
ADHESION(S)	0	1	2	0	1
HEPATOCELLULAR NECROSIS	6	2	2	3	5
HEPATOCELLULAR HYPERTROPHY	1	0	0	0	0
HEPATOCELLULAR HYPERPLASIA	1	0	0	3	2
08 HEPATOCELLULAR ADENOMA	4	2	6	6	9
08 HEPATOCELLULAR ADENOMA WITH CARCINOMA IN SITU	0	0	0	0	1
0N HEPATOCELLULAR CARCINOMA	8	12	6	12	15
0N HEMANGIOSARCOMA	1	0	3	2	1
0N HYLEOSARCOMA	0	0	0	0	1
GALLBLADDER					
TOTAL NUMBER EXAMINED	12	12	0	1	23
EXAMINED, UNREMARKABLE	8	12	-	0	22
TOO AUTOLYZED TO EVALUATE	2	4	-	1	3
KISSING	1	1	-	0	2
DILATION	3	0	-	0	1
IMPASSATED SECRETION	1	0	-	0	0
CHOLECYSTITIS	1	0	-	1	0
PANCREAS					
TOTAL NUMBER EXAMINED	15	17	0	2	28
EXAMINED, UNREMARKABLE	14	17	-	1	27
PANCREATITIS	0	0	-	1	0
ACTHAR ATROPHY	1	0	-	0	0
ISLET CELL HYPERPLASIA	0	0	-	0	1

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 5.0 %, 4 is 25.0 %, 5 is 50.0 %

0 = NEOPLASM, B = BENIGN, N = MALIGNANT

TABLE 23 (Continued)
 TRIETHYLENE GLYCOL DIMETHACRYLATE (TRGDMA): CHRONIC DERMAL
 BIOASSAY IN C3H/HEWED 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	17	22	28
DUODENUM					
TOTAL NUMBER EXAMINED	15	10	2	0	22
EXAMINED, UNREMARKABLE	14	10	1	-	22
TOO AUTOLYZED TO EVALUATE	0	7	0	-	6
ENTERITIS	1	0	1	-	0
JEJUNUM					
TOTAL NUMBER EXAMINED	13	7	1	0	20
EXAMINED, UNREMARKABLE	13	7	0	-	20
TOO AUTOLYZED TO EVALUATE	2	10	0	-	8
ADHESION(S)	0	0	1	-	0
ILEUM					
TOTAL NUMBER EXAMINED	15	11	0	0	20
EXAMINED, UNREMARKABLE	15	11	-	-	20
TOO AUTOLYZED TO EVALUATE	0	6	-	-	8
CECUM					
TOTAL NUMBER EXAMINED	14	9	1	0	20
EXAMINED, UNREMARKABLE	14	9	0	-	20
TOO AUTOLYZED TO EVALUATE	1	8	0	-	8
TYPHLOITIS	0	0	1	-	0
COLON					
TOTAL NUMBER EXAMINED	15	16	1	0	25
EXAMINED, UNREMARKABLE	15	16	0	-	25
TOO AUTOLYZED TO EVALUATE	0	1	0	-	3
DIVERTICULUM	0	0	1	-	0
RECTUM					
TOTAL NUMBER EXAMINED	15	16	1	0	27
EXAMINED, UNREMARKABLE	15	16	0	-	27
TOO AUTOLYZED TO EVALUATE	0	1	0	-	1
PROCTITIS	0	0	1	-	0
PITUITARY					
TOTAL NUMBER EXAMINED	15	17	0	1	28
EXAMINED, UNREMARKABLE	15	13	-	0	27
CYST(S)	0	1	-	0	1
CYSTIC RATEKE'S CLEFT	0	2	-	0	0
CONGESTION	0	0	-	1	0
HEMORRHAGE	0	1	-	0	0
THYROID GL					
TOTAL NUMBER EXAMINED	15	17	0	0	28
EXAMINED, UNREMARKABLE	7	11	-	-	14

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 5.0 %, 4 is 25.0 %, 5 is 50.0 %

TABLE 23 (Continued)
 TRINITYLENE GLYCOL DIMETHACRYLATE (TRIGONA): CHRONIC DERMAL
 EXPOSURE IN C3H/HEMIED 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	17	22	28
THYROID GL. (CONTINUED)					
THYROGLOSSAL DUCT CYST	4	1	-	-	10
COLLOID CRYSTALLIZATION	3	5	-	-	4
THYROIDITIS	0	0	-	-	1
FOLLICULAR ECTASIA	1	1	-	-	1
FOLLICULAR CELL HYPERPLASIA/B. HYPTROPHY	2	1	-	-	2
OB FOLLICULAR CELL ADENOMA	0	1	-	-	1
PARATHYROID GL					
TOTAL NUMBER EXAMINED	5	8	0	0	12
EXAMINED, UNREMARKABLE	5	8	-	-	12
MISSING	10	9	-	-	16
ADRENAL GL					
TOTAL NUMBER EXAMINED	15	17	9	16	28
EXAMINED, UNREMARKABLE	0	3	0	0	2
CONGESTION	0	0	0	0	1
HEMORRHAGE	1	0	0	0	0
CORTICAL CYST	1	0	3	0	3
CORTICAL CELL VACUOLIZATION	1	0	0	0	0
CORTICAL CERIOD DEGENERATION	11	11	8	4	18
CORTICAL ATROPHY	0	0	1	2	0
CORTICAL CELL HYPERPLASIA	2	0	0	0	0
SPINDLE CELL HYPERPLASIA	15	14	9	15	25
NOULAR CORTICAL CELL HYPERPLASIA	11	13	9	13	21
SKIN, TREATED					
TOTAL NUMBER EXAMINED	15	17	17	22	28
EXAMINED, UNREMARKABLE	8	5	2	0	2
ACANTHOSIS	2	1	5	15	22
HYPERKERATOSIS/PARAKERATOSIS	1	6	8	18	25
DERMATITIS	3	0	3	5	3
INTRACORNEAL PUSTULE FORMATION	1	0	8	4	1
SUPRIFICIAL EPIDERMAL NECROLYSIS	0	0	0	1	0
BASAL ZONE EPIDERMAL NECROLYSIS	0	0	0	1	1
ULCER/ULCERATION	0	0	2	0	0
MINERALIZATION	0	0	0	1	0
ADRENAL ATROPHY	4	10	14	17	18
DERMAL FIBROSIS	0	0	0	1	0
OB HEMANGIOSARCOMA	0	1	0	0	0
SKIN					
TOTAL NUMBER EXAMINED	15	17	17	22	28
EXAMINED, UNREMARKABLE	8	9	4	14	12
ACANTHOSIS	2	3	4	1	4
HYPERKERATOSIS/PARAKERATOSIS	0	1	2	1	2
DERMATITIS	4	4	6	0	1

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 5.0 %, 4 is 25.0 %, 5 is 50.0 %

† = NEOPLASM, B = BENIGN, M = MALIGNANT

TABLE 23 (Continued)
 TRIETHYLENE GLYCOL DIMETHACRYLATE (TRGDMA): 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	17	22	28
SKIN (CONTINUED)						
INTRACORNEAL PUSTULE FORMATION		0	0	2	0	1
ULCER/ULCERATION		1	1	3	0	0
CLITORAL/PREPUTIAL GLAND ABSCESS		2	1	1	1	1
CLITORAL/PREPUTIAL GLAND ADENITIS		1	3	1	0	8
CLITORAL/PREPUTIAL GLAND DUCT ECTASIA		1	3	1	1	5
ADMEAL GLAND ECTASIA		0	0	1	1	0
ADMEAL ATROPHY		1	5	8	6	9
DERMAL FIBROSIS		0	0	2	0	0
SUBCUTIS						
TOTAL NUMBER EXAMINED		0	1	0	2	0
PANNICULITIS (UNDER TREATED SKIN)		-	0	-	1	-
PANNICULITIS (UNDER UNTREATED SKIN)		-	1	-	1	-
HEAD						
TOTAL NUMBER EXAMINED		1	1	1	1	1
CONGESTION		1	0	0	0	0
HEMORRHAGE		0	1	0	0	0
BOTRYOMYCOSIS		0	0	1	0	1
#M ADENOCARCINOMA		0	0	0	1	0
TAIL						
TOTAL NUMBER EXAMINED		0	0	0	0	2
NECROSIS		-	-	-	-	2
SPLEEN						
TOTAL NUMBER EXAMINED		15	17	17	22	28
EXAMINED, UNREMARKABLE		2	6	5	3	5
ANEMIA		0	0	0	1	0
EXTRAMEDULLARY HEMATOPOIESIS		12	9	12	18	19
SPLENITIS		1	0	0	0	1
HEMOSIDEROSIS		2	3	0	3	4
CONGESTION		1	0	0	2	2
INFARCTION		0	0	0	0	1
FIBROSIS		0	0	0	0	1
LYMPHOID DEPLETION		1	3	0	4	7
LYMPHOID HYPERPLASIA		0	0	0	1	1
#M MYELOSARCOMA		0	0	0	0	1
LYMPH ND, S-NAE						
TOTAL NUMBER EXAMINED		14	16	0	1	27
EXAMINED, UNREMARKABLE		10	11	-	0	14
MISSING		1	1	-	0	-
SINUS ERYTHROCYTOSIS		0	1	-	0	0
HEMOSIDEROSIS		4	5	-	0	10

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 5.0%, 4 is 25.0%, 5 is 50.0%

= NEOPLASM, M = MALIGNANT

TABLE 23 (Continued)
 TRIETHYLENE GLYCOL DIMETHACRYLATE (TRIGDMA): 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	17	22	28
LYMPH ND, S-NAM (CONTINUED)					
SINUS HISTIOCYTOSIS	2	2	-	0	3
PIGMENT GRANULOMA(S)	0	1	-	0	0
LYMPHOID HYPERPLASIA	0	0	-	1	1
LYMPHOID DEPLETION	0	0	-	0	1
LYMPH ND, MED					
TOTAL NUMBER EXAMINED	3	3	0	0	4
SINUS ERITHROCYTOSIS	1	2	-	-	2
HEMOSIDEROSIS	2	0	-	-	0
SINUS HISTIOCYTOSIS	1	2	-	-	4
LYMPH ND, MES					
TOTAL NUMBER EXAMINED	15	15	5	6	27
EXAMINED, UNREMARKABLE	5	6	1	1	10
TOO AUTOLYZED TO EVALUATE	0	1	0	0	1
MISSING	0	1	0	0	0
CYSTIC LYMPHATIC ECTASIA	3	1	2	2	4
SINUS ERITHROCYTOSIS	3	2	2	3	3
HEMORRHAGE	1	0	0	0	2
HEMOSIDEROSIS	1	2	1	0	1
SINUS HISTIOCYTOSIS	5	4	2	1	4
PIGMENT GRANULOMA(S)	5	3	1	3	8
LYMPHOID ATROPHY	0	1	0	2	1
LYMPH ND, RES					
TOTAL NUMBER EXAMINED	0	1	0	0	1
SINUS HISTIOCYTOSIS	-	1	-	-	1
HEMOSIDEROSIS	-	0	-	-	1
LYMPHOID HYPERPLASIA	-	1	-	-	0
LYMPH ND, OTHER					
TOTAL NUMBER EXAMINED	0	1	0	0	0
SINUS HISTIOCYTOSIS	-	1	-	-	-
LYMPHOID HYPERPLASIA	-	1	-	-	-
THYMIC REGION					
TOTAL NUMBER EXAMINED	15	17	0	1	28
EXAMINED, UNREMARKABLE	8	10	-	1	12
THYMIC TISSUE NOT PRESENT	4	6	-	0	15
PIGMENT GRANULOMA(S)	0	1	-	0	0
INFLAMMATION, GRANULOMATOUS	1	0	-	0	0
LYMPHATIC ECTASIA	3	0	-	0	0
EPITHELIAL CYST(S)	0	0	-	0	1
BONE/JOINT					
TOTAL NUMBER EXAMINED	15	17	0	0	28
EXAMINED, UNREMARKABLE	15	17	-	-	28

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 5.0 %, 4 is 25.0 %, 5 is 50.0 %

TABLE 23 (Continued)
 TRIETHYLENE GLYCOL DIMETHACRYLATE (TREGDMA): CHRONIC DERMAL
 BIOASSAY IN C3H/HEBESD MALE MICE
 SUMMARY OF MICROSCOPIC DIAGNOSES

ALL ANIMALS FOUND DEAD/SACRIFICED NORIBUND
 MALES

GROUP:	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP	70	70	70	70	70
NUMBER OF ANIMALS FOUND DEAD/SACRIFICED NORIBUND	15	17	17	22	28
BONE, STERNUM					
TOTAL NUMBER EXAMINED	15	17	1	1	28
EXAMINED, UNREMARKABLE	10	13	1	1	22
CARTILAGE DEGENERATION:	5	4	0	0	6
BONE, FEMUR					
TOTAL NUMBER EXAMINED	15	17	0	0	28
EXAMINED, UNREMARKABLE	15	17	-	-	28
BONE MARROW					
TOTAL NUMBER EXAMINED	15	17	0	0	28
EXAMINED, UNREMARKABLE	12	15	-	-	24
HEMOSIDEROSIS	0	1	-	-	0
INFARCTION	1	0	-	-	0
MYELITIS	1	0	-	-	0
MYELOFIBROSIS	1	0	-	-	0
HYPERPLASIA	2	0	-	-	2
GRANULOCYTTIC CELL HYPERPLASIA	0	1	-	-	2
SKELETAL MUSCLE					
TOTAL NUMBER EXAMINED	15	17	1	3	28
EXAMINED, UNREMARKABLE	7	13	0	1	26
ABSCESS	1	0	0	0	0
ATROPHY	7	4	1	2	2
BRAIN					
TOTAL NUMBER EXAMINED	15	17	1	3	28
EXAMINED, UNREMARKABLE	3	4	0	2	6
COMPRESSION DEFORMITY	0	0	0	0	1
BRAIN HEMORRHAGE	0	3	0	0	1
MINERALIZATION	10	11	1	1	21
ENCEPHALOMALACIA	2	3	0	0	2
NEURITIS	0	0	0	0	1
ENCEPHALITIS	2	0	0	0	2
NEUROFIL VACUOLATION	2	0	0	0	2
NEURON LOSS	1	0	0	0	0
GLIOSIS	0	1	0	0	0
SPINAL CORD					
TOTAL NUMBER EXAMINED	15	17	0	0	28
EXAMINED, UNREMARKABLE	15	16	-	-	26
HEMORRHAGE	0	1	-	-	1
MYELIN SHEATH SWELLING	0	0	-	-	2
MYELITIS	0	0	-	-	1
NERVE, SCIATIC					
TOTAL NUMBER EXAMINED	15	17	0	0	28
EXAMINED, UNREMARKABLE	13	15	-	-	28

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 5.0%, 4 is 25.0%, 5 is 50.0%

TABLE 23 (Continued)
 TRIS(2-HYDROXYETHYL)AMMONIUM METHACRYLATE (TRISOMA): CHRONIC DERMAL
 BIOASSAY IN C3H/HEWED 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	17	22	28
NERVE, SCIATIC (CONTINUED)						
MYELIN SHEATH SWELLING		0	1	-	-	0
MYELIN DEGENERATION		2	1	-	-	0
NERVE, OTHER						
TOTAL NUMBER EXAMINED		0	1	0	0	0
VACUOLATION		-	1	-	-	-
EYE						
TOTAL NUMBER EXAMINED		15	16	0	1	28
TOO AUTOLYZED TO EVALUATE		0	1	-	0	0
CORNEAL MINERALIZATION		8	3	-	0	12
KERATITIS		1	1	-	0	1
SURFACE EXUDATE		0	0	-	1	0
CATARACT		2	3	-	0	1
RETINAL ATROPHY		14	16	-	1	27
PHARYNGITIS		1	0	-	0	0
ATROPHY, OCULAR MUSCLES		0	1	-	0	0
HARDERIAN GL						
TOTAL NUMBER EXAMINED		15	17	2	2	28
EXAMINED, UNREMARKABLE		13	16	1	1	26
BOTRYOMYCOSIS		0	0	0	0	1
ADENITIS		1	1	1	0	0
FIBROSIS		1	0	1	0	0
ATROPHY		0	0	1	1	0
4B ADENOMA		0	0	0	0	1
TESTES						
TOTAL NUMBER EXAMINED		15	17	11	14	27
EXAMINED, UNREMARKABLE		3	2	0	0	4
MISSING		0	0	0	0	1
INFARCTION		1	0	0	0	0
MINERALIZATION		10	12	7	11	15
SEMINIFEROUS TUBULAR ATROPHY		12	15	11	14	23
ORCHITIS		1	0	0	0	0
PERIORCHITIS		0	0	0	1	0
EPIDIDYMIDES						
TOTAL NUMBER EXAMINED		15	17	1	2	26
EXAMINED, UNREMARKABLE		15	17	1	0	26
MISSING		0	0	0	0	2
EPIDIDYMITIS		0	0	0	2	0
SEMINAL VESICLE						
TOTAL NUMBER EXAMINED		5	16	3	2	26
EXAMINED, UNREMARKABLE		4	10	0	0	16
TOO AUTOLYZED TO EVALUATE		0	0	0	0	1
MISSING		0	1	0	0	1

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 5.0%, 4 is 25.0%, 5 is 50.0%

= NEOPLASM, B = BENIGN

TABLE 23 (Continued)
 TRIPHTYLENE GLYCOL DIMETHACRYLATE (TAECDMA): 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	17	22	28
SEMINAL VESICLE (CONTINUED)					
ECTASIA	0	1	1	0	1
SEMINAL VESICULITIS	5	5	2	1	7
MINERALIZATION	1	1	0	0	0
ATROPHY	2	4	2	2	7
COAGULATING GL					
TOTAL NUMBER EXAMINED	0	1	0	0	0
ADENITIS					
	-	1	-	-	-
PROSTATE					
TOTAL NUMBER EXAMINED	15	14	0	1	26
EXAMINED, UNREMARKABLE	10	11	-	1	22
TOO AUTOLYZED TO EVALUATE	0	0	-	0	1
MISSING	0	3	-	0	1
MINERALIZATION	1	0	-	0	0
PROSTATITIS	4	3	-	0	4
PENIS					
TOTAL NUMBER EXAMINED	6	11	6	6	14
EXAMINED, UNREMARKABLE	1	1	0	0	0
CONGESTION	1	3	3	3	7
BALANITIS	4	3	4	4	9
EDEMA	0	0	0	1	0
POSTHITIS	0	3	0	0	1
BALANOPOSTHITIS	1	1	0	0	0
ULCER/ULCERATION	1	4	4	3	8
TRACHEA					
TOTAL NUMBER EXAMINED	15	17	0	0	28
EXAMINED, UNREMARKABLE	15	17	-	-	27
GLAND ECTASIA	0	0	-	-	1
TRACHEITIS	0	0	-	-	1
MUCOSAL HYPERPLASIA	0	0	-	-	1
LUNGS					
TOTAL NUMBER EXAMINED	15	17	17	22	28
EXAMINED, UNREMARKABLE	4	0	0	1	2
CONGESTION	10	14	11	15	22
ALVEOLAR PROTEIN DEPOSITS	0	1	0	1	2
ALVEOLAR HISTIOCYTOSIS	4	6	4	9	13
VASCULAR THROMBOSIS	0	0	0	0	2
HEMORRHAGE	3	5	2	5	6
MINERALIZATION	3	7	5	4	5
BROCHOPNEUMONIA	0	1	1	0	2
INTERSTITIAL PNEUMONITIS	1	3	3	4	7

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 5.0%, 4 is 25.0%, 5 is 50.0%

TABLE 23 (Continued)
 TRIETHYLENE GLYCOL DIMETHACRYLATE (TRIGDMA): CHRONIC DERMAL
 BIOASSAY IN C57/BL6J 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	17	22	28
LUNGS (CONTINUED)						
GRANULOMATOUS PNEUMONITIS		0	0	0	0	2
INTERSTITIAL FIBROSIS		0	1	0	0	3
BRONCHIOALVEOLAR CELL HYPERPLASIA		0	0	1	0	0
#B ADENOMA		1	0	1	2	1
#M HYDROCARCOMA		0	0	0	0	1
#N HEPATOMA, METASTATIC		1	3	2	2	3
KIDNEYS						
TOTAL NUMBER EXAMINED		15	17	17	22	28
EXAMINED, UNREMARKABLE		0	1	0	0	0
CYST(S)		1	2	2	0	1
CONGESTION		0	0	0	1	0
HYDRONEPHROSIS		0	13	13	12	13
BACTERIAL INCOLIZATION		0	0	0	2	1
INFARCTION		1	0	0	2	1
PAPILLARY NECROSIS		1	1	3	3	3
MINERALIZATION		11	12	12	19	24
OSSEIFICATION, DYSTROPHIC		0	0	0	0	1
HEMORRHAGE		0	0	0	0	1
HEMOSIDEROSIS		0	1	0	0	0
PYELITIS		0	1	4	0	0
PYELONEPHRITIS		3	7	5	5	6
NEPHRITIS, PURULENT		0	1	0	0	0
TUBULAR DILATION		0	1	3	4	5
CORTICAL ATROPHY		0	0	3	1	2
TUBULAR PIGMENTATION		2	0	1	1	1
TUBULAR PROTEINOSIS		6	7	7	8	14
GLOMERULONEPHRITIS		1	0	0	0	0
GLOMERULOSCLEROSIS		2	3	2	3	6
DILATED GLOMERULAR SPACE(S)		0	0	0	0	1
NEPHRITIS, INTERSTITIAL		1	1	1	1	3
FIBROSIS, INTERSTITIAL		1	4	6	3	8
FIBROSIS, PERIGLOMERULAR		0	0	0	1	0
DILATED HYPERPLASTIC TUBULES		4	4	4	2	7
URETER						
TOTAL NUMBER EXAMINED		2	3	2	4	1
TOO AUTOLYZED TO EVALUATE		0	1	0	0	1
ECTASIA		1	2	2	4	0
URETERITIS		1	2	2	2	1
URINARY BLADDER						
TOTAL NUMBER EXAMINED		15	14	5	3	26
EXAMINED, UNREMARKABLE		9	6	0	0	14
TOO AUTOLYZED TO EVALUATE		0	2	0	0	2
MISSING		0	1	0	0	0
ECTASIA		3	1	4	2	5
GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 5.0 %, 4 is 25.0 %, 5 is 50.0 %						
# = NEOPLASM, B = BENIGN, M = MALIGNANT						

TABLE 23 (Continued)
 TRIMETHYLENE GLYCOL DIMETHACRYLATE (TREGDMA): 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	17	22	28
URINARY BLADDER (CONTINUED)						
DIVERTICULUM		1	0	0	0	0
PROMINENT MUCOSAL FOLD		0	0	0	0	1
HEMORRHAGE		0	0	0	1	0
LYMPHOCYTIC INFILTRATE(S)		0	2	1	0	3
CYSTITIS		3	6	2	2	5
URETHRA						
TOTAL NUMBER EXAMINED		1	1	0	0	0
INTRALUMINAL PROTEIN COAGULUM		1	1	-	-	-
CAUSE OF DEATH						
TOTAL NUMBER EXAMINED		15	17	0	0	28
UNDETERMINED		1	1	-	-	3
TRAUMA		1	1	-	-	0
BOTRYOMYCOSIS		0	0	-	-	1
CHRONIC RENAL DISEASE		0	2	-	-	1
PYELONEPHRITIS		2	2	-	-	3
ENDOCARDITIS		3	0	-	-	1
ATRIAL THROMBOSIS/CONGESTIVE HEART FAILURE		0	1	-	-	1
HEPATOCELLULAR ADENOMA		1	0	-	-	2
HEPATOCELLULAR CARCINOMA		7	10	-	-	14
HEMANGIOSARCOMA		0	0	-	-	1
MYELOSARCOMA		0	0	-	-	1

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 5.0 %, 4 is 25.0 %, 5 is 50.0 %

TABLE 24
 TRIS(2-HYDROXYETHYL)AMMONIUM GLYCOL DIMETHACRYLATE (TRIGDMA): CHRONIC DERMAL
 BIGASSAY IN C57BL/6J MALE MICE
 SUMMARY OF MICROSCOPIC DIAGNOSES BY GRADE (SKIN, TREATED)
 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	17	22	29
SKIN, TREATED					
TOTAL NUMBER EXAMINED	15	17	17	22	28
EXAMINED, UNREMARKABLE	8	5	2	0	2
ACROSIS	2	1	5	15	22
MINIMAL	0	1	1	5	1
MILD	2	0	4	9	19
MODERATE	0	0	0	1	2
HYPERKERATOSIS/PARAKERATOSIS	1	6	8	18	25
MINIMAL	1	6	6	9	7
MILD	0	0	2	9	17
MODERATE	0	0	0	0	1
DERMATITIS	3	0	3	5	3
MINIMAL	1	0	2	4	3
MILD	0	0	1	1	0
MODERATE	2	0	0	0	0
INTRACORNEAL PUSTULE FORMATION	1	0	8	4	1
MINIMAL	0	0	4	3	1
MILD	0	0	4	1	0
MODERATE	1	0	0	0	0
SUPERFICIAL EPIDERMAL NECROLYSIS	0	0	0	1	0
MILD	0	0	0	1	0
BASAL SOME EPIDERMAL NECROLYSIS	0	0	0	1	1
MINIMAL	0	0	0	0	1
MILD	0	0	0	1	0
ULCER/ULCERATION	0	0	2	0	0
MINIMAL	0	0	2	0	0
MINERALIZATION	0	0	0	1	0
MINIMAL	0	0	0	1	0

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 5.0%, 4 is 25.0%, 5 is 50.0%

TABLE 24 (Continued)
 TRIMETHYLENE GLYCOL DIMETHACRYLATE (TREGOMA): CHRONIC DERMAL
 BIOASSAY IN C3H/HEBESD MALE MICE
 SUMMARY OF MICROSCOPIC DIAGNOSES BY GRADE (SKIN, TREATED)

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	17	22	28
SKIN, TREATED (CONTINUED)						
ADRENAL ATROPHY		4	10	14	17	18
MINIMAL		1	1	3	5	4
MILD		3	9	8	12	13
MODERATE		0	0	3	0	1
DERMAL FIBROSIS		0	0	0	1	0
MILD		0	0	0	1	0
OR HEMANGIOSARCOMA		0	1	0	0	0
MARKED		0	1	0	0	0

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 5.0%, 4 is 25.0%, 5 is 50.0%

0 = NEOPLASM, M = MALIGNANT

TABLE 25
TRIBENYLAMINE GLYCOL DIMETHACRYLATE (TRIGDMA): CHRONIC DERMAL
BIOASSAY IN C57/BL6NED MALE MICE
SUMMARY OF MICROSCOPIC DIAGNOSES BY GRADE (KIDNEYS)
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	17	22	28
KIDNEYS					
TOTAL NUMBER EXAMINED	15	17	17	22	28
EXAMINED, UNREMARKABLE	0	1	0	0	0
CYST(S)	1	2	2	0	1
MINIMAL	1	0	2	0	1
MODERATE	0	2	0	0	0
CONGESTION	0	0	0	1	0
MODERATE	0	0	0	1	0
HYDROMINEROSIS	0	13	13	12	13
MINIMAL	0	0	1	1	1
MILD	1	7	6	9	7
MODERATE	4	5	6	2	3
MARKED	3	1	0	0	2
BACTERIAL EMBOLIATION	0	0	0	2	1
MILD	0	0	0	1	1
MODERATE	0	0	0	1	0
INFARCTION	1	0	0	2	1
MILD	0	0	0	1	0
MODERATE	1	0	0	1	1
CAPILLARY NECROSIS	1	1	3	3	3
MODERATE	1	1	1	1	1
MARKED	0	0	2	2	2
MINERALIZATION	11	12	12	19	24
MINIMAL	6	7	11	16	20
MILD	5	4	1	3	4
MODERATE	0	1	0	0	0
OSSEIFICATION, DYSTROPHIC	0	0	0	0	1
MILD	0	0	0	0	1

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 5.0%, 4 is 25.0%, 5 is 50.0%

TABLE 25 (Continued)
 TRIETHYLENE GLYCOL DIMETHACRYLATE (TREGDMA): CHRONIC DERMAL
 BIOASSAY IN C57BL/6J MALE MICE
 SUMMARY OF MICROSCOPIC DIAGNOSES BY GRADE (KIDNEYS)

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	17	22	28
KIDNEYS (CONTINUED)					
HEMORRHAGE	0	0	0	0	1
MARKED	0	0	0	0	1
HEMOSIDEROSIS	0	1	0	0	0
MILD	0	1	0	0	0
PYELITIS	0	1	4	0	0
MILD	0	1	2	0	0
MODERATE	0	0	2	0	0
PYELONEPHRITIS	3	7	5	5	6
MILD	0	1	1	1	1
MODERATE	0	0	0	1	1
MARKED	3	6	4	2	3
SEVERE	0	0	0	1	1
NEPHRITIS, FOCAL	0	1	0	0	0
MILD	0	1	0	0	0
TUBULAR DILATION	0	1	3	4	5
MINIMAL	0	0	2	2	1
MILD	0	0	1	1	3
MODERATE	0	1	0	0	1
MARKED	0	0	0	1	0
CORTICAL ATROPHY	0	0	3	1	2
MILD	0	0	1	1	1
MODERATE	0	0	1	0	1
MARKED	0	0	1	0	0
TUBULAR PIGMENTATION	2	0	1	1	1
MILD	1	0	0	0	0
MODERATE	1	0	1	1	1

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 5.0%, 4 is 25.0%, 5 is 50.0%

TABLE 25 (Continued)
 TRIS(2-HYDROXYETHYL)AMMONIUM METHACRYLATE (TRISDMA): CHRONIC DERMAL
 BIOASSAY IN C57BL/6J MALE MICE
 SUMMARY OF MICROSCOPIC DIAGNOSES BY GRADE (KIDNEYS)
 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	17	22	28
KIDNEYS (CONTINUED)						
TUBULAR PROTEINOSIS		6	7	7	8	14
MINIMAL		2	2	4	3	6
MILD		3	3	2	4	6
MODERATE		1	2	1	1	2
GLOMERULONEPHRITIS		1	0	0	0	0
MILD		1	0	0	0	0
GLOMERULOSCLEROSIS		2	3	2	3	6
MILD		1	1	1	1	4
MODERATE		1	1	0	1	1
MARKED		0	1	1	1	1
DILATED GLOMERULAR SPACE(S)		0	0	0	0	1
MILD		0	0	0	0	1
NEPHRITIS, INTERSTITIAL		1	1	1	1	3
MINIMAL		1	0	0	0	0
MILD		0	1	0	1	1
MODERATE		0	0	1	0	1
MARKED		0	0	0	0	1
FIBROSIS, INTERSTITIAL		1	4	6	3	8
MINIMAL		0	0	1	1	2
MILD		1	2	3	1	4
MODERATE		0	2	2	1	2
FIBROSIS, PERICLOMERULAR		0	0	0	1	0
MODERATE		0	0	0	1	0
DILATED HYPERPLASTIC TUBULES		4	4	4	2	7
MINIMAL		2	2	3	2	4
MILD		2	2	1	0	3

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 5.0 %, 4 is 25.0 %, 5 is 50.0 %

TABLE 26
 DIETHYLENE GLYCOL DIMETHACRYLATE (DEGDMA): CHRONIC DERMAL
 BIOASSAY IN C3H/HEMISP 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
ADIPOSE TISSUE						
TOTAL NUMBER EXAMINED		0	0	0	1	1
§B LIPOMA		-	-	-	0	1
§M HEMANGIOSARCOMA		-	-	-	1	0
PERITONEUM						
TOTAL NUMBER EXAMINED		0	0	1	0	0
HEART						
TOTAL NUMBER EXAMINED		55	56	6	6	55
EXAMINED, UNREMARKABLE		13	16	0	1	9
§M HEMANGIOSARCOMA		0	1	1	1	2
AORTA						
TOTAL NUMBER EXAMINED		55	56	0	0	54
EXAMINED, UNREMARKABLE		55	55	-	-	52
MISSING		0	0	-	-	1
VASCULATURE						
TOTAL NUMBER EXAMINED		2	2	0	0	2
SALIVARY GL						
TOTAL NUMBER EXAMINED		55	56	0	2	55
EXAMINED, UNREMARKABLE		44	36	-	1	42
ESOPHAGUS						
TOTAL NUMBER EXAMINED		55	56	0	0	55
EXAMINED, UNREMARKABLE		55	55	-	-	55
STOMACH						
TOTAL NUMBER EXAMINED		55	56	54	56	55
EXAMINED, UNREMARKABLE		44	48	46	48	43
TOO AUTOLYZED TO EVALUATE		0	0	1	0	0
MISSING		0	0	1	0	0
LIVER						
TOTAL NUMBER EXAMINED		55	56	56	56	55
EXAMINED, UNREMARKABLE		11	13	20	8	13
§B HEPATOCELLULAR ADENOMA		26	21	0	27	24
§B HEPATOCELLULAR ADENOMA WITH CARCINOMA IN SITU		0	1	0	0	1
§M HEPATOCELLULAR CARCINOMA		14	25 ^a	13 ^c	23	19

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 5.0%, 4 is 25.0%, 5 is 50.0%

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

TABLE 26 (Continued)
 TRIS(1,2-DICHLOROETHYL) GLYCOL DIMETHACRYLATE (TRIGDMA): CHRONIC DERMAL
 BIOASSAY IN C57BL/6J 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)						
(OH HEMANGIOSARCOMA)		2	1	6	4	1
(OH MYELOsarcoma)		0	0	0	0	1
GALLBLADDER						
TOTAL NUMBER EXAMINED		49	46	0	3	48
EXAMINED, UNREMARKABLE		45	42	-	0	47
TOO AUTOLYZED TO EVALUATE		2	4	-	1	3
MISSING		4	6	-	0	4
PANCREAS						
TOTAL NUMBER EXAMINED		55	56	0	2	55
EXAMINED, UNREMARKABLE		54	56	-	1	54
DUODENUM						
TOTAL NUMBER EXAMINED		55	49	2	0	49
EXAMINED, UNREMARKABLE		54	49	1	-	49
TOO AUTOLYZED TO EVALUATE		0	7	0	-	6
JEJUNUM						
TOTAL NUMBER EXAMINED		53	46	1	0	47
EXAMINED, UNREMARKABLE		53	46	0	-	47
TOO AUTOLYZED TO EVALUATE		2	10	0	-	8
ILEUM						
TOTAL NUMBER EXAMINED		55	50	0	0	47
EXAMINED, UNREMARKABLE		55	50	-	-	46
TOO AUTOLYZED TO EVALUATE		0	6	-	-	8
CECUM						
TOTAL NUMBER EXAMINED		54	48	2	0	47
EXAMINED, UNREMARKABLE		54	48	0	-	47
TOO AUTOLYZED TO EVALUATE		1	8	0	-	8
COLON						
TOTAL NUMBER EXAMINED		55	55	1	0	52
EXAMINED, UNREMARKABLE		54	55	0	-	52
TOO AUTOLYZED TO EVALUATE		0	1	0	-	3
RECTUM						
TOTAL NUMBER EXAMINED		55	55	1	0	54
EXAMINED, UNREMARKABLE		54	55	0	-	52
TOO AUTOLYZED TO EVALUATE		0	1	0	-	1

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 5.0%, 4 is 25.0%, 5 is 50.0%

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

0 8 1 5

TABLE 26 (Continued)
 TRITYLENE GLYCOL DIMETHACRYLATE (TRIGEMA): CHRONIC DERMAL
 BIOASSAY 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
PITUITARY					
TOTAL NUMBER EXAMINED	55	56	0	1	55
EXAMINED, UNREMARKABLE	52	48	-	0	51
THYROID GL					
TOTAL NUMBER EXAMINED	55	56	0	0	55
EXAMINED, UNREMARKABLE	20	25	-	-	37
#B FOLLICULAR CELL ADENOMA	3	7	-	-	3
PARATHYROID GL					
TOTAL NUMBER EXAMINED	28	23	0	0	19
EXAMINED, UNREMARKABLE	28	23	-	-	19
MISSING	27	33	-	-	36
ADRENAL GL					
TOTAL NUMBER EXAMINED	55	56	43	43	55
EXAMINED, UNREMARKABLE	1	3	0	0	2
#B ADENOMA	0	0	0	1	0
#M PHEOCHROMOCYTOMA	0	0	0	1	0
SKIN, TREATED					
TOTAL NUMBER EXAMINED	55	56	56	56	55
EXAMINED, UNREMARKABLE	35	19	19	4	2
#M HEMANGIOSARCOMA	0	1	0	0	0
SKIN					
TOTAL NUMBER EXAMINED	55	56	56	56	55
EXAMINED, UNREMARKABLE	38	36	23	30	23
SUBCUTIS					
TOTAL NUMBER EXAMINED	2	2	2	5	0
#M HEMANGIOSARCOMA	1	0	0	0	-
HEAD					
TOTAL NUMBER EXAMINED	1	1	1	1	1
#M ADENOCARCINOMA	0	0	0	1	0
EARS					
TOTAL NUMBER EXAMINED	0	0	1	0	0
#M HEMANGIOSARCOMA	-	-	1	-	-
TAIL					
TOTAL NUMBER EXAMINED	0	0	0	0	2

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 5.0 %, 4 is 25.0 %, 5 is 50.0 %

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

TABLE 26 (Continued)
 TRINITYLENE / LYCOL DIMETHACRYLATE (TRDCMA): CHRONIC DERMAL
 BIOASSAY IN C3H/HEMISP 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					
TOTAL NUMBER EXAMINED	55	56	56	56	55
EXAMINED, UNREMARKABLE	30	29	33	23	25
0N MYELOSARCOMA	1	0	0	0	1
0N HEMANGIOSARCOMA	1	0	0	0	0
LYMPH NO. S-MAN					
TOTAL NUMBER EXAMINED	52	55	0	1	54
EXAMINED, UNREMARKABLE	42	47	-	0	33
MISSING	3	1	-	0	1
LYMPH NO. MED					
TOTAL NUMBER EXAMINED	4	4	0	0	4
LYMPH NO. MES					
TOTAL NUMBER EXAMINED	54	54	11	19	54
EXAMINED, UNREMARKABLE	22	28	1	1	22
TOO AUTOLYSED TO EVALUATE	0	1	0	0	1
MISSING	1	1	0	0	0
0N MYELOSARCOMA	1	0	0	0	0
LYMPH NO. REN					
TOTAL NUMBER EXAMINED	0	1	0	0	1
LYMPH NO. OTHER					
TOTAL NUMBER EXAMINED	2	1	0	0	1
0N MYELOSARCOMA	1	0	-	-	0
0N HEMANGIOSARCOMA	1	0	-	-	0
THYMIC REGION					
TOTAL NUMBER EXAMINED	55	56	0	1	55
EXAMINED, UNREMARKABLE	38	43	-	1	33
0N MYELOSARCOMA	1	0	-	0	0
BONE/JOINT					
TOTAL NUMBER EXAMINED	55	56	0	0	55
EXAMINED, UNREMARKABLE	55	56	-	-	55
BONE, STERNUM					
TOTAL NUMBER EXAMINED	55	56	1	1	55
EXAMINED, UNREMARKABLE	38	45	1	1	43
BONE, FEMUR					
TOTAL NUMBER EXAMINED	55	56	0	0	55
EXAMINED, UNREMARKABLE	55	56	-	-	55

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 5.0%, 4 is 25.0%, 5 is 50.0%

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

TABLE 26 (Continued)
 TRIETHYLENE GLYCOL DIMETHACRYLATE (TRIGEMA): CHRONIC DERMAL
 BIOASSAY 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
BONE MARROW						
TOTAL NUMBER EXAMINED		55	56	0	0	55
EXAMINED, UNREMARKABLE		50	54	-	-	51
#N HEMANGIOSARCOMA		1	0	-	-	0
SKELTAL MUSCLE						
TOTAL NUMBER EXAMINED		55	56	1	3	55
EXAMINED, UNREMARKABLE		45	52	0	1	52
BRAIN						
TOTAL NUMBER EXAMINED		55	56	1	4	55
EXAMINED, UNREMARKABLE		6	10	0	2	11
SPINAL CORD						
TOTAL NUMBER EXAMINED		55	56	0	0	55
EXAMINED, UNREMARKABLE		53	40	-	-	49
NERVE, SCIATIC						
TOTAL NUMBER EXAMINED		55	56	0	0	55
EXAMINED, UNREMARKABLE		51	51	-	-	55
NERVE, OTHER						
TOTAL NUMBER EXAMINED		0	1	0	0	0
EYE						
TOTAL NUMBER EXAMINED		55	55	0	1	55
TOO AUTOLYZED TO EVALUATE		0	1	-	0	0
HARDERIAN GL						
TOTAL NUMBER EXAMINED		55	56	0	4	55
EXAMINED, UNREMARKABLE		49	52	2	1	47
MISSING		0	0	0	1	0
#B ADENOMA		1	0	0	0	3
TESTES						
TOTAL NUMBER EXAMINED		55	56	43	45	54
EXAMINED, UNREMARKABLE		3	2	0	0	4
MISSING		0	0	0	0	1
#N HEMANGIOSARCOMA		0	0	0	1	0
EPIDIDYMIDES						
TOTAL NUMBER EXAMINED		55	56	1	4	53
EXAMINED, UNREMARKABLE		52	56	1	1	53
MISSING		0	0	0	0	2

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 5.0%, 4 is 25.0%, 5 is 50.0%

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

TABLE 26 (Continued)
 TRIETHYLENE GLYCOL DIMETHACRYLATE (TRGDMA): CHRONIC DERMAL
 BIOASSAY IN C3H/HEMISP 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
SEMINAL VESICLE						
TOTAL NUMBER EXAMINED		55	55	7	3	53
EXAMINED, UNREMARKABLE		46	42	0	0	41
TOO AUTOLYZED TO EVALUATE		0	0	0	0	1
MISSING		0	1	0	0	1
COAGULATING GL						
TOTAL NUMBER EXAMINED		0	1	0	0	0
PROSTATE						
TOTAL NUMBER EXAMINED		55	53	0	1	52
EXAMINED, UNREMARKABLE		46	45	-	1	47
TOO AUTOLYZED TO EVALUATE		0	0	-	0	1
MISSING		0	3	-	0	2
#B ADENOMA		1	0	-	0	0
PENIS						
TOTAL NUMBER EXAMINED		8	20	11	11	15
EXAMINED, UNREMARKABLE		2	3	3	2	0
TRACHEA						
TOTAL NUMBER EXAMINED		55	56	0	0	55
EXAMINED, UNREMARKABLE		55	56	-	-	54
LUNGS						
TOTAL NUMBER EXAMINED		55	56	56	56	55
EXAMINED, UNREMARKABLE		22	2	9	14	15
#B ADENOMA		5	3	4	5	2
#M MYELOSARCOMA		1	0	0	0	1
#M HEPATOMA, METASTATIC		1	4	3	5	4
KIDNEYS						
TOTAL NUMBER EXAMINED		55	56	56	56	55
EXAMINED, UNREMARKABLE		0	1	0	0	0
#B TUBULAR CELL ADENOMA		0	0	0	1	0
URETER						
TOTAL NUMBER EXAMINED		4	6	4	4	3
TOO AUTOLYZED TO EVALUATE		0	1	0	0	1
URINARY BLADDER						
TOTAL NUMBER EXAMINED		55	53	10	4	53
EXAMINED, UNREMARKABLE		42	37	0	0	32
TOO AUTOLYZED TO EVALUATE		0	2	0	0	2
MISSING		0	1	0	0	0
URETHRA						
TOTAL NUMBER EXAMINED		1	1	0	0	0

GROUP LEGEND: 1 is 0% (UNTREATED), 2 is 0% (VEHICLE), 3 is 5.0%, 4 is 25.0%, 5 is 50.0%

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

Triethylene Glycol Dimethacrylate (TREGDMA): Chronic Dermal
Bioassay in C3H/HeNHsd Male Mice

QUALITY ASSURANCE UNIT INSPECTION SUMMARY

<u>Inspection Date(s)</u>	<u>Inspection Type</u>	<u>Date OAU Report Issued To</u>	
		<u>Study Director</u>	<u>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		
08-16-93	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 Dimethacrylate (TREGDMA): Chronic Dermal
Bioassay in C3H/HeNHsd Male Mice

COMPLIANCE WITH GOOD LABORATORY PRACTICE STANDARDS

The portions of this study conducted by BIRC 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 8-24-95
Edward H. Fowler, DVM, Diplomate ACVP Date
Bushy Run Research Center

Submitter/Sponsor:

Marian K. Stanley _____ Date
Panel Manager