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FINAL REPORT

Twenty-six Week Subchronic Toxicity Study in Dogs with SC-19129 Admixed in the Diet

HLA Study No. 6127-111
Searle Study No. S.A. 2530

for

G. D. Searle & Co.
Skokie, Illinois

by

Hazleton Laboratories America, Inc.
3301 Kinsman Boulevard
Madison, Wisconsin 53704

September 26, 1986

QUALITY ASSURANCE STATEMENT

Twenty-six Week Subchronic Toxicity Study in Dogs
with SC-19129 Admixed in the Diet

Study No. 6127-111

The report as herein attached for the above-mentioned study has been reviewed by the assigned Quality Assurance Unit of Hazleton Laboratories America, Inc. in accordance with the Good Laboratory Practice Regulations as set forth in 21 CFR 58.35 (b) (6) (7). It has been found to identify and/or describe the authorized methods and standard operating procedures followed in the conduct of the study. Furthermore, the Quality Assurance Unit has conducted the following inspections of the testing facilities utilized in the conduct of this study and has submitted written reports of said inspections to the study director and/or management.

Judy Schaefer
Judy Schaefer
Inspector, Quality Assurance Unit

9/30/86
Date

QUALITY ASSURANCE INSPECTIONS

Study No. 6127-111

Date of Inspection	Type of Inspection	Date Issued to Management
6/10/85	Protocol Review	6/10/85
7/08/85	Diet Preparation	7/08/85
7/10/85	Animal/Cage ID/Animal Care Body Weights/Test Article Administration Clinical Sampling	7/10/85
8/30/85	Clinical Sampling	8/30/85
9/25/85	Clinical Sampling	9/25/85
10/07/85	Diet Preparation	10/07/85
9/30-10/2/85	Data Review	10/17/85
10/30/85	Animal/Cage ID/Animal Care Clinical Sampling Test Article Administration	10/30/85
10/31/85	Physical Examination	10/31/85
10/31, 11/1/85	Data Review	11/01/85
11/04/85	Electrocardiography	11/04/85
12/16/85	Diet Preparation	12/16/85
12/19-30/85	Data Review	12/30/85
12/24/85	Animal/Cage ID/Animal Care Body Weights/Feed Consumption	12/24/85
12/26/85	Animal Observations	12/26/85
12/30/85	Clinical Sampling	12/30/85
1/02/86	Physical Examination Animal/Cage ID/Animal Care Electrocardiography	1/02/86
1/07/86	Clinical Sampling/Analysis/Recording	1/07/86
1/08/86	Pathology, Necropsy, Recording	1/08/86
1/13-14/86	Data Review	1/14/86

QUALITY ASSURANCE INSPECTIONS

Study No. 6127-111

Date of Inspection	Type of Inspection	Date Issued to Management
1/30/86	Physical Examination Ophthalmic	1/30/86
2/03/86	Electrocardiography	2/03/86
2/05/86	Animal/Cage ID/Animal Care	2/05/86
2/5-6/86	Clinical Sampling	2/06/86
2/06/86	Animal/Cage ID/Animal Care Body Weights Clinical Sampling Pathology, Necropsy, Recording	2/06/86
5/28-6/2/86	Report Review	6/02/86

STUDY IDENTIFICATION

Twenty-six Week Subchronic Toxicity Study in Dogs with SC-19129 Admixed in the Diet

Study No.	6127-111
Study Location	Hazleton Laboratories America, Inc. 3301 Kinsman Boulevard Madison, Wisconsin 53704
Test Material	SC-19129
Sponsor's Study Coordinator	Christopher P. Chengelis, PhD Searle Research and Development 4901 Searle Parkway Skokie, Illinois 60077 (312) 982-7545
Hazleton's Study Director	Bruce Dickie Hazleton Laboratories America, Inc. P.O. Box 7545 Madison, Wisconsin 53707 (608) 241-7217
Starting Date	July 10, 1985
Completion Date	
Week 27 sacrifice	January 8 through 10, 1986
Week 31 sacrifice	February 6 and 7, 1986

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SUMMARY

To determine the toxic effects, male and female beagle dogs were fed SC-19129 admixed in their diets for 26 weeks. A 4-week recovery study was done from Weeks 27 through 30 to assess any reversal of toxic effects. For the main study, six animals/sex were randomly assigned to four groups and dosed at 0, 250, 500, and 1,000 mg/kg of body weight/day, respectively. At the end of 26 weeks, two animals/sex/group were randomly selected from the main study and placed on the control diet for the recovery study.

Animals were carefully observed at least twice daily for toxic effects. Body weights and food consumptions were recorded weekly, including the recovery phase.

Slit lamp and indirect ophthalmoscopic examinations were conducted on all animals before study initiation and during Weeks 16, 25, and 30. Electrocardiograms were recorded for each animal before study initiation and during Weeks 8, 17, 26, and 30.

Before the study began and during Weeks 8, 17, 26, and 31, blood and urine were collected from all animals for hematology, clinical chemistry, and urinalysis tests.

At study conclusion and at the end of the recovery phase, all animals were anesthetized, sacrificed by exsanguination, and necropsied. At each necropsy, gross observations were recorded, selected organs weighed, and tissues collected as required by the protocol.

Tissues from all animals sacrificed at Week 27 were examined microscopically. The tissues from the animals sacrificed at Week 31 were not examined microscopically, except for a few gross lesions.

The antemortem observations, growth data, ophthalmological examinations, electrocardiograms, clinical laboratory data, anatomical pathology, and histopathology revealed no toxic effects on dogs fed SC-19129 admixed in their diets for 26 weeks.

Results of the diet analysis and the compound consumption calculations demonstrated that the animals were dosed at the correct levels.

OBJECTIVES

The objectives of this study were to determine the toxic effects, as evidenced by clinical signs and specific organ damage in dogs fed SC-19129 in the diet for 26 weeks and to assess any reversal of these effects from Weeks 27 through 30.

REGULATORY COMPLIANCE STATEMENT

All aspects of this study conformed to the U.S. Food and Drug Administration (FDA) guidelines for the safety assessment of food additives[1] and the Good Laboratory Practice Regulations for Nonclinical Laboratory Studies.[2]

TEST MATERIAL

Identification

G. D. Searle & Co. provided the test material N-L-β-aspartyl-L- phenylalanine, 1-methyl ester (SC-19129) in sufficient quantity. Six shipments and two lots of the test material were received as follows:

Date	Lot Number
May 29, 1985	84K-054-101
June 26, 1985	84K-054-101
July 30, 1985	84K-054-101
August 28, 1985	84K-054-101
October 16, 1985	84K-054-101
October 29, 1985	84K-056-101

All six shipments were assigned Hazleton Laboratories America, Inc. (HLA) Sample No. 50507498.

Upon completion of the diet preparation phase, the remaining test material was returned to the Sponsor.

Storage

The test compound, SC-19129, was stored in a well-closed, light-resistant container at room temperature.

Test diets were refrigerated from the time they were mixed until fed, and additional unfed diet was refrigerated through the end of the feeding period.

Safety Precautions

Personnel working with the test material, the finished diets, and in the animal rooms wore disposable gloves, hair covers, shoe covers, face masks, and other appropriate clothing such as laboratory coats and/or uniforms.

TEST SYSTEM

Test Animal

Beagle dogs, 5 to 7 months old, purchased from Hazleton Research Products, Cumberland, Virginia were used as test animals. Upon receipt, the animals were taken to Room Nos. 225 and 226 and acclimated for more than 11 weeks before being placed on test. During acclimation, the animals were examined for clinical abnormalities indicative of health problems (e.g., diarrhea, ectoparasites, endoparasites, nasal or ocular discharge, evidence of injury, etc.). Animals judged to be unacceptable for the study because of clinical signs, ophthalmic abnormalities, abnormal blood chemistry, temperament, or low body weight were discarded and the reasons were documented.

Beagle dogs have been used for toxicity studies at HLA, and growth and pathology data are available for historical comparisons.

Identification

Before being placed on test, each animal in the study was assigned an identification number and was permanently identified with a numbered ear tag. All data collected from an animal were recorded and filed under its identification number, except for certain clinical pathology parameters which use only a portion of the number.

Housing and Maintenance

Two temperature- and humidity-controlled rooms (Room Nos. 225 and 226) were assigned solely to this study. The rooms had a temperature of 22°C ±3°, a relative humidity of 50% ±25%, and a minimum of 10 changes/hour of filtered, 100% outside air. The rooms were kept on a 12-hour light/12-hour dark cycle. Variations from prescribed environmental conditions were documented.

Animal husbandry and housing at HLA comply with the "Guide for the Care and Use of Laboratory Animals." The animals were housed individually in stainless steel, mesh-bottom cages with urine- and feces-collecting pans. The pans were cleaned daily, and cages were changed every 2 weeks. Care was taken not to disturb the animals for reasons other than data collection and routine maintenance.

Food was provided for a 3-hour period daily from J-type feeders that limit spillage and allow easy inspection of the amount and condition of the food. Tap water was provided *ad libitum* from an automatic water system (Systems Engineering, Palo Alto, California). The water is analyzed at HLA quarterly on a retrospective basis for total dissolved solids, conductivity, specified microbiological content, and selected elements (e.g., heavy metals, organophosphates, and chlorinated hydrocarbons); the data are kept on file at HLA.

Treatment Duration

Treatment was initiated when the animals were approximately 5 to 7 months old. All animals received test diets for a 3-hour period daily for at least 182 days (26 weeks). Those animals not selected for necropsy during Week 27 were placed on a 4-week recovery phase and were fed the basal diet.

Study Design

Animals, from a supply of 54 dogs, were randomly assigned to test and control groups using a random block design on the basis of body weights.

Group	Sex	Animal Numbers	Number of Animals	SC-19129 (mg/kg/body weight/day)
1	M	H00961-H00966	6	0
1	F	H00967-H00972	6	0
2	M	H00973-H00978	6	250
2	F	H00979-H00984	6	250
3	M	H00985-H00990	6	500
3	F	H00991-H00996	6	500
4	M	H00997-H00003	6	1,000
4	F	H00004-H00009	6	1,000

This study was divided into two phases: the main phase and a 4-week recovery phase. During the main phase of the study, the following were collected for all animals: observations, body weights, food consumptions, ophthalmic examinations, electrocardiograph measurements, and clinical laboratory data.

Two randomly selected animals/sex/group were assigned to the 4-week recovery phase after 26 weeks on test and were placed on the control diet from Weeks 27 through 30. Observations, body weights, and food consumptions were recorded for Weeks 27 through 30. After 30 weeks on test (4-week recovery phase), all animals in the recovery study had ophthalmic examinations, electrocardiograph measurements, and clinical laboratory data collected.

PROCEDURES

All procedures were done according to HLA Standard Operating Procedures (SOPs) and the study protocol, "Twenty-six Week Subchronic Toxicity Study in Dogs with SC-19129 Admixed in the Diet" (June 7, 1985). The study was monitored by the HLA Quality Assurance Unit.

Test Diet

Because humans will be exposed to the test material by the oral route, the test material (SC-19129) was administered to the test animals in their basal diet. The basal diet for this study was Purina Certified Canine Diet #5007 (Ralston Purina Company). This food is routinely analyzed by the manufacturer for nutritional components and environmental contaminants. No known components or contaminants of the basal diet are expected to have interfered with the study. A record was maintained of all lot numbers of food used in this study.

Dosage Levels

Four test diets were fed ad libitum for a 3-hour period daily throughout the study:

SC-19129 mg/kg/ Body Weight	Dosage Level
0	Control
250	Low
500	Mid
1,000	High

Diet Preparation

Based on estimated body weights and food consumptions for the subsequent feeding period, the appropriate amount of SC-19129 was admixed with the basal diet to achieve the proper concentration in the food. Dosages were recalculated weekly through Week 27. Diets were mixed fresh weekly.

All diet equipment was thoroughly cleaned before and after each mixing. Prepared diets were refrigerated in covered polyethylene containers.

Stability and Characterization of the Test Material in the Diet

Except for determining the purity of the test material and on-shelf stability, HLA conducted all analyses for this study. Analysis for impurities in the test material are the responsibility of the Sponsor.

Before study initiation, HLA conducted a homogeneity of mixing, and in-cage homogeneity and stability study as described in Appendix A of the study protocol. The results are in Tables 2 and 3 of this report.

HLA assayed each dose level (finished diet) and the control diet mixed and fed during Weeks 1, 3, 5, 10, 15, 20, and 25 of the study for dosage verification (Tables 4 and 5).

Antemortem Observations

At least twice daily (pre- and post-prandial), all dogs were observed for moribundity, death, and obvious indications of a toxic effect. At least once each week, dogs were removed from their cages and carefully examined for behavioral abnormalities and clinical signs of toxic or pharmacologic effects. A complete physical examination was done on each animal before study initiation and immediately after the 3-hour feeding period during Weeks 8, 17, 26, and 30.

Body Weights and Food Consumptions

Individual body weights were recorded weekly before study initiation, at initiation, and weekly thereafter through 26 weeks.

Individual food consumptions were recorded to the nearest gram weekly from Week -3 through termination. Food consumptions were determined on days of pharmacokinetic blood sampling. Dogs in the recovery phase had weekly body weights and food consumptions collected during Weeks 27 through 30.

Ophthalmological Examinations

A veterinary ophthalmologist concluded slit lamp and indirect ophthalmoscopic examinations on all animals before study initiation and during Weeks 16, 25, and 30.

Electrocardiography

An electrocardiogram (ECG) (Leads I, II, III, aVR, aVL, aVF, CV_5RL, CV_6LL, CV_6LU, and V_{10}) was recorded for each dog before study initiation and immediately after the 3-hour feeding period during Weeks 8, 17, 26, and 30.

Clinical Laboratory Studies

Blood and urine samples were collected from all animals for hematology, clinical chemistry, and urinalysis before study initiation, and during Weeks 8, 17, 26, and 31.

Blood was collected from the jugular vein. Urine was collected for a 24-hour period in metabolism pans.

Parameter	Abbreviation
Hematology Tests	
Total erythrocyte count	RBC
Hemoglobin content	HGB
Hematocrit	HCT
Mean corpuscular volume	MCV

Parameter	Abbreviation
Hematology Tests (Continued)	
Mean corpuscular hemoglobin	MCH
Mean corpuscular hemoglobin concentration	MCHC
Platelet count	PLT
Total leukocyte count	WBC
Differential leukocyte count (relative and absolute)	
Lymphocyte	L
Monocyte	M
Eosinophil	E
Basophil	B
Neutrophils	N-SEG
Immature neutrophils	BANDS-N
Nucleated red blood cell count	NRBC
Prothrombin time	PT
Activated partial thromboplastin time	PTT
Bone marrow smears prepared at scheduled necropsies	-
Clinical Chemistry Tests	
Alanine aminotransferase	ALT/SGPT
Alkaline phosphatase	ALK PHOS
Urea nitrogen	UN
Aspartate aminotransferase	AST/SGOT
Glucose	GLU
Total bilirubin	T BILI
Creatinine	CREAT
Total protein	T PRO
Albumin	ALB
Globulin	GLOB
Albumin/globulin ratio	A/G
Total cholesterol	CHOL
Calcium	CA
Sodium	NA
Potassium	K
Chloride	CL
Urinalysis Tests	
Volume (24 hour)	U VOL
Appearance	URINE APP
pH	PH
Blood	U BLOOD
Protein	U PRO
Bilirubin	U BILI
Glucose	U GLU
Urobilinogen	UROBILI
Ketones	U KET
Specific gravity	SP GR
Microscopic examination of sediment	-

Pharmacokinetic Sampling

Venous blood samples (approximately 5 mL in heparinized tubes) were collected from the jugular veins of all animals at 3, 5, 7, and 24 hours after the start of the feeding period on Day 1 and during Weeks 12, 25, and 26.

Plasma samples were transferred to the Sponsor for SC-19200 (a metabolite of SC-19219) analysis. The results of the Day 1 and Weeks 12 and 26 analyses will appear in a report prepared by the Sponsor's Drug Metabolism Department.

Anatomical Pathology

All animals placed on test, regardless of their fate, were subjected to gross postmortem examination (necropsy) and tissue collection.

The necropsy included examination of the external surface, all orifices, cranial cavity, carcass, external and cut surfaces of the brain, spinal cord, nasal cavity and paranasal sinuses, and abdominal, thoracic, and pelvic cavities and their viscera.

The following tissues and organs were examined grossly and preserved in 10% phosphate-buffered formalin.

Adrenal glands
Aorta
Bone with marrow (femur with articular surfaces and sternum)
Brain (sections to include medulla, pons, cerebral cortex, and cerebellar cortex)
Cecum
Cervix
Colon
Duodenum
Epididymides
Esophagus
Eyes*
Gallbladder
Heart
Ileum
Jejunum
Kidneys
Liver
Lungs
Lymph nodes (submandibular and mesenteric)
Mammary gland (females only)
Muscle (skeletal, posterior to femur to include sciatic nerve)
Ovaries
Pancreas
Parathyroid glands
Pituitary
Prostate
Rectum
Salivary glands
Skin
Spleen
Spinal cord (three sections: cervical, mid-thoracic, lumbar)
Stomach
Testes**
Thymus
Thyroid glands
Tongue
Trachea
Urinary bladder
Uterus
Vagina

*Eyes fixed in Zenker's fixative at scheduled sacrifices.
**Testes fixed in Bouin's fixative at scheduled sacrifices.

Bone marrow smears were prepared for all animals, but were not deemed necessary for evaluation by the clinical pathologist.

In addition to terminal body weight, the following organs were weighed from all animals (paired organs were weighed together):

Adrenals
Brain
Epididymides
Heart
Kidneys
Liver
Ovaries
Pituitary
Prostate
Salivary gland
Spleen
Testes
Thymus
Thyroid with parathyroids
Uterus

Histopathology

All tissues stained with hematoxylin and eosin (H&E) from all animals that were sacrificed during Week 27 were examined microscopically. Parathyroids were examined only when present in the thyroid section. Tissues from animals sacrificed at Week 31 were not examined microscopically, except for a few gross lesions.

Statistical Analysis

Body weight; food consumption; electrocardiograph and physical examination measurements; clinical chemistry; hematology (except erythrocyte morphology); urine pH, volume, and specific gravity; organ weight data; and organ-to-body weight and organ-to-brain weight ratios are analyzed separately for each sex using the standard one-way analysis of variance (ANOVA)[3] or covariance (ANCOVA)[4] programs available from the HLA statistics library. Electrocardiograph and physical examination measurements; clinical chemistry; hemotology (except erythrocyte morphology); urine pH, volume, and specific gravity and organ weight data will be analyzed after pooling sexes. The methods used are diagrammed in Figure 3 (Appendix K) and described below.

Levene's test[5] is used before ANOVA or ANCOVA to test for variance homogeneity. In the case of heterogeneity of variance at $p \leq 0.05$, the following transformations are used to stabilize the variance.

- Log X = Data analyzed following $\log_{10}$ transformation
- X^2 = Data analyzed following square transformation
- $X^{1/2}$ = Data analyzed following square root transformation
- 1/X = Data analyzed following reciprocal transformation
- Arcsine $X^{1/2}$ = Data analyzed following angular transformation
- Rank X = Data analyzed following rank transformation

The final data transformations used for various parameters in this study are summarized in Appendix K.

ANOVA or ANCOVA is then performed on the homogeneous or ranked data. If the ANOVA or ANCOVA is significant, Dunnett's t-test[6] is used for pairwise comparisons between groups. When no transformation establishes variance

homogeneity at p 0.001, the data are also examined by nonparametric techniques. These statistics include the Kruskal-Wallis H-test ANOVA[7] and, if this test is significant, the Nemenyi-Kruskal-Wallis test for multiple comparisons[8] or the Wilcoxon-Mann-Whitney two-sample rank test.[9] All group comparisons found to be statistically significant at the 5.0%, 1.0%, or 0.1% two-tailed probability levels are indicated with an asterisk (*).

Maintenance of Raw Data and Specimens

Original data or copies thereof were available at HLA to facilitate auditing during the study. All original paper data and magnetically encoded records generated by HLA, as well as the final report and all specimens (wet tissues, blocks, slides, etc.), will be retained in the archives of HLA. Upon completion of the in-life portion of the study, HLA transferred the remainder of the test material to G. D. Searle & Co.

RESULTS

Verification of Dosage

A complete analytical chemistry report presenting the method and the results of all analyses is in Appendix A. HLA analyzed "mock study" samples submitted by the Sponsor, homogeneity of mixing samples, in-cage stability and homogeneity samples, a mixing contamination sample, and all dose-verification samples required by the protocol. The mixing procedure produced a homogeneous mixture (Table 2). SC-19129 was stable in the food under actual test conditions for the duration of the feeding interval (Table 3).

Results of the prescribed analyses demonstrated that the animals were presented the correct amounts of SC-19129. The concentrations of the analyzed admixtures were within $\pm$11% of those expected (Tables 4 and 5).

Weekly mean compound consumption for each group was calculated using the theoretical concentration of SC-19129, mean body weight, and mean food consumption. The overall mean compound consumption ranged from 97% to 111% of the expected values (Tables 6 and 7).

Antemortem Observations

Selected clinical observations are summarized in Tables 8 and 9.

Generalized erythema and alopecia occurred with approximately equal incidence in all groups. Other common signs, such as soft stool and vomitus, were seen occasionally throughout the study in all groups. These observations are typical of Hazleton Research Products beagle dogs, and not due to test article treatment.

SC-19129 caused no apparent effect in beagle dogs on body weight (Tables 10 and 11), food consumption (Tables 12 and 13), eyes (Tables 14 and 15), heart rate (Table 16), respiration rate (Table 17), or rectal temperature (Table 18).

ECG

The ECG measurements are summarized in Table 19. A discussion of the data is included with the Cardiology Report (Appendix A); individual data are in Appendix F.

There was no apparent effect of SC-19129 on the electrocardiographic measurements.

Clinical Laboratory Data

Summaries of hematology, blood chemistry, and urinalysis values are in Tables 20 through 34; individual clinical pathology data are in Appendices G through I. A complete discussion of the data is in the Pathology Report (Appendix A).

There was no apparent toxicologic effect of SC-19129 on clinical pathology parameters.

Pharmacokinetic Study Data

The pharmacokinetic data will be presented by the Sponsor in a separate report.

Anatomical Pathology

Summaries of organ weights, organ to body weight ratios, and organ to brain weight ratios are in Tables 37 through 42. Macroscopic and microscopic observations are summarized in Tables 35, 36, 43, and 44. Individual anatomical pathology data are in Appendix J. A complete discussion of the data is in the Pathology Report (Appendix A).

There was no apparent toxicologic effect of SC-19129 on anatomical pathology findings.

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Study Coordinator
Toxicology

9-30-86
Date

Bruce C. Dickie
Study Director
Toxicology

9/30/86
Date

Karen M. MacKenzie, PhD
Director
Toxicology

9.30.86
Date

by and for Hazleton Laboratories America, Inc.

(1944N/emm)

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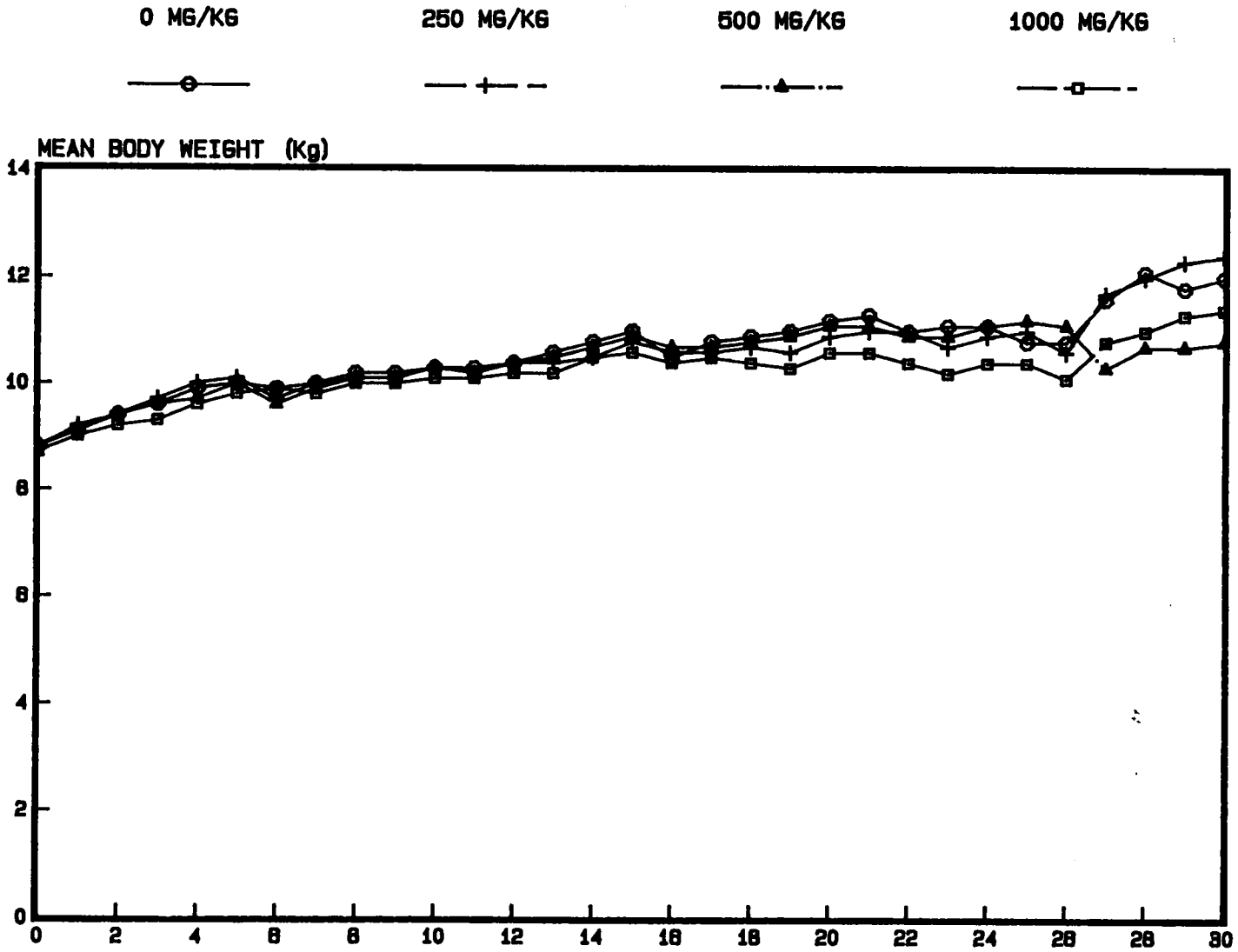
FIGURE 1 STUDY NO. 6127-111*

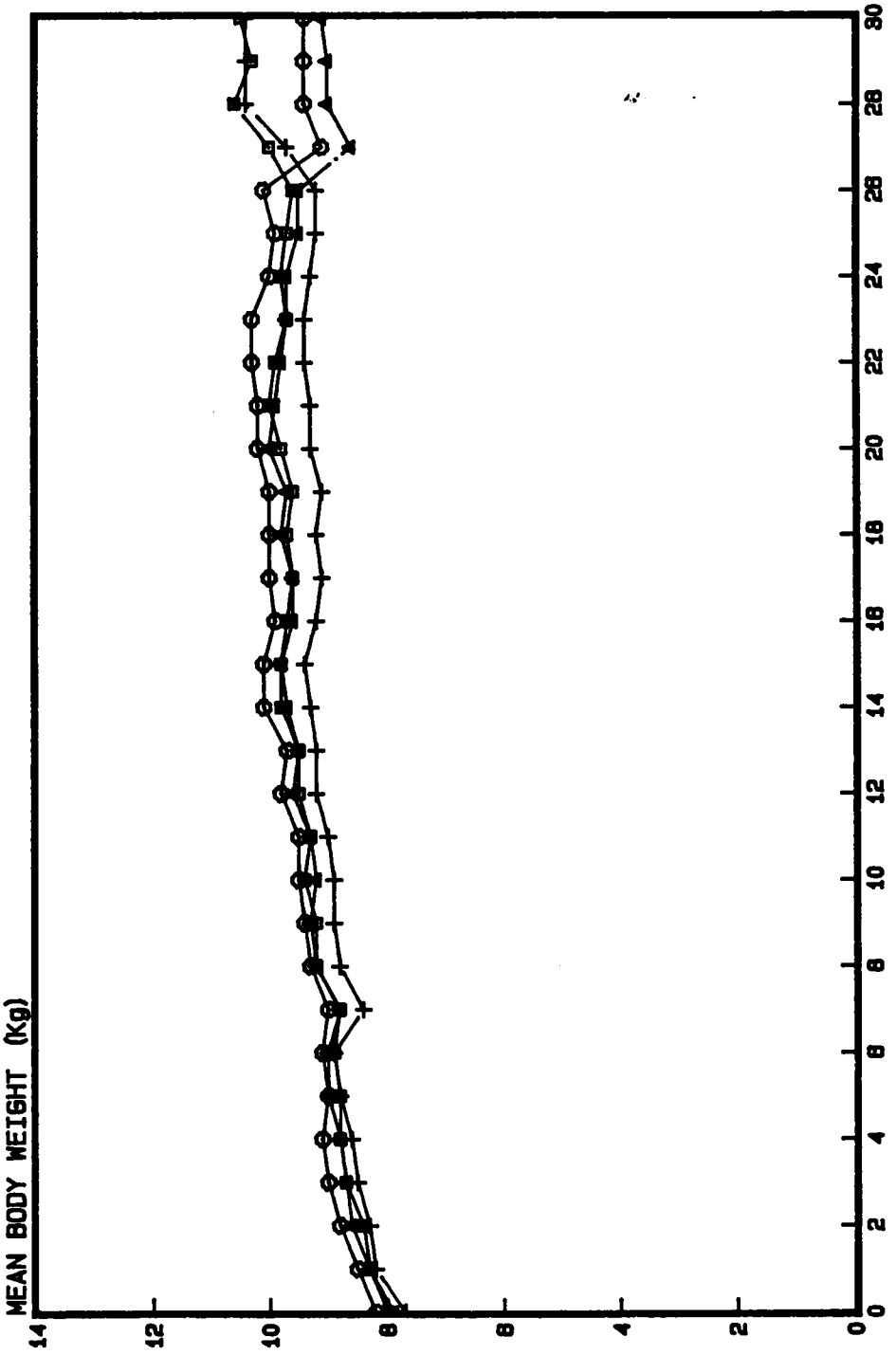
MEAN BODY WEIGHTS (Kg) - MALES



*RECOVERY STUDY WEEKS 27-30: ALL GROUPS FED BASAL DIET ONLY

FIGURE 2 STUDY NO. 6127-111*

MEAN BODY WEIGHTS (Kg) - FEMALES



*RECOVERY STUDY WEEKS 27-30: ALL GROUPS FED BASAL DIET ONLY

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Table 1

Explanation of Statistical Terms

Mean	Arithmetic mean.
SD	Standard deviation.
N	The number of measurements in a group.
†	The Levene test indicated the data were heterogeneous at $p \leq 0.001$; the Wilcoxon-Mann-Whitney multiple comparisons procedure was used.
*	A significant difference between the group and the control was found at $p \leq 0.05$ using Dunnett's t-test following an indication of overall significance ($p \leq 0.05$) by a one-way analysis of variance for food consumption data or a one-way analysis of covariance for body weight data.
**	A significant difference between the group and the control was found at $p \leq 0.01$ using Dunnett's t-test following an indication of overall significance ($p \leq 0.01$) by a one-way analysis of variance for food consumption data or a one-way analysis of covariance for body weight data.
***	A significant difference between the group and the control was found at $p \leq 0.001$ using Dunnett's t-test following an indication of overall significance ($p \leq 0.001$) by a one-way analysis of variance for food consumption data or a one-way analysis of covariance for body weight data.

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Table 2

Results of Homogeneity of Mixing Study

Sample Number	Concentration Found (g/kg)	Percent of Theoretical
	Theoretical Concentration (6.579 g/kg)	
1	6.40	97.3
2	6.50	98.8
3	6.50	98.8
4	6.43	97.7
5	6.26	95.2
6	6.35	96.5
7	6.38	97.0
8	6.24	94.8
9	6.32	96.1
Mean	6.38	96.9
Standard deviation	0.094	
Coefficient of variation	1.47	
	Theoretical Concentration (36.111 g/kg)	
1	35.9	99.4
2	35.1	97.2
3	35.1	97.2
4	35.2	97.5
5	35.3	97.8
6	35.1	97.2
7	35.3	97.8
8	35.2	97.5
9	35.4	98.0
Mean	35.3	97.7
Standard deviation	0.25	
Coefficient of variation	0.71	

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Table 3

Results of In-cage Stability and Homogeneity Study

Sample Number	Concentration Found (g/kg) Day 0	Day 8
Theoretical Concentration (6.579 g/kg)		
1	6.58	6.64
2	6.65	6.67
3	6.76	6.67
4	6.74	
5	6.61	
6	6.68	
7	6.65	
8	6.64	
9	6.60	
Mean	6.66	6.66
Percent of theoretical	101.2	101.2
Theoretical Concentration (36.111 g/kg)		
1	36.1	36.3
2	36.1	35.7
3	35.5	35.4
4	35.8	
5	35.7	
6	35.7	
7	35.5	
8	35.9	
9	35.9	
Mean	35.8	35.8
Percent of theoretical	99.1	99.1

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Table 4

Results of Analytical Assays of SC-19129 in Diet - Males

Group 2 (250 mg/kg/day)

Week	Dosing Concentration (g/kg) Theoretical	Actual	Percent of Theoretical
1	8.794	9.18	104.4
		8.95	101.8
		9.20	104.6
3	8.393	8.06	96.0
		8.15	97.1
		8.08	96.3
5	8.684	8.62	99.3
		8.84	101.8
		8.72	100.4
10	10.000	9.87	98.7
		9.86	98.6
		9.97	99.7
15	9.052	8.80	97.2
		8.76	96.8
		8.63	95.3
20	10.283	10.2	99.2
		10.3	100.2
		10.4	101.1
25	9.130	9.09	99.6
		9.20	100.8
		9.11	99.8

Group 3 (500 mg/kg/day)

Week	Dosing Concentration (g/kg) Theoretical	Actual	Percent of Theoretical
1	17.729	18.0	101.5
		18.5	104.3
		18.2	102.7
3	16.727	16.3	97.4
		16.2	96.8
		16.2	96.8

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Table 4 (Continued)

Results of Analytical Assays of SC-19129 in Diet - Males

Group 3 (500 mg/kg/day) (Continued)

Week	Dosing Concentration (g/kg) Theoretical	Actual	Percent of Theoretical
5	17.818	18.0	101.0
		18.2	102.1
		18.1	101.6
10	17.895	18.3	102.3
		18.5	103.4
		18.3	102.3
15	17.627	17.8	101.0
		17.4	98.7
		17.3	98.1
20	19.604	19.6	100.0
		19.3	98.4
		19.3	98.4
25	19.604	19.4	99.0
		18.9	96.4
		19.3	98.4

Group 4 (1,000 mg/kg/day)

Week	Dosing Concentration (g/kg) Theoretical	Actual	Percent of Theoretical
1	35.200	33.7	95.7
		33.1	94.0
		33.0	93.8
3	31.507	32.1	101.9
		31.0	98.4
		31.2	99.0
5	32.526	33.9	104.2
		33.9	104.2
		33.2	102.1
10	30.909	31.1	100.6
		30.3	98.0
		27.8	89.9

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Table 4 (Continued)

Results of Analytical Assays of SC-19129 in Diet - Males

Group 4 (1,000 mg/kg/day) (Continued)

Week	Dosing Concentration (g/kg) Theoretical	Actual	Percent of Theoretical
15	34.576	35.5	102.7
		34.4	99.5
		35.4	102.4
20	37.234	37.0	99.4
		38.4	103.1
		38.3	102.9
25	42.678	42.2	98.9
		42.4	99.4
		43.1	101.0

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Table 5

Results of Analytical Assays of SC-19129 in Diet - Females

Group 2 (250 mg/kg/day)

Week	Dosing Concentration (g/kg) Theoretical	Actual	Percent of Theoretical
1	8.475	8.25	97.3
		8.43	99.5
		8.30	97.9
3	8.300	8.12	97.8
		8.07	97.2
		8.16	98.3
5	9.062	10.0	110.4
		10.0	110.4
		10.0	110.4
10	9.783	9.89	101.1
		9.66	98.7
		9.88	101.0
15	9.118	8.84	97.0
		9.27	101.7
		9.06	99.4
20	9.688	9.92	102.4
		9.90	102.2
		9.86	101.8
25	9.833	9.80	99.7
		9.87	100.4
		9.88	100.5

Group 3 (500 mg/kg/day)

Week	Dosing Concentration (g/kg) Theoretical	Actual	Percent of Theoretical
1	17.017	17.1	100.5
		16.8	98.7
		17.0	99.9
3	16.667	16.3	97.8
		16.4	98.4
		16.5	99.0

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Table 5 (Continued)

Results of Analytical Assays of SC-19129 in Diet - Females

Group 3 (500 mg/kg/day) (Continued)

Week	Dosing Concentration (g/kg) Theoretical	Actual	Percent of Theoretical
5	18.107	20.1	111.0
		20.0	110.5
		20.0	110.5
10	18.039	18.3	101.4
		18.5	102.6
		18.3	101.4
15	16.964	17.4	102.6
		17.4	102.6
		16.6	97.9
20	19.216	19.3	100.4
		19.4	101.0
		19.4	101.0
25	24.010	24.2	100.8
		24.6	102.5
		23.7	98.7

Group 4 (1,000 mg/kg/day)

Week	Dosing Concentration (g/kg) Theoretical	Actual	Percent of Theoretical
1	32.794	32.6	99.4
		33.7	102.8
		34.3	104.6
3	30.686	31.0	101.0
		31.1	101.3
		31.1	101.3
5	36.975	40.1	108.5
		40.2	108.7
		39.6	107.1

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Table 5 (Continued)

Results of Analytical Assays of SC-19129 in Diet - Females

Group 4 (1,000 mg/kg/day) (Continued)

Week	Dosing Concentration (g/kg) Theoretical	Actual	Percent of Theoretical
10	37.959	37.3	98.3
		38.3	100.9
		36.3	95.6
15	33.929	33.5	98.7
		33.8	99.6
		33.1	97.6
20	39.200	37.8	96.4
		37.5	95.7
		38.1	97.2
25	36.330	36.8	101.3
		35.8	98.5
		35.5	97.7

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Table 6

Summary of Mean Compound Consumption (mg/kg/day)

Males

Week	Concentration (mg/kg/day) 250	500	1,000
1	274	548	1,168
2	255	491	1,041
3	249	484	990
4	217	432	873
5	253	527	993
6	272	490	1,085
7	189	426	866
8	282	541	1,164
9	280	471	951
10	309	516	986
11	286	569	1,138
12	218	453	929
13	234	500	898
14	252	555	1,095
15	252	486	966
16	232	434	925
17	219	447	917
18	220	497	976
19	297	549	1,069
20	256	494	906
21	260	506	1,022
22	259	514	1,169
23	241	472	806
24	235	467	916
25	233	494	1,133
26	212	469	917
Mean	249	494	996
Standard deviation	28.7	39.1	103.9
Percent of theoretical	100	99	100

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Table 7

Summary of Mean Compound Consumption (mg/kg/day)

Females

Week	Concentration (mg/kg/day) 250	500	1,000
1	268	536	1,108
2	259	483	923
3	237	471	849
4	210	446	948
5	267	572	1,122
6	249	461	923
7	202	395	874
8	248	541	1,010
9	277	488	979
10	274	520	1,139
11	236	485	1,019
12	232	436	900
13	245	557	1,011
14	269	555	1,041
15	231	419	879
16	242	443	937
17	224	514	1,000
18	215	479	924
19	240	486	1,052
20	232	469	950
21	272	504	995
22	226	492	970
23	234	458	1,028
24	251	442	939
25	254	515	842
26	197	463	813
Mean	242	486	968
Standard deviation	22.0	44.3	85.0
Percent of theoretical	97	97	97

Table 8

Summary of Selected Observations[a]

Males

Observation	Study Week 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Group 1															
Erythema (generalized)	-	-	-	1	1	2	2	2	2	2	1	1	1	1	1
Alopecia (generalized)	-	-	-	-	-	-	-	-	-	1	1	1	1	1	1
Group 2															
Erythema (generalized)	-	-	-	1	1	1	1	1	1	1	1	1	1	1	1
Alopecia (head)	-	-	-	1	1	1	1	1	1	1	1	1	1	1	1
Group 3															
Erythema (generalized)	-	-	-	-	-	-	1	2	2	2	2	2	2	2	2
Alopecia (head)	-	-	-	-	-	-	-	-	-	-	-	-	-	1	1
Ocular discharge	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Group 4															
Erythema (generalized)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

[a]Number of dogs in the group which exhibited signs at least once during the week.

Table 8 (Continued)

Summary of Selected Observations[a]

Males

Observation	Study Week											Recovery Week				
	16	17	18	19	20	21	22	23	24	25	26	27[b]	28	29	30	31
Group 1																
Erythema (generalized)	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Alopecia (generalized)	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Group 2																
Erythema (generalized)	1	1	1	1	1	1	1	1	1	1	1	1	-	-	-	-
Alopecia (head)	1	1	1	1	1	1	1	1	1	1	1	1	-	-	-	-
Group 3																
Erythema (generalized)	2	2	2	2	2	2	2	2	2	2	2	2	-	-	-	-
Alopecia (head)	1	1	1	1	1	1	1	1	1	1	1	1	-	-	-	-
Ocular discharge	-	1	1	1	1	1	1	1	1	1	1	1	-	-	-	-
Group 4																
Erythema (generalized)	-	-	-	1	1	1	1	1	1	1	1	1	-	-	-	-

[a]Number of dogs in the group which exhibited signs at least once during the week.
[b]Week 27 includes animals in the main study which were sacrificed during the week and animals in the recovery study.

Table 9

Summary of Selected Observations[a]

Females

Observation	Study Week 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Group 1															
Erythema (generalized)	-	-	-	1	1	1	1	2	2	2	2	2	2	2	2
(head)	-	-	-	-	-	-	-	1	1	1	1	1	1	1	1
Alopecia (extremities)	-	-	-	-	-	-	-	-	1	1	1	-	-	-	-
(generalized)	-	-	-	-	-	-	-	-	-	-	-	1	1	1	1
Group 2															
Alopecia (extremities)	-	-	-	1	1	1	1	1	1	-	-	-	-	-	-
Group 3															
Erythema (generalized)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Ocular discharge	-	-	-	-	-	-	-	-	-	-	-	-	-	1	1
Group 4															
Erythema (generalized)	-	-	1	1	1	1	1	1	-	1	1	1	1	1	1
Alopecia (thorax)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Ocular discharge	-	-	-	-	-	1	1	1	1	1	1	1	1	1	1

[a]Number of dogs in the group which exhibited signs at least once during the week.

Table 9 (Continued)

Summary of Selected Observations[a]

Females

Observation	Study Week											Recovery Week				
	16	17	18	19	20	21	22	23	24	25	26	27[b]	28	29	30	31
Group 1																
Erythema (generalized)	2	2	2	2	2	2	2	2	2	2	2	2	1	1	1	1
(head)	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Alopecia (extremities)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
(generalized)	1	1	1	1	1	1	1	1	1	1	1	1	-	-	-	-
Group 2																
Alopecia (extremities)	-	-	-	-	-	-	-	-	-	1	1	1	-	-	-	-
Group 3																
Erythema (generalized)	-	1	1	1	1	1	1	1	1	1	1	1	-	-	-	-
Ocular discharge	1	1	1	1	-	-	-	-	-	-	-	-	-	-	-	-
Group 4																
Erythema (generalized)	1	1	1	1	1	1	1	1	1	1	1	1	-	-	-	-
Alopecia (thorax)	-	1	1	1	1	1	1	1	1	1	-	-	-	-	-	-
Ocular discharge	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1

[a]Number of dogs in the group which exhibited signs at least once during the week.
[b]Week 27 includes animals in the main study which were sacrificed during the week and animals in the recovery study.

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Table 10

Summary of Mean Body Weights (kg)

Males

Week on Study		Treatment SC-19129 (mg/kg/BW/Day) 0	250	500	1,000
0	Mean	8.8	8.8	8.8	8.7
	SD	0.95	0.85	0.80	0.99
	N	6	6	6	6
1	Mean	9.1	9.2	9.1	9.0
	SD	1.05	0.84	0.84	1.00
	N	6	6	6	6
2	Mean	9.4	9.4	9.4	9.2
	SD	1.01	0.93	0.87	1.14
	N	6	6	6	6
3	Mean	9.6	9.7	9.6	9.3
	SD	1.09	0.95	0.91	1.06
	N	6	6	6	6
4	Mean	9.9	10.0	9.7	9.6
	SD	1.21	1.13	0.97	1.13
	N	6	6	6	6
5	Mean	10.0	10.1	10.0	9.8
	SD	1.18	1.20	0.90	1.27
	N	6	6	6	6
6	Mean	9.9	9.7	9.6	9.9
	SD	1.28	1.25	0.65	1.22
	N	6	6	6	6
7	Mean	10.0	10.0	9.9	9.8
	SD	1.30	1.27	0.88	1.21
	N	6	6	6	6
8	Mean	10.2	10.1	10.1	10.0
	SD	1.24	1.09	1.01	1.31
	N	6	6	6	6

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Table 10 (Continued)

Summary of Mean Body Weights (kg)

Males

Week on Study		Treatment SC-19129 (mg/kg/BW/Day) 0	250	500	1,000
9	Mean	10.2	10.1	10.1	10.0
	SD	1.34	1.17	0.98	1.23
	N	6	6	6	6
10	Mean	10.3	10.3	10.3	10.1
	SD	1.33	1.21	0.96	1.28
	N	6	6	6	6
11	Mean	10.3	10.2	10.2	10.1
	SD	1.32	1.05	0.95	1.42
	N	6	6	6	6
12	Mean	10.4	10.4	10.4	10.2
	SD	1.44	1.09	0.96	1.45
	N	6	6	6	6
13	Mean	10.6	10.4	10.5	10.2
	SD	1.53	1.07	1.15	1.46
	N	6	6	6	6
14	Mean	10.8	10.5	10.7	10.5
	SD	1.64	1.16	1.14	1.43
	N	6	6	6	6
15	Mean	11.0	10.8	10.9	10.6
	SD	1.70	1.13	1.04	1.56
	N	6	6	6	6
16	Mean	10.5	10.6	10.7	10.4
	SD	1.45	0.94	1.15	1.38
	N	6	6	6	6
17	Mean	10.8	10.6	10.7	10.5
	SD	1.67	1.10	1.16	1.59
	N	6	6	6	6

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Table 10 (Continued)

Summary of Mean Body Weights (kg)

Males

Week on Study		Treatment SC-19129 (mg/kg/BW/Day) 0	250	500	1,000
18	Mean	10.9	10.7	10.8	10.4
	SD	1.71	1.26	1.13	1.40
	N	6	6	6	6
19	Mean	11.0	10.6	10.9	10.3
	SD	1.68	1.03	1.21	1.32
	N	6	6	6	6
20	Mean	11.2	10.9	11.1	10.6
	SD	1.74	1.05	1.10	1.36
	N	6	6	6	6
21	Mean	11.3	11.0	11.1	10.6
	SD	1.75	1.13	1.20	1.20
	N	6	6	6	6
22	Mean	11.0	11.0	10.9	10.4
	SD	1.67	1.12	1.29	1.40
	N	6	6	6	6
23	Mean	11.1	10.7	10.9	10.2
	SD	1.40	1.21	1.07	1.38
	N	6	6	6	6
24	Mean	11.1	10.9	11.1	10.4
	SD	1.64	1.04	0.96	1.20
	N	6	6	6	6
25	Mean	10.8	11.0	11.2	10.4
	SD	1.52	1.19	1.16	1.20
	N	6	6	6	6
26	Mean	10.8	10.6	11.1	10.1
	SD	1.68	1.18	1.19	1.45
	N	6	6	6	6

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Table 10 (Continued)

Summary of Mean Body Weights (kg)
Recovery Study

Males

Week on Study		Treatment SC-19129 (mg/kg/BW/Day) 0	250	500	1,000
27	Mean	11.6	11.7	10.3	10.8
	SD	0.85	1.56	0.99	1.06
	N	2	2	2	2
28	Mean	12.1	12.0	10.7	11.0
	SD	0.85	1.98	0.85	1.27
	N	2	2	2	2
29	Mean	11.8	12.3	10.7	11.3
	SD	1.20	1.56	0.85	1.41
	N	2	2	2	2
30	Mean	12.0	12.4	10.8	11.4
	SD	0.99	1.63	0.71	1.20
	N	2	2	2	2

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Table 11

Summary of Mean Body Weights (kg)

Females

Week on Study		Treatment SC-19129 (mg/kg/BW/Day) 0	250	500	1,000
0	Mean	8.2	7.7	7.9	8.0
	SD	0.68	0.72	0.77	0.49
	N	6	6	6	6
1	Mean	8.5	8.2	8.3	8.3
	SD	0.76	0.77	0.71	0.71
	N	6	6	6	6
2	Mean	8.8	8.3	8.6	8.4
	SD	0.79	0.70	0.71	0.72
	N	6	6	6	6
3	Mean	9.0	8.5	8.7	8.7
	SD	0.97	0.74	0.82	0.52
	N	6	6	6	6
4	Mean	9.1	8.6	8.8	8.8
	SD	0.82	0.83	0.87	0.62
	N	6	6	6	6
5	Mean	9.0	8.8	9.0	8.8
	SD	0.86	0.85	0.87	0.77
	N	6	6	6	6
6	Mean	9.1	8.9	9.0	8.9
	SD	0.99	0.80	0.74	0.59
	N	6	6	6	6
7	Mean	9.0	8.4	8.8	8.8
	SD	0.75	0.97	0.88	0.66
	N	6	6	6	6
8	Mean	9.3	8.8	9.2	9.2
	SD	0.96	0.80	0.89	0.60
	N	6	6	6	6

Study No. 6127-111

Table 11 (Continued)

Summary of Mean Body Weights (kg)

Females

Week on Study		Treatment SC-19129 (mg/kg/BW/Day) 0	250	500	1,000
9	Mean	9.4	8.9	9.3	9.2
	SD	1.10	0.83	0.83	0.60
	N	6	6	6	6
10	Mean	9.5	8.9	9.2	9.4
	SD	1.06	0.82	0.71	0.60
	N	6	6	6	6
11	Mean	9.5	9.0	9.3	9.3
	SD	1.20	0.92	0.65	0.66
	N	6	6	6	6
12	Mean	9.8	9.2	9.6	9.5
	SD	0.95	0.95	0.68	0.60
	N	6	6	6	6
13	Mean	9.7	9.2	9.5	9.5
	SD	0.92	1.05	0.75	0.58
	N	6	6	6	6
14	Mean	10.1	9.3	9.7	9.8
	SD	1.16	1.01	0.66	0.66
	N	6	6	6	6
15	Mean	10.1	9.4	9.8	9.8
	SD	1.18	1.02	0.65	0.56
	N	6	6	6	6
16	Mean	9.9	9.2	9.6	9.7
	SD	1.08	1.00	0.58	0.54
	N	6	6	6	6
17	Mean	10.0	9.1	9.6	9.6
	SD	1.14	0.96	0.58	0.56
	N	6	6	6	6

Study No. 6127-111

Table 11 (Continued)

Summary of Mean Body Weights (kg)

Females

Week on Study		Treatment SC-19129 (mg/kg/BW/Day) 0	250	500	1,000
18	Mean	10.0	9.2	9.8	9.7
	SD	1.25	1.01	0.71	0.54
	N	6	6	6	6
19	Mean	10.0	9.1	9.7	9.6
	SD	0.97	0.97	0.65	0.69
	N	6	6	6	6
20	Mean	10.2	9.3	10.0	9.8
	SD	1.10	0.98	0.64	0.78
	N	6	6	6	6
21	Mean	10.2	9.3	9.9	10.0
	SD	1.07	0.99	0.49	0.83
	N	6	6	6	6
22	Mean	10.3	9.4	9.8	9.9
	SD	1.23	1.19	0.69	0.78
	N	6	6	6	6
23	Mean	10.3	9.4	9.7	9.7
	SD	1.13	1.05	0.85	0.82
	N	6	6	6	6
24	Mean	10.0	9.3	9.7	9.8
	SD	1.5	9.5	0.71	0.73
	N	6	6	6	6
25	Mean	9.9	9.2	9.5	9.7
	SD	1.19	1.06	0.92	0.97
	N	6	6	6	6
26	Mean	10.1	9.2	9.5	9.6
	SD	1.30	1.03	0.85	0.84
	N	6	6	6	6

Study No. 6127-111

Table 11 (Continued)

Summary of Mean Body Weights (kg)
Recovery Study

Females

Week on Study		Treatment SC-19129 (mg/kg/BW/Day) 0	250	500	1,000
27	Mean	9.1	9.7	8.6	10.0
	SD	0.14	0.57	0.57	0.21
	N	2	2	2	2
28	Mean	9.4	10.4	9.0	10.6
	SD	0.49	0.21	0.78	0.50
	N	2	2	2	2
29	Mean	9.4	10.4	9.0	10.3
	SD	0.21	0.14	0.57	0.14
	N	2	2	2	2
30	Mean	9.4	10.4	9.1	10.5
	SD	0.14	0.14	0.57	0.42
	N	2	2	2	2

Study No. 6127-111

Table 12

Summary of Mean Food Consumptions (g)

Males

Week on Study		Treatment SC-19129 (mg/kg/BW/Day) 0	250	500	1,000
-1	Mean	1,959	1,919	1,950	1,933
	SD	294.1	280.7	202.1	281.7
	N	6	6	6	6
1	Mean	1,976	1,959	1,949	2,043
	SD	242.2	294.1	379.3	264.3
	N	6	6	6	6
2	Mean	1,988	2,043	1,978	2,081
	SD	281.8	318.6	319.0	275.4
	N	6	6	6	6
3	Mean	1,912	1,995	1,925	2,024
	SD	274.7	303	226.5	323.2
	N	6	6	6	6
4	Mean	1,955	1,899	1,792	1,897
	SD	288.7	310.4	296.1	201.1
	N	6	6	6	6
5	Mean	2,105	2,038	2,032	2,077
	SD	407.3	277.3	333.8	287.9
	N	6	6	6	6
6	Mean	1,866	1,907	1,713	2,006
	SD	309.0	366.4	409.3	235.5
	N	6	6	6	6
7	Mean	1,782	1,497	1,690	1,803
	SD	334.3	245.8	376.5	288.2
	N	6	6	6	6
8	Mean	2,057	2,214	1,931.8	2,233
	SD	316.8	322.3	347.8	281.9
	N	6	6	6	6

Study No. 6127-111

Table 12 (Continued)

Summary of Mean Food Consumptions (g)

Males

Week on Study		Treatment SC-19129 (mg/kg/BW/Day) 0	250	500	1,000
9	Mean	1,850	1,764	1,764	1,884
	SD	295.2	188.7	214.2	369.9
	N	6	6	6	6
10	Mean	2,128	2,203	2,060	2,235
	SD	361.5	306.6	287.3	233.9
	N	6	6	6	6
11	Mean	2,164	2,024	2,052	2,171
	SD	264.7	336.7	292.0	364.1
	N	6	6	6	6
12	Mean	2,015	1,930	1,882	2,110
	SD	368.0	300.9	349.6	339.6
	N	6	6	6	6
13	Mean	1,996	2,051	2,100	2,034
	SD	311.3	303.3	325.9	228.5
	N	6	6	6	6
14	Mean	2,058	1,993	2,154	2,050
	SD	339.5	282.4	347.6	204.3
	N	6	6	6	6
15	Mean	2,210	2,065	2,087	2,074
	SD	382.7	243.6	298.5	320.3
	N	6	6	6	6
16	Mean	2,022	1,901	1,882	1,927
	SD	326.8	358.3	254.0	295.5
	N	6	6	6	6
17	Mean	1,864	1,791	1,825	1,856
	SD	272.8	275.9	346.7	289.4
	N	6	6	6	6

Study No. 6127-111

Table 12 (Continued)

Summary of Mean Food Consumptions (g)

Males

Week on Study		Treatment SC-19129 (mg/kg/BW/Day) 0	250	500	1,000
18	Mean	1,963	1,800	1,944	1,972
	SD	326.8	269.0	338.4	275.4
	N	6	6	6	6
19	Mean	2,032	2,204	2,034	2,005
	SD	310.1	407.6	243.3	244.9
	N	6	6	6	6
20	Mean	2,048	1,882	1,937	1,770
	SD	374.2	258.8	272.4	225.5
	N	6	6	6	6
21	Mean	2,260	2,147	2,093	2,113
	SD	372.5	360.8	331.5	283.5
	N	6	6	6	6
22	Mean	2,000	1,997	2,018	2,130
	SD	299.5	284.7	300.5	302.0
	N	6	6	6	6
23	Mean	2,217	2,049	1,943	1,673
	SD	345.5	208.6	202.9	660.4
	N	6	6	6	6
24	Mean	1,978	1,855	1,895	1,916
	SD	284.0	267.9	256.2	267.1
	N	6	6	6	6
25	Mean	1,944	1,969	1,974	1,932
	SD	313.4	234.4	264.7	233.2
	N	6	6	6	6
26	Mean	1,987	1,604	1,824	1,708
	SD	359.6	314.0	336.0	544.5
	N	6	6	6	6

Study No. 6127-111

Table 12 (Continued)

Summary of Mean Food Consumptions (g)
Recovery Study

Males

Week on Study		Treatment SC-19129 (mg/kg/BW/Day) 0	250	500	1,000
27	Mean	2,196	1,924	1,439	1,890
	SD	161.9	471.6	147.1	536.7
	N	2	2	2	2
28	Mean	2,118	1,695	1,775	2,087
	SD	244.7	352.1	366.3	743.9
	N	2	2	2	2
29	Mean	2,206	2,099	1,918	2,208
	SD	846.4	292.7	241.1	583.4
	N	2	2	2	2
30	Mean	2,125	2,064	1,841	2,204
	SD	367.7	364.2	721.2	427.1
	B	2	2	2	2

Study No. 6127-111

Table 13

Summary of Mean Food Consumptions (g)

Females

Week on Study		Treatment SC-19129 (mg/kg/BW/Day) 0	250	500	1,000
-1	Mean	1,955	1,706	1,839	1,912
	SD	253.7	237.1	149.5	138.0
	N	6	6	6	6
1	Mean	1,948	1,770	1,783	1,938
	SD	274.8	175.1	264.9	174.7
	N	6	6	6	6
2	Mean	1,932	1,860	1,879	1,866
	SD	156.3	191.7	236.0	315.0
	N	6	6	6	6
3	Mean	1,848	1,683	1,701	1,668
	SD	253.7	170.0	174.5	145.4
	N	6	6	6	6
4	Mean	1,830	1,661	1,755	1,828
	SD	167.9	126.9	187.3	142.6
	N	6	6	6	6
5	Mean	1,920	1,791	1,968	1,871
	SD	199.5	187.2	238.2	167.6
	N	6	6	6	6
6	Mean	1,767	1,653	1,610	1,638
	SD	116.1	149.2	132.1	263.3
	N	6	6	6	6
7	Mean	1,574	1,414	1,532	1,636
	SD	295.6	283.8	79.7	251.9
	N	6	6	6	6
8	Mean	1,940	1,582	1,742	1,669
	SD	371.6	365.6	247.8	192.4
	N	6	6	6	6

Study No. 6127-111

Table 13 (Continued)

Summary of Mean Food Consumptions (g)

Females

Week on Study		Treatment SC-19129 (mg/kg/BW/Day) 0	250	500	1,000
9	Mean	1,742	1,805	1,689	1,803
	SD	163.6	237.2	169.7	288.5
	N	6	6	6	6
10	Mean	2,036	1,745	1,852	1,953
	SD	229.1	138.0	185.2	280.8
	N	6	6	6	6
11	Mean	1,860	1,722	1,648	1,879
	SD	163.1	267.8	161.0	228.9
	N	6	6	6	6
12	Mean	1,906	1,660	1,664	1,770
	SD	149.8	219.3	102.0	155.7
	N	6	6	6	6
13	Mean	1,967	1,772	1,930	1,936
	SD	137.2	312.0	146.1	240.2
	N	6	6	6	6
14	Mean	2,009	1,804	1,883	1,910
	SD	153.1	243.4	102.8	123.2
	N	6	6	6	6
15	Mean	1,942	1,667	1,695	1,776
	SD	217.1	147.7	264.7	209.1
	N	6	6	6	6
16	Mean	1,870	1,746	1,662	1,783
	SD	154.8	260.6	142.2	105.3
	N	6	6	6	6
17	Mean	1,853	1,494	1,743	1,763
	SD	212.6	136.7	86.9	195.5
	N	6	6	6	6

Study No. 6127-111

Table 13 (Continued)

Summary of Mean Food Consumptions (g)

Females

Week on Study		Treatment SC-19129 (mg/kg/BW/Day) 0	250	500	1,000
18	Mean	1,898	1,542**	1,657*	1,633*
	SD	136.5	93.7	226.8	105.2
	N	6	6	6	6
19	Mean	1,894	1,593*	1,736	1,873
	SD	200.9	178.0	206.1	166.4
	N	6	6	6	6
20	Mean	1,864	1,543	1,674	1,647
	SD	201.6	210.2	145.8	286.9
	N	6	6	6	6
21	Mean	2,177	1,774*	1,902	1,852*
	SD	188.1	179.8	150.5	324.9
	N	6	6	6	6
22	Mean	1,901	1,457*	1,638	1,682
	SD	175.8	323.3	117.0	279.6
	N	6	6	6	6
23	Mean	1,865	1,675	1,716	1,868
	SD	290.8	235.9	296.9	269.5
	N	6	6	6	6
24	Mean	1,655	1,548	1,487	1,625
	SD	530.7	137.3	249.3	274.6
	N	6	6	6	6
25	Mean	1,581	1,663	1,443	1,591
	SD	274.9	196.3	292.2	430.6
	N	6	6	6	6
26	Mean	1,615	1,289	1,284	1,392
	SD	234.6	191.1	281.1	375.0
	N	6	6	6	6

Study No. 6127-111

Table 13 (Continued)

Summary of Mean Food Consumptions (g)
Recovery Study

Females

Week on Study		Treatment SC-19129 (mg/kg/BW/Day) 0	250	500	1,000
27	Mean	1,719	1,267	1,193	1,366
	SD	198.0	67.9	120.2	369.8
	N	2	2	2	2
28	Mean	1,798	1,668	1,388	1,840
	SD	248.2	352.8	57.3	118.1
	N	2	2	2	2
29	Mean	1,985	1,997	1,776	1,914
	SD	148.5	200.8	132.2	315.4
	N	2	2	2	2
30	Mean	1,807	1,620	1,762	1,824
	SD	52.3	533.2	21.9	176.1
	N	2	2	2	2

Table 14

Individual Ophthalmic Examinations

Males

Animal Number	Baseline	16 Weeks	25 Weeks
		Group 1	
H00961	NVL	NVL	NVL
H00962	NVL	NVL	NVL
H00963	NVL	NVL	NVL
H00964	NVL	NVL	NVL
H00965	NVL	NVL	NVL
H00966	NVL	NVL	NVL
		Group 2	
H00973	NVL	NVL	NVL
H00974	NVL	NVL	NVL
H00975	OS - depressed optic disc; OD - NVL	OU - recessed optic discs	OU - recessed optic discs
H00976	NVL	NVL	NVL
H00977	NVL	NVL	NVL
H00978	NVL	NVL	NVL
		Group 3	
H00985	NVL	OU - excessive tearing	OU - excessive tearing
H00986	NVL	NVL	NVL
H00987	NVL	NVL	OS - NVL; OD - tapetal pigment spot temporal to disc
H00988	OS - excessive tearing; OD - NVL	OS - NVL; OD - tapetal pigment spot temporal to disc	NVL
H00989	NVL	NVL	NVL
H00990	NVL	NVL	NVL
		Group 4	
H00997	OU - multifocal pigment foci	OU - tapetal pigment spots	NVL
H00998	NVL	NVL	NVL
H00999	NVL	NVL	NVL
H00001	OD - retinal folds; OS - distichia	OU - retinal folds; OU - distichia (upper lid)	OU - retinal folds; OU - distichia (upper lid)
H00002	NVL	NVL	NVL
H00003	NVL	NVL	NVL

NVL = No visible lesions.
OS = Left eye.
OD = Right eye.
OU = Both eyes.

Study No. 6127-111

Table 14 (Continued)

Individual Ophthalmic Examinations
Recovery Study

Males

Animal Number	30 Weeks
	Group 1
H00964	OS - NVL; OD - retinal hemorrhage, arcuate retinal fold
H00965	NVL
	Group 2
H00973	NVL
H00977	NVL
	Group 3
H00988	NVL
H00990	NVL
	Group 4
H00998	OU - tearing
H00001	OS - distichia; OU - retinal fold

NVL = No visible lesions.
OS = Left eye.
OD = Right eye.
OU = Both eyes.

Table 15

Individual Ophthalmic Examinations

Females

Animal Number	Baseline	16 Weeks	25 Weeks
		Group 1	
H00967	OS - NVL; OD - angoid streak	OS - NVL; OD - angoid streak	OU - excessive tearing; OD - angoid streak
H00968	NVL	NVL	NVL
H00969	NVL	NVL	NVL
H00970	NVL	NVL	NVL
H00971	NVL	OS - NVL; OD - recessed nerve head	OS - NVL; OD - recessed nerve head
H00972	NVL	NVL	OS - NVL; OD - focal depigmentation on nontapetal zone
		Group 2	
H00979	NVL	NVL	NVL
H00980	NVL	NVL	NVL
H00981	NVL	NVL	NVL
H00982	NVL	OS - NVL; OD - protruding optic disc	OU - protruding optic discs
H00983	OU - micropapillae	OU - micropapillae	OU - micropapillae
H00984	NVL	NVL	NVL
		Group 3	
H00991	NVL	NVL	NVL
H00992	NVL	NVL	NVL
H00993	NVL	OS - circinate retinopathy; OD - NVL	OS - circinate retinopathy; OD - NVL
H00994	NVL	NVL	NVL
H00995	NVL	OS - NVL; OD - distichia, upper lid	OU - distichia; OD - multifocal pigment spots temporal to disc
H00996	NVL	OU - excessive tearing	OU - excessive tearing
		Group 4	
H00004	NVL	NVL	NVL
H00005	NVL	OS - Retinal folds in tapetum OD - NVL	OS - Retinal folds OD - NVL
H00006	NVL	NVL	NVL
H00007	NVL	NVL	NVL
H00008	NVL	NVL	NVL
H00009	NVL	NVL	NVL

NVL = No visible lesions.
OS = Left eye.
OD = Right eye.
OU = Both eyes.

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Table 15 (Continued)

Individual Ophthalmic Examinations
Recovery Study

Females

Animal Number	30 Weeks
	Group 1
H00971	OS - NVL; OD - recessed nerve head
H00972	OS - NVL; OD - focal depigmentation, nontapetal zone
	Group 2
H00979	NVL
H00981	NVL
	Group 3
H00995	OS - NVL; OD - multifocal pigment spots temporal to disc
H00996	OU - excessive tearing
	Group 4
H00005	OU - retinal fold
H00006	NVL

NVL = No visible lesions.
OS = Left eye.
OD = Right eye.
OU = Both eyes.

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Table 16

Summary of Mean Heart Rates (Beats/Minute)

Group	Week -2	Week 8	Week 17	Week 26	Recovery Study Week 30
			Males		
1	127	119	107	125	127
2	141	128	123	123	121
3	138	122	126	121	119
4	143	123	110	121	133
			Females		
1	129	125	125	128	112
2	141	135	133	136	118
3	130	133	126	126	127
4	131	131	128	130	136
			Combined		
1	128	122	116	126	120
2	141	132	128	130	120
3	134	128	126	124	123
4	137	127	119	126	134

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Table 17

Summary of Mean Respiration Rates (Breaths/Minute)

Group	Week -2	Week 8	Week 17	Week 26	Recovery Study Week 30
			Males		
1	41	38	41	35	36
2	40	36	39	33	40
3	39	38	37	36	34
4	42	39	40	38	33
			Females		
1	44	40	32	35	30
2	51	39	41**	41	24
3	42	36	35	36	30
4	46	36	39*	37	35
			Combined		
1	43	39	36	35	33
2	46	38	40	37	32
3	40	37	36	36	32
4	44	38	40	38	34

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Table 18

Summary of Mean Rectal Temperatures (°F)

Group	Week -2	Week 8	Week 17	Week 26	Recovery Study Week 30
			Males		
1	101.4	100.3	100.4	102.1	100.8
2	101.6	100.8	101.0	101.3	100.1
3	101.4	100.5	101.1	100.9	100.4
4	101.8	100.4	100.7	101.0	101.0
			Females		
1	101.4	100.2	100.6	100.9	101.0
2	101.1	100.3	100.8	101.3	100.8
3	101.0	100.5	100.9	100.7	101.1
4	101.2	101.0	100.8	101.0	101.0
			Combined		
1	101.4	100.3	100.5	101.5	100.8
2	101.4	100.6	100.9	101.3	100.5
3	101.2	100.5	101.0	100.8	100.8
4	101.5	100.8	100.8	101.0	101.0

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Table 19

Summary of Mean Electrocardiograph Measurements

Week -2

	Group 1	2	3	4
Male				
Heart rate	133	153	147	150
P-R Int (sec)	0.08	0.09	0.08	0.07
QRS Int (sec)	0.04	0.04	0.04	0.04
Q-T Int (sec)	0.17	0.17	0.17	0.17
Elec. axis (°)	60	60	66	65
P-wave (sec)	0.03	0.03	0.03	0.03
P-wave (mV)	0.2	0.3	0.2	0.2
Q Amp (mV)	0.4	0.6	0.5	0.5
R Amp (mV)	1.7	2.1	1.6	2.0
S Amp (mV)	0.1	0.0	0.0	0.0
Female				
Heart rate	147	143	140	140
P-R Int (sec)	0.09	0.08	0.09	0.08
QRS Int (sec)	0.04	0.05	0.04	0.04
Q-T Int (sec)	0.17	0.17	0.18	0.17
Elec. axis (°)	70	70	58	60
P-wave (sec)	0.03	0.03	0.03	0.03
P-wave (mV)	0.2	0.2	0.3	0.2
Q Amp (mV)	0.4	0.6	0.2	0.4
R Amp (mV)	1.9	2.1	1.9	1.9
S Amp (mV)	0.0	0.0	0.2	0.1
Combined				
Heart rate	140	148	143	145
P-R Int (sec)	0.08	0.08	0.08	0.08
QRS Int (sec)	0.04	0.04	0.04	0.04
Q-T Int (sec)	0.17	0.17	0.17	0.17
Elec. axis (°)	65	65	61	62
P-wave (sec)	0.03	0.03	0.03	0.03
P-wave (mV)	0.2	0.2	0.3	0.2
Q Amp (mV)	0.4	0.6	0.4	0.5
R Amp (mV)	1.8	2.1	1.8	2.0
S Amp (mV)	0.0	0.0	0.1	0.1

Study No. 6127-111

Table 19 (Continued)

Summary of Mean Electrocardiograph Measurements

Week 8

	Group 1	2	3	4
Male				
Heart rate	140	153	150	140
P-R Int (sec)	0.08	0.09	0.09	0.08
QRS Int (sec)	0.04	0.04	0.04	0.04
Q-T Int (sec)	0.18	0.17	0.18	0.17
Elec. axis (°)	68	70	75	70
P-wave (sec)	0.03	0.04	0.03	0.03
P-wave (mV)	0.3	0.3	0.2	0.2
Q Amp (mV)	0.4	0.3	0.4	0.4
R Amp (mV)	1.9	2.4	1.5	2.3
S Amp (mV)	0.1	0.0	0.1	0.0
Female				
Heart rate	137	147	153	150
P-R Int (sec)	0.09	0.08	0.08	0.07
QRS Int (sec)	0.04	0.04	0.04	0.04
Q-T Int (sec)	0.18	0.17	0.17	0.18
Elec. axis (°)	70	78	72	73
P-wave (sec)	0.03	0.03	0.03	0.03
P-wave (mV)	0.2	0.3	0.3	0.3
Q Amp (mV)	0.3	0.5	0.4	0.3
R Amp (mV)	2.1	2.3	1.9	2.1
S Amp (mV)	0.1	0.0	0.1	0.0
Combined				
Heart rate	138	150	152	145
P-R Int (sec)	0.09	0.08	0.09	0.08
QRS Int (sec)	0.04	0.04	0.04	0.04
Q-T Int (sec)	0.18	0.17	0.18	0.17
Elec. axis (°)	69	74	74	72
P-wave (sec)	0.03	0.03	0.03	0.03
P-wave (mV)	0.2	0.3	0.3	0.3
Q Amp (mV)	0.4	0.4	0.4	0.4
R Amp (mV)	2.0	2.3	1.7	2.2
S Amp (mV)	0.1	0.0	0.1	0.0

Study No. 6127-111

Table 19 (Continued)

Summary of Mean Electrocardiograph Measurements

Week 17

	Group 1	2	3	4
		Male		
Heart rate	140	137	128	133
P-R Int (sec)	0.08	0.10	0.09	0.08
QRS Int (sec)	0.04	0.05	0.04	0.04
Q-T Int (sec)	0.18	0.18	0.17	0.18
Elec. axis (°)	55	68	63	60
P-wave (sec)	0.03	0.04	0.03	0.03
P-wave (mV)	0.3	0.3	0.3	0.2
Q Amp (mV)	0.4	0.3	0.6	0.3
R Amp (mV)	2.0	2.4	1.7	2.3
S Amp (mV)	0.1	0.0	0.1	0.0
		Female		
Heart rate	133	147	157	150
P-R Int (sec)	0.10	0.09	0.08	0.09
QRS Int (sec)	0.04	0.05	0.04	0.04
Q-T Int (sec)	0.18	0.18	0.18	0.17
Elec. axis (°)	58	70	62	62
P-wave (sec)	0.03	0.03	0.04	0.03
P-wave (mV)	0.3	0.3	0.3	0.3
Q Amp (mV)	0.5	0.5	0.9	0.5
R Amp (mV)	2.0	2.2	2.0	2.0
S Amp (mV)	0.1	0.0	0.1	0.1
		Combined		
Heart rate	137	142	142	142
P-R Int (sec)	0.09	0.09	0.09	0.08
QRS Int (sec)	0.04	0.05	0.04	0.04
Q-T Int (sec)	0.18	0.18	0.17	0.17
Elec. axis (°)	56	69	63	61
P-wave (sec)	0.03	0.03	0.03	0.03
P-wave (mV)	0.3	0.6	0.3	0.2
Q Amp (mV)	0.5	0.4	0.6	0.4
R Amp (mV)	2.0	2.3	1.8	2.1
S Amp (mV)	0.1	0.0	0.1	0.10

Study No. 6127-111

Table 19 (Continued)

Summary of Mean Electrocardiograph Measurements

Week 26

	Group 1	2	3	4
Male				
Heart rate	140	153	140	120
P-R Int (sec)	0.08	0.09	0.08	0.08
QRS Int (sec)	0.04	0.05	0.05	0.04
Q-T Int (sec)	0.18	0.18	0.18	0.18
Elec. axis (°)	70	68	66	70
P-wave (sec)	0.03	0.03	0.03	0.03
P-wave (mV)	0.2	0.3	0.2	0.2
Q Amp (mV)	0.4	0.3	0.5	0.4
R Amp (mV)	1.6	2.5*	1.9	2.4
S Amp (mV)	0.1	0.0	0.1	0.0
Female				
Heart rate	147	143	140	153
P-R Int (sec)	0.09	0.08	0.09	0.09
QRS Int (sec)	0.04	0.05	0.05*	0.04
Q-T Int (sec)	0.18	0.17	0.18	0.17
Elec. axis (°)	50	62	60	70
P-wave (sec)	0.03	0.03	0.03	0.03
P-wave (mV)	0.2	0.3	0.3	0.3
Q Amp (mV)	0.3	0.6	0.3	0.5
R Amp (mV)	1.8	2.4	1.9	2.1
S Amp (mV)	0.0	0.0	0.1	0.0
Combined				
Heart rate	143	148	140	137
P-R Int (sec)	0.08	0.09	0.09	0.08
QRS Int (sec)	0.04	0.05**	0.05*	0.04
Q-T Int (sec)	0.18	0.17	0.18	0.18
Elec. axis (°)	60	65	62	70
P-wave (sec)	0.05	0.03	0.03	0.03
P-wave (mV)	0.2	0.3	0.3	0.3
Q Amp (mV)	0.4	0.4	0.4	0.5
R Amp (mV)	1.7	2.4*	1.9	2.2
S Amp (mV)	0.1	0.0	0.1	0.0

Study No. 6127-111

Table 19 (Continued)

Summary of Mean Electrocardiograph Measurements

Week 30

	Group 1	Group 2	Group 3	Group 4
Male				
Heart rate	130	130	160	160
P-R Int (sec)	0.08	0.10	0.09	0.08
QRS Int (sec)	0.04	0.05	0.04	0.04
Q-T Int (sec)	0.18	0.18	0.17	0.17
Elec. axis (°)	75	82	75	75
P-wave (sec)	0.03	0.04	0.03	0.03
P-wave (mV)	0.2	0.3	0.2	0.2
Q Amp (mV)	0.2	0.2	0.2	0.3
R Amp (mV)	1.8	2.5	1.5	2.0
S Amp (mV)	0.8	0.0	0.2	0.2
Female				
Heart rate	110	120	130	150
P-R Int (sec)	0.08	0.08	0.08	0.08
QRS Int (sec)	0.04	0.04	0.06	0.04
Q-T Int (sec)	0.20	0.18	0.18	0.16*
Elec. axis (°)	85	90	75	68
P-wave (sec)	0.03	0.04	0.03	0.03
P-wave (mV)	0.3	0.2	0.2	0.2
Q Amp (mV)	0.2	0.5	0.3	0.4
R Amp (mV)	2.3	2.2	2.1	1.8
S Amp (mV)	0.2	0.0	0.2	0.2
Combined				
Heart rate	120	125	145	155*
P-R Int (sec)	0.08	0.09	0.08	0.08
QRS Int (sec)	0.04	0.04	0.05	0.04
Q-T Int (sec)	0.19	0.18	0.18	0.17*
Elec. axis (°)	80	86	75	71
P-wave (sec)	0.03	0.04	0.03	0.03
P-wave (mV)	0.3	0.3	0.2	0.2
Q Amp (mV)	0.2	0.3	0.2	0.3
R Amp (mV)	2.1	2.3	1.8	1.9
S Amp (mV)	0.5	0.0	0.2	0.2

S6127111 DOG POOL M+F Table 20 WEEK: -02

Summary of Hematology Data

DOSE MG/KG		RBC E6/CU MM	HGB G/DL	HCT %	MCV FL	MCH PICO GMS	MCHC %	PLT E3/CU MM	NRBC /100 WBC
0 M									
	N=	6	6	6	6	6	6	6	6
	MEAN	6.30	12.5	44.0	70	19.9	28.4	394	0
	S.D.	.493	.74	2.80	1.5	.69	.54	68.1	.4
0 F									
	N=	6	6	6	6	6	6	6	6
	MEAN	6.28	11.6	42.9	68	18.5	27.1	417	0
	S.D.	.217	.64	2.20	2.4	.71	.36	80.6	.0
M+F									
	N=	12	12	12	12	12	12	12	12
	MEAN M+F	6.29	12.1	43.5	69	19.2	27.8	406	0
	S.D. M+F	.363	.80	2.47	2.0	.98	.81	72.2	.3
250 M									
	N=	6	6	6	6	6	6	6	6
	MEAN	6.58	12.2	43.8	67	18.6	27.9	413	0
	S.D.	.368	.80	2.76	5.4	1.59	.47	72.1	.4
250 F									
	N=	6	6	6	6	6	6	6	6
	MEAN	6.46	11.8	43.4	67	18.3	27.2	326	0
	S.D.	.263	.80	3.09	4.1	1.01	.48	51.4	.0
M+F									
	N=	12	12	12	12	12	12	12	12
	MEAN M+F	6.52	12.0	43.6	67	18.5	27.6	369	0
	S.D. M+F	.312	.79	2.80	4.5	1.28	.58	75.2	.3
500 M									
	N=	6	6	6	6	6	6	6	6
	MEAN	6.43	12.1	44.5	70	18.9	27.2 **	350	0
	S.D.	.402	.43	1.83	1.6	.80	.60	58.1	.5
500 F									
	N=	6	6	6	6	6	6	6	6
	MEAN	6.34	12.0	43.9	69	18.9	27.4	433	0
	S.D.	.462	.91	3.68	3.4	1.35	1.26	59.3	.0
M+F									
	N=	12	12	12	12	12	12	12	12
	MEAN M+F	6.38	12.0	44.2	69	18.9	27.3	392	0
	S.D. M+F	.416	.68	2.79	2.5	1.06	.94	70.8	.4
1000 M									
	N=	6	6	6	6	6	6	6	6
	MEAN	6.44	12.1	43.1	67	18.8	28.1	402	0
	S.D.	.277	.54	1.90	3.4	.94	.60	38.6	.0
1000 F									
	N=	6	6	6	6	6	6	6	6
	MEAN	6.48	12.0	43.5	67	18.5	27.6	396	0
	S.D.	.151	.85	3.27	3.8	.95	.42	106.6	.0
M+F									
	N=	12	12	12	12	12	12	12	12
	MEAN M+F	6.46	12.0	43.3	67	18.6	27.8	399	0
	S.D. M+F	.213	.68	2.56	3.4	.92	.56	76.5	.0

Table 20 (Continued)

S6127111 DOG POOL M+F WEEK: -02

Summary of Hematology Data

DOSE MG/KG		WBC E3/CU MM	N-SEG E3/CU MM	L E3/CU MM	M E3/CU MM	E E3/CU MM	B E3/CU MM	N-SEG %	L %	M %	E %	B %	BANDS-N %
0 M													
	N=	6	6	6	6	6	6	6	6	6	6	6	6
	MEAN	7.6	3.58	3.45	.39	.21	.00	47	45	6	3	0	0
	S.D.	1.39	.815	1.155	.168	.033	.000	7.2	7.9	2.8	.4	.0	.0
0 F													
	N=	6	6	6	6	6	6	6	6	6	6	6	6
	MEAN	8.7	5.53	2.66	.31	.21	.00	63	31	4	2	0	0
	S.D.	1.42	1.427	.429	.165	.242	.000	6.9	5.4	2.2	2.9	.0	.0
M+F													
	N=	12	12	12	12	12	12	12	12	12	12	12	12
	MEAN M+F	8.2	4.55	3.06	.35	.21	.00	55	38	4	2	0	0
	S.D. M+F	1.45	1.508	.929	.165	.165	.000	10.7	9.6	2.6	2.0	.0	.0
250 M													
	N=	6	6	6	6	6	6	6	6	6	6	6	6
	MEAN	9.2	5.50	3.30	.30	.16	.00	59	36	3	2	0	0
	S.D.	1.52	1.255	.854	.166	.063	.000	7.8	7.7	1.6	.5	.0	.0
250 F													
	N=	6	6	6	6	6	6	6	6	6	6	6	6
	MEAN	7.8	4.75	2.61	.25	.15	.01	62	32	3	2	0	0
	S.D.	1.38	.682	1.090	.109	.092	.028	9.5	11.2	1.4	1.1	.4	.0
M+F													
	N=	12	12	12	12	12	12	12	12	12	12	12	12
	MEAN M+F	8.5	5.12	2.96	.28	.15	.00	61	34	3	2	0	0
	S.D. M+F	1.58	1.039	1.000	.136	.075	.020	8.4	9.3	1.4	.8	.3	.0
500 M													
	N=	6	6	6	6	6	6	6	6	6	6	6	6
	MEAN	7.5	3.89	2.97	.24	.33	.04	52	40	3	4	0	0
	S.D.	1.05	1.016	.808	.108	.137	.061	10.6	9.6	1.5	1.5	.8	.0
500 F													
	N=	6	6	6	6	6	6	6	6	6	6	6	6
	MEAN	6.6	3.61 *	2.69	.19	.13	.00	55	40	3	2	0	0
	S.D.	.91	.469	.744	.062	.108	.000	6.8	6.6	1.0	1.7	.0	.0
M+F													
	N=	12	12	12	12	12	12	12	12	12	12	12	12
	MEAN M+F	7.0	3.75	2.83	.21	.23	.02	54	40	3	3	0	0
	S.D. M+F	1.04	.768	.755	.088	.159	.046	8.6	7.9	1.2	1.9	.6	.0
1000 M													
	N=	6	6	6	6	6	6	6	6	6	6	6	6
	MEAN	7.3	4.18	2.47	.28	.35	.00	57	34	4	4	0	0
	S.D.	1.44	1.258	.631	.116	.203	.000	9.4	8.4	1.5	1.9	.0	.0
1000 F													
	N=	6	6	6	6	6	6	6	6	6	6	6	6
	MEAN	7.9	4.79	2.72	.21	.15	.00	61	35	2	2	0	0
	S.D.	1.96	1.440	.791	.217	.137	.000	6.7	7.0	2.2	2.2	.0	.0
M+F													
	N=	12	12	12	12	12	12	12	12	12	12	12	12
	MEAN M+F	7.6	4.49	2.59	.25	.25	.00	59	35	3	3	0	0
	S.D. M+F	1.67	1.328	.695	.171	.196	.000	8.0	7.4	2.0	2.3	.0	.0

Table 20 (Conti)

S6127111 DOG POOL M+F WEEK: -02

Summary of Hematology Data

DOSE MG/KG		BANDS-N E3/CU MM	PT SEC	PTT SEC
0 M				
	N=	6	6	6
	MEAN	.00	8.4	10.8
	S.D.	.000	3.00	.63
0 F				
	N=	6	6	6
	MEAN	.00	6.6	11.3
	S.D.	.000	.39	.66
M+F				
	N=	12	12	12
	MEAN M+F	.00	7.4	11.0
	S.D. M+F	.000	2.25	.67
250 M				
	N=	6	6	6
	MEAN	.00	7.4	11.9
	S.D.	.000	1.97	2.21
250 F				
	N=	6	6	6
	MEAN	.00	8.6	11.7
	S.D.	.000	3.27	.99
M+F				
	N=	12	12	12
	MEAN M+F	.00	8.0	11.8
	S.D. M+F	.000	2.64	1.63
500 M				
	N=	6	6	6
	MEAN	.00	8.2	12.4
	S.D.	.000	2.32	1.13
500 F				
	N=	6	6	6
	MEAN	.00	7.3	11.4
	S.D.	.000	1.54	.71
M+F				
	N=	12	12	12
	MEAN M+F	.00	7.7	11.9
	S.D. M+F	.000	1.93	1.05
1000 M				
	N=	6	6	6
	MEAN	.00	6.8	11.6
	S.D.	.000	1.18	.59
1000 F				
	N=	6	6	6
	MEAN	.00	6.4	11.4
	S.D.	.000	.45	1.48
M+F				
	N=	12	12	12
	MEAN M+F	.00	6.6	11.5
	S.D. M+F	.000	.88	1.08

Table 21

S6127111 DOG POOL M+F WEEK: 008

Summary of Hematology Data

DOSE MG/KG		RBC E6/CU MM	HGB G/DL	HCT %	MCV FL	MCH PICO GMS	MCHC %	PLT E3/CU MM	NRBC /100 WBC
0 M									
	N=	6	6	6	6	6	6	6	6
	MEAN	6.90	13.2	45.3	66	19.1	29.0	398	0
	S.D.	.339	.51	1.91	2.8	.55	.76	65.3	.0
0F									
	N=	6	6	6	6	6	6	6	6
	MEAN	7.46	13.3	46.8	63	17.8	28.4	346	0
	S.D.	.360	.63	2.88	2.6	.69	.64	96.5	.5
M+F									
	N=	12	12	12	12	12	12	12	12
	MEAN M+F	7.18	13.2	46.0	64	18.5	28.7	372	0
	S.D. M+F	.447	.55	2.45	3.0	.89	.73	83.1	.4
250 M									
	N=	6	6	6	6	6	6	6	6
	MEAN	7.10	12.8	43.7	62	18.0	29.3	360	0
	S.D.	.334	.86	3.32	4.3	1.12	.32	52.5	.0
250 F									
	N=	6	6	6	6	6	6	6	6
	MEAN	7.81	13.9	48.2	62	17.9	28.9	272	0
	S.D.	.665	.67	3.63	5.5	1.29	.96	63.8	.4
M+F									
	N=	12	12	12	12	12	12	12	12
	MEAN M+F	7.45	13.4	46.0	62	18.0	29.1	316	0
	S.D. M+F	.624	.92	4.04	4.7	1.15	.72	72.1	.3
500 M									
	N=	6	6	6	6	6	6	6	6
	MEAN	7.08	12.8	45.2	64	18.2	28.4	324	0
	S.D.	.392	.63	1.66	2.2	.31	.76	56.2	.8
500 F									
	N=	6	6	6	6	6	6	6	6
	MEAN	7.23	13.3	46.0	64	18.4	28.8	367	0
	S.D.	.423	.35	1.89	3.5	1.01	.68	52.8	.0
M+F									
	N=	12	12	12	12	12	12	12	12
	MEAN M+F	7.16	13.0	45.6	64	18.3	28.6	345	0
	S.D. M+F	.396	.53	1.74	2.8	.72	.72	56.6	.6
1000 M									
	N=	6	6	6	6	6	6	6	6
	MEAN	6.78	12.2	42.4	63	18.1	28.9	374	0
	S.D.	.492	.85	2.59	2.7	.63	.36	61.7	.4
1000 F									
	N=	6	6	6	6	6	6	6	6
	MEAN	7.69	13.6	47.6	62	17.7	28.5	342	0
	S.D.	.411	.63	2.88	2.4	.63	.48	53.0	.4
M+F									
	N=	12	12	12	12	12	12	12	12
	MEAN M+F	7.23	12.9	45.0	62	17.9	28.7	358	0
	S.D. M+F	.644	1.00	3.77	2.5	.64	.44	57.4	.4

Table 21 (Contin.

96127111 DOG POOL M+F WEEK: 008

Summary of Hematology Data

DOSE MG/KG		WBC E3/CU MM	N-SEG E3/CU MM	L E3/CU MM	M E3/CU MM	E E3/CU MM	B E3/CU MM	N-SEG %	L %	M %	E %	B %	BANDS-N %
0 M													
	N=	6	6	6	6	6	6	6	6	6	6	6	6
	MEAN	7.6	3.95	3.22	.22	.17	.00	52	42	3	2	0	0
	S.D.	1.24	.694	.858	.117	.133	.000	6.9	6.6	1.3	2.0	.0	.0
0 F													
	N=	6	6	6	6	6	6	6	6	6	6	6	6
	MEAN	8.2	3.85	3.90	.19	.24	.00	47	48	2	3	0	0
	S.D.	.85	.621	.504	.154	.190	.000	5.3	5.4	1.9	2.1	.0	.0
M+F													
	N=	12	12	12	12	12	12	12	12	12	12	12	12
	MEAN M+F	7.9	3.90	3.56	.20	.20	.00	50	45	2	2	0	0
	S.D. M+F	1.06	.630	.760	.131	.160	.000	6.6	6.4	1.6	2.0	.0	.0
250 M													
	N=	6	6	6	6	6	6	6	6	6	6	6	6
	MEAN	9.2	5.48	3.27	.16	.28	.00	59	36	2	3	0	0
	S.D.	1.34	1.256	.428	.169	.214	.000	6.2	6.4	1.9	2.0	.0	.4
250 F													
	N=	6	6	6	6	6	6	6	6	6	6	6	6
	MEAN	7.6	4.03	3.12	.16	.23	.00	54	40	2	3	0	0
	S.D.	1.07	.477	1.084	.090	.133	.000	9.4	9.1	1.2	1.8	.0	.0
M+F													
	N=	12	12	12	12	12	12	12	12	12	12	12	12
	MEAN M+F	8.4	4.76	3.19	.16	.26	.00	57	38	2	3	0	0
	S.D. M+F	1.44	1.181	.789	.129	.172	.000	8.0	7.9	1.5	1.8	.0	.3
500 M													
	N=	6	6	6	6	6	6	6	6	6	6	6	6
	MEAN	8.4	4.99	2.91	.17	.32	.00	59	36	2	4	0	0
	S.D.	2.13	1.582	.535	.143	.285	.000	5.3	6.5	1.7	2.3	.0	.0
500 F													
	N=	6	6	6	6	6	6	6	6	6	6	6	6
	MEAN	7.2	3.84	3.01	.22	.15	.00	53	42	3	2	0	0
	S.D.	.90	.880	.848	.129	.115	.000	10.2	9.0	1.5	1.7	.0	.0
M+F													
	N=	12	12	12	12	12	12	12	12	12	12	12	12
	MEAN M+F	7.8	4.41	2.96	.19	.24	.00	56	38	2	3	0	0
	S.D. M+F	1.68	1.362	.678	.133	.227	.000	8.2	8.1	1.6	2.1	.0	.0
1000 M													
	N=	6	6	6	6	6	6	6	6	6	6	6	6
	MEAN	7.4	3.92	2.82	.29	.32	.00	53	38	4	4	0	0
	S.D.	1.19	.727	1.035	.159	.255	.000	7.2	10.6	2.0	3.1	.0	.4
1000 F													
	N=	6	6	6	6	6	6	6	6	6	6	6	6
	MEAN	9.2	5.44	3.24	.26	.26	.00	59	36	3	2	0	0
	S.D.	2.36	1.801	.930	.054	.239	.000	8.1	8.4	.9	1.9	.0	.0
M+F													
	N=	12	12	12	12	12	12	12	12	12	12	12	12
	MEAN M+F	8.3	4.68	3.03	.28	.29	.00	56	37	4	4	0	0
	S.D. M+F	2.02	1.531	.963	.114	.238	.000	7.8	9.2	1.6	2.7	.0	.3

Table 21 (Continued)

S6127111 DOG POOL M+F WEEK: 008

Summary of Hematology Data

DOSE MG/KG		BANDS-N E3/CU MM	PT SEC	PTT SEC
0 M				
	N=	6	6	6
	MEAN	.00	8.2	10.6
	S.D.	.000	3.04	.69
0 F				
	N=	6	6	6
	MEAN	.00	6.3	11.4
	S.D.	.000	.66	1.20
M+F				
	N=	12	12	12
	MEAN M+F	.00	7.3	11.0
	S.D. M+F	.000	2.33	1.02
250 M				
	N=	6	6	6
	MEAN	.02	7.3	11.0
	S.D.	.037	1.91	.49
250 F				
	N=	6	6	6
	MEAN	.00	7.9	11.8
	S.D.	.000	2.39	.38
M+F				
	N=	12	12	12
	MEAN M+F	.01	7.2	11.4
	S.D. M+F	.026	2.07	.60
500 M				
	N=	6	6	6
	MEAN	.00	6.1	10.6
	S.D.	.000	.41	.47
500 F				
	N=	6	6	6
	MEAN	.00	7.4	11.6
	S.D.	.000	2.95	.27
M+F				
	N=	12	12	12
	MEAN M+F	.00	6.7	11.1
	S.D. M+F	.000	2.12	.66
1000 M				
	N=	6	6	6
	MEAN	.01	6.3	11.2
	S.D.	.028	.38	.41
1000 F				
	N=	6	6	6
	MEAN	.00	6.1	10.8
	S.D.	.000	.26	.66
M+F				
	N=	12	12	12
	MEAN M+F	.00	6.2	11.0
	S.D. M+F	.020	.33	.57

Table 22

S6127111 DOG POOL M+F WEEK: 017

Summary of Hematology Data

DOSE MG/KG		RBC E6/CU MM	HGB G/DL	HCT %	MCV FL	MCH PICO GMS	MCHC %	PLT E3/CU MM	NRBC /100 WBC
0 M									
	N=	6	6	6	6	6	6	6	6
	MEAN	7.29	13.2	45.6	62	18.0	28.9	381	0
	S.D.	.513	.71	2.92	3.1	.60	.69	52.9	.0
0 F									
	N=	6	6	6	6	6	6	6	6
	MEAN	8.06	13.5	48.5	60	16.7	27.8	394	0
	S.D.	.329	.33	.95	1.8	.47	.35	63.4	.0
M+F									
	N=	12	12	12	12	12	12	12	12
	MEAN M+F	7.68	13.3	47.0	61	17.4	28.4	388	0
	S.D. M+F	.574	.55	2.55	2.7	.86	.78	56.0	.0
250 M									
	N=	6	6	6	6	6	6	6	6
	MEAN	7.92	13.7	46.7	59	17.4	29.4	374	0
	S.D.	.272	.60	2.25	3.0	.81	.50	43.1	.0
250 F									
	N=	6	6	6	6	6	6	6	6
	MEAN	8.03	13.7	48.7	61	17.0	28.1	315	0
	S.D.	.603	.94	3.12	3.2	.79	.84	48.2	.0
M+F									
	N=	12	12	12	12	12	12	12	12
	MEAN M+F	7.97	13.7	47.7	60	17.2	28.8	344	0
	S.D. M+F	.450	.75	2.79	3.1	.78	.96	53.4	.0
500M									
	N=	6	6	6	6	6	6	6	6
	MEAN	7.63	13.4	46.8	62	17.6	28.7	338	0
	S.D.	.488	.70	2.50	1.5	.28	.78	22.2	.0
500F									
	N=	6	6	6	6	6	6	6	6
	MEAN	7.78	13.4	48.1	62	17.2	27.8	415	0
	S.D.	.484	.76	2.76	2.2	.54	.68	32.4	.0
M+F									
	N=	12	12	12	12	12	12	12	12
	MEAN M+F	7.70	13.4	47.5	62	17.4	28.2	376	0
	S.D. M+F	.470	.70	2.59	1.8	.47	.83	48.3	.0
1000 M									
	N=	6	6	6	6	6	6	6	6
	MEAN	7.54	13.0	44.8	59	17.3	29.1	369	0
	S.D.	.442	.66	1.93	2.1	.50	.36	49.9	.0
1000 F									
	N=	6	6	6	6	6	6	6	6
	MEAN	8.07	13.4	47.5	59	16.6	28.2	421	0
	S.D.	.517	.77	3.14	1.2	.40	.43	74.2	.4
M+F									
	N=	12	12	12	12	12	12	12	12
	MEAN M+F	7.80	13.2	46.1	59	17.0	28.6	395	0
	S.D. M+F	.534	.72	2.86	1.6	.54	.57	66.2	.3

Table 22 (Continued)

86127111 DOG POOL M+F WEEK: 017

Summary of Hematology Data

DOSE MG/KG		WBC E3/CU MM	N-SEG E3/CU MM	L E3/CU MM	M E3/CU MM	E E3/CU MM	B E3/CU MM	N-SEG %	L %	M %	E %	B %	BANDS-N %
0 M													
N=		6	6	6	6	6	6	6	6	6	6	6	6
MEAN		8.6	5.66	2.18	.40	.35	.00	64	27	5	4	0	0
S.D.		3.63	3.296	.742	.210	.126	.000	12.8	10.2	1.4	2.2	.0	.0
0 F													
N=		6	6	6	6	6	6	6	6	6	6	6	6
MEAN		8.6	5.69	2.36	.42	.14	.00	66	28	5	2	0	0
S.D.		.93	.969	.598	.170	.203	.000	6.4	7.7	1.5	2.2	.0	.0
M+F													
N=		12	12	12	12	12	12	12	12	12	12	12	12
MEAN	M+F	8.6	5.68	2.27	.41	.25	.00	65	27	5	3	0	0
S.D.	M+F	2.53	2.316	.649	.182	.193	.000	9.7	8.6	1.4	2.6	.0	.0
250 M													
N=		6	6	6	6	6	6	6	6	6 *	6	6	6
MEAN		8.9	5.72	2.56	.19	.45	.00	64	29	2	5	0	0
S.D.		.71	.937	.646	.107	.247	.000	7.0	7.3	1.3	2.6	.0	.0
250 F													
N=		6	6	6	6 *	6	6	6	6	6	6	6	6
MEAN		7.3 *	4.94	1.92	.23	.17	.00	68	26	3	2	0	0
S.D.		.42	.422	.362	.108	.092	.000	5.6	4.2	1.6	1.2	.0	.5
M+F													
N=		12	12	12	12	12	12	12	12	12	12	12	12
MEAN	M+F	8.1	5.33	2.24	.21 **	.31	.00	66	28	3 **	4	0	0
S.D.	M+F	1.02	.806	.598	.105	.228	.000	6.3	5.8	1.5	2.4	.0	.4
500 M													
N=		6	6	6	6	6	6	6	6	6 *	6	6	6
MEAN		8.2	5.43	2.12	.22	.45	.00	65	27	3	5	0	0
S.D.		1.74	1.595	.438	.115	.319	.000	7.3	7.9	1.5	3.4	.0	.4
500 F													
N=		6	6	6	6 *	6	6	6	6	6 *	6	6	6
MEAN		8.0	5.37	2.17	.21	.21	.00	67	28	2	3	0	0
S.D.		1.41	1.463	.732	.112	.160	.000	8.5	9.6	1.0	2.1	.0	.4
M+F													
N=		12	12	12	12 **	12	12	12	12	12 **	12	12	12
MEAN	M+F	8.1	5.40	2.15	.21	.33	.00	66	27	2	4	0	0
S.D.	M+F	1.51	1.460	.576	.108	.271	.000	7.6	8.4	1.2	3.0	.0	.4
1000 M													
N=		6	6	6	6	6	6	6	6	6	6	6	6
MEAN		7.6	4.75	2.26	.28	.34	.00	61	30	4	5	0	0
S.D.		1.80	1.623	.798	.103	.144	.000	11.6	10.6	1.0	2.2	.0	.4
1000 F													
N=		6	6	6	6	6	6	6	6	6 *	6	6	6
MEAN		10.6	7.10	2.94	.25	.25	.00	68	27	2	3	0	0
S.D.		2.83	1.975	2.123	.126	.259	.000	11.1	12.5	1.5	3.3	.0	.4
M+F													
N=		12	12	12	12 *	12	12	12	12	12 *	12	12	12
MEAN	M+F	9.1	5.93	2.60	.26	.30	.00	65	28	3	4	0	0
S.D.	M+F	2.73	2.116	1.570	.110	.206	.000	11.4	11.2	1.4	2.9	.0	.4

Summary of Hematology Data

DOSE MG/KG		BANDS-N E3/CU MM	PT SEC	PTT SEC
0 M				
	N=	6	6	6
	MEAN	.00	7.9	10.4
	S.D.	.000	2.55	.73
0 F				
	N=	6	6	6
	MEAN	.00	6.3	9.1
	S.D.	.000	.38	.47
M+F				
	N=	12	12	12
	MEAN M+F	.00	7.1	9.8
	S.D. M+F	.000	1.92	.91
250 M				
	N=	6	6	6
	MEAN	.00	7.1	10.9
	S.D.	.000	1.89	.36
250 F				
	N=	6	6	6
	MEAN	.02	7.2	10.2 **
	S.D.	.039	2.04	.88
M+F				
	N=	12	12	12
	MEAN M+F	.01	7.2	10.6 *
	S.D. M+F	.029	1.88	.74
500 M				
	N=	6	6	6
	MEAN	.01	6.2	10.1
	S.D.	.028	.52	.52
500 F				
	N=	6	6	6
	MEAN	.01	6.7	9.6
	S.D.	.028	2.04	.26
M+F				
	N=	12	12	12
	MEAN M+F	.01	6.5	9.8
	S.D. M+F	.027	1.44	.47
1000 M				
	N=	6	6	6
	MEAN	.02	6.3	9.4 *
	S.D.	.045	.38	.71
1000 F				
	N=	6	6	6 *
	MEAN	.02	6.1	10.0
	S.D.	.053	.24	.38
M+F				
	N=	12	12	12
	MEAN M+F	.02	6.2	9.7
	S.D. M+F	.047	.32	.62

Table 23

S6127111 DOG POOL M+F WEEK: 026

Summary of Hematology Data

DOSE MG/KG		RBC E6/CU MM	HGB G/DL	HCT %	MCV FL	MCH PICO GMS	MCHC %	PLT E3/CU MM	NRBC /100 WBC
0 M									
	N=	6	6	6	6	6	6	6	6
	MEAN	8.34	15.2	48.2	58	18.3	31.7	411	0
	S.D.	.478	.63	2.02	2.0	.81	1.05	74.0	.0
0 F									
	N=	6	6	6	6	6	6	6	6
	MEAN	8.90	15.2	51.0	58	17.1	29.8	434	0
	S.D.	.589	.86	2.69	2.4	.76	.38	43.1	.4
M+F									
	N=	12	12	12	12	12	12	12	12
	MEAN M+F	8.62	15.2	49.6	58	17.7	30.7	422	0
	S.D. M+F	.587	.72	2.69	2.1	.98	1.25	58.9	.3
250 M									
	N=	6	6	6	6	6	6	6	6
	MEAN	8.91	15.8	49.3	55	17.7	32.0	373	0
	S.D.	.350	.39	1.55	2.1	.61	.46	38.2	.4
250 F									
	N=	6	6	6	6	6	6	6	6
	MEAN	9.29	16.0	54.2	58	17.2	29.4	365	0
	S.D.	.792	1.00	3.23	2.4	.91	.88	61.1	.0
M+F									
	N=	12	12	12	12	12	12	12	12
	MEAN M+F	9.10	15.9	51.7	57	17.5	30.7	369	0
	S.D. M+F	.616	.73	3.51	2.6	.78	1.51	48.8	.3
500 M									
	N=	6	6	6	6	6	6	6	6
	MEAN	8.53	15.0	49.0	58	17.5	30.5	362	0
	S.D.	.588	1.03	3.40	2.4	.46	1.19	43.5	.0
500 F									
	N=	6	6	6	6	6	6	6	6
	MEAN	8.38	14.9	49.2	59	17.8	30.2	418	0
	S.D.	.666	1.03	3.27	3.3	.56	.83	52.2	.5
M+F									
	N=	12	12	12	12	12	12	12	12
	MEAN M+F	8.46	14.9	49.1	58	17.6	30.4	390	0
	S.D. M+F	.604	.98	3.18	2.9	.50	.99	54.4	.4
1000 M									
	N=	6	6	6	6	6	6	6	6
	MEAN	8.54	14.9	47.8	56	17.4	31.1	406	0
	S.D.	.470	.89	2.93	2.8	.91	.71	64.0	.0
1000 F									
	N=	6	6	6	6	6	6	6	6
	MEAN	8.74	14.8	49.6	57	17.0	29.8	417	0
	S.D.	.303	.44	1.69	1.8	.43	.71	45.6	.4
M+F									
	N=	12	12	12	12	12	12	12	12
	MEAN M+F	8.64	14.8	48.7	56	17.2	30.4	411	0
	S.D. M+F	.390	.67	2.45	2.3	.72	.94	53.3	.3

Summary of Hematology Data

DOSE MG/KG		WBC E3/CU MM	N-SEG E3/CU MM	L E3/CU MM	M E3/CU MM	E E3/CU MM	B E3/CU MM	N-SEG %	L %	M %	E %	B %	BANDS-N %
0 M													
	N=	6	6	6	6	6	6	6	6	6	6	6	6
	MEAN	7.4	5.03	1.94	.37	.07	.00	68	26	5	1	0	0
	S.D.	1.58	1.351	.472	.194	.082	.000	5.0	5.8	2.8	1.3	.0	.0
0 F													
	N=	6	6	6	6	6	6	6	6	6	6	6	6
	MEAN	8.4	5.89	1.86	.50	.18	.00	70	22	6	2	0	0
	S.D.	1.06	1.035	.259	.139	.162	.000	4.4	5.0	1.2	1.8	.0	.0
M+F													
	N=	12	12	12	12	12	12	12	12	12	12	12	12
	MEAN M+F	7.9	5.46	1.90	.43	.12	.00	68	24	5	2	0	0
	S.D. M+F	1.39	1.232	.366	.174	.135	.000	4.7	5.5	2.1	1.6	.0	.0
250 M													
	N=	6	6	6	6	6	6	6	6	6	6	6	6
	MEAN	8.1	5.96	1.51	.38	.23	.00	74	19	5	3	0	0
	S.D.	1.24	1.066	.477	.236	.118	.000	4.3	5.0	3.0	1.5	.0	.0
250 F													
	N=	6	6	6	6	6	6	6	6	6	6	6	6
	MEAN	7.0	4.90	1.70	.26 *	.18	.00	69	24	4	2	0	0
	S.D.	.80	.936	.532	.157	.217	.000	6.9	8.5	2.2	2.9	.0	.0
M+F													
	N=	12	12	12	12	12	12	12	12	12	12	12	12
	MEAN M+F	7.6	5.44	1.60	.32	.20	.00	72	22	4	3	0	0
	S.D. M+F	1.14	1.105	.491	.202	.169	.000	5.9	7.3	2.6	2.2	.0	.0
500 M													
	N=	6	6	6	6	6	6	6	6	6	6	6	6
	MEAN	8.6	6.31	1.78	.26	.24	.00	73	21	3	3	0	0
	S.D.	2.04	1.619	.253	.130	.203	.000	2.5	3.1	.9	1.6	.0	.0
500 F													
	N=	6	6	6	6	6	6	6	6	6	6	6	6
	MEAN	7.0	4.85	1.78	.22 *	.18	.00	69	26	3	2	0	0
	S.D.	.93	.897	.174	.137	.083	.000	4.3	3.8	1.9	1.2	.0	.0
M+F													
	N=	12	12	12	12	12	12	12	12	12	12	12	12
	MEAN M+F	7.8	5.58	1.78	.24 *	.21	.00	71	23	3	2	0	0
	S.D. M+F	1.72	1.462	.207	.129	.151	.000	4.1	4.8	1.4	1.4	.0	.0
1000 M													
	N=	6	6	6	6	6	6	6	6	6	6	6	6
	MEAN	7.1	5.19	1.41	.26	.25	.00	73	20	4	4	0	0
	S.D.	.42	.843	.428	.196	.139	.000	9.1	6.6	2.9	1.9	.0	.0
1000 F													
	N=	6	6	6	6	6	6	6	6	6	6	6	6
	MEAN	7.8	5.18	2.16	.23 *	.25	.00	67	27	3	3	0	0
	S.D.	1.07	.676	.937	.172	.234	.000	8.5	8.5	2.5	2.6	.0	.0
M+F													
	N=	12	12	12	12	12	12	12	12	12	12	12	12
	MEAN M+F	7.5	5.18	1.78	.25 *	.25	.00	70	24	3	3	0	0
	S.D. M+F	.86	.728	.797	.177	.184	.000	8.9	8.1	2.6	2.2	.0	.0

Table 23 (Continued)

S6127111 DOG POOL M+F WEEK: 026

Summary of Hematology Data

DOSE MG/KG		BANDS-N E3/CU MM	PT SEC	PTT SEC
0 M				
	N=	6	6	6
	MEAN	.00	7.6	10.3
	S.D.	.000	2.52	.56
0 F				
	N=	6	6	6
	MEAN	.00	6.5	11.8
	S.D.	.000	.20	.37
M+F				
	N=	12	12	12
	MEAN M+F	.00	7.1	11.0
	S.D. M+F	.000	1.81	.91
250 M				
	N=	6	6	6
	MEAN	.00	7.2	11.8
	S.D.	.000	1.84	1.19
250 F				
	N=	6	6	6
	MEAN	.00	7.2	12.8
	S.D.	.000	2.06	1.24
M+F				
	N=	12	12	12
	MEAN M+F	.00	7.2	12.3
	S.D. M+F	.000	1.86	1.28
500 M				
	N=	6	6	6
	MEAN	.00	6.7	12.2
	S.D.	.000	.41	1.74
500 F				
	N=	6	6	6
	MEAN	.00	7.0	11.6
	S.D.	.000	1.90	.41
M+F				
	N=	12	12	12
	MEAN M+F	.00	6.9	11.9
	S.D. M+F	.000	1.32	1.25
1000 M				
	N=	6	6	6
	MEAN	.00	6.5	11.3 **
	S.D.	.000	.49	.38
1000 F				
	N=	6	6	6
	MEAN	.00	6.4	11.7
	S.D.	.000	.32	.41
M+F				
	N=	12	12	12
	MEAN M+F	.00	6.4	11.5
	S.D. M+F	.000	.40	.43

Table 24

S6127111 DOG POOL M+F WEEK: 031

Summary of Hematology Data

DOSE MG/KG		RBC E6/CU MM	HGB G/DL	HCT %	MCV FL	MCH PICO GMS	MCHC %	PLT E3/CU MM	NRBC /100 WBC
0 M									
	N=	2	2	2	2	2	2	2	2
	MEAN	6.08	14.3	43.4	71	23.6	33.1	398	0
	S.D.	.389	.78	2.90	.0	.21	.42	46.0	.0
0 F									
	N=	2	2	2	2	2	2	2	2
	MEAN	6.70	15.5	47.0	70	23.1	33.0	419	0
	S.D.	.389	1.27	3.18	.7	.56	.49	52.3	.0
M+F									
	N=	4	4	4	4	4	4	4	4
	MEAN M+F	6.39	14.9	45.2	71	23.4	33.0	409	0
	S.D. M+F	.483	1.09	3.28	.5	.47	.39	41.9	.0
250 M									
	N=	2	2	2	2	2	2	2	2
	MEAN	6.72	15.2	46.0	68	22.5	32.9	334	0
	S.D.	.170	.35	1.20	3.5	1.06	.14	23.3	.0
250 F									
	N=	2	2	2	2	2	2	2	2
	MEAN	6.24	14.3	43.8	70	23.0	32.8	294	0
	S.D.	.410	.78	.78	3.5	.28	1.20	39.6	.0
M+F									
	N=	4	4	4	4	4	4	4	4
	MEAN M+F	6.48	14.8	45.0	70	22.8	32.8	314 **	0
	S.D. M+F	.377	.68	1.52	3.1	.68	.70	35.0	.0
500 M									
	N=	2	2	2	2	2	2	2	2
	MEAN	6.64	15.4	47.3	72	23.2	32.5	307	0
	S.D.	.092	.14	.21	.7	.56	.42	26.9	.0
500 F									
	N=	2	2	2	2	2	2	2	2
	MEAN	6.09	14.6	43.9	72	24.0	33.3	368	0
	S.D.	.339	.00	1.27	2.1	1.34	.99	42.4	.0
M+F									
	N=	4	4	4	4	4	4	4	4
	MEAN M+F	6.36	15.0	45.6	72	23.6	32.9	338 *	0
	S.D. M+F	.374	.47	2.13	1.4	.97	.77	45.6	.0
1000M									
	N=	2	2	2	2	2	2	2	2
	MEAN	6.28	15.0	44.2	70	23.9	33.9	342	0
	S.D.	.163	.28	.64	.7	.14	.14	2.1	.0
1000F									
	N=	2	2	2	2	2	2	2	2
	MEAN	6.94	15.6	48.0	70	22.5	32.6	364	0
	S.D.	.389	.92	3.25	.7	.07	.28	.7	.0
M+F									
	N=	4	4	4	4	4	4	4	4
	MEAN M+F	6.62	15.3	46.1	70	23.2	33.2	353	0
	S.D. M+F	.452	.67	2.89	.8	.78	.77	13.3	.0

Table 24 (Continued)

S6127111 DOG POOL M+F WEEK: 031

Summary of Hematology Data

DOSE MG/KG		WBC E3/CU MM	N-SEG E3/CU MM	L E3/CU MM	M E3/CU MM	E E3/CU MM	B E3/CU MM	N-SEG %	L %	M %	E %	B %	BANDS-N %
0 M													
	N=	2	2	2	2	2	2	2	2	2	2	2	2
	MEAN	9.0	5.52	2.72	.30	.40	.00	62	30	4	4	0	0
	S.D.	1.06	.156	.954	.156	.106	.000	5.6	7.1	2.1	.7	.0	.0
0 F													
	N=	2	2	2	2	2	2	2	2	2	2	2	2
	MEAN	11.2	7.52	2.84	.54	.30	.00	67	26	4	2	0	0
	S.D.	1.84	1.393	.318	.481	.283	.000	1.4	7.1	3.5	2.1	.0	.0
M+F													
	N=	4	4	4	4	4	4	4	4	4	4	4	4
	MEAN M+F	10.1	6.52	2.78	.42	.35	.00	64	28	4	4	0	0
	S.D. M+F	1.78	1.408	.585	.323	.185	.000	4.4	6.2	2.4	1.7	.0	.0
250 M													
	N=	2	2	2	2	2	2	2	2	2	2	2	2
	MEAN	12.6	8.62 *	3.22	.55	.20	.00	68	26	4	2	0	0
	S.D.	1.27	.601	.587	.212	.283	.000	2.1	2.1	2.1	2.1	.0	.0
250 F													
	N=	2	2	2	2	2	2	2	2	2	2	2	2
	MEAN	8.8	5.64	2.50	.35	.26	.00	64	28	4	3	0	0
	S.D.	.21	.078	.120	.014	.007	.000	.7	.7	.0	.0	.0	.0
M+F													
	N=	4	4	4	4	4	4	4	4	4	4	4	4
	MEAN M+F	10.7	7.13	2.86	.45	.23	.00	66	27	4	2	0	0
	S.D. M+F	2.34	1.750	.545	.168	.168	.000	2.6	2.2	1.2	1.5	.0	.0
500 M													
	N=	2	2	2	2	2	2	2	2	2	2	2	2
	MEAN	9.3	6.36	2.14	.37	.42	.00	68	23	4	4	0	0
	S.D.	1.41	.898	.325	.058	.134	.000	.7	.0	.0	.7	.0	.0
500 F													
	N=	2	2	2	2	2	2	2	2	2	2	2	2
	MEAN	9.2	6.12	2.53	.28	.27	.00	66	28	3	3	0	0
	S.D.	.28	.382	.141	.007	.254	.000	2.1	.7	.0	2.8	.0	.0
M+F													
	N=	4	4	4	4	4	4	4	4	4	4	4	4
	MEAN M+F	9.2	6.24	2.34	.32	.35	.00	68	25	4	4	0	0
	S.D. M+F	.83	.581	.304	.064	.189	.000	1.7	2.6	.6	1.9	.0	.0
1000 M													
	N=	2	2	2	2	2	2	2	2	2	2	2	2
	MEAN	9.4	5.32	3.26	.44	.44	.00	57	34	4	5	0	0
	S.D.	2.33	.792	1.520	.177	.156	.000	5.6	7.8	.7	2.8	.0	.0
1000 F													
	N=	2	2	2	2	2	2	2	2	2	2	2	2
	MEAN	9.2	6.58	2.10	.30	.28	.00	71	22	4	3	0	0
	S.D.	.78	.686	.502	.431	.021	.000	1.4	3.5	4.9	.0	.0	.0
M+F													
	N=	4	4	4	4	4	4	4	4	4	4	4	4
	MEAN M+F	9.4	5.95	2.68	.37	.36	.00	64	28	4	4	0	0
	S.D. M+F	1.42	.944	1.141	.279	.131	.000	8.8	8.0	2.9	2.0	.0	.0

Table 24 (Cont:)

S6127111 DOG POOL M+F WEEK: 031

Summary of Hematology Data

DOSE MG/KG		BANDS-N E3/CU MM	PT SEC	PTT SEC
0 M				
	N=	2	2	2
	MEAN	.00	8.4	10.2
	S.D.	.000	3.54	1.06
0 F				
	N=	2	2	2
	MEAN	.00	6.6	12.1
	S.D.	.000	.35	.28
M+F				
	N=	4	4	4
	MEAN M+F	.00	7.5	11.1
	S.D. M+F	.000	2.29	1.29
250 M				
	N=	2	2	2
	MEAN	.00	8.4	11.3
	S.D.	.000	2.83	.71
250 F				
	N=	2	2	2
	MEAN	.00	6.4	11.4
	S.D.	.000	.00	2.12
M+F				
	N=	4	4	4
	MEAN M+F	.00	7.4	11.3
	S.D. M+F	.000	2.00	1.29
500 M				
	N=	2	2	2
	MEAN	.00	5.9	11.1
	S.D.	.000	.00	.28
500 F				
	N=	2	2	2
	MEAN	.00	6.4	11.8
	S.D.	.000	.00	.78
M+F				
	N=	4	4	4
	MEAN M+F	.00	6.2	11.5
	S.D. M+F	.000	.29	.64
1000 M				
	N=	2	2	2
	MEAN	.00	6.4	10.1
	S.D.	.000	.64	.42
1000 F				
	N=	2	2	2
	MEAN	.00	6.2	10.9
	S.D.	.000	.35	1.41
M+F				
	N=	4	4	4
	MEAN M+F	.00	6.2	10.5
	S.D. M+F	.000	.44	.97

Table 25

S6127111 DOG POOL M+F WEEK: -02

Summary of Clinical Chemistry Data

DOSE MG/KG		GLU MG/DL	T PRO G/DL	ALB G/DL	GLOB G/DL	A/G	T BILI MG/DL	CHOL MG/DL	AST/SGOT IU/L	ALT/SGPT IU/L	ALK PHOS IU/L
0 M											
	N=	6	6	6	6	6	6	6	6	6	6
	MEAN	104.1	5.2	3.2	2.0	1.7	.0	138	20	22	79
	S.D.	4.16	.10	.21	.21	.22	.00	28.0	2.0	3.1	13.5
0 F											
	N=	6	6	6	6	6	6	6	6	6	6
	MEAN	108.2	5.4	3.4	2.0	1.7	.0	108	20	22	85
	S.D.	5.99	.29	.19	.21	.21	.04	12.8	2.3	3.3	18.2
M+F											
	N=	12	12	12	12	12	12	12	12	12	12
	MEAN M+F	106.2	5.2	3.3	2.0	1.7	.0	123	20	22	82
	S.D. M+F	5.36	.24	.21	.20	.20	.03	25.8	2.1	3.0	15.5
250 M											
	N=	6	6	6	6	6	6	6	6	6	6
	MEAN	110.1	5.9 *	3.5 *	2.4 *	1.4	.0	143	20	23	72
	S.D.	4.91	.15	.23	.24	.22	.00	28.0	3.3	2.4	19.7
250 F											
	N=	6	6	6	6	6	6	6	6	6	6
	MEAN	108.7	5.5	3.4	2.1	1.6	.0	132	19	23	73
	S.D.	3.83	.17	.18	.10	.14	.08	22.1	3.1	1.9	18.0
M+F											
	N=	12	12	12	12	12	12	12	12	12	12
	MEAN M+F	109.4	5.7 **	3.4	2.2 *	1.5	.0	138	20	23	73
	S.D. M+F	4.26	.25	.20	.27	.21	.06	24.7	3.1	2.1	18.0
500 M											
	N=	6	6	6	6	6	6	6	6	6	6
	MEAN	108.2	5.2	3.3	2.0	1.7	.0	117	20	22	78
	S.D.	7.36	.34	.17	.34	.30	.12	22.8	2.0	1.8	21.0
500 F											
	N=	6	6	6	6	6	6	6	6	6	6
	MEAN	106.9	5.6	3.5	2.1	1.7	.1	128	20	23	82
	S.D.	4.02	.29	.28	.17	.20	.15	36.8	2.2	1.2	21.3
M+F											
	N=	12	12	12	12	12	12	12	12	12	12
	MEAN M+F	107.6	5.4	3.4	2.0	1.7	.1	123	20	22	80
	S.D. M+F	5.70	.35	.24	.27	.24	.14	29.8	2.0	1.5	20.3
1000 M											
	N=	6	6	6	6	6	6	6	6	6	6
	MEAN	108.8	5.4	3.2	2.2	1.4	.0	142	19	28 **	79
	S.D.	5.56	.29	.12	.35	.24	.00	24.0	1.5	3.5	9.3
1000 F											
	N=	6	6	6	6	6	6	6	6	6	6
	MEAN	109.0	5.4	3.3	2.1	1.6	.1	128	19	22	78
	S.D.	6.70	.13	.16	.16	.19	.10	25.0	1.9	3.3	11.8
M+F											
	N=	12	12	12	12	12	12	12	12	12	12
	MEAN M+F	108.9	5.4	3.2	2.2	1.5	.0	135	19	26	78
	S.D. M+F	5.87	.22	.15	.26	.22	.08	24.4	1.6	4.5	10.1

S6127111 DOG POOL M+F WEEK: -02

Summary of Clinical Chemistry Data

DOSE MG/KG		UN MG/DL	CREAT MG/DL	CA MG/DL	NA MMOL/L	K MMOL/L	CL MMOL/L
0 M							
	N=	6	6	6	6	6	6
	MEAN	10.0	.7	10.8	143	4.7	106
	S.D.	1.03	.10	.36	1.7	.19	.9
0 F							
	N=	6	6	6	6	6	6
	MEAN	10.0	.8	11.0	142	4.7	110
	S.D.	1.49	.08	.25	1.6	.29	2.0
M+F							
	N=	12	12	12	12	12	12
	MEAN M+F	10.0	.8	10.9	143	4.7	108
	S.D. M+F	1.22	.09	.30	1.6	.23	2.7
250 M							
	N=	6	6	6	6	6	6
	MEAN	10.4	.8	10.8	143	4.8	105
	S.D.	1.19	.05	.18	1.2	.20	.9
250 F							
	N=	6	6	6	6	6	6
	MEAN	11.1	.7	11.1	143	4.7	110
	S.D.	3.15	.08	.21	1.4	.24	1.4
M+F							
	N=	12	12	12	12	12	12
	MEAN M+F	10.8	.8	11.0	143	4.8	107
	S.D. M+F	2.30	.07	.24	1.2	.22	2.7
500 M							
	N=	6	6	6	6	6	6
	MEAN	9.9	.7	10.7	143	4.8	106
	S.D.	1.49	.08	.20	1.3	.47	1.0
500 F							
	N=	6	6	6	6	6	6
	MEAN	11.6	.8	11.1	143	4.7	110
	S.D.	2.67	.10	.16	.8	.25	1.2
M+F							
	N=	12	12	12	12	12	12
	MEAN M+F	10.7	.8	10.9	143	4.8	108
	S.D. M+F	2.25	.09	.28	1.0	.36	2.2
1000 M							
	N=	6	6	6	6	6	6
	MEAN	9.5	.8	10.7	143	4.9	106
	S.D.	1.63	.05	.39	1.0	.23	.6
1000 F							
	N=	6	6	6	6	6	6
	MEAN	11.0	.8	10.8	143	4.9	110
	S.D.	1.71	.10	.21	1.0	.31	.8
M+F							
	N=	12	12	12	12	12	12
	MEAN M+F	10.2	.8	10.8	143	4.9	108
	S.D. M+F	1.78	.08	.30	1.0	.26	2.1

Table 26

S6127111 DOG POOL M+F WEEK: 008

Summary of Clinical Chemistry Data

DOSE MG/KG		GLU MG/DL	T PRO G/DL	ALB G/DL	GLOB G/DL	A/G	T BILI MG/DL	CHOL MG/DL	AST/SGOT IU/L	ALT/SGPT IU/L	ALK PHOS IU/L
0 M											
	N=	6	6	6	6	6	6	6	6	6	6
	MEAN	96.7	5.9	3.3	2.6	1.3	.2	119	23	27	50
	S.D.	7.18	.19	.25	.34	.25	.05	17.0	1.9	4.5	10.3
0 F											
	N=	6	6	6	6	6	6	6	6	6	6
	MEAN	100.3	6.0	3.2	2.8	1.2	.2	90	21	25	54
	S.D.	3.48	.60	.31	.43	.16	.12	16.9	2.2	7.4	17.4
M+F											
	N=	12	12	12	12	12	12	12	12	12	12
	MEAN M+F	98.5	6.0	3.3	2.7	1.2	.2	104	22	26	52
	S.D. M+F	5.70	.43	.27	.38	.21	.10	22.0	2.2	6.0	13.8
250 M											
	N=	6	6	6	6	6	6	6	6	6	6
	MEAN	95.2	5.9	3.4	2.6	1.3	.2	118	23	29	48
	S.D.	3.15	.26	.26	.33	.23	.12	24.6	4.5	4.4	15.9
250 F											
	N=	6	6	6	6	6	6	6	6	6	6
	MEAN	100.4	5.6	3.3	2.4 *	1.4 *	.4	99	20	26	45
	S.D.	5.55	.29	.18	.19	.13	.44	13.3	1.7	2.2	11.7
M+F											
	N=	12	12	12	12	12	12	12	12	12	12
	MEAN M+F	97.8	5.8	3.3	2.5	1.4	.3	108	21	27	46
	S.D. M+F	5.10	.30	.22	.28	.19	.33	21.5	3.5	3.9	13.4
500 M											
	N=	6	6	6	6	6	6	6	6	6	6
	MEAN	106.0 **	5.7	3.3	2.4	1.4	.2	106	21	27	48
	S.D.	3.04	.30	.14	.29	.20	.08	9.6	3.2	3.6	13.5
500 F											
	N=	6	6	6	6	6	6	6	6	6	6
	MEAN	95.5	5.8	3.3	2.5	1.4	.2	106	19	24	56
	S.D.	3.51	.33	.25	.28	.18	.08	27.2	2.2	2.2	12.1
M+F											
	N=	12	12	12	12	12	12	12	12	12	12
	MEAN M+F	100.8	5.8	3.3	2.4	1.4	.2	106	20	25	52
	S.D. M+F	6.34	.30	.19	.27	.18	.08	19.4	2.9	3.4	12.9
1000 M											
	N=	6	6	6	6	6	6	6	6	6	6
	MEAN	95.8	5.9	3.2	2.7	1.2	.1	130	19	34	54
	S.D.	4.70	.39	.26	.44	.24	.04	30.7	.8	7.6	6.4
1000 F											
	N=	6	6	6	6	6	6	6	6	6	6
	MEAN	98.6	6.0	3.2	2.8	1.1	.2	119	18 *	26	56
	S.D.	3.50	.17	.19	.22	.15	.05	45.3	1.8	4.2	16.9
M+F											
	N=	12	12	12	12	12	12	12	12 **	12	12
	MEAN M+F	97.2	6.0	3.2	2.8	1.2	.1	125	18	30	55
	S.D. M+F	4.20	.30	.22	.34	.20	.05	37.3	1.6	7.4	12.2

Table 26 (Continued)

86127111 DOG POOL M+F WEEK: 008

Summary of Clinical Chemistry Data

DOSE MG/KG		UN MG/DL	CREAT MG/DL	CA MG/DL	NA MMOL/L	K MMOL/L	CL MMOL/L
0 M							
	N=	6	6	6	6	6	6
	MEAN	11.4	.8	11.2	145	4.6	110
	S.D.	1.04	.08	.26	2.0	.32	1.7
0 F							
	N=	6	6	6	6	6	6
	MEAN	12.2	.9	10.8	146	4.8	110
	S.D.	1.88	.08	.27	1.7	.41	2.3
M+F							
	N=	12	12	12	12	12	12
	MEAN M+F	11.8	.9	11.0	146	4.7	110
	S.D. M+F	1.52	.10	.35	1.8	.37	1.9
250 M							
	N=	6	6	6	6	6	6
	MEAN	11.5	.8	11.2	145	4.8	108
	S.D.	1.04	.08	.25	1.0	.22	1.7
250 F							
	N=	6	6	6	6	6	6
	MEAN	12.0	.9	10.6	145	4.8	109
	S.D.	1.75	.10	.29	1.9	.25	1.4
M+F							
	N=	12	12	12	12	12	12
	MEAN M+F	11.8	.8	10.9	145	4.8	109
	S.D. M+F	1.40	.10	.42	1.5	.22	1.6
500 M							
	N=	6	6	6	6	6	6
	MEAN	12.2	.8	11.2	146	4.6	110
	S.D.	1.78	.10	.25	1.5	.23	2.0
500 F							
	N=	6	6	6	6	6	6
	MEAN	12.4	.9	10.5	146	4.6	110
	S.D.	1.38	.08	.35	1.4	.16	2.1
M+F							
	N=	12	12	12	12	12	12
	MEAN M+F	12.3	.9	10.9	146	4.6	110
	S.D. M+F	1.52	.10	.49	1.4	.19	2.0
1000 M							
	N=	6	6	6	6	6	6
	MEAN	11.8	.8	11.1	145	4.8	110
	S.D.	2.21	.05	.16	.9	.36	1.0
1000 F							
	N=	6	6	6	6	6	6
	MEAN	12.6	1.0	10.5	145	4.8	110
	S.D.	1.10	.05	.16	1.0	.08	1.6
M+F							
	N=	12	12	12	12	12	12
	MEAN M+F	12.2	.9	10.8	145	4.8	110
	S.D. M+F	1.71	.07	.35	.9	.25	1.4

Table 27

S6127111 DOG POOL M+F WEEK: 017

Summary of Clinical Chemistry Data

DOSE MG/KG		GLU MG/DL	T PRO G/DL	ALB G/DL	GLOB G/DL	A/G	T BILI MG/DL	CHOL MG/DL	AST/SGOT IU/L	ALT/SGPT IU/L	ALK PHOS IU/L
0 M											
	N=	6	6	6	6	6	6	6	6	6	6
	MEAN	96.0	6.5	3.5	3.0	1.2	.3	114	22	29	41
	S.D.	4.09	.28	.22	.45	.26	.06	13.9	2.2	3.4	6.0
0 F											
	N=	6	6	6	6	6	6	6	6	6	6
	MEAN	101.8	6.5	3.5	3.0	1.2	.3	96	22	26	40
	S.D.	5.39	.44	.21	.40	.15	.12	14.8	3.2	4.8	11.9
M+F											
	N=	12	12	12	12	12	12	12	12	12	12
	MEAN M+F	98.9	6.5	3.5	3.0	1.2	.3	105	22	28	40
	S.D. M+F	5.47	.35	.21	.41	.20	.09	16.6	2.6	4.2	9.0
250 M											
	N=	6	6	6	6	6	6	6	6	6	6
	MEAN	92.8	6.8	3.6	3.2	1.2	.3	121	22	27	39
	S.D.	5.04	.36	.21	.48	.19	.04	21.9	3.1	3.9	11.3
250 F											
	N=	6	6	6	6 *	6 *	6	6	6	6	6
	MEAN	95.4	6.0	3.6	2.5	1.4	.3	112	20	25	39
	S.D.	5.91	.14	.10	.13	.08	.09	25.8	2.2	1.4	10.5
M+F											
	N=	12	12	12	12	12	12	12	12	12	12
	MEAN M+F	94.1	6.4	3.6	2.8	1.3	.3	116	21	26	39
	S.D. M+F	5.42	.48	.16	.48	.18	.07	23.3	2.6	3.1	10.4
500 M											
	N=	6	6	6	6	6	6	6	6	6	6
	MEAN	98.4	6.3	3.6	2.6	1.4	.2	108	21	26	44
	S.D.	2.20	.08	.19	.22	.20	.12	12.7	1.7	3.5	14.7
500 F											
	N=	6	6	6	6 *	6 *	6	6	6	6	6
	MEAN	98.1	6.0	3.6	2.5	1.4	.2	118	21	28	45
	S.D.	5.96	.33	.24	.20	.18	.05	31.8	5.2	3.3	11.8
M+F											
	N=	12	12	12	12	12 **	12	12	12	12	12
	MEAN M+F	96.2	6.2	3.6	2.6	1.4	.2	113	21	27	45
	S.D. M+F	4.28	.26	.21	.21	.18	.09	23.6	3.7	3.4	12.7
1000 M											
	N=	6	6	6	6	6	6	6	6	6	6
	MEAN	93.6	6.4	3.4	3.0	1.2	.2	125	20	33	50
	S.D.	4.44	.43	.12	.52	.22	.06	27.3	1.4	3.7	5.2
1000 F											
	N=	6	6	6	6	6	6	6	6	6	6
	MEAN	98.1	6.1	3.3	2.8	1.2	.3	123	18	26	46
	S.D.	4.54	.12	.21	.35	.22	.20	30.0	3.2	4.3	13.7
M+F											
	N=	12	12	12	12	12	12	12	12	12	12
	MEAN M+F	95.8	6.2	3.4	2.8	1.2	.2	124	19	30	48
	S.D. M+F	4.89	.34	.18	.44	.22	.15	27.4	2.7	5.3	10.1

Table 27 (Continued)

86127111 DOG POOL M+F WEEK: 017

Summary of Clinical Chemistry Data

DOSE MG/KG		UN MG/DL	CREAT MG/DL	CA MG/DL	NA MMOL/L	K MMOL/L	CL MMOL/L
0 M							
	N=	6	6	6	6	6	6
	MEAN	10.6	.9	10.7	142	4.4	109
	S.D.	1.90	.08	.27	1.0	.20	1.0
0 F							
	N=	6	6	6	6	6	6
	MEAN	12.0	.9	11.0	142	4.3	109
	S.D.	1.24	.08	.19	.9	.32	1.0
M+F							
	N=	12	12	12	12	12	12
	MEAN M+F	11.3	.9	10.8	142	4.4	109
	S.D. M+F	1.70	.08	.26	1.0	.26	1.0
250 M							
	N=	6	6	6	6	6	6
	MEAN	11.4	.9	11.0	142	4.4	108
	S.D.	1.35	.08	.22	1.0	.10	1.7
250 F							
	N=	6	6	6	6	6	6
	MEAN	12.2	.9	10.6	142	4.1	108
	S.D.	1.47	.09	.36	1.2	.16	1.5
M+F							
	N=	12	12	12	12	12	12
	MEAN M+F	11.8	.9	10.8	142	4.2	108
	S.D. M+F	1.41	.08	.33	1.0	.20	1.5
500 M							
	N=	6	6	6	6	6	6
	MEAN	11.7	.9	11.1	143	4.3	109
	S.D.	2.18	.08	.26	1.3	.21	1.4
500 F							
	N=	6	6	6	6	6	6
	MEAN	12.1	1.0	10.8	142	4.2	109
	S.D.	2.00	.08	.43	1.2	.18	1.5
M+F							
	N=	12	12	12	12	12	12
	MEAN M+F	11.9	.9	10.9	143	4.2	109
	S.D. M+F	2.00	.08	.38	1.2	.20	1.4
1000 M							
	N=	6	6	6	6	6	6
	MEAN	11.0	.9	10.9	142	4.4	110
	S.D.	1.42	.08	.21	.8	.10	1.2
1000 F							
	N=	6	6	6	6	6	6
	MEAN	11.2	.9	10.5	142	4.2	109
	S.D.	1.38	.05	.31	1.2	.12	1.0
M+F							
	N=	12	12	12	12	12	12
	MEAN M+F	11.1	.9	10.7	142	4.3	110
	S.D. M+F	1.34	.06	.33	1.0	.13	1.1

Table 28

S6127111 DOG POOL M+F WEEK: 026

Summary of Clinical Chemistry Data

DOSE MG/KG		GLU MG/DL	T PRO G/DL	ALB G/DL	GLOB G/DL	A/G	T BILI MG/DL	CHOL MG/DL	AST/OT IU/L	ALT/PT IU/L	ALK PHOS IU/L
0 M											
	N=	6	6	6	6	6	6	6	6	6	6
	MEAN	104.8	6.5	3.3	3.2	1.1	.3	105	20	27	32
	S.D.	7.24	.37	.23	.51	.23	.10	16.8	2.5	3.8	5.2
0 F											
	N=	6	6	6	6	6	6	6	6	6	6
	MEAN	103.8	6.4	3.5	3.0	1.2	.4	112	20	27	33
	S.D.	5.48	.44	.15	.46	.19	.40	15.4	3.8	6.8	12.5
M+F											
	N=	12	12	12	12	12	12	12	12	12	12
	MEAN	M+F104.3	6.4	3.4	3.0	1.2	.4	108	20	27	33
	S.D.	M+F 6.15	.39	.20	.48	.22	.29	15.7	3.1	5.3	9.1
250 M											
	N=	6	6	6	6	6	6	6	6	6	6
	MEAN	103.0	6.7	3.6	3.0	1.2	.3	112	23	29	30
	S.D.	4.26	.40	.19	.50	.22	.14	19.6	7.8	6.3	10.2
250 F											
	N=	6	6	6	6	6	6	6	6	6	6
	MEAN	100.7	6.2	3.7	2.5	1.5	.2	139	17	26	32
	S.D.	2.75	.37	.18	.26	.12	.05	27.2	1.8	3.1	10.3
M+F											
	N=	12	12	12	12	12	12	12	12	12	12
	MEAN	M+F101.8	6.4	3.6 **	2.8	1.4	.2	125	20	28	30
	S.D.	M+F 3.62	.44	.17	.46	.21	.10	26.8	6.2	4.9	9.8
500 M											
	N=	6	6	6	6	6	6	6	6	6	6
	MEAN	114.3	5.7 **	3.4 **	2.3 *	1.5	.2	95	18	26	33
	S.D.	11.72	.37	.18	.33	.26	.05	17.6	2.1	2.1	11.1
500 F											
	N=	6	6	6	6	6	6	6	6	6	6
	MEAN	104.0	6.1	3.6	2.6	1.4	.2	135	18	27	40
	S.D.	6.05	.27	.15	.24	.15	.06	37.7	1.8	3.2	13.7
M+F											
	N=	12	12	12	12	12	12	12	12	12	12
	MEAN	M+F109.1	5.9 **	3.5	2.4 **	1.4 **	.2	115	18	26	36
	S.D.	M+F 10.38	.37	.17	.30	.21	.06	34.9	1.9	2.7	12.5
1000M											
	N=	6	6	6	6	6	6	6	6	6	6
	MEAN	108.2	6.1	3.4	2.7	1.3	.2	144 **	17	33 *	40
	S.D.	3.66	.40	.21	.46	.31	.05	25.6	1.4	3.0	7.3
1000F											
	N=	6	6	6	6	6	6	6	6	6	6
	MEAN	107.5	6.2	3.4	2.9	1.2	.3	156	18	29	37
	S.D.	5.32	.33	.19	.35	.21	.18	33.1	2.4	4.9	16.8
M+F											
	N=	12	12	12	12	12	12	12	12	12	12
	MEAN	M+F107.9	6.2	3.4	2.8	1.2	.3	150 **	18	31 *	38
	S.D.	M+F 4.37	.36	.19	.40	.26	.13	28.8	1.9	4.4	12.4

Table 28 (Continued)

S6127111 DOG POOL M+F WEEK: 026

Summary of Clinical Chemistry Data

DOSE MG/KG		UN MG/DL	CREAT MG/DL	CA MG/DL	NA MMOL/L	K MMOL/L	CL MMOL/L
0 M							
	N=	6	6	6	6	6	6
	MEAN	11.1	.9	10.4	143	5.0	111
	S.D.	.87	.08	.29	1.2	.15	1.8
0 F							
	N=	6	6	6	6	6	6
	MEAN	9.9	.8	10.8	143	4.6	110
	S.D.	.78	.12	.46	1.3	.18	1.4
M+F							
	N=	12	12	12	12	12	12
	MEAN M+F	10.5	.9	10.6	143	4.8	110
	S.D. M+F	1.00	.10	.41	1.2	.27	1.6
250 M							
	N=	6	6	6	6	6	6
	MEAN	11.4	1.0	10.5	142	4.9	111
	S.D.	1.45	.08	.22	.8	.29	1.0
250 F							
	N=	6	6	6	6	6	6
	MEAN	11.0	1.0	10.6	143	4.8	110
	S.D.	2.69	.11	.25	1.7	.36	1.3
M+F							
	N=	12	12	12	12	12	12
	MEAN M+F	11.2	1.0 **	10.6	143	4.9	110
	S.D. M+F	2.08	.09	.23	1.3	.31	1.2
500 M							
	N=	6	6	6	6	6	6
	MEAN	11.5	1.0	10.4	143	4.6	111
	S.D.	2.24	.10	.35	.9	.29	1.0
500 F							
	N=	6	6	6	6	6	6
	MEAN	12.3	1.0 **	10.6	143	4.5	109
	S.D.	2.09	.10	.22	1.0	.11	1.0
M+F							
	N=	12	12	12	12	12	12
	MEAN M+F	11.9	1.0 *	10.5	143	4.6	110
	S.D. M+F	2.10	.11	.29	.9	.22	1.4
1000 M							
	N=	6	6	6	6	6	6
	MEAN	11.3	1.0	10.4	143	4.9	111
	S.D.	2.18	.11	.25	1.3	.20	2.0
1000 F							
	N=	6	6	6	6	6	6
	MEAN	13.3 *	1.0	10.3	143	4.6	110
	S.D.	2.05	.08	.37	.8	.10	.8
M+F							
	N=	12	12	12	12	12	12
	MEAN M+F	12.3	1.0 *	10.3	143	4.7	111
	S.D. M+F	2.28	.09	.30	1.0	.22	1.5

Table 29

S6127111 DOG POOL M+F WEEK: 031

Summary of Clinical Chemistry Data

DOSE MG/KG		GLU MG/DL	T PRO G/DL	ALB G/DL	GLOB G/DL	A/G	T BILI MG/DL	CHOL MG/DL	AST/OT IU/L	ALT/PT IU/L	ALK PHOS IU/L
0 M											
	N=	2	2	2	2	2	2	2	2	2	2
	MEAN	98.6	6.2	3.0	3.2	1.0	.2	114	22	26	41
	S.D.	3.18	.35	.21	.49	.21	.00	26.9	2.1	2.8	1.4
0 F											
	N=	2	2	2	2	2	2	2	2	2	2
	MEAN	104.2	6.1	3.3	2.8	1.2	.2	88	22	26	48
	S.D.	.78	.71	.00	.71	.28	.00	3.5	2.1	4.9	23.3
M+F											
	N=	4	4	4	4	4	4	4	4	4	4
	MEAN M+F	101.4	6.1	3.2	3.0	1.1	.2	101	22	26	45
	S.D. M+F	3.80	.46	.19	.54	.25	.00	21.5	1.8	3.3	14.2
250 M											
	N=	2	2	2	2	2	2	2	2	2	2
	MEAN	99.0	6.6	3.3	3.3	1.0	.2	132	24	30	40
	S.D.	.14	.35	.28	.56	.21	.07	31.1	2.1	9.2	2.1
250 F											
	N=	2	2	2	2	2	2	2	2	2	2
	MEAN	107.7	5.6	3.4	2.2	1.6	.2	134	22	22	28
	S.D.	.14	.21	.14	.07	.00	.00	26.2	3.5	.7	2.1
M+F											
	N=	4	4	4	4	4	4	4	4	4	4
	MEAN M+F	103.4	6.0	3.4	2.7	1.3	.2	133	23	26	34
	S.D. M+F	5.02	.62	.19	.74	.34	.05	23.5	2.9	7.0	7.1
500 M											
	N=	2	2	2	2	2	2	2	2	2	2
	MEAN	99.7	5.6	3.4	2.2	1.5	.2	102	19	26	22
	S.D.	7.50	.07	.00	.07	.00	.00	6.4	1.4	2.1	15.6
500 F											
	N=	2	2	2	2	2	2	2	2	2	2
	MEAN	106.7	5.8	3.4	2.3	1.6	.2	104	20	25	35
	S.D.	6.22	.07	.07	.14	.07	.00	.7	.7	.0	5.6
M+F											
	N=	4	4	4	4	4	4	4	4	4	4
	MEAN M+F	103.2	5.7	3.4	2.3	1.5	.2	104	19	25	28
	S.D. M+F	6.92	.08	.05	.10	.05	.00	3.9	1.0	1.2	12.2
1000 M											
	N=	2	2	2	2	2	2	2	2	2	2
	MEAN	102.4	5.6	3.4	2.2	1.6 *	.2	148	20	28	39
	S.D.	8.13	.14	.00	.07	.07	.00	1.4	2.1	4.9	.0
1000 F											
	N=	2	2	2	2	2	2	2	2	2	2
	MEAN	107.1	5.8	3.6	2.2	1.6	.2	133	20	29	58
	S.D.	8.34	.35	.07	.42	.35	.00	55.2	2.1	2.8	43.8
M+F											
	N=	4	4	4	4	4	4	4	4	4	4
	MEAN M+F	104.8	5.7	3.5 *	2.2	1.6 *	.2	140	20	29	48
	S.D. M+F	7.24	.24	.15	.25	.22	.00	33.0	1.7	3.3	27.6

Table 29 (Continued)

S6127111 DOG POOL M+F WEEK: 031

Summary of Clinical Chemistry Data

DOSE MG/KG		UN MG/DL	CREAT MG/DL	CA MG/DL	NA MMOL/L	K MMOL/L	CL MMOL/L
0 M							
N=		2	2	2	2	2	2
MEAN		10.2	1.0	10.3	145	4.6	113
S.D.		.92	.07	.14	1.4	.35	1.4
0 F							
N=		2	2	2	2	2	2
MEAN		11.1	1.0	10.8	144	4.4	114
S.D.		1.41	.07	.28	2.1	.07	1.4
M+F							
N=		4	4	4	4	4	4
MEAN	M+F	10.7	1.0	10.6	144	4.4	114
S.D.	M+F	1.09	.08	.34	1.7	.24	1.3
250 M							
N=		2	2	2	2	2	2
MEAN		10.2	1.0	10.6	144	4.4	114
S.D.		1.91	.07	.07	.7	.21	.0
250 F							
N=		2	2	2	2	2	2
MEAN		13.0	1.0	10.4	142	4.6	113
S.D.		1.48	.07	.21	.0	.21	1.4
M+F							
N=		4	4	4	4	4	4
MEAN	M+F	11.6	1.0	10.6	143	4.5	114
S.D.	M+F	2.14	.08	.17	1.5	.18	1.0
500 M							
N=		2	2	2	2	2	2
MEAN		10.9	1.0	10.6	144	4.2	116
S.D.		1.70	.07	.49	.7	.07	2.1
500 F							
N=		2	2	2	2	2	2
MEAN		12.2	1.2 *	10.6	142	4.6	113
S.D.		3.04	.00	.14	.7	.28	1.4
M+F							
N=		4	4	4	4	4	4
MEAN	M+F	11.5	1.1	10.6	144	4.4	114
S.D.	M+F	2.14	.15	.30	1.3	.26	2.1
1000M							
N=		2	2	2	2	2	2
MEAN		11.5	1.1	10.6	143	4.4	114
S.D.		.71	.00	.00	1.4	.00	.7
1000F							
N=		2	2	2	2	2	2
MEAN		13.2	1.2	10.8	144	4.4	112
S.D.		.56	.07	.07	.0	.07	.7
M+F							
N=		4	4	4	4	4	4
MEAN	M+F	12.4	1.1	10.7	144	4.4	114
S.D.	M+F	1.11	.05	.15	1.0	.05	1.3

Table 30

S6127111 DOG POOL M+F WEEK: -02

Summary of Urinalysis Data

DOSE MG/KG		SP GR	PH	U. VOL ML
0 M				
	N=	6	6	6
	MEAN	1.019	8.5	338.3
	S.D.	.0055	.00	121.65
0 F				
	N=	6	6	6
	MEAN	1.022	8.4	347.2
	S.D.	.0056	.20	187.14
M+F				
	N=	12	12	12
	MEAN M+F	1.020	8.4	342.8
	S.D. M+F	.0054	.14	150.56
250 M				
	N=	6	6	6
	MEAN	1.022	8.4	335.2
	S.D.	.0070	.20	152.54
250 F				
	N=	6	6	6
	MEAN	1.021	8.5	391.0
	S.D.	.0072	.00	243.45
M+F				
	N=	12	12	12
	MEAN M+F	1.022	8.4	363.1
	S.D. M+F	.0068	.14	195.88
500 M				
	N=	6	6	6
	MEAN	1.021	8.3	429.8
	S.D.	.0064	.41	234.25
500 F				
	N=	5	5	6
	MEAN	1.025	8.5	346.2
	S.D.	.0142	.00	220.80
M+F				
	N=	11	11	12
	MEAN M+F	1.023	8.4	388.0
	S.D. M+F	.0103	.30	221.38
1000 M				
	N=	6	6	6
	MEAN	1.017	8.5	510.2
	S.D.	.0030	.00	107.72
1000 F				
	N=	6	6	6
	MEAN	1.019	8.4	374.3
	S.D.	.0039	.20	106.66
M+F				
	N=	12	12	12
	MEAN M+F	1.018	8.4	442.2
	S.D. M+F	.0034	.14	124.41

Table 31

86127111 DOG POOL M+F WEEK: 008

Summary of Urinalysis Data

DOSE MG/KG		SP GR	PH	U. VOL ML
0 M				
	N=	6	6	6
	MEAN	1.014	8.5	665.8
	S.D.	.0047	.00	196.78
0 F				
	N=	6	6	6
	MEAN	1.017	8.2	560.0
	S.D.	.0061	.52	326.74
M+F				
	N=	12	12	12
	MEAN	M+F 1.016	8.3	612.9
	S.D.	M+F .0055	.39	263.03
250 M				
	N=	6	6	6
	MEAN	1.022	8.5	485.8
	S.D.	.0064	.00	193.89
250 F				
	N=	5	5	5
	MEAN	1.020	7.9	508.0
	S.D.	.0162	.65	445.05
M+F				
	N=	11	11	11
	MEAN	M+F 1.021	8.2	495.9
	S.D.	M+F .0112	.52	313.30
500 M				
	N=	6	6	6
	MEAN	1.016	8.5	467.5
	S.D.	.0052	.00	262.71
500 F				
	N=	6	6	6
	MEAN	1.020	8.0	389.2
	S.D.	.0061	.55	192.88
M+F				
	N=	12	12	12
	MEAN	M+F 1.018	8.2	428.3
	S.D.	M+F .0059	.45	223.51
1000 M				
	N=	6	6	6
	MEAN	1.016	8.3	646.7
	S.D.	.0068	.26	327.07
1000 F				
	N=	6	6	6
	MEAN	1.022	8.3	333.3
	S.D.	.0046	.26	157.28
M+F				
	N=	12	12	12
	MEAN	M+F 1.018	8.3	490.0
	S.D.	M+F .0064	.25	294.36

Table 32

86127111 DOG POOL M+F WEEK: 017

Summary of Urinalysis Data

DOSE MG/KG		SP GR	PH	U. VOL ML
0 M				
	N=	6	6	6
	MEAN	1.018	8.5	389.2
	S.D.	.0024	.00	131.77
0 F				
	N=	6	6	6
	MEAN	1.017	8.2	552.5
	S.D.	.0025	.52	163.52
M+F				
	N=	12	12	12
	MEAN	M+F1.018	8.3	470.8
	S.D.	M+F .0024	.39	185.29
250 M				
	N=	6	6	6
	MEAN	1.015	8.5	542.5
	S.D.	.0042	.00	215.28
250 F				
	N=	6	6	6
	MEAN	1.020	8.5	410.0
	S.D.	.0075	.00	182.43
M+F				
	N=	12	12	12
	MEAN	M+F1.017	8.5	476.2
	S.D.	M+F .0064	.00	202.44
500 M				
	N=	6	6	6
	MEAN	1.020	8.3	471.7
	S.D.	.0053	.26	269.64
500 F				
	N=	6	6	6
	MEAN	1.024	8.5	268.3 *
	S.D.	.0126	.00	121.02
M+F				
	N=	12	12	12
	MEAN	M+F1.022	8.4	370.0
	S.D.	M+F .0094	.19	225.79
1000M				
	N=	6	6	6
	MEAN	1.012	8.4	837.5 *
	S.D.	.0045	.20	357.36
1000F				
	N=	6	6	6
	MEAN	1.021	8.5	380.8
	S.D.	.0080	.00	162.71
M+F				
	N=	12	12	12
	MEAN	M+F1.016	8.4	609.2
	S.D.	M+F .0078	.14	356.31

Table 33

S6127111 DOG POOL M+F WEEK: 026

Summary of Urinalysis Data

DOSE MG/KG		SP GR	PH	U. VOL ML
0 M				
	N=	6	6	6
	MEAN	1.020	8.4	460.8
	S.D.	.0059	.20	211.03
0 F				
	N=	6	6	6
	MEAN	1.015	8.3	489.2
	S.D.	.0048	.26	153.38
M+F				
	N=	12	12	12
	MEAN	M+F 1.017	8.4	475.0
	S.D.	M+F .0056	.23	176.51
250 M				
	N=	6	6	6
	MEAN	1.021	8.2	321.7
	S.D.	.0088	.42	175.12
250 F				
	N=	5	6	6
	MEAN	1.031	7.5	275.2
	S.D.	.0236	1.14	347.10
M+F				
	N=	11	12	12
	MEAN	M+F 1.026	7.9	298.4
	S.D.	M+F .0171	.91	263.23
500 M				
	N=	6	6	6
	MEAN	1.019	8.0	515.0
	S.D.	.0067	.63	384.29
500 F				
	N=	6	6	6
	MEAN	1.027	8.0	159.8
	S.D.	.0068	.45	90.08
M+F				
	N=	12	12	12
	MEAN	M+F 1.023	8.0	337.4
	S.D.	M+F .0076	.52	324.37
1000 M				
	N=	6	6	6
	MEAN	1.016	7.4	501.7
	S.D.	.0034	1.07	115.40
1000 F				
	N=	6	6	6
	MEAN	1.030	7.6	259.5
	S.D.	.0158	1.02	172.92
M+F				
	N=	12	12	12
	MEAN	M+F 1.023	7.5	380.6
	S.D.	M+F .0129	1.00	188.78

Table 34

S6127111 DOG POOL M+F WEEK: 031

Summary of Urinalysis Data

DOSE MG/KG		SP GR	PH	U. VOL ML
0 M				
	N=	2	2	2
	MEAN	1.012	8.0	843.5
	S.D.	.0050	.71	241.12
0 F				
	N=	2	2	2
	MEAN	1.016	8.0	562.5
	S.D.	.0042	.71	123.74
M+F				
	N=	4	4	4
	MEAN M+F	1.014	8.0	703.0
	S.D. M+F	.0046	.58	225.40
250 M				
	N=	2	2	2
	MEAN	1.008	7.5	975.5
	S.D.	.0007	.00	161.93
250 F				
	N=	2	2	2
	MEAN	1.011	7.8	836.5
	S.D.	.0000	.35	345.78
M+F				
	N=	4	4	4
	MEAN M+F	1.010	7.6	906.0
	S.D. M+F	.0015	.25	234.59
500 M				
	N=	2	2	2
	MEAN	1.016	8.0	534.0
	S.D.	.0007	.00	48.08
500 F				
	N=	2	2	2
	MEAN	1.016	8.0	527.5
	S.D.	.0085	.00	276.48
M+F				
	N=	4	4	4
	MEAN M+F	1.016	8.0	530.8
	S.D. M+F	.0049	.00	162.06
1000 M				
	N=	2	2	2
	MEAN	1.011	7.8	917.5
	S.D.	.0042	1.06	403.76
1000 F				
	N=	2	2	2
	MEAN	1.012	7.8	818.0
	S.D.	.0035	.35	264.46
M+F				
	N=	4	4	4
	MEAN M+F	1.011	7.8	867.8
	S.D. M+F	.0032	.64	284.52

TABLE 35

INCIDENCE OF MACROSCOPIC OBSERVATIONS

27 WEEK SACRIFICE

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

PRINTED: 10-JUN-86
TABLE.PAGE: 35.1

STUDY NUMBER: 6127111

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=T;SUBSET=ALL

ORGAN AND KEYWORD(S) OR PHRASE		--- NUMBER-OF-ANIMALS-AFFECTED ---							
	SEX:	-------MALE-------				------FEMALE------			
	GROUP:	-1-	-2-	-3-	-4-	-1-	-2-	-3-	-4-
	NUMBER:	4	4	4	4	4	4	4	4
** TOP OF LIST **									
GENERAL COMMENT (GC)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	1	4	1	2	1	1	1	1
ALL TISSUES/ORGANS NORMAL		3	0	3	2	3	3	3	3
BRAIN (BR)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	4	4	4	4	4	4	4
LUNG (LU)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	3	4	4	4	4	4	4
LIGHT FOCUS(I)/AREA(S)		0	1	0	0	0	0	0	0
HEART (HT)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	4	4	4	4	4	4	4
KIDNEY(S) (KD)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	4	4	4	4	4	4	4
LIVER (LI)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	4	4	4	4	4	4	4

TABLE 35

INCIDENCE OF MACROSCOPIC OBSERVATIONS

27 WEEK SACRIFICE

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

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TABLE.PAGE: 35.2

STUDY NUMBER: 6127111

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=T;SUBSET=ALL

ORGAN AND KEYWORD(S) OR PHRASE		--- NUMBER-OF-ANIMALS-AFFECTED ---							
SEX:		-------MALE-------				------FEMALE------			
GROUP:		-1-	-2-	-3-	-4-	-1-	-2-	-3-	-4-
NUMBER:		4	4	4	4	4	4	4	4
GALL BLADDER (GB)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	4	4	4	4	4	4	4
SPLEEN (SP)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	4	4	4	4	4	4	3
ADHESION(S)		0	0	0	0	0	0	0	1
OPAQUE CAPSULE		0	0	0	0	0	0	0	1
EYE(S) (EY)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	4	4	4	4	4	4	4
THYROID(S) (TY)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	3	4	4	4	4	4	4
DIFFUSELY LIGHT		0	1	0	0	0	0	0	0
PARATHYROID(S) (PT)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	4	4	4	4	4	4	4
TRACHEA (TR)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	4	4	4	4	4	4	4

TABLE 35

INCIDENCE OF MACROSCOPIC OBSERVATIONS

27 WEEK SACRIFICE

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

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TABLE.PAGE: 35.3

STUDY NUMBER: 6127111

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=T;SUBSET=ALL

ORGAN AND KEYWORD(S) OR PHRASE		— NUMBER-OF-ANIMALS-AFFECTED —							
	SEX:	-------MALE-------				------FEMALE------			
	GROUP:	-1-	-2-	-3-	-4-	-1-	-2-	-3-	-4-
	NUMBER:	4	4	4	4	4	4	4	4
ESOPHAGUS (ES)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	4	4	4	4	4	4	4
PITUITARY (PI)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	4	4	4	4	4	4	4
ADRENAL(S) (AD)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	4	4	4	4	4	4	4
AORTA (AO)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	4	4	4	4	4	4	4
TONGUE (TO)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	4	4	4	4	3	4	4
MISSING/LOST/NOT IDENTIFIED		0	0	0	0	0	1	0	0
PANCREAS (PA)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	4	4	4	4	4	4	4
STOMACH (ST)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	4	4	4	4	4	4	4

TABLE 35

INCIDENCE OF MACROSCOPIC OBSERVATIONS

27 WEEK SACRIFICE

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

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TABLE.PAGE: 35.4

STUDY NUMBER: 6127111

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=T;SUBSET=ALL

ORGAN AND KEYWORD(S) OR PHRASE		--- NUMBER-OF-ANIMALS-AFFECTED ---							
	SEX:	-------MALE-------				------FEMALE------			
	GROUP:	-1-	-2-	-3-	-4-	-1-	-2-	-3-	-4-
	NUMBER:	4	4	4	4	4	4	4	4
DUODENUM (DU)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	4	4	4	4	4	4	4
JEJUNUM (JE)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	3	4	4	4	4	4	4	4
RED FOCUS(I)/AREA(S)		1	0	0	0	0	0	0	0
ILEUM (IL)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	3	4	4	4	4	4	4	4
RED FOCUS(I)/AREA(S)		1	0	0	0	0	0	0	0
CECUM (CE)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	4	4	4	4	4	4	4
COLON (CO)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	3	4	4	4	4	4	4	4
RED FOCUS(I)/AREA(S)		1	0	0	0	0	0	0	0
RECTUM (RE)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	4	4	4	4	4	4	4

TABLE 35

INCIDENCE OF MACROSCOPIC OBSERVATIONS

27 WEEK SACRIFICE

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

PRINTED: 10-JUN-86
TABLE.PAGE: 35.5

STUDY NUMBER: 6127111

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=T;SUBSET=ALL

ORGAN AND KEYWORD(S) OR PHRASE		--- NUMBER-OF-ANIMALS-AFFECTED ---							
SEX:		-------MALE-------				------FEMALE------			
GROUP:		-1-	-2-	-3-	-4-	-1-	-2-	-3-	-4-
NUMBER:		4	4	4	4	4	4	4	4
SKIN (SK)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	2	3	2	3	3	3	4
) FOCUS(I)/AREA(S)		0	1	1	1	0	0	1	0
ALOPECIA-BILATERAL		0	0	0	0	0	1	0	0
ALOPECIA-DIFFUSE		0	0	0	1	1	0	0	0
THICKENED		0	0	0	1	0	0	0	0
ALOPECIA-FOCAL		0	1	0	0	0	0	0	0
SCIATIC NERVE (SN)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	4	4	4	4	4	4	4
SKELETAL MUSCLE (SM)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	4	4	4	4	4	4	4
SALIVARY GLD(S) (SG)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	4	4	4	4	4	4	4
MANDIB/CERV LN (MN)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	4	4	4	4	4	4	4

TABLE 35

INCIDENCE OF MACROSCOPIC OBSERVATIONS

27 WEEK SACRIFICE

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

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TABLE.PAGE: 35.6

STUDY NUMBER: 6127111

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=T;SUBSET=ALL

ORGAN AND KEYWORD(S) OR PHRASE		--- NUMBER-OF-ANIMALS-AFFECTED ---							
	SEX:	-------MALE-------				------FEMALE------			
	GROUP:	-1-	-2-	-3-	-4-	-1-	-2-	-3-	-4-
	NUMBER:	4	4	4	4	4	4	4	4
THYMUS (TH)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	3	4	4	4	4	4	4
DIFFUSELY RED		0	1	0	0	0	0	0	0
MESENTERIC LN (MS)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	4	4	4	4	4	4	4
FEMUR M/MARROW (FE)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	4	4	4	4	4	4	4
FEMUR M/ART SURF (FEQ)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	4	4	4	4	4	4	4
STERNUM M/MARROW (SE)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	4	4	4	4	4	4	4
SPINAL CORD (SC)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	4	4	4	4	4	4	4
URINARY BLADDER (UB)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	4	4	4	4	4	4	4

TABLE 35

INCIDENCE OF MACROSCOPIC OBSERVATIONS

27 WEEK SACRIFICE

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

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TABLE.PAGE: 35.7

STUDY NUMBER: 6127111

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=T;SUBSET=ALL

ORGAN AND KEYWORD(S) OR PHRASE		--- NUMBER-OF-ANIMALS-AFFECTED ---							
	SEX:	-------MALE-------				------FEMALE------			
	GROUP:	-1-	-2-	-3-	-4-	-1-	-2-	-3-	-4-
	NUMBER:	4	4	4	4	4	4	4	4
PROSTATE (PR)	NUMBER EXAMINED:	4	4	4	4	0	0	0	0
	NOT REMARKABLE:	4	4	4	4	0	0	0	0
TESTES (TE)	NUMBER EXAMINED:	4	4	4	4	0	0	0	0
	NOT REMARKABLE:	4	4	4	4	0	0	0	0
EPIDIDYMIDES (EP)	NUMBER EXAMINED:	4	4	4	4	0	0	0	0
	NOT REMARKABLE:	4	4	4	4	0	0	0	0
MAMMARY GLAND (MG)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	4	4	4	4	4	4	4
UTERUS (UT)	NUMBER EXAMINED:	0	0	0	0	4	4	4	4
	NOT REMARKABLE:	0	0	0	0	4	4	4	4
CERVIX (CV)	NUMBER EXAMINED:	0	0	0	0	4	4	4	4
	NOT REMARKABLE:	0	0	0	0	4	4	4	4
VAGINA (VA)	NUMBER EXAMINED:	0	0	0	0	4	4	4	4
	NOT REMARKABLE:	0	0	0	0	4	4	4	4

TABLE 35

INCIDENCE OF MACROSCOPIC OBSERVATIONS

27 WEEK SACRIFICE

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

PRINTED: 10-JUN-86
TABLE.PAGE: 35.8

STUDY NUMBER: 6127111

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=T;SUBSET=ALL

ORGAN AND KEYWORD(S) OR PHRASE		--- NUMBER-OF-ANIMALS-AFFECTED ---							
	SEX:	-------MALE-------				------FEMALE------			
	GROUP:	-1-	-2-	-3-	-4-	-1-	-2-	-3-	-4-
	NUMBER:	4	4	4	4	4	4	4	4
OVARIES (OV)	NUMBER EXAMINED:	0	0	0	0	4	4	4	4
	NOT REMARKABLE:	0	0	0	0	4	4	4	4
EAR (ER)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	4	3	4	4	4	4	4
THICKENED		0	0	1	0	0	0	0	0
PINNA (PN)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	4	4	4	4	4	4	4
ANT.MES/PANC LN (AM)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	4	4	4	4	4	4	4
MEDIAST/BRONC LN (ML)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	4	4	4	4	4	4	4

** END OF LIST **

TABLE 36

INCIDENCE OF MACROSCOPIC OBSERVATIONS

31 WEEK SACRIFICE

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

PRINTED: 19-MAY-86
TABLE.PAGE: 36.1

STUDY NUMBER: 6127111

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=U;SUBSET=ALL

		--- NUMBER-OF-ANIMALS-AFFECTED ---							
	SEX:	-------MALE-------				------FEMALE------			
	GROUP:	-1-	-2-	-3-	-4-	-1-	-2-	-3-	-4-
ORGAN AND KEYWORD(S) OR PHRASE	NUMBER:	2	2	2	2	2	2	2	2
** TOP OF LIST **									
GENERAL COMMENT (GC)	NUMBER EXAMINED:	2	2	2	2	2	2	2	2
	NOT REMARKABLE:	2	1	2	0	1	0	0	0
ALL TISSUES/ORGANS NORMAL		0	1	0	2	1	2	2	2
BRAIN (BR)	NUMBER EXAMINED:	2	2	2	2	2	2	2	2
	NOT REMARKABLE:	2	2	2	2	2	2	2	2
LUNG (LU)	NUMBER EXAMINED:	2	2	2	2	2	2	2	2
	NOT REMARKABLE:	1	2	2	2	2	2	2	2
RED FOCUS(I)/AREA(S)		1	0	0	0	0	0	0	0
HEART (HT)	NUMBER EXAMINED:	2	2	2	2	2	2	2	2
	NOT REMARKABLE:	2	2	2	2	2	2	2	2
KIDNEY(S) (KD)	NUMBER EXAMINED:	2	2	2	2	2	2	2	2
	NOT REMARKABLE:	2	2	1	2	2	2	2	2
CYST(S)		0	0	1	0	0	0	0	0
LIVER (LI)	NUMBER EXAMINED:	2	2	2	2	2	2	2	2
	NOT REMARKABLE:	2	2	2	2	2	2	2	2

TABLE 36

INCIDENCE OF MACROSCOPIC OBSERVATIONS

31 WEEK SACRIFICE

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

PRINTED: 19-MAY-86
TABLE.PAGE: 36.2

STUDY NUMBER: 6127111

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=U;SUBSET=ALL

ORGAN AND KEYWORD(S) OR PHRASE		--- NUMBER-OF-ANIMALS-AFFECTED ---							
SEX:		-------MALE-------				------FEMALE------			
GROUP:		-1-	-2-	-3-	-4-	-1-	-2-	-3-	-4-
NUMBER:		2	2	2	2	2	2	2	2
GALL BLADDER (GB)	NUMBER EXAMINED:	2	2	2	2	2	2	2	2
	NOT REMARKABLE:	2	2	2	2	2	2	2	2
SPLEEN (SP)	NUMBER EXAMINED:	2	2	2	2	2	2	2	2
	NOT REMARKABLE:	2	2	2	2	2	2	2	2
EYE(S) (EY)	NUMBER EXAMINED:	2	2	2	2	2	2	2	2
	NOT REMARKABLE:	2	2	2	2	2	2	2	2
THYROID(S) (TY)	NUMBER EXAMINED:	2	2	2	2	2	2	2	2
	NOT REMARKABLE:	2	2	2	2	2	2	2	2
PARATHYROID(S) (PT)	NUMBER EXAMINED:	2	2	2	2	2	2	2	2
	NOT REMARKABLE:	2	2	2	2	2	2	2	2
TRACHEA (TR)	NUMBER EXAMINED:	2	2	2	2	2	2	2	2
	NOT REMARKABLE:	2	2	2	2	2	2	2	2
ESOPHAGUS (ES)	NUMBER EXAMINED:	2	2	2	2	2	2	2	2
	NOT REMARKABLE:	2	2	2	2	2	2	2	2

TABLE 36

INCIDENCE OF MACROSCOPIC OBSERVATIONS

31 WEEK SACRIFICE

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

PRINTED: 19-MAY-86
TABLE.PAGE: 36.3

STUDY NUMBER: 6127111

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=U;SUBSET=ALL

ORGAN AND KEYWORD(S) OR PHRASE		--- NUMBER-OF-ANIMALS-AFFECTED ---							
	SEX:	-------MALE-------				------FEMALE------			
	GROUP:	-1-	-2-	-3-	-4-	-1-	-2-	-3-	-4-
	NUMBER:	2	2	2	2	2	2	2	2
PITUITARY (PI)	NUMBER EXAMINED:	2	2	2	2	2	2	2	2
	NOT REMARKABLE:	2	2	2	2	2	2	2	2
ADRENAL(S) (AD)	NUMBER EXAMINED:	2	2	2	2	2	2	2	2
	NOT REMARKABLE:	2	2	2	2	2	2	2	2
AORTA (AO)	NUMBER EXAMINED:	2	2	2	2	2	2	2	2
	NOT REMARKABLE:	2	2	2	2	2	2	2	2
TONGUE (TO)	NUMBER EXAMINED:	2	2	2	2	2	2	2	2
	NOT REMARKABLE:	2	2	2	2	2	2	2	2
PANCREAS (PA)	NUMBER EXAMINED:	2	2	2	2	2	2	2	2
	NOT REMARKABLE:	2	2	2	2	2	2	2	2
STOMACH (ST)	NUMBER EXAMINED:	2	2	2	2	2	2	2	2
	NOT REMARKABLE:	2	2	2	2	2	2	2	2
DUODENUM (DU)	NUMBER EXAMINED:	2	2	2	2	2	2	2	2
	NOT REMARKABLE:	2	2	2	2	2	2	2	2

TABLE 36

INCIDENCE OF MACROSCOPIC OBSERVATIONS

31 WEEK SACRIFICE

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

PRINTED: 19-MAY-86
TABLE.PAGE: 36.4

STUDY NUMBER: 6127111

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=U;SUBSET=ALL

ORGAN AND KEYWORD(S) OR PHRASE		--- NUMBER-OF-ANIMALS-AFFECTED ---							
SEX:		-------MALE-------				------FEMALE------			
GROUP:		-1-	-2-	-3-	-4-	-1-	-2-	-3-	-4-
NUMBER:		2	2	2	2	2	2	2	2
JEJUNUM (JE)	NUMBER EXAMINED:	2	2	2	2	2	2	2	2
	NOT REMARKABLE:	2	2	2	2	2	2	2	2
ILEUM (IL)	NUMBER EXAMINED:	2	2	2	2	2	2	2	2
	NOT REMARKABLE:	2	2	2	2	2	2	2	2
CECUM (CE)	NUMBER EXAMINED:	2	2	2	2	2	2	2	2
	NOT REMARKABLE:	2	2	2	2	2	2	2	2
COLON (CO)	NUMBER EXAMINED:	2	2	2	2	2	2	2	2
	NOT REMARKABLE:	2	2	2	2	2	2	2	2
RECTUM (RE)	NUMBER EXAMINED:	2	2	2	2	2	2	2	2
	NOT REMARKABLE:	2	2	2	2	2	2	2	2
SKIN (SK)	NUMBER EXAMINED:	2	2	2	2	2	2	2	2
	NOT REMARKABLE:	2	2	2	2	2	2	2	2
SCIATIC NERVE (SN)	NUMBER EXAMINED:	2	2	2	2	2	2	2	2
	NOT REMARKABLE:	2	2	2	2	2	2	2	2

TABLE 36

INCIDENCE OF MACROSCOPIC OBSERVATIONS

31 WEEK SACRIFICE

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

PRINTED: 19-MAY-86
TABLE.PAGE: 36.5

STUDY NUMBER: 6127111

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=U;SUBSET=ALL

ORGAN AND KEYWORD(S) OR PHRASE		--- NUMBER-OF-ANIMALS-AFFECTED ---							
	SEX:	-------MALE-------				------FEMALE------			
	GROUP:	-1-	-2-	-3-	-4-	-1-	-2-	-3-	-4-
	NUMBER:	2	2	2	2	2	2	2	2
SKELETAL MUSCLE (SM)	NUMBER EXAMINED:	2	2	2	2	2	2	2	2
	NOT REMARKABLE:	2	2	2	2	2	2	2	2
SALIVARY GLD(S) (SG)	NUMBER EXAMINED:	2	2	2	2	2	2	2	2
	NOT REMARKABLE:	2	2	2	2	2	2	2	2
MANDIB/CERV LN (MN)	NUMBER EXAMINED:	2	2	2	2	2	2	2	2
	NOT REMARKABLE:	2	2	2	2	2	2	2	2
THYMUS (TH)	NUMBER EXAMINED:	2	2	2	2	2	2	2	2
	NOT REMARKABLE:	2	2	2	2	2	2	2	2
MESENTERIC LN (MS)	NUMBER EXAMINED:	2	2	2	2	2	2	2	2
	NOT REMARKABLE:	2	2	2	2	2	2	2	2
FEMUR W/MARROW (FE)	NUMBER EXAMINED:	2	2	2	2	2	2	2	2
	NOT REMARKABLE:	2	2	2	2	2	2	2	2
FEMUR W/ART SURF (FEQ)	NUMBER EXAMINED:	2	2	2	2	2	2	2	2
	NOT REMARKABLE:	2	2	2	2	2	2	2	2

TABLE 36

INCIDENCE OF MACROSCOPIC OBSERVATIONS

31 WEEK SACRIFICE

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

PRINTED: 19-MAY-86
TABLE.PAGE: 36.6

STUDY NUMBER: 6127111

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=U;SUBSET=ALL

ORGAN AND KEYWORD(S) OR PHRASE		--- NUMBER-OF-ANIMALS-AFFECTED ---							
	SEX:	-------MALE-------				------FEMALE------			
	GROUP:	-1-	-2-	-3-	-4-	-1-	-2-	-3-	-4-
	NUMBER:	2	2	2	2	2	2	2	2
STERNUM W/MARROW (SE)	NUMBER EXAMINED:	2	2	2	2	2	2	2	2
	NOT REMARKABLE:	2	2	2	2	2	2	2	2
SPINAL CORD (SC)	NUMBER EXAMINED:	2	2	2	2	2	2	2	2
	NOT REMARKABLE:	2	2	2	2	2	2	2	2
URINARY BLADDER (UB)	NUMBER EXAMINED:	2	2	2	2	2	2	2	2
	NOT REMARKABLE:	2	2	2	2	2	2	2	2
PROSTATE (PR)	NUMBER EXAMINED:	2	2	2	2	0	0	0	0
	NOT REMARKABLE:	2	2	2	2	0	0	0	0
TESTES (TE)	NUMBER EXAMINED:	2	2	2	2	0	0	0	0
	NOT REMARKABLE:	2	2	2	2	0	0	0	0
EPIDIDYMIDES (EP)	NUMBER EXAMINED:	2	2	2	2	0	0	0	0
	NOT REMARKABLE:	2	2	2	2	0	0	0	0
MAMMARY GLAND (MG)	NUMBER EXAMINED:	2	2	2	2	2	2	2	2
	NOT REMARKABLE:	2	2	2	2	2	2	2	2

TABLE 36

INCIDENCE OF MACROSCOPIC OBSERVATIONS

31 WEEK SACRIFICE

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

PRINTED: 19-MAY-86
TABLE.PAGE: 36.7

STUDY NUMBER: 6127111

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=U;SUBSET=ALL

ORGAN AND KEYWORD(S) OR PHRASE		--- NUMBER-OF-ANIMALS-AFFECTED ---							
	SEX:	-------MALE-------				------FEMALE------			
	GROUP:	-1-	-2-	-3-	-4-	-1-	-2-	-3-	-4-
	NUMBER:	2	2	2	2	2	2	2	2
UTERUS (UT)	NUMBER EXAMINED:	0	0	0	0	2	2	2	2
	NOT REMARKABLE:	0	0	0	0	2	2	2	2
CERVIX (CV)	NUMBER EXAMINED:	0	0	0	0	2	2	2	2
	NOT REMARKABLE:	0	0	0	0	2	2	2	2
VAGINA (VA)	NUMBER EXAMINED:	0	0	0	0	2	2	2	2
	NOT REMARKABLE:	0	0	0	0	2	2	2	2
OVARIES (OV)	NUMBER EXAMINED:	0	0	0	0	2	2	2	2
	NOT REMARKABLE:	0	0	0	0	2	2	2	2
EAR (ER)	NUMBER EXAMINED:	2	2	2	2	2	2	2	2
	NOT REMARKABLE:	2	2	2	2	2	2	2	2
PINNA (PN)	NUMBER EXAMINED:	2	2	2	2	2	2	2	2
	NOT REMARKABLE:	2	2	2	2	1	2	2	2
DIFFUSELY RED		0	0	0	0	1	0	0	0

TABLE 36

INCIDENCE OF MACROSCOPIC OBSERVATIONS

31 WEEK SACRIFICE

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

PRINTED: 19-MAY-86
TABLE.PAGE: 36.8

STUDY NUMBER: 6127111

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=U;SUBSET=ALL

ORGAN AND KEYWORD(S) OR PHRASE		--- NUMBER-OF-ANIMALS-AFFECTED ---							
SEX:		-------MALE-------				------FEMALE------			
GROUP:		-1-	-2-	-3-	-4-	-1-	-2-	-3-	-4-
NUMBER:		2	2	2	2	2	2	2	2
ANT.MES/PANC LN (AM)	NUMBER EXAMINED:	2	2	2	2	2	2	2	2
	NOT REMARKABLE:	2	2	1	2	2	2	2	2
DIFFUSELY RED		0	0	1	0	0	0	0	0
MEDIAST/BRONC LN (ML)	NUMBER EXAMINED:	2	2	2	2	2	2	2	2
	NOT REMARKABLE:	1	1	2	2	2	2	2	2
LARGE		1	0	0	0	0	0	0	0
DIFFUSELY RED		1	1	0	0	0	0	0	0

** END OF LIST **

TABLE 37

SUMMARY OF ABSOLUTE ORGAN WEIGHT DATA (G)

27 WEEK SACRIFICE

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

PRINTED: 10-JUN-86
TABLE.PAGE: 37.1

STUDY NUMBER: 6127111

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=T;SUBSET=ALL

SIGNIFICANCE USING DUNNETT'S TEST IS INDICATED NEXT TO THE '# IN GRP.' AS FOLLOWS: '*' = .05 LEVEL, '**' = .01 LEVEL

SEX:	MALE				FEMALE			
GROUP:	1	2	3	4	1	2	3	4
NUMBER:	4	4	4	4	4	4	4	4
>>> TERMINAL BODY WEIGHT (g) <<<								
# IN GRP.:	4	4	4	4	4	4	4	4
MEAN:	10200.0	9800.0	10875.0	9350.0	10075.0	8275.0	9525.0	8925.0
S DEV:	1930.5	637.7	826.1	1605.2	1325.1	984.5	434.9	895.8
>>> TYO - THYROID(S)/PARA <<<								
# IN GRP.:	4	4	4	4	4	4	4	4
MEAN:	1.018	1.153	1.119	1.022	.860	.867	.908	.914
STAND DEV:	.169	.182	.125	.173	.110	.122	.136	.187
>>> HT - HEART <<<								
# IN GRP.:	4	4	4	4	4	4	4	4
MEAN:	86.331	88.015	87.168	79.154	77.590	69.773	85.942	67.499
STAND DEV:	14.545	12.205	8.803	13.294	12.886	6.564	4.198	4.729
>>> AD - ADRENAL(S) <<<								
# IN GRP.:	4	4	4	4	4	4 *	4 **	4 **
MEAN:	1.018	1.053	1.272	1.094	1.569	1.206	1.130	1.032
STAND DEV:	.157	.101	.264	.147	.087	.198	.176	.184
>>> SP - SPLEEN <<<								
# IN GRP.:	4	4	4	4	4	4	4	4
MEAN:	34.000	27.956	33.540	27.501	37.900	27.758	27.126	22.710
STAND DEV:	12.991	6.261	7.869	11.211	12.089	6.758	3.228	1.858

TABLE 37

SUMMARY OF ABSOLUTE ORGAN WEIGHT DATA (G)

27 WEEK SACRIFICE

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

PRINTED: 10-JUN-86
TABLE.PAGE: 37.2

STUDY NUMBER: 6127111

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=T;SUBSET=ALL

SIGNIFICANCE USING DUNNETT'S TEST IS INDICATED NEXT TO THE '# IN GRP.' AS FOLLOWS: '*' = .05 LEVEL, '**' = .01 LEVEL

SEX:	MALE				FEMALE			
GROUP:	1	2	3	4	1	2	3	4
NUMBER:	4	4	4	4	4	4	4	4
>>> TH - THYMUS <<<								
# IN GRP.:	4	4	4	4	4	4	4	4
M E A N :	7.085	7.877	9.362	6.535	9.231	5.231	6.251	4.950
STAND DEV:	1.570	4.588	4.413	4.478	4.114	2.079	3.466	1.441
>>> SG - SALIVARY GLD(S) <<<								
# IN GRP.:	4	4	4	4	4	4 *	4	4
M E A N :	17.3223	14.6810	16.2423	15.8775	17.2870	12.8415	14.4035	14.0163
STAND DEV:	2.7127	2.9936	2.0560	3.2508	1.8986	2.6539	.6870	2.0060
>>> KD - KIDNEY(S) <<<								
# IN GRP.:	4	4	4	4	4	4	4	4
M E A N :	60.293	51.647	51.186	49.257	40.380	37.383	41.755	37.686
STAND DEV:	16.574	8.618	9.294	4.837	2.444	1.758	1.499	5.076
>>> LI - LIVER <<<								
# IN GRP.:	4	4	4	4	4	4	4	4
M E A N :	286.715	262.982	284.122	280.373	268.609	216.306	240.033	235.870
STAND DEV:	47.907	50.820	32.130	63.564	32.801	39.465	15.705	4.599
>>> TE - TESTES <<<								
# IN GRP.:	4	4	4	4	0	0	0	0
M E A N :	15.871	15.671	15.527	15.283				
STAND DEV:	2.621	3.006	2.028	2.873				

TABLE 37

SUMMARY OF ABSOLUTE ORGAN WEIGHT DATA (G)

27 WEEK SACRIFICE

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

PRINTED: 10-JUN-86
TABLE.PAGE: 37.3

STUDY NUMBER: 6127111

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=T;SUBSET=ALL

SIGNIFICANCE USING DUNNETT'S TEST IS INDICATED NEXT TO THE '# IN GRP.' AS FOLLOWS: '*' = .05 LEVEL, '**' = .01 LEVEL

SEX:	MALE				FEMALE			
GROUP:	1	2	3	4	1	2	3	4
NUMBER:	4	4	4	4	4	4	4	4
>>> EP - EPIDIDYMIDES <<<								
# IN GRP.:	4	4	4	4	0	0	0	0
M E A N :	4.2148	3.5377	3.5798	3.6943				
STAND DEV:	.6241	.5210	.7408	.9736				
>>> PR - PROSTATE <<<								
# IN GRP.:	4	4	4	4	0	0	0	0
M E A N :	7.886	4.886	5.182	4.485				
STAND DEV:	1.280	2.216	3.579	3.225				
>>> UT - UTERUS <<<								
# IN GRP.:	0	0	0	0	4	4	4	4
M E A N :					14.2103	2.8733	7.1337	9.9773
STAND DEV:					8.2063	1.7716	7.0207	10.1167
>>> OV - OVARIES <<<								
# IN GRP.:	0	0	0	0	4	4	4	4
M E A N :					1.476	.832	1.006	1.092
STAND DEV:					.569	.332	.183	.408
>>> BR - BRAIN <<<								
# IN GRP.:	4	4	4	4	4	4	4	4
M E A N :	77.732	71.587	73.702	71.667	73.970	71.759	70.486	72.943
STAND DEV:	6.699	1.579	6.583	5.726	3.376	3.600	2.746	6.869

TABLE 37

SUMMARY OF ABSOLUTE ORGAN WEIGHT DATA (G)

27 WEEK SACRIFICE

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

PRINTED: 10-JUN-86
TABLE.PAGE: 37.4

STUDY NUMBER: 6127111

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=T;SUBSET=ALL

SIGNIFICANCE USING DUNNETT'S TEST IS INDICATED NEXT TO THE '# IN GRP.' AS FOLLOWS: '*' = .05 LEVEL, '**' = .01 LEVEL

SEX:	MALE				FEMALE			
GROUP:	1	2	3	4	1	2	3	4
NUMBER:	4	4	4	4	4	4	4	4
>>> PI - PITUITARY <<<								
# IN GRP.:	4	4	4	4	4	4	4	4
M E A N :	.050	.039	.056	.057	.064	.047	.054	.050
STAND DEV:	.010	.007	.033	.016	.012	.021	.007	.006

TABLE 38

SUMMARY OF ABSOLUTE ORGAN WEIGHT DATA (G)

31 WEEK SACRIFICE

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

PRINTED: 19-MAY-86
TABLE.PAGE: 38.1

STUDY NUMBER: 6127111

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=U;SUBSET=ALL

SIGNIFICANCE USING DUNNETT'S TEST IS INDICATED NEXT TO THE '# IN GRP.' AS FOLLOWS: '*' = .05 LEVEL, '**' = .01 LEVEL

SEX:	MALE				FEMALE			
GROUP:	1	2	3	4	1	2	3	4
NUMBER:	2	2	2	2	2	2	2	2
>>> TERMINAL BODY WEIGHT (g) <<<								
# IN GRP.:	2	2	2	2	2	2	2	2
M E A N :	11000.0	11400.0	10200.0	10400.0	8800.0	9700.0	8600.0	9750.0
STAND DEV:	1131.4	1414.2	848.5	848.5	141.4	141.4	565.7	212.2
>>> TYO - THYROID(S)/PARA <<<								
# IN GRP.:	2	2	2	2	2	2	2	2
M E A N :	.999	1.429	.975	1.026	1.022	.974	.764	.907
STAND DEV:	.191	.165	.054	.395	.090	.178	.041	.029
>>> HT - HEART <<<								
# IN GRP.:	2	2	2	2	2	2	2	2
M E A N :	83.951	89.605	83.356	82.477	75.296	72.014	67.742	78.348
STAND DEV:	2.385	21.210	5.261	7.729	3.183	10.431	4.522	7.021
>>> AD - ADRENAL(S) <<<								
# IN GRP.:	2	2	2	2	2	2	2	2
M E A N :	1.127	1.332	1.107	1.326	1.010	1.354	1.156	1.193
STAND DEV:	.127	.004	.011	.308	.005	.346	.290	.110
>>> SP - SPLEEN <<<								
# IN GRP.:	2	2	2	2	2	2	2	2
M E A N :	26.903	29.294	32.990	26.554	23.226	32.289	24.049	26.346
STAND DEV:	9.004	4.472	7.904	8.801	2.366	3.856	1.261	1.179

TABLE 38

SUMMARY OF ABSOLUTE ORGAN WEIGHT DATA (G)

31 WEEK SACRIFICE

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

PRINTED: 19-MAY-86
TABLE.PAGE: 38.2

STUDY NUMBER: 6127111

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=U;SUBSET=ALL

SIGNIFICANCE USING DUNNETT'S TEST IS INDICATED NEXT TO THE '# IN GRP.' AS FOLLOWS: '*' = .05 LEVEL, '**' = .01 LEVEL

SEX:	MALE				FEMALE			
GROUP:	1	2	3	4	1	2	3	4
NUMBER:	2	2	2	2	2	2	2	2
>>> TH - THYMUS <<<								
# IN GRP.:	2	2	2	2	2	2	2	2
M E A N :	7.299	6.953	5.965	10.975	8.119	7.589	6.431	7.327
STAND DEV:	1.467	1.324	2.964	5.897	.072	1.293	.950	1.978
>>> SG - SALIVARY GLD(S) <<<								
# IN GRP.:	2	2	2	2	2	2	2	2
M E A N :	17.3180	16.4195	15.9645	15.1160	15.0790	15.4050	13.7315	14.5140
STAND DEV:	4.6782	.0632	5.9376	.9065	1.4821	3.0363	3.0766	1.5797
>>> KD - KIDNEY(S) <<<								
# IN GRP.:	2	2	2	2	2	2	2	2
M E A N :	52.996	51.522	48.078	44.573	37.476	38.977	35.150	42.034
STAND DEV:	7.737	3.592	1.587	1.524	4.341	4.585	1.259	2.976
>>> LI - LIVER <<<								
# IN GRP.:	2	2	2	2	2	2	2	2
M E A N :	320.661	308.227	284.663	267.396	242.185	254.182	213.863	275.620
STAND DEV:	16.582	38.710	19.203	23.953	32.612	41.986	31.573	17.435
>>> TE - TESTES <<<								
# IN GRP.:	2	2	2	2	0	0	0	0
M E A N :	14.000	14.846	14.635	12.695				
STAND DEV:	1.081	3.185	3.355	4.697				

TABLE 38

SUMMARY OF ABSOLUTE ORGAN WEIGHT DATA (G)

31 WEEK SACRIFICE

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

PRINTED: 19-MAY-86
TABLE.PAGE: 38.3

STUDY NUMBER: 6127111

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=U;SUBSET=ALL

SIGNIFICANCE USING DUNNETT'S TEST IS INDICATED NEXT TO THE '# IN GRP.' AS FOLLOWS: '*' = .05 LEVEL, '**' = .01 LEVEL

SEX:	MALE				FEMALE			
GROUP:	1	2	3	4	1	2	3	4
NUMBER:	2	2	2	2	2	2	2	2
>>> EP - EPIDIDYMIDES <<<								
# IN GRP.:	2	2	2	2	0	0	0	0
M E A N :	3.8760	3.6960	3.6530	4.0555				
'D DEV:	.5303	.9433	1.0225	.4985				
>>> PR - PROSTATE <<<								
# IN GRP.:	2	2	2	2	0	0	0	0
M E A N :	6.349	6.163	5.026	5.019				
STAND DEV:	.013	2.454	.473	.795				
>>> UT - UTERUS <<<								
# IN GRP.:	0	0	0	0	2	2	2	2
M E A N :					8.7560	18.0295	4.3000	5.7310
STAND DEV:					7.3539	4.9985	.2178	.0763
>>> OV - OVARIES <<<								
# IN GRP.:	0	0	0	0	2	2	2	2
M E A N :					.905	1.551	.990	.884
STAND DEV:					.197	.532	.132	.318
>>> BR - BRAIN <<<								
# IN GRP.:	2	2	2	2	2	2	2	2
M E A N :	82.018	75.084	78.108	78.421	70.199	68.756	73.708	72.680
STAND DEV:	1.358	6.613	8.791	1.775	6.022	1.318	.966	2.343

TABLE 38

SUMMARY OF ABSOLUTE ORGAN WEIGHT DATA (G)

31 WEEK SACRIFICE

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

PRINTED: 19-MAY-86
TABLE.PAGE: 38.4

STUDY NUMBER: 6127111

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=U;SUBSET=ALL

SIGNIFICANCE USING DUNNETT'S TEST IS INDICATED NEXT TO THE '# IN GRP.' AS FOLLOWS: '*' = .05 LEVEL, '**' = .01 LEVEL

SEX:	MALE				FEMALE			
GROUP:	1	2	3	4	1	2	3	4
NUMBER:	2	2	2	2	2	2	2	2
	>>> PI - PITUITARY <<<							
# IN GRP.:	2	2	2	2	2	2	2	2
M E A N :	.052	.048	.050	.052	.055	.053	.047	.054
STAND DEV:	.011	.010	.016	.018	.021	.008	.004	.009

TABLE 39

SUMMARY OF ORGAN-TO-BODY WEIGHT PERCENTAGES

27 WEEK SACRIFICE

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

PRINTED: 10-JUN-86
TABLE.PAGE: 39.1

STUDY NUMBER: 6127111

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=T;SUBSET=ALL

SIGNIFICANCE USING DUNNETT'S TEST IS INDICATED NEXT TO THE '# IN GRP.' AS FOLLOWS: '*' = .05 LEVEL, '**' = .01 LEVEL

SEX:	MALE				FEMALE			
GROUP:	1	2	3	4	1	2	3	4
NUMBER:	4	4	4	4	4	4	4	4
>>> TERMINAL BODY WEIGHT (g) <<<								
# IN GRP.:	4	4	4	4	4	4	4	4
M E A N :	10200.0	9800.0	10875.0	9350.0	10075.0	8275.0	9525.0	8925.0
STAND DEV:	1930.5	637.7	826.1	1605.2	1325.1	984.5	434.9	895.8
>>> TYO - THYROID(S)/PARA <<<								
# IN GRP.:	4	4	4	4	4	4	4	4
M E A N :	.0101	.0118	.0103	.0110	.0087	.0105	.0095	.0104
STAND DEV:	.0019	.0018	.0015	.0014	.0017	.0016	.0013	.0024
>>> HT - HEART <<<								
# IN GRP.:	4	4	4	4	4	4	4 *	4
M E A N :	.8502	.9000	.8026	.8475	.7685	.8465	.9025	.7614
STAND DEV:	.0492	.1268	.0720	.0485	.0566	.0566	.0291	.0658
>>> AD - ADRENAL(S) <<<								
# IN GRP.:	4	4	4	4	4	4	4	4
M E A N :	.0102	.0107	.0116	.0119	.0157	.0148	.0118	.0116
STAND DEV:	.0023	.0006	.0019	.0023	.0011	.0036	.0015	.0018
>>> SP - SPLEEN <<<								
# IN GRP.:	4	4	4	4	4	4	4	4
M E A N :	.3368	.2847	.3071	.2854	.3798	.3342	.2859	.2571
STAND DEV:	.1148	.0568	.0563	.0705	.1341	.0600	.0424	.0419

TABLE 39

SUMMARY OF ORGAN-TO-BODY WEIGHT PERCENTAGES

27 WEEK SACRIFICE

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

PRINTED: 10-JUN-86
TABLE.PAGE: 39.2

STUDY NUMBER: 6127111

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=T;SUBSET=ALL

SIGNIFICANCE USING DUNNETT'S TEST IS INDICATED NEXT TO THE '# IN GRP.' AS FOLLOWS: '*' = .05 LEVEL, '**' = .01 LEVEL

SEX:	MALE				FEMALE			
GROUP:	1	2	3	4	1	2	3	4
NUMBER:	4	4	4	4	4	4	4	4
>>> TH - THYMUS <<<								
# IN GRP.:	4	4	4	4	4	4	4	4
M E A N :	.0699	.0829	.0871	.0664	.0895	.0628	.0655	.0359
STAND DEV:	.0140	.0548	.0412	.0402	.0279	.0232	.0355	.0162
>>> SG - SALIVARY GLD(S) <<<								
# IN GRP.:	4	4	4	4	4	4	4	4
M E A N :	.1708	.1491	.1500	.1692	.1733	.1547	.1514	.1578
STAND DEV:	.0100	.0250	.0220	.0106	.0265	.0200	.0085	.0246
>>> KI - KIDNEY(S) <<<								
# IN GRP.:	4	4	4	4	4	4	4	4
M E A N :	.5916	.5263	.4716	.5318	.4039	.4564	.4390	.4221
STAND DEV:	.1347	.0759	.0830	.0388	.0360	.0559	.0251	.0345
>>> LI - LIVER <<<								
# IN GRP.:	4	4	4	4	4	4	4	4
M E A N :	2.8335	2.6792	2.6110	2.9793	2.6687	2.6067	2.5280	2.6603
STAND DEV:	.3591	.4549	.1759	.1870	.0469	.2659	.2656	.2356
>>> TE - TESTES <<<								
# IN GRP.:	4	4	4	4	0	0	0	0
M E A N :	.1568	.1594	.1426	.1641				
STAND DEV:	.0190	.0248	.0132	.0213				

TABLE 39

SUMMARY OF ORGAN-TO-BODY WEIGHT PERCENTAGES

27 WEEK SACRIFICE

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

PRINTED: 10-JUN-86
TABLE.PAGE: 39.3

STUDY NUMBER: 6127111

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=T;SUBSET=ALL

SIGNIFICANCE USING DUNNETT'S TEST IS INDICATED NEXT TO THE '# IN GRP.' AS FOLLOWS: '*' = .05 LEVEL, '**' = .01 LEVEL

SEX:	MALE				FEMALE			
GROUP:	1	2	3	4	1	2	3	4
NUMBER:	4	4	4	4	4	4	4	4
>>> EP - EPIDIDYMIDES <<<								
# IN GRP.:	4	4	4	4	0	0	0	0
MEAN:	.0421	.0360	.0328	.0391				
STAND DEV:	.0082	.0035	.0061	.0049				
>>> PR - PROSTATE <<<								
# IN GRP.:	4	4	4	4	0	0	0	0
MEAN:	.0778	.0500	.0478	.0447				
STAND DEV:	.0082	.0223	.0324	.0273				
>>> UT - UTERUS <<<								
# IN GRP.:	0	0	0	0	4	4	4	4
MEAN:					.1355	.0348	.0776	.1099
STAND DEV:					.0606	.0223	.0806	.1072
>>> OV - OVARIES <<<								
# IN GRP.:	0	0	0	0	4	4	4	4
MEAN:					.0143	.0102	.0106	.0122
STAND DEV:					.0035	.0044	.0024	.0041
>>> BR - BRAIN <<<								
# IN GRP.:	4	4	4	4	4	4	4	4
MEAN:	.7737	.7334	.6817	.7783	.7416	.8747	.7419	.8183
STAND DEV:	.0872	.0611	.0919	.1074	.0817	.0908	.0595	.0351

TABLE 39

SUMMARY OF ORGAN-TO-BODY WEIGHT PERCENTAGES

27 WEEK SACRIFICE

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

PRINTED: 10-JUN-86
TABLE.PAGE: 39.4

STUDY NUMBER: 6127111

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=T;SUBSET=ALL

SIGNIFICANCE USING DUNNETT'S TEST IS INDICATED NEXT TO THE '# IN GRP.' AS FOLLOWS: '*' = .05 LEVEL, '**' = .01 LEVEL

SEX:	MALE				FEMALE			
GROUP:	1	2	3	4	1	2	3	4
NUMBER:	4	4	4	4	4	4	4	4
			>>> PI - PITUITARY <<<					
# IN GRP.:	4	4	4	4	4	4	4	4
M E A N :	.0005	.0006	.0005	.0006	.0006	.0006	.0006	.0006
STAND DEV:	.0001	.0001	.0003	.0001	.0001	.0002	.0001	.0000

TABLE 40

SUMMARY OF ORGAN-TO-BODY WEIGHT PERCENTAGES

31 WEEK SACRIFICE

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

PRINTED: 19-MAY-86
TABLE.PAGE: 40.1

STUDY NUMBER: 6127111

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=U;SUBSET=ALL

SIGNIFICANCE USING DUNNETT'S TEST IS INDICATED NEXT TO THE '# IN GRP.' AS FOLLOWS: '*' = .05 LEVEL, '**' = .01 LEVEL

SEX:	MALE				FEMALE			
GROUP:	1	2	3	4	1	2	3	4
NUMBER:	2	2	2	2	2	2	2	2
>>> TERMINAL BODY WEIGHT (g) <<<								
# IN GRP.:	2	2	2	2	2	2	2	2
MEAN:	11000.0	11400.0	10200.0	10400.0	8800.0	9700.0	8600.0	9750.0
STAND DEV:	1131.4	1414.2	848.5	848.5	141.4	141.4	565.7	212.2
>>> TYD - THYROID(S)/PARA <<<								
# IN GRP.:	2	2	2	2	2	2	2	2
MEAN:	.0092	.0127	.0096	.0097	.0116	.0100	.0089	.0093
STAND DEV:	.0027	.0030	.0013	.0030	.0008	.0017	.0001	.0005
>>> HT - HEART <<<								
# IN GRP.:	2	2	2	2	2	2	2	2
MEAN:	.7661	.7805	.8222	.7926	.8555	.7417	.7911	.8030
STAND DEV:	.0571	.0892	.1200	.0097	.0224	.0967	.1046	.0545
>>> AD - ADRENAL(S) <<<								
# IN GRP.:	2	2	2	2	2	2	2	2
MEAN:	.0104	.0118	.0109	.0127	.0115	.0139	.0136	.0122
STAND DEV:	.0022	.0015	.0010	.0019	.0002	.0034	.0043	.0009
>>> SP - SPLEEN <<<								
# IN GRP.:	2	2	2	2	2	2	2	2
MEAN:	.2416	.2565	.3213	.2527	.2642	.3326	.2798	.2704
STAND DEV:	.0570	.0074	.0508	.0640	.0311	.0349	.0037	.0180

TABLE 40

SUMMARY OF ORGAN-TO-BODY WEIGHT PERCENTAGES

31 WEEK SACRIFICE

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MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

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TABLE.PAGE: 40.2

STUDY NUMBER: 6127111

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=U;SUBSET=ALL

SIGNIFICANCE USING DUNNETT'S TEST IS INDICATED NEXT TO THE '# IN GRP.' AS FOLLOWS: '*' = .05 LEVEL, '**' = .01 LEVEL

SEX:	MALE				FEMALE			
GROUP:	1	2	3	4	1	2	3	4
NUMBER:	2	2	2	2	2	2	2	2
>>> TH - THYMUS <<<								
# IN GRP.:	2	2	2	2	2	2	2	2
M E A N :	.0674	.0622	.0575	.1036	.0923	.0781	.0753	.0749
STAND DEV:	.0203	.0193	.0243	.0482	.0007	.0122	.0160	.0187
>>> SG - SALIVARY GLD(S) <<<								
# IN GRP.:	2	2	2	2	2	2	2	2
M E A N :	.1561	.1451	.1546	.1455	.1715	.1586	.1588	.1491
STAND DEV:	.0265	.0174	.0453	.0032	.0196	.0290	.0253	.0194
>>> KB - KIDNEY(S) <<<								
# IN GRP.:	2	2	2	2	2	2	2	2
M E A N :	.4807	.4535	.4723	.4306	.4255	.4015	.4101	.4309
STAND DEV:	.0209	.0247	.0237	.0498	.0425	.0414	.0416	.0211
>>> LI - LIVER <<<								
# IN GRP.:	2	2	2	2	2	2	2	2
M E A N :	2.9228	2.7035	2.7926	2.5891	2.7495	2.6176	2.5043	2.8256
STAND DEV:	.1499	.0037	.0440	.4416	.3264	.3947	.5319	.1174
>>> TE - TESTES <<<								
# IN GRP.:	2	2	2	2	0	0	0	0
M E A N :	.1285	.1295	.1426	.1243				
STAND DEV:	.0230	.0119	.0210	.0553				

TABLE 40

SUMMARY OF ORGAN-TO-BODY WEIGHT PERCENTAGES

31 WEEK SACRIFICE

HAZLETON LABORATORIES AMERICA, INC.
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TABLE.PAGE: 40.3

STUDY NUMBER: 6127111

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=U;SUBSET=ALL

SIGNIFICANCE USING DUNNETT'S TEST IS INDICATED NEXT TO THE '# IN GRP.' AS FOLLOWS: '*' = .05 LEVEL, '**' = .01 LEVEL

SEX:	MALE				FEMALE			
GROUP:	1	2	3	4	1	2	3	4
NUMBER:	2	2	2	2	2	2	2	2
>>> EP - EPIDIDYMIDES <<<								
# IN GRP.:	2	2	2	2	0	0	0	0
M E A N :	.0352	.0322	.0355	.0389				
STND DEV:	.0012	.0043	.0071	.0016				
>>> PR - PROSTATE <<<								
# IN GRP.:	2	2	2	2	0	0	0	0
M E A N :	.0580	.0531	.0492	.0481				
STAND DEV:	.0058	.0149	.0005	.0037				
>>> UT - UTERUS <<<								
# IN GRP.:	0	0	0	0	2	2	2	2
M E A N :					.1002	.1855	.0500	.0588
STAND DEV:					.0852	.0488	.0008	.0021
>>> OV - OVARIES <<<								
# IN GRP.:	0	0	0	0	2	2	2	2
M E A N :					.0103	.0160	.0116	.0090
STAND DEV:					.0024	.0052	.0023	.0031
>>> BR - BRAIN <<<								
# IN GRP.:	2	2	2	2	2	2	2	2
M E A N :	.7502	.6601	.7648	.7559	.7973	.7090	.8586	.7459
STAND DEV:	.0895	.0239	.0226	.0446	.0556	.0239	.0452	.0403

TABLE 40

SUMMARY OF ORGAN-TO-BODY WEIGHT PERCENTAGES

31 WEEK SACRIFICE

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

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STUDY NUMBER: 6127111

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=U;SUBSET=ALL

SIGNIFICANCE USING DUNNETT'S TEST IS INDICATED NEXT TO THE '# IN GRP.' AS FOLLOWS: '*' = .05 LEVEL, '**' = .01 LEVEL

SEX:	MALE				FEMALE			
GROUP:	1	2	3	4	1	2	3	4
NUMBER:	2	2	2	2	2	2	2	2
	>>> PI - PITUITARY <<<							
# IN GRP.:	2	2	2	2	2	2	2	2
M E A N :	.0005	.0004	.0005	.0005	.0006	.0005	.0006	.0005
STAND DEV:	.0000	.0000	.0001	.0002	.0002	.0001	.0001	.0001

TABLE 41

SUMMARY OF ORGAN-TO-BRAIN WEIGHT RATIOS

27 WEEK SACRIFICE

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

PRINTED: 11-JUN-86
TABLE.PAGE: 41.1

STUDY NUMBER: 6127111

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=T;SUBSET=ALL

SIGNIFICANCE USING DUNNETT'S TEST IS INDICATED NEXT TO THE '# IN GRP.' AS FOLLOWS: '*' = .05 LEVEL, '**' = .01 LEVEL

SEX:	MALE				FEMALE			
GROUP:	1	2	3	4	1	2	3	4
NUMBER:	4	4	4	4	4	4	4	4
>>> TYO - THYROID(S)/PARA <<<								
# IN GRP.:	4	4	4	4	4	4	4	4
M E A N :	.0131	.0161	.0153	.0142	.0116	.0121	.0129	.0127
D DEV:	.0016	.0024	.0024	.0017	.0011	.0015	.0023	.0034
>>> HT - HEART <<<								
# IN GRP.:	4	4	4	4	4	4	4	4
M E A N :	1.1064	1.2322	1.1933	1.1052	1.0461	.9740	1.2223	.9306
STAND DEV:	.1055	.1949	.1913	.1653	.1428	.1040	.1053	.0958
>>> AD - ADRENAL(S) <<<								
# IN GRP.:	4	4	4	4	4	4	4 *	4 **
M E A N :	.0131	.0147	.0176	.0152	.0212	.0169	.0161	.0142
STAND DEV:	.0018	.0016	.0032	.0011	.0012	.0033	.0025	.0023
>>> SP - SPLEEN <<<								
# IN GRP.:	4	4	4	4	4	4	4	4
M E A N :	.4387	.3907	.4549	.3787	.5176	.3850	.3853	.3137
STAND DEV:	.1641	.0875	.0957	.1331	.1875	.0786	.0477	.0431
>>> TH - THYMUS <<<								
# IN GRP.:	4	4	4	4	4	4	4	4
M E A N :	.0905	.1095	.1316	.0900	.1245	.0723	.0897	.0681
STAND DEV:	.0155	.0626	.0761	.0603	.0532	.0269	.0532	.0186

TABLE 41

SUMMARY OF ORGAN-TO-BRAIN WEIGHT RATIOS

27 WEEK SACRIFICE

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

PRINTED: 11-JUN-86
TABLE.PAGE: 41.2

STUDY NUMBER: 6127111

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=T;SUBSET=ALL

SIGNIFICANCE USING DUNNETT'S TEST IS INDICATED NEXT TO THE '# IN GRP.' AS FOLLOWS: '*' = .05 LEVEL, '**' = .01 LEVEL

SEX:	MALE				FEMALE			
GROUP:	1	2	3	4	1	2	3	4
NUMBER:	4	4	4	4	4	4	4	4
>>> SG - SALIVARY GLD(S) <<<								
# IN GRP.:	4	4	4	4	4	4 **	4	4
M E A N :	.2220	.2051	.2205	.2210	.2338	.1780	.2044	.1922
STAND DEV:	.0170	.0415	.0204	.0371	.0247	.0275	.0086	.0225
>>> KD - KIDNEY(S) <<<								
# IN GRP.:	4	4	4	4	4	4	4	4
M E A N :	.7754	.7212	.6910	.6883	.5459	.5211	.5931	.5156
STAND DEV:	.1987	.1159	.0833	.0567	.0218	.0124	.0332	.0321
>>> LI - LIVER <<<								
# IN GRP.:	4	4	4	4	4	4	4	4
M E A N :	3.6895	3.6723	3.8719	3.8892	3.6303	3.0180	3.4068	3.2511
STAND DEV:	.5255	.6888	.4772	.6482	.3892	.5715	.2131	.2483
>>> TE - TESTES <<<								
# IN GRP.:	4	4	4	4	0	0	0	0
M E A N :	.2032	.2192	.2136	.2119				
STAND DEV:	.0176	.0438	.0467	.0234				
>>> EP - EPIDIDYMIDES <<<								
# IN GRP.:	4	4	4	4	0	0	0	0
M E A N :	.0541	.0495	.0495	.0512				
STAND DEV:	.0057	.0076	.0149	.0108				

TABLE 41

SUMMARY OF ORGAN-TO-BRAIN WEIGHT RATIOS

27 WEEK SACRIFICE

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
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*** PATH/TOX SYSTEM OUTPUT ***

PRINTED: 11-JUN-86
TABLE.PAGE: 41.3

STUDY NUMBER: 6127111

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=T;SUBSET=ALL

SIGNIFICANCE USING DUNNETT'S TEST IS INDICATED NEXT TO THE '# IN GRP.' AS FOLLOWS: '*' = .05 LEVEL, '**' = .01 LEVEL

SEX:	MALE				FEMALE			
GROUP:	1	2	3	4	1	2	3	4
NUMBER:	4	4	4	4	4	4	4	4
>>> PR - PROSTATE <<<								
# IN GRP.:	4	4	4	4	0	0	0	0
M E A N :	.1010	.0680	.0742	.0610				
STAND DEV:	.0099	.0301	.0603	.0417				
>>> UT - UTERUS <<<								
# IN GRP.:	0	0	0	0	4	4	4	4
M E A N :					.1904	.0400	.0992	.1326
STAND DEV:					.1059	.0250	.0937	.1267
>>> OV - OVARIES <<<								
# IN GRP.:	0	0	0	0	4	4	4	4
M E A N :					.0198	.0116	.0142	.0149
STAND DEV:					.0071	.0047	.0021	.0047
>>> BR - BRAIN <<<								
# IN GRP.:	4	4	4	4	4	4	4	4
M E A N :	1.0000	1.0000	1.0000	1.0000	1.0000	1.0000	1.0000	1.0000
STAND DEV:	.0000	.0000	.0000	.0000	.0000	.0000	.0000	.0000
>>> PI - PITUITARY <<<								
# IN GRP.:	4	4	4	4	4	4	4	4
M E A N :	.0007	.0008	.0008	.0008	.0009	.0006	.0008	.0007
STAND DEV:	.0002	.0001	.0005	.0002	.0001	.0003	.0001	.0001

TABLE 42

SUMMARY OF ORGAN-TO-BRAIN WEIGHT RATIOS

31 WEEK SACRIFICE

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

PRINTED: 19-MAY-86
TABLE.PAGE: 42.1

STUDY NUMBER: 6127111

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=U;SUBSET=ALL

SIGNIFICANCE USING DUNNETT'S TEST IS INDICATED NEXT TO THE '# IN GRP.' AS FOLLOWS: '*' = .05 LEVEL, '**' = .01 LEVEL

SEX:	MALE				FEMALE			
GROUP:	1	2	3	4	1	2	3	4
NUMBER:	2	2	2	2	2	2	2	2
>>> TERMINAL BODY WEIGHT (g) <<<								
# IN GRP.:	2	2	2	2	2	2	2	2
MEAN:	11000.0	11400.0	10200.0	10400.0	8800.0	9700.0	8600.0	9750.0
STAND DEV:	1131.4	1414.2	848.5	848.5	141.4	141.4	565.7	212.2
>>> TYO - THYROID(S)/PARA <<<								
# IN GRP.:	2	2	2	2	2	2	2	2
MEAN:	.0122	.0192	.0126	.0130	.0146	.0142	.0104	.0125
STAND DEV:	.0021	.0039	.0021	.0047	.0000	.0029	.0004	.0000
>>> HT - HEART <<<								
# IN GRP.:	2	2	2	2	2	2	2	2
MEAN:	1.0239	1.1856	1.0778	1.0509	1.0746	1.0490	.9195	1.0801
STAND DEV:	.0460	.1781	.1887	.0748	.0468	.1718	.0734	.1314
>>> AD - ADRENAL(S) <<<								
# IN GRP.:	2	2	2	2	2	2	2	2
MEAN:	.0137	.0178	.0143	.0169	.0145	.0197	.0157	.0164
STAND DEV:	.0013	.0016	.0017	.0035	.0013	.0054	.0041	.0020
>>> SP - SPLEEN <<<								
# IN GRP.:	2	2	2	2	2	2	2	2
MEAN:	.3290	.3890	.4193	.3374	.3335	.4702	.3262	.3624
STAND DEV:	.1152	.0253	.0540	.1046	.0623	.0651	.0128	.0045

TABLE 42

SUMMARY OF ORGAN-TO-BRAIN WEIGHT RATIOS

31 WEEK SACRIFICE

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

PRINTED: 19-MAY-86
TABLE.PAGE: 42.2

STUDY NUMBER: 6127111

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=U;SUBSET=ALL

SIGNIFICANCE USING DUNNETT'S TEST IS INDICATED NEXT TO THE '# IN GRP.' AS FOLLOWS: '*' = .05 LEVEL, '**' = .01 LEVEL

SEX:	MALE				FEMALE			
GROUP:	1	2	3	4	1	2	3	4
NUMBER:	2	2	2	2	2	2	2	2
>>> TH - THYMUS <<<								
# IN GRP.:	2	2	2	2	2	2	2	2
M E A N :	.0889	.0937	.0747	.1391	.1160	.1106	.0873	.1013
STAND DEV:	.0164	.0259	.0295	.0720	.0089	.0209	.0140	.0305
>>> SG - SALIVARY GLD(S) <<<								
# IN GRP.:	2	2	2	2	2	2	2	2
M E A N :	.2117	.2195	.2014	.1927	.2165	.2245	.1860	.1995
STAND DEV:	.0605	.0185	.0534	.0072	.0397	.0485	.0393	.0153
>>> KD - KIDNEY(S) <<<								
# IN GRP.:	2	2	2	2	2	2	2	2
M E A N :	.6470	.6867	.6183	.5687	.5332	.5676	.4770	.5793
STAND DEV:	.1051	.0126	.0493	.0323	.0161	.0776	.0233	.0596
>>> LI - LIVER <<<								
# IN GRP.:	2	2	2	2	2	2	2	2
M E A N :	3.9119	4.0983	3.6538	3.4141	3.4427	3.7034	2.9045	3.7981
STAND DEV:	.2670	.1546	.1653	.3827	.1692	.6817	.4664	.3624
>>> TE - TESTES <<<								
# IN GRP.:	2	2	2	2	0	0	0	0
M E A N :	.1706	.1966	.1861	.1626				
STAND DEV:	.0104	.0251	.0220	.0636				

TABLE 42

SUMMARY OF ORGAN-TO-BRAIN WEIGHT RATIOS

31 WEEK SACRIFICE

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

PRINTED: 19-MAY-86
TABLE.PAGE: 42.3

STUDY NUMBER: 6127111

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=U;SUBSET=ALL

SIGNIFICANCE USING DUNNETT'S TEST IS INDICATED NEXT TO THE '# IN GRP.' AS FOLLOWS: '*' = .05 LEVEL, '**' = .01 LEVEL

SEX:	MALE				FEMALE			
GROUP:	1	2	3	4	1	2	3	4
NUMBER:	2	2	2	2	2	2	2	2
>>> EP - EPIDIDYMIDES <<<								
# IN GRP.:	2	2	2	2	0	0	0	0
M E A N :	.0473	.0489	.0463	.0517				
STAND DEV:	.0072	.0083	.0079	.0052				
>>> PR - PROSTATE <<<								
# IN GRP.:	2	2	2	2	0	0	0	0
M E A N :	.0774	.0810	.0644	.0639				
STAND DEV:	.0014	.0255	.0012	.0087				
>>> UT - UTERUS <<<								
# IN GRP.:	0	0	0	0	2	2	2	2
M E A N :					.1297	.2630	.0583	.0789
STAND DEV:					.1159	.0777	.0022	.0015
>>> OV - OVARIES <<<								
# IN GRP.:	0	0	0	0	2	2	2	2
M E A N :					.0131	.0226	.0134	.0122
STAND DEV:					.0039	.0082	.0020	.0048
>>> BR - BRAIN <<<								
# IN GRP.:	2	2	2	2	2	2	2	2
M E A N :	1.0000	1.0000	1.0000	1.0000	1.0000	1.0000	1.0000	1.0000
STAND DEV:	.0000	.0000	.0000	.0000	.0000	.0000	.0000	.0000

TABLE 42

SUMMARY OF ORGAN-TO-BRAIN WEIGHT RATIOS

31 WEEK SACRIFICE

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

PRINTED: 19-MAY-86
TABLE.PAGE: 42.4

STUDY NUMBER: 6127111

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=U;SUBSET=ALL

SIGNIFICANCE USING DUNNETT'S TEST IS INDICATED NEXT TO THE '# IN GRP.' AS FOLLOWS: '*' = .05 LEVEL, '**' = .01 LEVEL

SEX:	MALE				FEMALE			
GROUP:	1	2	3	4	1	2	3	4
NUMBER:	2	2	2	2	2	2	2	2
	>>> PI - PITUITARY <<<							
# IN GRP.:	2	2	2	2	2	2	2	2
MEAN:	.0006	.0006	.0006	.0007	.0008	.0008	.0006	.0007
S.D.EV:	.0001	.0001	.0001	.0002	.0002	.0001	.0001	.0001

TABLE 43

INCIDENCE OF MICROSCOPIC OBSERVATIONS

27 WEEK SACRIFICE

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

PRINTED: 10-JUN-86
TABLE.PAGE: 43.1

STUDY NUMBER: 6127111

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;SCREEN=ALL;WEEKS=ALL
DEATH=T;FIND=ALL;SUBSET=ALL

ORGAN AND FINDING DESCRIPTION		--- NUMBER-OF-ANIMALS-AFFECTED ---							
SEX:		-------MALE-------				------FEMALE------			
GROUP:		-1-	-2-	-3-	-4-	-1-	-2-	-3-	-4-
NUMBER:		4	4	4	4	4	4	4	4
** TOP OF LIST **									
BRAIN (BR)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	4	4	4	4	4	4	4
LUNG (LU)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	3	4	4	4	4	3	4
--PNEUMONITIS		0	1	0	0	0	0	1	0
HEART (HT)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	4	4	4	4	4	4	4
KIDNEY, LEFT (KD0)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	1	0	1	1	0	3	1	1
--MINERALIZATION		3	4	3	3	4	1	3	3
KIDNEY, RIGHT (KD1)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	0	0	0	0	1	2	0	2
--MINERALIZATION		4	4	4	4	3	2	4	2
LIVER (LI)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	4	3	4	4	4	4	4
--INFILTRATE,MONONUCLEAR CELL		0	0	1	0	0	0	0	0

TABLE 43

INCIDENCE OF MICROSCOPIC OBSERVATIONS

27 WEEK SACRIFICE

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

PRINTED: 10-JUN-86
TABLE.PAGE: 43.2

STUDY NUMBER: 6127111

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;SCREEN=ALL;WEEKS=ALL
DEATH=T;FIND=ALL;SUBSET=ALL

ORGAN AND FINDING DESCRIPTION		--- NUMBER-OF-ANIMALS-AFFECTED ---							
SEX:		-------MALE-------				------FEMALE------			
GROUP:		-1-	-2-	-3-	-4-	-1-	-2-	-3-	-4-
	NUMBER:	4	4	4	4	4	4	4	4
GALL BLADDER (GB)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	4	4	4	4	4	4	4
SPLEEN (SP)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	4	4	4	4	4	4	3
--FIBROSIS,CAPSULAR		0	0	0	0	0	0	0	1
EYE(S) (EY)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	4	4	4	4	4	4	4
THYROID(S) (TY)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	3	4	3	3	4	4	3
--"C" CELL HYPERPLASIA		0	1	0	1	1	0	0	0
--CYST(S),NOS.		0	0	0	1	0	0	0	0
--ONE EXAMINED		0	0	0	0	0	0	0	1
PARATHYROID(S) (PT)	NUMBER EXAMINED:	4	4	4	4	3	4	4	4
	NOT REMARKABLE:	3	2	2	2	3	3	3	3
--ONE EXAMINED		1	2	1	2	0	1	0	1
--CYST(S)		0	0	1	0	0	0	1	0

TABLE 43

INCIDENCE OF MICROSCOPIC OBSERVATIONS

27 WEEK SACRIFICE

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

PRINTED: 10-JUN-86
TABLE.PAGE: 43.3

STUDY NUMBER: 6127111

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;SCREEN=ALL;WEEKS=ALL
DEATH=T;FIND=ALL;SUBSET=ALL

ORGAN AND FINDING DESCRIPTION		--- NUMBER-OF-ANIMALS-AFFECTED ---							
	SEX:	-------MALE-------				------FEMALE------			
	GROUP:	-1-	-2-	-3-	-4-	-1-	-2-	-3-	-4-
	NUMBER:	4	4	4	4	4	4	4	4
TRACHEA (TR)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	4	4	4	4	4	4	4
ESOPHAGUS (ES)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	4	4	4	4	4	4	4
PITUITARY (PI)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	4	4	4	4	3	4	4
—CYST(S)		0	0	0	0	0	1	0	0
ADRENAL(S) (AD)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	4	4	4	4	4	4	4
AORTA (AO)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	4	4	4	4	4	4	4
TONGUE (TO)	NUMBER EXAMINED:	4	4	4	4	4	3	4	4
	NOT REMARKABLE:	4	4	4	4	4	3	3	4
—INFILTRATE,MONONUCLEAR CELLS		0	0	0	0	0	0	1	0

TABLE 43

INCIDENCE OF MICROSCOPIC OBSERVATIONS

27 WEEK SACRIFICE

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

PRINTED: 10-JUN-86
TABLE.PAGE: 43.4

STUDY NUMBER: 6127111

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;SCREEN=ALL;WEEKS=ALL
DEATH=T;FIND=ALL;SUBSET=ALL

ORGAN AND FINDING DESCRIPTION		--- NUMBER-OF-ANIMALS-AFFECTED ---							
SEX:		-------MALE-------				------FEMALE------			
GROUP:		-1-	-2-	-3-	-4-	-1-	-2-	-3-	-4-
	NUMBER:	4	4	4	4	4	4	4	4
PANCREAS (PA)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	4	4	4	4	4	4	4
STOMACH (ST)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	4	4	4	4	4	4	4
DUODENUM (DU)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	4	4	4	4	4	4	4
JEJUNUM (JE)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	3	4	4	4	4	4	4	4
--MUCOUS ON MUCOSA		1	0	0	0	0	0	0	0
ILEUM (IL)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	3	4	4	4	4	4	4	4
--MUCOUS ON MUCOSA		1	0	0	0	0	0	0	0
CECUM (CE)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	4	4	4	4	4	4	4

TABLE 43

INCIDENCE OF MICROSCOPIC OBSERVATIONS

27 WEEK SACRIFICE

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

PRINTED: 10-JUN-86
TABLE.PAGE: 43.5

STUDY NUMBER: 6127111

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;SCREEN=ALL;WEEKS=ALL
DEATH=T;FIND=ALL;SUBSET=ALL

ORGAN AND FINDING DESCRIPTION		--- NUMBER-OF-ANIMALS-AFFECTED ---							
	SEX:	-------MALE-------				------FEMALE------			
	GROUP:	-1-	-2-	-3-	-4-	-1-	-2-	-3-	-4-
	NUMBER:	4	4	4	4	4	4	4	4
COLON (CO)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	3	4	4	4	4	4	4	4
--MUCOUS ON MUCOSA		1	0	0	0	0	0	0	0
RECTUM (RE)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	4	4	4	4	4	4	4
SKIN (SK)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	2	3	3	3	4	4	4
--ACANTHOSIS		0	2	1	1	0	0	0	0
--HYPERKERATOSIS		0	1	0	1	0	0	0	0
--DERMATITIS		0	0	1	0	0	0	0	0
--ULCERATIVE DERMATITIS		0	0	0	1	0	0	0	0
--FOLLICULITIS,NOS.		0	0	0	0	1	0	0	0
SCIATIC NERVE (SN)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	4	4	4	4	4	4	4
SKELETAL MUSCLE (SM)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	4	4	4	4	4	4	4

TABLE 43

INCIDENCE OF MICROSCOPIC OBSERVATIONS

27 WEEK SACRIFICE

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

PRINTED: 10-JUN-86
TABLE.PAGE:-43.6

STUDY NUMBER: 6127111

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;SCREEN=ALL;WEEKS=ALL
DEATH=T;FIND=ALL;SUBSET=ALL

ORGAN AND FINDING DESCRIPTION		--- NUMBER-OF-ANIMALS-AFFECTED ---							
SEX:		-------MALE-------				------FEMALE------			
GROUP:		-1-	-2-	-3-	-4-	-1-	-2-	-3-	-4-
NUMBER:		4	4	4	4	4	4	4	4
SALIVARY GLD(S) (SG)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	4	3	4	4	4	3	4
-MONONUCLEAR INFILTRATION		0	0	1	0	0	0	1	0
MANDIB/CERV LN (MN)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	4	4	4	4	4	4	4
THYMUS (TH)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	2	3	3	4	4	4	3
--INVOLUTION		0	2	1	1	0	0	0	1
--HEMORRHAGE		0	1	0	0	0	0	0	0
--CYST(S)		0	0	1	1	0	0	0	0
MESENTERIC LN (MS)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	4	4	4	4	4	4	4
FEMUR M/MARROW (FE)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	4	4	4	4	4	4	4
FEMUR M/ART SURF (FEO)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	4	4	4	4	4	4	4

TABLE 43

INCIDENCE OF MICROSCOPIC OBSERVATIONS

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DEPARTMENT OF PATHOLOGY
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*** PATH/TOX SYSTEM OUTPUT ***

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STUDY NUMBER: 6127111

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;SCREEN=ALL;WEEKS=ALL
DEATH=T;FIND=ALL;SUBSET=ALL

ORGAN AND FINDING DESCRIPTION		--- NUMBER-OF-ANIMALS-AFFECTED ---							
SEX:		-------MALE-------				------FEMALE------			
GROUP:		-1-	-2-	-3-	-4-	-1-	-2-	-3-	-4-
	NUMBER:	4	4	4	4	4	4	4	4
STERNUM W/MARROW (SE)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	4	4	4	4	4	4	4
SPINAL CORD (SC)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	4	4	4	4	4	4	4
URINARY BLADDER (UB)	NUMBER EXAMINED:	4	4	4	4	4	4	4	4
	NOT REMARKABLE:	4	4	4	4	4	4	4	4
PROSTATE (PR)	NUMBER EXAMINED:	4	4	4	4	0	0	0	0
	NOT REMARKABLE:	4	4	4	4	0	0	0	0
TESTES (TE)	NUMBER EXAMINED:	4	4	4	4	0	0	0	0
	NOT REMARKABLE:	4	4	4	4	0	0	0	0
EPIDIDYMIDES (EP)	NUMBER EXAMINED:	4	4	4	4	0	0	0	0
	NOT REMARKABLE:	3	4	4	4	0	0	0	0
--SPERM GRANULOMA		1	0	0	0	0	0	0	0
MAMMARY GLAND (MG)	NUMBER EXAMINED:	0	0	0	0	4	4	3	3
	NOT REMARKABLE:	0	0	0	0	4	4	3	3

TABLE 43

INCIDENCE OF MICROSCOPIC OBSERVATIONS

27 WEEK SACRIFICE

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

PRINTED: 10-JUN-86
TABLE.PAGE: 43.8

STUDY NUMBER: 6127111

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;SCREEN=ALL;WEEKS=ALL
DEATH=T;FIND=ALL;SUBSET=ALL

ORGAN AND FINDING DESCRIPTION		--- NUMBER-OF-ANIMALS-AFFECTED ---							
SEX:		-------MALE-------				------FEMALE------			
GROUP:		-1-	-2-	-3-	-4-	-1-	-2-	-3-	-4-
	NUMBER:	4	4	4	4	4	4	4	4
UTERUS (UT)	NUMBER EXAMINED:	0	0	0	0	4	4	4	4
	NOT REMARKABLE:	0	0	0	0	4	4	4	4
CERVIX (CV)	NUMBER EXAMINED:	0	0	0	0	4	4	4	4
	NOT REMARKABLE:	0	0	0	0	4	4	4	4
VAGINA (VA)	NUMBER EXAMINED:	0	0	0	0	4	4	4	4
	NOT REMARKABLE:	0	0	0	0	4	4	4	4
OVARIES (OV)	NUMBER EXAMINED:	0	0	0	0	4	4	4	4
	NOT REMARKABLE:	0	0	0	0	4	4	4	4
EAR (ER)	NUMBER EXAMINED:	0	0	1	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0	0
--DERMATITIS		0	0	1	0	0	0	0	0
--ACANTHOSIS		0	0	1	0	0	0	0	0
MEDIAST/BRONC LN (ML)	NUMBER EXAMINED:	0	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0	0

TABLE 43

INCIDENCE OF MICROSCOPIC OBSERVATIONS

27 WEEK SACRIFICE

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

PRINTED: 10-JUN-86
TABLE.PAGE: 43.9

STUDY NUMBER: 6127111

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;SCREEN=ALL;WEEKS=ALL
DEATH=T;FIND=ALL;SUBSET=ALL

ORGAN AND FINDING DESCRIPTION		--- NUMBER-OF-ANIMALS-AFFECTED ---							
	SEX:	-------MALE-------				------FEMALE------			
	GROUP:	-1-	-2-	-3-	-4-	-1-	-2-	-3-	-4-
	NUMBER:	4	4	4	4	4	4	4	4
ANT.MES/PANC LM (AN)	NUMBER EXAMINED:	0	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0	0

** END OF LIST **

TABLE 44

INCIDENCE OF MICROSCOPIC OBSERVATIONS

31 WEEK SACRIFICE

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

PRINTED: 19-MAY-86
TABLE.PAGE: 44.1

STUDY NUMBER: 6127111

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;SCREEN=ALL;WEEKS=ALL
DEATH=U;FIND=ALL;SUBSET=ALL

ORGAN AND FINDING DESCRIPTION		--- NUMBER-OF-ANIMALS-AFFECTED ---							
SEX:		-------MALE-------				------FEMALE------			
GROUP:		-1-	-2-	-3-	-4-	-1-	-2-	-3-	-4-
NUMBER:		2	2	2	2	2	2	2	2
** TOP OF LIST **									
BRAIN (BR)	NUMBER EXAMINED:	0	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0	0
LUNG (LU)	NUMBER EXAMINED:	1	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0	0
--PNEUMONITIS		1	0	0	0	0	0	0	0
--CONGESTION/HEMORRHAGE		1	0	0	0	0	0	0	0
HEART (HT)	NUMBER EXAMINED:	0	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0	0
KIDNEY, LEFT (KD0)	NUMBER EXAMINED:	0	0	1	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0	0
--CYST(S)		0	0	1	0	0	0	0	0
KIDNEY, RIGHT (KD1)	NUMBER EXAMINED:	0	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0	0
LIVER (LI)	NUMBER EXAMINED:	0	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0	0

TABLE 44

INCIDENCE OF MICROSCOPIC OBSERVATIONS

31 WEEK SACRIFICE

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

PRINTED: 19-MAY-86
TABLE.PAGE: 44.2

STUDY NUMBER: 6127111

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;SCREEN=ALL;WEEKS=ALL
DEATH=U;FIND=ALL;SUBSET=ALL

ORGAN AND FINDING DESCRIPTION		--- NUMBER-OF-ANIMALS-AFFECTED ---							
SEX:		-------MALE-------				------FEMALE------			
GROUP:		-1-	-2-	-3-	-4-	-1-	-2-	-3-	-4-
NUMBER:		2	2	2	2	2	2	2	2
GALL BLADDER (GB)	NUMBER EXAMINED:	0	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0	0
SPLEEN (SP)	NUMBER EXAMINED:	0	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0	0
EYE(S) (EY)	NUMBER EXAMINED:	0	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0	0
THYROID(S) (TY)	NUMBER EXAMINED:	0	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0	0
PARATHYROID(S) (PT)	NUMBER EXAMINED:	0	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0	0
TRACHEA (TR)	NUMBER EXAMINED:	0	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0	0
ESOPHAGUS (ES)	NUMBER EXAMINED:	0	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0	0

TABLE 44

INCIDENCE OF MICROSCOPIC OBSERVATIONS

31 WEEK SACRIFICE

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

PRINTED: 19-MAY-86
TABLE.PAGE: 44.3

STUDY NUMBER: 6127111

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;SCREEN=ALL;WEEKS=ALL
DEATH=U;FIND=ALL;SUBSET=ALL

ORGAN AND FINDING DESCRIPTION		--- NUMBER-OF-ANIMALS-AFFECTED ---							
	SEX:	-------MALE-------				------FEMALE------			
	GROUP:	-1-	-2-	-3-	-4-	-1-	-2-	-3-	-4-
	NUMBER:	2	2	2	2	2	2	2	2
PITUITARY (PI)	NUMBER EXAMINED:	0	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0	0
ADRENAL(S) (AD)	NUMBER EXAMINED:	0	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0	0
AORTA (AO)	NUMBER EXAMINED:	0	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0	0
TONGUE (TO)	NUMBER EXAMINED:	0	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0	0
PANCREAS (PA)	NUMBER EXAMINED:	0	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0	0
STOMACH (ST)	NUMBER EXAMINED:	0	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0	0
DUODENUM (DU)	NUMBER EXAMINED:	0	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0	0

TABLE 44

INCIDENCE OF MICROSCOPIC OBSERVATIONS

31 WEEK SACRIFICE

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

PRINTED: 19-MAY-86
TABLE.PAGE: 44.4

STUDY NUMBER: 6127111

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;SCREEN=ALL;WEEKS=ALL
DEATH=U;FIND=ALL;SUBSET=ALL

ORGAN AND FINDING DESCRIPTION		--- NUMBER-OF-ANIMALS-AFFECTED ---							
SEX:		-------MALE-------				------FEMALE------			
GROUP:		-1-	-2-	-3-	-4-	-1-	-2-	-3-	-4-
NUMBER:		2	2	2	2	2	2	2	2
JEJUNUM (JE)	NUMBER EXAMINED:	0	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0	0
ILEUM (IL)	NUMBER EXAMINED:	0	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0	0
CECUM (CE)	NUMBER EXAMINED:	0	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0	0
COLON (CO)	NUMBER EXAMINED:	0	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0	0
RECTUM (RE)	NUMBER EXAMINED:	0	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0	0
SKIN (SK)	NUMBER EXAMINED:	0	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0	0
SCIATIC NERVE (SN)	NUMBER EXAMINED:	0	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0	0

TABLE 44

INCIDENCE OF MICROSCOPIC OBSERVATIONS

31 WEEK SACRIFICE

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

PRINTED: 19-MAY-86
TABLE.PAGE: 44.5

STUDY NUMBER: 6127111

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;SCREEN=ALL;WEEKS=ALL
DEATH=U;FIND=ALL;SUBSET=ALL

ORGAN AND FINDING DESCRIPTION		--- NUMBER-OF-ANIMALS-AFFECTED ---							
SEX:		-------MALE-------				------FEMALE------			
GROUP:		-1-	-2-	-3-	-4-	-1-	-2-	-3-	-4-
NUMBER:		2	2	2	2	2	2	2	2
SKELETAL MUSCLE (SM)	NUMBER EXAMINED:	0	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0	0
SALIVARY GLD(S) (SG)	NUMBER EXAMINED:	0	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0	0
MANDIB/CERV LN (MN)	NUMBER EXAMINED:	0	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0	0
THYMUS (TH)	NUMBER EXAMINED:	0	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0	0
MESENTERIC LN (MS)	NUMBER EXAMINED:	0	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0	0
FEMUR W/MARROW (FE)	NUMBER EXAMINED:	0	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0	0
FEMUR W/ART SURF (FEQ)	NUMBER EXAMINED:	0	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0	0

TABLE 44

INCIDENCE OF MICROSCOPIC OBSERVATIONS

31 WEEK SACRIFICE

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DEPARTMENT OF PATHOLOGY
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STUDY NUMBER: 6127111

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;SCREEN=ALL;WEEKS=ALL
DEATH=U;FIND=ALL;SUBSET=ALL

ORGAN AND FINDING DESCRIPTION		--- NUMBER-OF-ANIMALS-AFFECTED ---							
	SEX:	-------MALE-------				------FEMALE------			
	GROUP:	-1-	-2-	-3-	-4-	-1-	-2-	-3-	-4-
	NUMBER:	2	2	2	2	2	2	2	2
STERNUM W/MARROW (SE)	NUMBER EXAMINED:	0	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0	0
SPINAL CORD (SC)	NUMBER EXAMINED:	0	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0	0
URINARY BLADDER (UB)	NUMBER EXAMINED:	0	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0	0
PROSTATE (PR)	NUMBER EXAMINED:	0	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0	0
TESTES (TE)	NUMBER EXAMINED:	0	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0	0
EPIDIDYMIDES (EP)	NUMBER EXAMINED:	0	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0	0
MAMMARY GLAND (MG)	NUMBER EXAMINED:	0	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0	0

TABLE 44

INCIDENCE OF MICROSCOPIC OBSERVATIONS

31 WEEK SACRIFICE

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STUDY NUMBER: 6127111

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;SCREEN=ALL;WEEKS=ALL
DEATH=U;FIND=ALL;SUBSET=ALL

ORGAN AND FINDING DESCRIPTION		--- NUMBER-OF-ANIMALS-AFFECTED ---							
	SEX:	-------MALE-------				------FEMALE------			
	GROUP:	-1-	-2-	-3-	-4-	-1-	-2-	-3-	-4-
	NUMBER:	2	2	2	2	2	2	2	2
UTERUS (UT)	NUMBER EXAMINED:	0	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0	0
CERVIX (CU)	NUMBER EXAMINED:	0	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0	0
VAGINA (VA)	NUMBER EXAMINED:	0	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0	0
OVARIES (OV)	NUMBER EXAMINED:	0	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0	0
EAR (ER)	NUMBER EXAMINED:	0	0	0	0	1	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0	0
--ACANTHOSIS		0	0	0	0	1	0	0	0
MEDIAST/BRONC LN (ML)	NUMBER EXAMINED:	1	1	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0	0
--CONGESTION		1	1	0	0	0	0	0	0

TABLE 44

INCIDENCE OF MICROSCOPIC OBSERVATIONS

31 WEEK SACRIFICE

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

PRINTED: 19-MAY-86
TABLE.PAGE: 44.8

STUDY NUMBER: 6127111

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;SCREEN=ALL;WEEKS=ALL
DEATH=U;FIND=ALL;SUBSET=ALL

ORGAN AND FINDING DESCRIPTION		--- NUMBER-OF-ANIMALS-AFFECTED ---							
SEX:		-------MALE-------				------FEMALE------			
GROUP:		-1-	-2-	-3-	-4-	-1-	-2-	-3-	-4-
NUMBER:		2	2	2	2	2	2	2	2
ANT.MES/PANC LN (AM)	NUMBER EXAMINED:	0	0	1	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0	0
--CONGESTION		0	0	1	0	0	0	0	0

** END OF LIST **

APPENDIX A

Analytical Chemistry Report
Ophthalmology Report
Cardiology Report
Pathology Report

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ANALYTICAL CHEMISTRY REPORT

Twenty-Six Week Subchronic Toxicity Study in Dogs with SC-19129 Admixed in the Diet

Study No. 6127-111
Searle Study No. S.A. 2530

for

G. D. Searle & Co.
Skokie, Illinois

by

Hazleton Laboratories America, Inc.
3301 Kinsman Boulevard
Madison, Wisconsin 53704

August 21, 1986

INTRODUCTION

Diets of canine feed admixed with SC-19129 were analyzed to determine test material concentrations in support of Study No. 6127-111. The assays were run using Hazleton Laboratories America, Inc. (HLA) Method Procedure MP-GD11-MA (Appendix A).

Analyses included method validation, a supplemental linearity study, homogeneity of mixing samples, in-cage stability and homogeneity samples, a mixing contamination sample, and periodic dosing concentration samples.

Four dose levels/sex were used in this study. Control groups of each sex were fed basal diet. The low-, mid-, and high-dose levels were 250, 500, and 1,000 mg SC-19129/kg body weight/day, respectively. To give the desired dose (mg SC-19129/kg body weight/day), dosing concentrations (g SC-19129/kg diet) in the diet were adjusted weekly based on body weight and food consumption data.

METHOD

Method Procedure MP-GD11-MA was used to analyze all samples in this study. Where SC-19129 was added to basal diet, an appropriate number of 5-g samples was extracted with water. The extracts were centrifuged and the supernatants were filtered to remove any particulates in suspension. The samples were then diluted and quantitated by high performance liquid chromatography (HPLC).

Dosing control samples, which consisted of basal diet, were analyzed by the same method.

For the mixing contamination sample, the methanol used to rinse the mixing bowl was concentrated and analyzed for SC-19129 by HPLC.

RESULTS

Validation

A validation study was conducted to determine the linearity, recovery, and variance characteristics of the method. A supplementary linearity study was also conducted. The minimum detectable amount of SC-19129 was also determined using Method Procedure MP-GD11-MA.

Validation was done at three dosing concentrations: 1, 100, and 200 g SC-19129/kg diet. Validation samples were prepared in the laboratory by adding an accurately weighed amount of SC-19129 to approximately 5 g of diet. Five samples/dosing concentration/day were analyzed on each of 3 separate days by two different analysts.

For each set of five samples, two were arbitrarily selected for use as a control standard and a standard check. The other three samples were used to calculate the validation results. Basal diets were analyzed with each run to determine the background contribution.

The correlation coefficients determined in the linearity study conducted with the validation were all greater than 0.99; overall values were 0.9982 for each analyst. Analysis results are listed in Table 1. In the original SC-19129 validation work, two of the three dosing concentrations validated were diluted to a final concentration of approximately 0.05 mg/mL. The third dosing concentration was diluted to approximately 0.025 mg/mL. This dilution scheme resulted in essentially a two-point standard curve. To determine linearity of response over a broader range, a supplementary linearity study was conducted. A stock standard of SC-19129 was diluted to give four concentrations varying from 0.02 to 0.1 mg/mL. Equal volumes of each standard were injected, and the relative responses were used to determine linearity. The results of the supplementary linearity study are listed in Table 2.

The validation indicated a mean recovery of 99.8% for 54 samples and a coefficient of variation of 1.78%. Analysis results are listed in Table 3.

The minimum detectable amount of SC-19129 in canine diet was determined to be 0.05 g SC-19129/kg using the above method and normal sensitivities.

Homogeneity of Test Article When Mixed Into the Carrier

Before study initiation HLA conducted homogeneity determinations to certify that the test material was adequately mixed in the diet.

Two dosing concentrations, representing the projected lowest and highest dosing concentrations to be mixed in the study, were checked for homogeneity. These dosing concentrations were 6.579 and 36.111 g SC-19129/kg, respectively. The same parameters and procedures expected to be used throughout the study were used in preparing the homogeneity diets. These parameters included the mixing vessel, batch size, and sampling technique.

Nine samples of approximately 5 g each were taken from various locations throughout the mixing bowl in a roughly spiral pattern. One sample came from beneath the paddle. These samples were submitted to the analytical laboratory for analysis using Method Procedure MP-GD11-MA.

The results of the homogeneity determinations are listed in Table 4. Both mixes resulted in coefficients of variation of less than 1.5%.

In-Cage Stability and Homogeniety of Test Article in Carrier

Before study initiation HLA conducted studies to determine the in-cage stability and homogeneity of SC-19129 in canine diet. Tests were conducted at the lowest (6.579 g/kg) and the highest (36.111 g/kg) dosing concentrations

projected to be used in the study. Diets were prepared in the same manner as used for the in-life portion of the study. For each dosing concentration, portions of the diet were then presented to three animals for consumption.

At the time of mixing, nine 5-g samples from each dosing concentration were taken in a manner identical to that used for the homogeneity study. These samples were designated as Day 0 samples and submitted to the analytical laboratory for analysis. On Day 8, the feed jars were removed from the animal cages. One 5-g sample of diet was collected from each feed jar and submitted to the analytical laboratory for analysis.

The results of the in-cage stability and homogeneity analyses are listed in Table 5.

The mean values of the samples at the 8-day interval were the same as the mean values of the Day 0 samples at both the low and high dosing concentrations.

Mixing Contamination Study

Before study initiation HLA conducted a study to determine the maximum possible carry-over contamination caused by mixing.

After preparing the high dosing concentration homogeneity mix (36.111 g SC-19129/kg), the mixing bowl was cleaned according to HLA Standard Operating Procedure (SOP) OP-TARC-316. Following the normal cleanup, the interior of the bowl was rinsed with 4 L of methanol. The methanol rinse was collected and concentrated by rotary evaporation, and the residual SC-19129 was quantitated by HPLC.

The amount of SC-19129 detected by this procedure was less than the minimum detectable amount of 0.05 g SC-19129/kg.

Concentration of Test Article in Carrier

Dosing concentration analyses were conducted on all diets for Weeks 1, 3, 5, 10, 15, 20, and 25 of the study. At each time point, nine 5-g samples were taken from the mixer at each dosing concentration. Three of these samples were submitted to the analytical laboratory for analysis and the remaining six were stored frozen for use as replacement or archive samples.

The results of the individual analyses are listed in Tables 6 and 7. Summary results for each week are listed in Tables 8 and 9. Individual values ranged from 89.9% to 111.0% of theoretical dosing concentrations (100%). The weekly mean recovery values ranged from 94.5% to 110.6% of theoretical for all dosing concentrations. Over the entire course of the study, the mean percent recovery for each dosing concentration ranged from 99.5% to 101.9%.

DISCUSSION

Method Procedure MP-GD11-MA was proven to be valid for the determination of SC-19129 in canine diet. The method was linear (correlation coefficient was >0.99), accurate (recovery was >99%), and reproducible (coefficient of variation was 1.78%) using 54 samples at concentrations varying from 1 to 200 g SC-19129/kg diet.

The supplementary linearity study demonstrated that the method for detecting SC-19129 by HPLC was linear between 0.02 and 0.1 mg/mL. The correlation coefficient obtained using the linear regression of area as a function of concentration was 0.9998.

The limit of detection of the method was 0.05 g SC-19129/kg of diet.

SC-19129 was mixed into the carrier consistently and homogeneously using the procedure outlined in HLA SOP OP-TARC-316. Because the nine samples taken from mixes at 6.579 and 36.111 g/kg had coefficients of variation of less than 1.5%, the mixing procedure was deemed adequate at these dosing concentrations and at all dosing concentrations between them.

The results of the in-cage stability and homogeneity study showed that the dosing concentration of SC-19129 did not change significantly when stored in a dog cage in the presence of an animal for 8 days at ambient conditions. The mean values of the samples at the 8-day interval were the same as the mean values of the Day 0 samples at both the low and high dosing concentrations. Therefore, SC-19129 is considered stable and homogeneous in canine diet for all dosing concentrations between 6.579 and 36.111 g/kg when stored in a dog cage in the presence of an animal for 8 days at ambient conditions.

The amount of SC-19129 detected in the contamination study was less than the minimum detectable amount of 0.05 g SC-19129/kg. The 4 L of methanol rinse was concentrated to 5 mL. This solution was analyzed and found to contain 7.144 ug SC-19129/mL. Multiplying this by the final volume of 5 mL resulted in a total of 35.72 ug of residual SC-19129. The minimum batch size of any mix in this study was 20 kg. Therefore, the maximum possible contamination would be 1.79 ug SC-19129/kg diet. This is less than 0.0001% of the lowest dosing concentration of 8.3 g SC-19129/kg.

The results of the weekly analyses demonstrate that the animals on study were presented the correct amount of SC-19129 as prescribed in the protocol for Study No. 6127-111. The mean recovery of SC-19129 from most diets analyzed was well within ±10% of theoretical (100%) and no individual diet was outside ±15% of theoretical. The exceptions are the mean values for Groups 2 and 3 females during Week 5.

All sampling for Week 1 was taken as a single 150-g sample. The analytical laboratory then took three 5-g subsamples for analysis. This is a deviation from the protocol.

The Groups 2 and 3 diets (male and female) from Week 15 were analyzed using 8- to 10-g samples. This is a deviation from the method which called for a 5-g sample. The technician who sampled the diets from the mixing bowl incorrectly estimated the sample amount. Rather than compound the error by subsampling further, the entire sample was analyzed. The analytical laboratory adjusted the dilutions to obtain a final concentration that was within the limits of the linearity study (between 0.02 and 0.1 mg/mL). The error in sampling the diet was noted and corrected before the Group 4 diets were mixed. All Group 4 samples analyzed were 5-g samples as per the method. No significant difference in the results of the Group 4 samples versus the other samples was noted.

APPROVAL

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Study Director, Toxicology

8/21/86
Date

James Nettum
Formulation and Quality Control

8/21/86
Date

Robert D. Fischbeck
Director, Marketing and Client Services

8/21/86
Date

by and for Hazleton Laboratories America, Inc.

(2419F/s1)

Study No. 6127-111

Table 1

Linearity Results from Validation

Dosing Concentration[a]	Sample Number	Analyst 1 Concentration (mg/mL)	Analyst 1 Average Peak Area (mcV-Sec)[b]	Analyst 2 Concentration (mg/mL)	Analyst 2 Average Peak Area (mcV-Sec)[b]
		Day 1			
1	1	0.02751	691,448	0.02651	411,188
	2	0.02675	679,169	0.02475	384,466
	3	0.02615	666,622	0.02531	392,634
100	1	0.04873	1,261,876	0.04991	764,264
	2	0.04938	1,257,992	0.04988	751,802
	3	0.05129	1,305,303	0.04979	748,758
200	1	0.04904	1,211,802	0.04994	771,479
	2	0.05032	1,244,292	0.04988	782,096
	3	0.05214	1,280,011	0.05001	742,694
Correlation coefficient (n=9)		0.9973		0.9978	
		Day 2			
1	1	0.02684	681,378	0.02762	427,890
	2	0.02640	678,044	0.02036	314,853
	3	0.02552	662,126	0.02743	444,182
100	1	0.05001	1,284,535	0.05026	786,014
	2	0.04965	1,271,385	0.04972	778,266
	3	0.05019	1,271,887	0.04965	779,882
200	1	0.04924	1,251,366	0.05020	773,406
	2	0.05144	1,317,642	0.05045	789,212
	3	0.05086	1,279,958	0.05002	780,156
Correlation coefficient (n=9)		0.9996		0.9994	

[a]Grams of SC-19129/kg diet.
[b]mcV-Sec = microvolt-seconds.

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Table 1 (Continued)

Linearity Results from Validation

Dosing Concentration[a]	Sample Number	Analyst 1 Concentration (mg/mL)	Analyst 1 Average Peak Area (mcV-Sec)[b]	Analyst 2 Concentration (mg/mL)	Analyst 2 Average Peak Area (mcV-Sec)[b]
			Day 3		
1	1	0.02627	660,776	0.02498	392,715
	2	0.02654	690,828	0.02714	419,644
	3	0.02782	720,778	0.02538	397,414
100	1	0.05145	1,309,064	0.05023	778,843
	2	0.05118	1,287,934	0.05004	772,880
	3	0.05032	1,234,688	0.05009	766,082
200	1	0.04987	1,253,075	0.04977	784,696
	2	0.04966	1,238,486	0.04953	762,517
	3	0.04914	1,245,432	0.05022	782,548
Correlation coefficient (n=9)		0.9987		0.9994	
Overall correlation coefficient (n=27)		0.9982		0.9982	

[a]Grams of SC-19129/kg diet.
[b]mcV-Sec = microvolt-seconds.

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Table 2

Supplementary Linearity Study

Concentration (mg/mL)	Average Peak Area (mcV-Sec)[a]
0.02	454,172
0.04	918,251
0.08	1,767,816
0.10	2,232,209

Correlation coefficient (concentration versus area) = 0.9998.

[a]mcV-Sec = microvolt-seconds.

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Table 3

Percent Recoveries and Variance Results (%)

Day	Dosing Concentration (g SC-19129/kg Diet)								
	1	100	200	1	100	200	1	100	200
	Analyst 1			Analyst 2			Overall		
1	99.3	101.2	98.3	96.8	103.9	99.8			
	100.3	99.5	98.3	96.9	102.3	101.3			
	100.7	99.4	97.6	96.7	102.0	96.0			
Mean of 3	100.1	100.0	98.1	96.8	102.7	99.0			
Mean of 6							98.4	101.4	98.6
2	99.1	100.5	101.1	96.4	99.3	99.0			
	100.2	100.2	102.0	96.2	99.4	100.6			
	101.2	99.2	100.2	100.7	99.7	100.3			
Mean of 3	100.2	100.0	101.1	97.8	99.5	100.0			
Mean of 6							99.0	99.7	100.5
3	98.6	99.5	99.3	101.6	102.0	101.6			
	102.1	98.4	98.6	100.0	101.6	99.2			
	101.6	96.0	100.2	101.2	100.6	100.4			
Mean of 3	100.8	98.0	99.4	100.9	101.4	100.4			
Mean of 6							100.8	99.7	99.9
Mean of 9	100.3	99.3	99.5	98.5	101.2	99.8			
Mean of 18							99.4	100.3	99.7

Total recovery and variance (n=54); 99.8% ±1.78%.
Coefficient of variation = 1.78%.

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Table 4

Results of Homogeneity of Mixing Study

Sample Number	Actual Concentration (g/kg)	Percent of Theoretical
Theoretical Dosing Concentration = 6.579 g/kg		
1	6.40	97.3
2	6.50	98.8
3	6.50	98.8
4	6.43	97.7
5	6.26	95.2
6	6.35	96.5
7	6.38	97.0
8	6.24	94.8
9	6.32	96.1
Mean	6.38	96.9
Standard deviation	0.094	
Coefficient of variation (%)	1.47	
Theoretical Dosing Concentration = 36.111 g/kg		
1	35.9	99.4
2	35.1	97.2
3	35.1	97.2
4	35.2	97.5
5	35.3	97.8
6	35.1	97.2
7	35.3	97.8
8	35.2	97.5
9	35.4	98.0
Mean	35.3	97.7
Standard deviation	0.25	
Coefficient of variation (%)	0.71	

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Table 5

Results of In-cage Stability and Homogeneity Study

Sample Number	Actual Concentration (g/kg) Day 0	Day 8
Theoretical Dosing Concentration = 6.579 g/kg		
1	6.58	6.64
2	6.65	6.67
3	6.76	6.67
4	6.74	
5	6.61	
6	6.68	
7	6.65	
8	6.64	
9	6.60	
Mean	6.66	6.66
Percent of theoretical	101.2	101.2
Theoretical Dosing Concentration = 36.111 g/kg		
1	36.1	36.3
2	36.1	35.7
3	35.5	35.4
4	35.8	
5	35.7	
6	35.7	
7	35.5	
8	35.9	
9	35.9	
Mean	35.8	35.8
Percent of theoretical	99.1	99.1

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Table 6

Results of Analytical Assays of SC-19129 in Diet - Males

Group 1 - 0 mg/kg/day

Week	Dosing Concentration (g/kg) Theoretical	Actual	Percent of Theoretical
1[a]	0.0	ND	NA
3	0.0	ND	NA
5	0.0	ND	NA
10	0.0	ND	NA
15	0.0	ND	NA
20	0.0	ND	NA
25	0.0	ND	NA

ND = Less than 0.05 g SC-19129/kg.
NA = Not applicable.

[a]A 150-g sample taken for analysis and then subsampled.

Study No. 6127-111

Table 6 (Continued)

Results of Analytical Assays of SC-19129 in Diet - Males

Group 2 - 250 mg/kg/day

Week	Dosing Concentration (g/kg) Theoretical	Actual	Percent of Theoretical
1[a]	8.794	9.18	104.4
		8.95	101.8
		9.20	104.6
3	8.393	8.06	96.0
		8.15	97.1
		8.08	96.3
5	8.684	8.62	99.3
		8.84	101.8
		8.72	100.4
10	10.000	9.87	98.7
		9.86	98.6
		9.97	99.7
15[b]	9.052	8.80	97.2
		8.76	96.8
		8.63	95.3
20	10.283	10.2	99.2
		10.3	100.2
		10.4	101.1
25	9.130	9.09	99.6
		9.20	100.8
		9.11	99.8

[a]A 150-g sample taken for analysis and then subsampled.
[b]An 8- to 10-g sample analyzed.

Study No. 6127-111

Table 6 (Continued)

Results of Analytical Assays of SC-19129 in Diet - Males

Group 3 - 500 mg/kg/day

Week	Dosing Concentration (g/kg) Theoretical	Actual	Percent of Theoretical
1[a]	17.729	18.0	101.5
		18.5	104.3
		18.2	102.7
3	16.727	16.3	97.4
		16.2	96.8
		16.2	96.8
5	17.818	18.0	101.0
		18.2	102.1
		18.1	101.6
10	17.895	18.3	102.3
		18.5	103.4
		18.3	102.3
15[b]	17.627	17.8	101.0
		17.4	98.7
		17.3	98.1
20	19.604	19.6	100.0
		19.3	98.4
		19.3	98.4
25	19.604	19.4	99.0
		18.9	96.4
		19.3	98.4

[a]A 150-g sample taken for analysis and then subsampled.
[b]An 8- to 10-g sample analyzed.

Study No. 6127-111

Table 6 (Continued)

Results of Analytical Assays of SC-19129 in Diet - Males

Group 4 - 1,000 mg/kg/day

Week	Dosing Concentration (g/kg) Theoretical	Actual	Percent of Theoretical
1[a]	35.200	33.7	95.7
		33.1	94.0
		33.0	93.8
3	31.507	32.1	101.9
		31.0	98.4
		31.2	99.0
5	32.526	33.9	104.2
		33.9	104.2
		33.2	102.1
10	30.909	31.1	100.6
		30.3	98.0
		27.8	89.9
15	34.576	35.5	102.7
		34.4	99.5
		35.4	102.4
20	37.234	37.0	99.4
		38.4	103.1
		38.3	102.9
25	42.678	42.2	98.9
		42.4	99.4
		43.1	101.0

[a]A 150-g sample taken for analysis and then subsampled.

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Table 7

Results of Analytical Assays of SC-19129 in Diet - Females

Group 1 - 0 mg/kg/day

Week	Dosing Concentration (g/kg) Theoretical	Actual	Percent of Theoretical
1[a]	0.0	ND	NA
3	0.0	ND	NA
5	0.0	ND	NA
10	0.0	ND	NA
15	0.0	ND	NA
20	0.0	ND	NA
25	0.0	ND	NA

ND = Less than 0.05 g SC-19129/kg.
NA = Not applicable.

[a]A 150-g sample taken for analysis and then subsampled.

Study No. 6127-111

Table 7 (Continued)

Results of Analytical Assays of SC-19129 in Diet - Females

Group 2 - 250 mg/kg/day

Week	Dosing Concentration (g/kg) Theoretical	Actual	Percent of Theoretical
1[a]	8.475	8.25	97.3
		8.43	99.5
		8.30	97.9
3	8.300	8.12	97.8
		8.07	97.2
		8.16	98.3
5	9.062	10.0	110.4
		10.0	110.4
		10.0	110.4
10	9.783	9.89	101.1
		9.66	98.7
		9.88	101.0
15[b]	9.118	8.84	97.0
		9.27	101.7
		9.06	99.4
20	9.688	9.92	102.4
		9.90	102.2
		9.86	101.8
25	9.833	9.80	99.7
		9.87	100.4
		9.88	100.5

[a] A 150-g sample taken for analysis and then subsampled.
[b] An 8- to 10-g sample analyzed.

Study No. 6127-111

Table 7 (Continued)

Results of Analytical Assays of SC-19129 in Diet - Females

Group 3 - 500 mg/kg/day

Week	Dosing Concentration (g/kg) Theoretical	Actual	Percent of Theoretical
1[a]	17.017	17.1	100.5
		16.8	98.7
		17.0	99.9
3	16.667	16.3	97.8
		16.4	98.4
		16.5	99.0
5	18.107	20.1	111.0
		20.0	110.5
		20.0	110.5
10	18.039	18.3	101.4
		18.5	102.6
		18.3	101.4
15[b]	16.964	17.4	102.6
		17.4	102.6
		16.6	97.9
20	19.216	19.3	100.4
		19.4	101.0
		19.4	101.0
25	24.010	24.2	100.8
		24.6	102.5
		23.7	98.7

[a]A 150-g sample taken for analysis and then subsampled.
[b]An 8- to 10-g sample analyzed.

Study No. 6127-111

Table 7 (Continued)

Results of Analytical Assays of SC-19129 in Diet - Females

Group 4 - 1,000 mg/kg/day

Week	Dosing Concentration (g/kg) Theoretical	Actual	Percent of Theoretical
1[a]	32.794	32.6	99.4
		33.7	102.8
		34.3	104.6
3	30.686	31.0	101.0
		31.1	101.3
		31.1	101.3
5	36.975	40.1	108.5
		40.2	108.7
		39.6	107.1
10	37.959	37.3	98.3
		38.3	100.9
		36.3	95.6
15	33.929	33.5	98.7
		33.8	99.6
		33.1	97.6
20	39.200	37.8	96.4
		37.5	95.7
		38.1	97.2
25	36.330	36.8	101.3
		35.8	98.5
		35.5	97.7

[a]A 150-g sample taken for analysis and then subsampled.

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Table 8

Tabulation of Dosing Concentration Data - Males

Group 2 - 250 mg/kg/day

Week	Theoretical Dosing Concentration (g/kg)	Actual Mean Concentration (g/kg)	Standard Deviation	Mean Percent Recovery
1	8.794	9.110	0.1389	103.6
3	8.393	8.097	0.0473	96.5
5	8.684	8.727	0.1102	100.5
10	10.000	9.900	0.0608	99.0
15	9.052	8.730	0.0889	96.4
20	10.283	10.300	0.1000	100.2
25	9.130	9.133	0.0586	100.0
Mean				99.5
Standard deviation				2.50
Coefficient of variation (%)				2.51

Group 3 - 500 mg/kg/day

Week	Theoretical Dosing Concentration (g/kg)	Actual Mean Concentration (g/kg)	Standard Deviation	Mean Percent Recovery
1	17.729	18.233	0.2517	102.8
3	16.727	16.233	0.0577	97.0
5	17.818	18.100	0.1000	101.6
10	17.895	18.367	0.1155	102.6
15	17.627	17.500	0.2646	99.3
20	19.604	19.400	0.1732	99.0
25	19.604	19.200	0.2646	97.9
Mean				100.0
Standard deviation				2.31
Coefficient of variation (%)				2.31

Study No. 6127-111

Table 8 (Continued)

Tabulation of Dosing Concentration Data - Males

Group 4 - 1,000 mg/kg/day

Week	Theoretical Dosing Concentration (g/kg)	Actual Mean Concentration (g/kg)	Standard Deviation	Mean Percent Recovery
1	35.200	33.267	0.3786	94.5
3	31.507	31.433	0.5859	99.8
5	32.526	33.667	0.4041	103.5
10	30.909	29.733	1.7214	96.2
15	34.576	35.100	0.6083	101.5
20	37.234	37.900	0.7810	101.8
25	42.678	42.567	0.4726	99.7
Mean				99.6
Standard deviation				3.20
Coefficient of variation (%)				3.21

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Table 9

Tabulation of Dosing Concentration Data - Females

Group 2 - 250 mg/kg/day

Week	Theoretical Dosing Concentration (g/kg)	Actual Mean Concentration (g/kg)	Standard Deviation	Mean Percent Recovery
1	8.475	8.327	0.0929	98.3
3	8.300	8.117	0.0451	97.8
5	9.062	10.000	<0.0001	110.4
10	9.783	9.810	0.1300	100.3
15	9.118	9.057	0.2150	99.3
20	9.688	9.893	0.0306	102.1
25	9.833	9.850	0.0436	100.2
Mean				101.2
Standard deviation				4.30
Coefficient of variation (%)				4.25

Group 3 - 500 mg/kg/day

Week	Theoretical Dosing Concentration (g/kg)	Actual Mean Concentration (g/kg)	Standard Deviation	Mean Percent Recovery
1	17.017	16.967	0.1528	99.7
3	16.667	16.400	0.1000	98.4
5	18.107	20.033	0.0577	110.6
10	18.039	18.367	0.1155	101.8
15	16.964	17.133	0.4619	101.0
20	19.216	19.367	0.0577	100.8
25	24.010	24.167	0.4509	100.7
Mean				101.9
Standard deviation				4.00
Coefficient of variation (%)				3.93

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Table 9 (Continued)

Tabulation of Dosing Concentration Data - Females

Group 4 - 1,000 mg/kg/day

Week	Theoretical Dosing Concentration (g/kg)	Actual Mean Concentration (g/kg)	Standard Deviation	Mean Percent Recovery
1	32.794	33.533	0.8622	102.3
3	30.686	31.067	0.0577	101.2
5	36.975	39.967	0.3215	108.1
10	37.959	37.300	1.0000	98.3
15	33.929	33.467	0.3512	98.6
20	39.200	37.800	0.3000	96.4
25	36.330	36.033	0.6807	99.2
Mean				100.6
Standard deviation				3.84
Coefficient of variation (%)				3.82

Study No. 6127-111

OPHTHALMOLOGY REPORT

Before examination, all canines to be examined had their eyes dilated with 1% Mydriacyl®. The anterior ocular segment of each eye was examined with a Kowa® portable biomicroscope and the posterior segment evaluated with a Fison® indirect ophthalmoscope. All findings were recorded in a laboratory notebook as per the Good Laboratory Practice Regulations.

No treatment-related ocular changes were found in any of the canines.

James F. Swanson for CECIL P. Moore 9/23/86

Cecil Moore, DVM
University of Wisconsin
Diplomate, American College of
Veterinary Ophthalmologists

Date

Study No. 6127-111

CARDIOLOGY REPORT

Group Mean ECG Values

There were no mean ECG abnormalities in any group at any test period during the study. There were no marked biological differences between males and females in any group. The Week 26 test period revealed significant differences between females of Groups 1 and 3 in QRS interval; this was also true between Groups 2 and 3 versus Group 1 in the combined analysis (males and females). At Week 26, the Group 2 male and combined R amplitude was increased as compared to the controls. Group 4 female and combined QT interval duration was significantly decreased and the combined heart rate at Week 30 was significantly greater than those of controls (Group 1) in the female and combined analyses, respectively. None of these differences were great enough to be considered abnormal.

Individual ECG Values

Mild sinus tachycardia was recognized in Groups 2 and 3 at baseline and at Week 8. Axis deviation was noted in two Group 1 and one Group 4 dogs at 26 weeks and in two Group 3 dogs, one at baseline and one at 8 weeks. Wide and/or tall QRS complexes were inconsistently observed in nine dogs at Weeks 8, 17, 26, and 30 in Groups 2, 3, and 4. The above changes were generally mild, sporadic, inconsistent, and not obviously related to group or duration. They are viewed as isolated, expected ECG abnormalities.

With one exception, there were no arrythmias or conduction disturbances observed. Animal No. 981 (Group 2) exhibited small numbers of ventricular premature complexes (VPC) at 17 and 26 weeks, but not at Week 30. Although this dog was in a treatment group and the VPC were not observed at baseline or the reversal examination (Week 30), the lack of similar findings in other dogs in the same group or in the two groups at higher compound doses makes it unlikely that this finding represents a compound-induced ECG abnormality.

Conclusion

The lack of toxicologically important mean ECG abnormalities, consistent individual ECG abnormalities, or severe or widespread conduction disturbances or arrythmias suggests that the compound being tested has no deleterious effects on the canine electrocardiogram at the doses and durations tested.

Clarke E. Atkins DVM

Clarke E. Atkins, DVM
University of Wisconsin
Diplomate, American College of
Veterinary Internal Medicine

9-26-86
Date

Study No. 6127-111

PATHOLOGY REPORT

INTRODUCTION

Young adult Beagle dogs were fed SC-19129 in their diets daily for 26 weeks. The animals were randomly assigned to the study as follows:

Group	Number of Animals* Male	Female	SC-19129 (mg/kg BW/day)
1	4/2	4/2	0
2	4/2	4/2	250
3	4/2	4/2	500
4	4/2	4/2	1,000

* Number of animals in numerator sacrificed for necropsy in 27th week (T Sac). Number in denominator sacrificed following 4-Week recovery during 31st week (R Sac).

Hematology, clinical chemistry, and urinalysis were done at pretest and 8, 17, 26, and 31 weeks. At study termination, (27 or 31-weeks) the animals were anesthetized, killed by exsanguination and necropsied. At necropsy, gross observations were recorded, specified organs were weighed, and selected tissues were collected, processed and examined microscopically as designated by the protocol.

RESULTS/CLINICAL PATHOLOGY

Individual values for hematology, clinical chemistry, and urinalysis at Pretest, 8, 17, 26, and 31 weeks are in Appendices G through I. Mean values for each group are in Tables 20 through 34. All results are based on mean values. Differences cited for a given parameter (higher or lower) are based on comparisons with the appropriate control group. There were no differences considered to be treatment related. Most, but not all, of the statistically significant differences are listed in this results section.

Pretest (-2 Weeks)

Pretest values for hematology, clinical chemistry, and urinalysis were similar to values observed previously in young adult Beagles. The males assigned to the 250-mg/kg/day group had significantly higher total protein, albumin, and globulin, but the changes were considered to be normal biological variation.

8 Weeks

Globulin was significantly lower and albumin/globulin ratio was significantly higher in females given 250 mg/kg/day of test compound. Aspartate aminotransferase was significantly lower in females and the combined sexes given 1,000 mg/kg/day of test compound. Glucose was significantly higher in 500-mg/kg/day males. All cited differences were slight.

17 Weeks

Relative and absolute monocyte counts were significantly lower in the combined sexes given 250, 500, or 1,000 mg/kg/day of test compound. Relative monocyte counts were significantly lower in males given 250 or 500 mg/kg/day and in females given 500 or 1,000 mg/kg/day. Absolute monocyte counts were significantly lower in females given 250 or 500 mg/kg/day. Partial thromboplastin time was significantly lower in males given 1,000 mg/kg/day and significantly higher in females given 250 and 1,000 mg/kg/day. Differences in mean values for monocyte counts and partial thromboplastin times were slight. Globulin was significantly lower and albumin/globulin ratio was significantly higher in females given 250 or 500 mg/kg/day of test compound. Albumin/globulin ratio was also significantly higher in the combined sexes given 500 mg/kg/day. Differences in globulin and albumin/globulin ratio were minimal. Urine volume was significantly higher in males given 1,000 mg/kg/day and significantly lower in females given 500 mg/kg/day.

26 Weeks

Absolute monocyte counts were significantly lower in females given 250, 500, and 1,000 mg/kg/day and the combined sexes given 500 or 1,000 mg/kg/day. Partial thromboplastin time was slighty, but significantly, higher in males given 1,000 mg/kg/day. Total protein and globulin were significantly lower and albumin/globulin ratio was significantly higher in the combined sexes given 500 mg/kg/day. Total protein and globulin were significantly lower in males given 500 mg/kg/day. Alanine aminotransferase was slightly, but significantly, higher in males given 1,000 mg/kg/day. Females given 1,000 mg/kg/day had significantly higher urea nitrogen. Females given 500 mg/kg/day and combined sexes given 250, 500, or 1,000 mg/kg/day of test compound had significantly higher creatinine. Differences in urea nitrogen and creatinine were minimal. Cholesterol was significantly higher in males and the combined sexes given 1,000 mg/kg/day.

31 Weeks (4 Week Recovery)

The combined sexes given 250 or 500 mg/kg/day of test compound for 26 weeks had significantly lower platelet counts. Albumin and albumin/globulin ratio were significantly higher in the combined sexes given 1,000 mg/kg/day. Albumin/globulin ratio was also significantly higher in males given 1,000 mg/kg/day.

RESULTS/ANATOMICAL PATHOLOGY

Individual animal data sheets with all anatomical pathology data for each animal are in Appendix J.

Organ, Organ/Body and Organ/Brain Weight

Individual values for the terminal body weights, absolute organ weights, organ-to-body weight percentages and organ-to-brain weight ratios for animals necropsied during the 27th (T SAC) and 31st (R SAC) week are in Appendix J.

Mean values for each T SAC group are in Tables 37, 39 and 41 and for each R SAC group in Tables 38, 40 and 42. Statistically significant differences, higher or lower, were seen only in T SAC females. Absolute adrenal weights were lower in females given 250, 500, and 1,000 mg/kg/day of test compound. Adrenal-to-brain weight ratios were lower in females given 500, and 1,000 mg/kg/day. Heart-to-body weight percentages were higher in females given 500 mg/kg/day and the salivary gland-to-brain weight ratios and absolute weights of the salivary glands were lower in females given 250 mg/kg/day.

There were no statistically significant differences from control in T SAC males or R SAC males and females.

Macroscopic Observations

Incidence summaries are in Table 35 for T SAC animals and Table 36 for R SAC animals. All gross findings were considered to be incidental and to have no relationship to treatment with the test compound.

Microscopic Observations

Incidence summaries are in Table 43 for T SAC animals. Only gross lesions were examined in R SAC animals, and these data are presented in Table 44. According to protocol, only target organs from the T SAC animals would be processed and examined microscopically in R SAC animals. There were only incidental findings common to the dog observed microscopically and none of the findings were related to treatment with the test compound.

DISCUSSION

There were statistically significant differences for many clinical pathology parameters between Beagle dogs given SC-19129 in their diets for 26 weeks and control dogs. Generally, the statistical differences were inconsistent over time or affected only intermediate dose dogs. These differences were consistently small, and the parameter values for dogs receiving the test compound were rarely outside of the Hazleton Laboratories America-Wisconsin reference range. All of the differences were considered to be normal biological variations, not important toxicologically, and not related to treatment.

Statistically significant differences in organ weights or organ-to-body or organ-to-brain weights were seen only in T SAC females. There were no treatment-related macroscopic or microscopic changes in any dogs. The organ weight changes were considered to be normal biological variations and not related to treatment.

SUMMARY

There were no changes in clinical pathology parameters considered to be treatment related.

There were no changes in body weight, organ-to-body weight, organ-to-brain weight, macroscopic, or microscopic findings in the test dogs that were considered to be treatment related. Compound SC-19129 does not appear to induce detectible changes in dogs at the doses administered.

Robert L. Hall

Robert L. Hall, DVM, PhD
Diplomate, American College of
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(Clinical Pathology)

9/30/86
Date

William E. Field

William E. Field, DVM, MS
Diplomate, American College of
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9/30/86
Date

(1267mcs
3/5/86)

APPENDIX B

Individual Body Weights

Study No. 6127-111

Individual Body Weights (kg)

Males

Animal Number	Week 0	1	2	3	4	5	6	7	8
				Group 1					
H00961	10.1	10.5	10.8	11.1	11.7	11.6	11.8	11.9	12.0
H00962	9.6	10.1	10.1	10.3	10.3	10.5	10.6	10.2	10.6
H00963	8.2	8.5	8.9	8.8	8.9	9.0	9.1	8.9	9.3
H00964	8.4	8.6	9.0	9.7	10.1	10.0	9.3	10.1	10.2
H00965	8.7	9.1	9.6	9.6	10.1	10.5	10.3	10.6	10.7
H00966	7.5	7.7	7.9	8.0	8.2	8.3	8.2	8.2	8.4
				Group 2					
H00973	10.2	10.7	11.0	11.3	12.1	12.4	12.1	12.3	12.2
H00974	9.5	9.6	10.0	10.2	10.4	10.4	10.0	10.6	10.3
H00975	8.2	8.7	9.0	9.6	9.1	9.6	9.1	9.4	9.4
H00976	8.1	8.6	8.6	8.8	9.4	9.2	8.7	8.9	9.3
H00977	8.4	9.0	8.9	9.1	9.4	9.5	9.4	9.5	9.8
H00978	8.4	8.5	8.8	9.0	9.5	9.5	9.0	9.2	9.6
				Group 3					
H00985	10.3	10.5	11.0	11.1	11.5	11.4	10.4	11.3	11.8
H00986	9.1	9.8	9.7	10.3	10.0	10.8	10.2	10.6	10.8
H00987	8.4	8.5	8.8	9.1	8.8	9.2	9.2	9.1	9.2
H00988	8.4	8.6	8.9	9.2	9.2	9.6	8.7	9.2	9.5
H00989	8.5	8.8	9.0	8.8	9.2	9.3	9.4	9.4	9.5
H00990	8.1	8.5	8.8	9.0	9.4	9.6	9.9	9.6	9.7
				Group 4					
H00997	10.0	10.4	10.8	10.7	11.2	11.4	11.6	11.4	11.8
H00998	9.8	10.2	10.5	10.5	10.6	11.2	11.3	11.1	11.1
H00999	8.4	8.8	8.7	8.9	9.5	9.5	9.6	9.6	10.1
H00001	8.2	8.5	8.9	8.9	9.4	9.4	9.4	9.5	9.6
H00002	8.0	8.4	8.5	8.6	9.1	8.8	9.0	9.0	8.8
H00003	7.6	8.0	8.0	8.1	8.0	8.3	8.7	8.3	8.4

Study No. 6127-111

Individual Body Weights (kg)

Males

Animal Number	Week 9	10	11	12	13	14	15	16	17
				Group 1					
H00961	11.9	11.8	11.9	12.4	12.7	13.1	13.5	12.2	13.0
H00962	10.6	10.9	10.7	10.7	11.1	11.2	11.5	11.1	11.1
H00963	9.2	9.1	9.3	9.4	9.3	9.5	9.8	9.0	9.3
H00964	10.4	10.5	10.4	10.4	10.6	10.8	10.9	10.5	10.9
H00965	10.9	11.2	11.3	11.3	11.3	11.8	11.9	11.7	12.0
H00966	8.1	8.3	8.3	8.3	8.4	8.5	8.6	8.6	8.5
				Group 2					
H00973	12.3	12.6	12.2	12.5	12.4	12.7	12.9	12.4	12.6
H00974	10.6	10.8	10.4	10.6	10.5	10.6	11.0	10.5	10.8
H00975	9.6	9.9	9.8	10.2	10.0	9.9	10.3	10.1	10.4
H00976	9.4	9.7	9.4	9.8	9.8	9.7	10.2	10.3	10.2
H00977	9.6	9.6	10.0	9.9	10.0	10.3	10.4	10.4	10.2
H00978	9.2	9.4	9.4	9.5	9.4	9.6	9.7	9.7	9.3
				Group 3					
H00985	11.8	11.9	11.6	12.1	12.5	12.4	12.6	12.7	12.8
H00986	10.7	11.0	11.1	11.0	11.2	11.7	11.8	11.4	11.4
H00987	9.2	9.5	9.5	9.7	9.7	9.7	9.9	9.8	9.9
H00988	9.5	9.6	9.4	9.8	9.7	9.8	10.5	9.7	10.0
H00989	9.5	9.7	9.4	9.7	9.6	9.8	10.3	10.2	9.9
H00990	10.0	10.1	10.1	10.4	10.5	10.6	10.5	10.5	10.4
				Group 4					
H00997	11.7	12.1	12.1	12.3	12.4	12.6	13.0	12.1	12.8
H00998	11.0	11.1	11.4	11.5	11.3	11.7	11.8	11.8	11.7
H00999	10.0	10.0	10.2	10.2	10.1	10.4	10.5	10.5	10.5
H00001	9.8	9.8	9.8	9.7	9.8	10.0	10.1	10.2	10.2
H00002	8.7	9.2	8.9	9.1	9.3	9.6	9.4	9.1	9.0
H00003	8.6	8.6	8.4	8.5	8.3	8.7	8.8	8.7	8.6

Study No. 6127-111

Individual Body Weights (kg)

Males

Animal Number	Week 18	19	20	21	22	23	24	25	26
				Group 1					
H00961	13.1	13.2	13.5	13.4	13.3	12.5	13.5	12.5	13.3
H00962	11.5	11.5	11.6	11.7	11.4	11.6	11.3	11.5	11.2
H00963	9.3	9.4	9.6	9.7	9.6	9.8	9.7	9.3	9.4
H00964	11.2	11.2	11.4	11.4	11.4	11.6	11.2	10.9	10.7
H00965	11.9	11.8	12.1	12.7	11.8	12.2	12.0	12.0	11.7
H00966	8.5	8.6	8.7	8.8	8.6	9.0	8.9	8.7	8.6
				Group 2					
H00973	13.1	12.4	12.8	13.0	12.9	12.9	12.8	13.2	12.8
H00974	10.9	11.0	11.3	11.3	11.6	10.7	11.3	11.1	10.7
H00975	10.3	10.2	10.5	10.8	10.6	10.4	10.5	10.6	10.2
H00976	10.2	9.9	10.3	10.6	10.3	10.4	10.4	10.5	10.2
H00977	10.4	10.4	10.8	10.6	11.0	10.8	10.7	10.6	10.2
H00978	9.4	9.5	9.8	9.6	9.7	9.2	9.8	9.7	9.3
				Group 3					
H00985	12.7	12.9	12.9	13.0	13.1	12.7	12.5	12.9	13.1
H00986	11.5	11.8	11.9	12.1	11.7	11.6	12.0	12.0	11.7
H00987	9.9	9.9	10.2	10.1	10.3	10.1	10.6	10.4	10.4
H00988	10.0	10.1	10.3	10.1	10.0	9.9	10.2	10.1	10.1
H00989	10.0	10.0	10.3	10.3	9.6	10.3	10.2	10.1	10.0
H00990	10.4	10.7	10.9	11.0	10.7	11.0	11.1	11.5	11.2
				Group 4					
H00997	12.4	12.1	12.0	12.5	12.2	11.8	12.0	12.1	12.0
H00998	11.6	11.4	11.8	11.4	11.6	11.3	11.1	11.2	11.3
H00999	10.8	10.7	11.3	10.9	10.9	11.0	10.9	10.9	10.5
H00001	9.9	9.9	10.2	10.1	10.2	10.2	10.4	10.3	10.0
H00002	9.1	9.1	9.2	9.5	8.8	8.6	9.0	9.1	8.2
H00003	8.9	8.7	8.8	9.4	8.9	8.6	9.0	9.1	8.8

Study No. 6127-111

Individual Body Weights (kg)
Recovery Study

Males

Animal Number	Week 27	28	29	30
		Group 1		
H00964	11.0	11.5	11.0	11.3
H00965	12.2	12.7	12.7	12.7
		Group 2		
H00973	12.8	13.4	13.4	13.5
H00977	10.6	10.6	11.2	11.2
		Group 3		
H00988	9.6	10.1	10.1	10.3
H00990	11.0	11.3	11.3	11.3
		Group 4		
H00998	11.5	11.9	12.3	12.2
H00001	10.0	10.1	10.3	10.5

Study No. 6127-111

Individual Body Weights (kg)

Females

Animal Number	Week 0	1	2	3	4	5	6	7	8
					Group 1				
H00967	9.4	9.9	10.2	10.7	10.6	10.6	10.9	10.2	11.0
H00968	8.4	8.8	8.9	9.3	9.2	9.1	9.4	9.3	9.4
H00969	8.2	8.4	8.7	8.7	8.8	8.9	9.0	9.1	8.9
H00970	8.3	8.4	8.6	8.8	9.1	9.0	9.0	9.0	9.4
H00971	7.6	7.9	8.0	8.2	8.5	8.3	8.5	8.7	8.7
H00972	7.5	7.8	8.1	8.0	8.3	8.2	8.0	7.9	8.2
					Group 2				
H00979	8.5	9.1	9.1	9.3	9.5	9.9	9.8	9.8	9.6
H00980	7.9	8.5	8.4	8.8	8.7	8.9	9.2	8.8	9.2
H00981	8.5	8.9	8.8	9.0	9.4	9.4	9.1	8.5	9.3
H00982	7.5	8.1	8.0	8.2	8.6	8.6	8.8	7.7	8.5
H00983	7.2	7.8	8.2	8.4	8.5	8.6	9.0	8.7	9.1
H00984	6.7	7.0	7.1	7.2	7.2	7.4	7.4	7.0	7.4
					Group 3				
H00991	8.8	9.2	9.4	9.6	9.6	9.8	9.6	9.5	9.9
H00992	8.8	8.9	9.3	9.5	9.8	9.8	10.0	9.7	10.4
H00993	8.2	8.7	8.8	9.0	9.3	9.3	9.3	9.3	9.5
H00994	7.4	8.0	8.3	8.6	8.7	8.9	8.5	9.0	9.0
H00995	7.2	7.6	7.9	8.1	8.1	8.3	8.5	8.0	8.7
H00996	7.2	7.5	7.7	7.5	7.6	7.6	8.1	7.5	7.9
					Group 4				
H00004	8.6	8.9	8.9	9.1	9.4	9.5	9.4	9.3	9.6
H00005	8.5	9.1	9.2	9.5	9.7	9.9	9.6	9.8	10.0
H00006	8.0	8.5	8.4	8.6	8.7	8.8	8.9	8.9	9.2
H00007	8.2	8.2	8.5	8.5	8.8	8.7	8.8	8.7	9.1
H00008	7.7	8.2	8.3	8.2	8.3	8.3	8.5	8.3	8.8
H00009	7.3	7.1	7.1	8.2	8.1	7.8	8.0	8.0	8.3

Study No. 6127-111

Individual Body Weights (kg)

Females

Animal Number	Week 9	10	11	12	13	14	15	16	17
				Group 1					
H00967	11.4	11.5	11.6	11.4	11.4	12.2	12.2	11.8	12.0
H00968	9.6	9.6	9.8	10.0	9.8	9.9	10.1	10.0	10.0
H00969	9.2	9.2	9.2	9.6	9.7	10.0	9.8	9.6	9.8
H00970	9.5	9.3	9.6	9.8	9.7	10.2	10.5	10.2	10.1
H00971	8.9	8.8	8.4	9.1	9.1	9.2	9.2	9.0	9.1
H00972	8.1	8.5	8.3	8.6	8.7	8.9	8.9	8.8	8.7
				Group 2					
H00979	9.9	9.9	10.0	10.2	10.3	10.3	10.6	10.4	10.3
H00980	9.4	9.2	9.4	9.6	9.7	9.7	9.8	9.7	9.5
H00981	9.0	9.1	9.4	9.6	9.6	9.7	9.7	9.7	9.4
H00982	8.5	8.5	8.6	8.5	8.3	8.8	8.9	8.8	8.5
H00983	9.2	9.2	9.4	9.6	9.6	9.8	9.6	9.2	9.3
H00984	7.5	7.5	7.4	7.6	7.5	7.5	7.6	7.5	7.5
				Group 3					
H00991	9.9	9.8	9.8	10.1	10.0	10.2	10.2	10.1	10.2
H00992	10.4	10.1	10.2	10.3	10.4	10.3	10.0	10.0	9.9
H00993	9.6	9.5	9.2	10.1	9.9	10.0	10.2	10.0	9.7
H00994	9.0	8.8	9.1	9.3	9.2	9.5	9.6	9.3	9.2
H00995	8.8	8.9	9.2	9.4	9.3	9.8	10.0	9.5	9.8
H00996	8.1	8.2	8.3	8.5	8.3	8.5	8.5	8.6	8.6
				Group 4					
H00004	9.5	9.9	10.1	10.2	9.9	10.4	10.4	10.3	10.2
H00005	10.0	10.1	9.9	10.1	10.1	10.5	10.4	10.1	10.2
H00006	9.5	9.6	9.6	9.8	9.8	10.1	10.2	10.0	9.7
H00007	9.2	9.3	9.2	9.4	9.5	9.7	9.7	9.6	9.6
H00008	8.6	8.4	8.4	8.8	8.6	8.8	9.2	9.0	8.9
H00009	8.4	9.2	8.8	8.9	9.0	9.3	9.2	9.1	9.0

Study No. 6127111

Individual Body Weights (kg)

Females

Animal Number	Week 18	19	20	21	22	23	24	25	26
				Group 1					
H00967	12.2	11.8	12.2	12.2	12.5	12.4	12.6	12.0	12.5
H00968	10.3	10.0	10.3	10.3	10.4	10.5	10.7	10.3	10.5
H00969	9.8	9.7	10.0	9.9	10.1	9.8	9.3	9.1	9.5
H00970	10.3	10.3	10.3	10.4	10.4	10.1	9.7	9.9	9.7
H00971	9.1	9.2	9.1	9.4	9.2	9.4	8.7	8.7	9.2
H00972	8.6	9.2	9.3	9.2	9.1	9.4	8.9	9.2	9.0
				Group 2					
H00979	10.5	10.1	10.4	10.4	10.7	10.7	10.5	10.5	10.2
H00980	9.7	9.6	9.7	9.7	9.8	9.9	9.7	9.6	9.4
H00981	9.6	9.8	9.9	9.9	10.1	9.7	9.4	9.9	10.0
H00982	8.4	8.5	8.9	8.4	8.4	8.5	8.6	8.4	8.7
H00983	9.6	9.2	9.5	9.7	9.7	9.7	9.7	9.5	9.5
H00984	7.7	7.5	7.6	7.8	7.5	7.8	7.8	7.6	7.4
				Group 3					
H00991	10.2	10.3	10.2	10.2	10.1	10.2	10.3	10.3	10.0
H00992	10.5	10.4	10.6	10.4	10.6	10.7	10.5	10.4	10.3
H00993	10.1	9.9	10.3	10.0	10.2	10.4	10.1	10.1	10.2
H00994	9.5	9.2	9.5	9.7	9.6	9.4	9.4	9.0	9.4
H00995	9.8	9.7	10.3	10.0	9.8	9.1	9.2	8.8	9.0
H00996	8.5	8.7	8.9	9.0	8.6	8.5	8.7	8.2	8.1
				Group 4					
H00004	10.3	10.4	10.7	10.6	10.7	10.3	10.6	10.1	9.9
H00005	10.1	10.2	10.5	10.8	10.4	10.3	10.4	10.8	10.3
H00006	9.9	9.8	10.1	10.1	10.1	10.2	10.1	10.0	9.9
H00007	9.8	9.7	9.9	10.3	10.2	10.2	9.8	10.1	10.0
H00008	8.9	8.9	8.6	8.6	8.5	8.4	8.6	8.2	8.0
H00009	9.2	8.7	9.3	9.4	9.6	9.0	9.4	8.8	9.2

Study No. 6127111

Individual Body Weights (kg)
Recovery Study

Females

Animal Number	Week 27	28	29	30
		Group 1		
H00971	9.2	9.7	9.5	9.5
H00972	9.0	9.0	9.2	9.3
		Group 2		
H00979	10.1	10.5	10.5	10.3
H00981	9.3	10.2	10.3	10.5
		Group 3		
H00995	9.0	9.5	9.4	9.5
H00996	8.2	8.4	8.6	8.7
		Group 4		
H00005	10.1	10.9	10.4	10.8
H00006	9.8	10.2	10.2	10.2

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APPENDIX C

Individual Food Consumptions

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Study No. 6127-111

Individual Food Consumptions (g)

Males

Animal Number	Week -1	1	2	3	4	5	6	7	8
				Group 1					
H00961	2,104	2,259	2,129	2,159	2,145	2,508	2,153	2,024	2,405
H00962	2,366	2,121	2,381	1,924	2,210	2,338	2,122	1,882	2,330
H00963	1,820	1,754	1,860	1,784	1,718	1,685	1,716	1,657	1,922
H00964	1,907	2,007	2,008	1,988	2,019	2,235	1,593	2,113	2,110
H00965	2,061	2,096	2,014	2,177	2,148	2,356	2,141	1,834	2,050
H00966	1,497	1,619	1,535	1,439	1,488	1,508	1,470	1,180	1,523
				Group 2					
H00973	2,418	2,408	2,606	2,461	2,475	2,513	2,322	1,946	2,467
H00974	1,995	1,685	1,909	1,972	1,868	2,131	1,450	1,594	2,216
H00975	1,951	2,130	1,819	1,828	1,829	2,015	1,831	1,465	2,261
H00976	1,685	2,058	2,243	2,217	1,953	2,032	2,258	1,303	2,305
H00977	1,650	1,829	1,831	1,889	1,615	1,819	2,051	1,319	1,918
H00978	1,814	1,643	1,849	1,604	1,653	1,719	1,532	1,353	1,577
				Group 3					
H00985	2,210	2,347	2,405	2,257	1,855	2,385	1,901	1,699	2,415
H00986	2,017	2,032	2,202	1,952	2,093	2,212	1,198	2,237	2,045
H00987	1,756	1,435	1,683	1,627	1,363	1,538	1,499	1,354	1,445
H00988	1,647	1,523	1,562	1,731	1,561	1,719	1,461	1,211	1,624
H00989	2,135	2,213	1,922	1,921	1,766	2,069	1,870	1,692	1,972
H00990	2,022	2,146	2,093	2,063	2,117	2,270	2,348	1,949	2,090
				Group 4					
H00997	2,277	2,401	2,344	2,603	2,108	2,395	2,120	1,522	2,628
H00998	2,167	2,233	2,389	2,160	2,023	2,279	2,046	1,789	2,390
H00999	2,036	2,144	2,253	2,000	2,084	2,284	2,205	2,326	2,402
H00001	1,798	1,872	1,859	1,787	1,821	1,872	1,787	1,789	1,981
H00002	1,810	1,926	1,846	1,867	1,650	1,809	1,650	1,555	1,913
H00003	1,509	1,680	1,796	1,729	1,697	1,772	2,226	1,835	2,084

Study No. 6127-111

Individual Food Consumptions (g)

Males

Animal Number	Week 9	10	11	12	13	14	15	16	17
				Group 1					
H00961	2,059	2,284	2,323	2,649	2,317	2,448	2,561	2,341	1,970
H00962	1,918	2,429	2,371	2,019	2,246	2,303	2,245	2,326	2,169
H00963	1,769	1,823	2,050	1,879	1,872	1,744	1,736	1,935	1,649
H00964	2,049	2,201	2,275	1,965	1,962	2,055	2,313	2,163	1,980
H00965	2,013	2,469	2,294	2,063	2,119	2,229	2,635	1,890	1,988
H00966	1,289	1,559	1,674	1,513	1,460	1,572	1,772	1,479	1,425
				Group 2					
H00973	2,043	2,344	2,472	2,267	2,186	2,306	2,246	2,255	2,061
H00974	1,631	2,240	1,944	1,695	2,181	2,278	2,291	2,095	1,731
H00975	1,781	2,467	1,989	2,117	1,981	1,840	2,053	1,808	1,607
H00976	1,885	2,479	2,359	2,047	2,495	2,106	2,164	2,148	2,179
H00977	1,742	1,996	1,800	2,006	1,830	1,835	2,019	1,833	1,713
H00978	1,505	1,693	1,581	1,451	1,634	1,595	1,617	1,265	1,454
				Group 3					
H00985	2,081	2,137	2,283	2,099	2,503	2,327	2,544	2,033	2,403
H00986	1,955	2,245	2,256	2,283	2,098	2,323	2,231	1,964	1,732
H00987	1,514	1,723	1,638	1,514	1,649	1,669	1,675	1,585	1,450
H00988	1,467	1,731	1,742	1,471	1,786	1,751	1,884	1,542	1,609
H00989	1,716	2,448	2,089	1,754	2,267	2,409	2,144	2,022	1,696
H00990	1,854	2,073	2,302	2,169	2,297	2,442	2,045	2,146	2,058
				Group 4					
H00997	2,320	2,525	2,718	2,314	2,414	2,351	2,345	2,095	2,051
H00998	1,665	2,216	2,249	1,940	2,174	2,247	2,266	2,088	1,930
H00999	2,221	2,343	2,224	2,564	2,047	2,038	2,326	2,225	2,231
H00001	1,641	2,098	1,729	1,838	1,882	1,897	1,699	1,830	1,660
H00002	1,393	1,860	1,797	1,683	1,857	1,886	1,639	1,394	1,413
H00003	2,064	2,369	2,311	2,319	1,828	1,880	2,171	1,932	1,848

Study No. 6127-111

Individual Food Consumptions (g)

Males

Animal Number	Week 18	19	20	21	22	23	24	25	26
				Group 1					
H00961	2,066	2,296	2,546	2,685	2,040	2,663	2,367	2,070	2,426
H00962	2,015	2,087	2,131	2,203	2,305	2,412	2,014	2,047	2,132
H00963	1,699	1,905	1,912	2,017	1,805	2,109	1,838	1,742	1,955
H00964	2,098	2,136	1,929	2,166	2,232	2,309	2,005	1,979	1,949
H00965	2,415	2,294	2,311	2,716	2,118	2,171	2,121	2,370	2,117
H00966	1,485	1,473	1,462	1,776	1,502	1,636	1,520	1,453	1,344
				Group 2					
H00973	1,854	2,272	2,032	2,346	1,924	2,309	1,919	2,191	1,814
H00974	2,196	2,648	2,015	2,622	2,199	2,221	2,086	1,831	1,733
H00975	1,894	2,105	1,798	1,900	1,962	2,041	2,002	2,058	1,409
H00976	1,653	2,655	2,236	2,366	2,409	2,108	2,024	2,165	2,017
H00977	1,817	1,916	1,672	2,011	1,916	1,800	1,732	1,997	1,513
H00978	1,386	1,627	1,538	1,639	1,571	1,815	1,369	1,570	1,140
				Group 3					
H00985	2,217	2,368	2,075	2,436	2,330	2,179	2,075	2,218	2,292
H00986	1,928	2,079	2,169	1,937	2,026	2,096	1,892	1,985	1,745
H00987	1,669	1,761	1,634	1,807	1,752	1,775	1,769	1,621	1,615
H00988	1,441	1,784	1,590	1,662	1,577	1,658	1,504	1,775	1,363
H00989	2,075	2,239	1,925	2,358	2,128	2,063	1,877	1,918	1,815
H00990	2,334	1,976	2,230	2,357	2,295	1,889	2,251	2,325	2,112
				Group 4					
H00997	2,108	1,803	1,615	2,330	2,457	2,086	1,654	2,195	2,338
H00998	2,259	2,090	1,979	2,000	2,112	1,849	1,787	1,841	1,964
H00999	2,129	2,439	1,962	2,389	2,158	2,450	2,023	2,249	1,824
H00001	1,823	1,831	1,643	1,769	1,777	1,819	1,731	1,741	1,413
H00002	1,493	1,826	1,459	1,825	1,804	591	1,911	1,868	776
H00003	2,017	2,041	1,962	2,367	2,472	1,245	2,391	1,701	1,934

Study No. 6127111

Individual Food Consumptions (g)
Recovery Study

Males

Animal Number	Week 27	28	29	30
		Group 1		
H00964	2,081	1,945	1,607	1,865
H00965	2,310	2,291	2,804	2,385
		Group 2		
H00973	2,257	1,944	2,306	2,321
H00977	1,590	1,446	1,892	1,806
		Group 3		
H00988	1,335	1,516	1,748	1,331
H00990	1,543	2,034	2,089	2,351
		Group 4		
H00998	2,269	2,613	2,621	2,506
H00001	1,510	1,561	1,796	1,902

Study No. 6127-111

Individual Food Consumptions (g)

Females

Animal Number	Week -1	1	2	3	4	5	6	7	8
					Group 1				
H00967	2,326	2,368	2,085	2,342	2,118	2,263	1,753	1,289	2,605
H00968	2,219	2,117	2,022	1,812	1,900	1,922	1,822	1,833	1,846
H00969	1,758	1,879	1,732	1,751	1,687	1,651	1,732	1,160	2,034
H00970	1,870	1,748	1,856	1,601	1,865	1,841	1,595	1,550	1,933
H00971	1,830	1,981	1,798	1,796	1,695	1,960	1,752	1,875	1,697
H00972	1,725	1,592	2,096	1,789	1,715	1,886	1,949	1,735	1,526
					Group 2				
H00979	1,641	1,793	1,980	1,812	1,696	1,896	1,667	1,847	1,240
H00980	1,972	1,942	1,926	1,839	1,709	1,908	1,551	1,511	1,807
H00981	1,805	1,937	1,902	1,759	1,766	2,014	1,771	1,492	1,253
H00982	1,747	1,815	1,975	1,524	1,705	1,675	1,676	1,388	1,391
H00983	1,795	1,639	1,903	1,745	1,683	1,753	1,833	1,248	2,177
H00984	1,274	1,494	1,475	1,421	1,409	1,498	1,421	1,000	1,626
					Group 3				
H00991	1,918	1,922	2,047	1,649	1,744	2,003	1,397	1,397	1,771
H00992	2,100	2,091	2,250	1,979	1,889	2,416	1,755	1,517	2,067
H00993	1,879	1,999	1,912	1,730	1,880	1,980	1,745	1,631	1,899
H00994	1,779	1,466	1,699	1,681	1,868	1,801	1,565	1,522	1,793
H00995	1,717	1,732	1,714	1,729	1,755	1,821	1,614	1,538	1,551
H00996	1,703	1,488	1,651	1,436	1,396	1,789	1,587	1,590	1,372
					Group 4				
H00004	2,132	2,000	2,376	1,513	1,885	2,103	1,898	1,837	1,984
H00005	1,795	2,136	1,918	1,875	2,009	1,934	1,928	2,023	1,666
H00006	1,985	2,038	1,634	1,647	1,747	1,816	1,728	1,659	1,667
H00007	1,961	1,998	1,956	1,643	1,796	1,974	1,607	1,415	1,756
H00008	1,785	1,790	1,857	1,529	1,607	1,628	1,369	1,414	1,458
H00009	1,816	1,666	1,452	1,804	1,924	1,771	1,301	1,467	1,485

Study No. 6127-111

Individual Food Consumptions (g)

Females

Animal Number	Week 9	10	11	12	13	14	15	16	17
				Group 1					
H00967	1,856	2,475	1,836	1,794	2,200	2,250	2,158	2,124	2,141
H00968	1,869	1,956	2,137	1,909	1,999	1,970	2,132	1,949	1,831
H00969	1,444	1,910	1,720	1,706	1,832	1,770	1,657	1,708	1,809
H00970	1,676	1,827	1,729	2,077	1,892	2,027	2,113	1,907	2,034
H00971	1,847	2,066	1,773	1,872	1,857	2,020	1,785	1,782	1,764
H00972	1,763	1,982	1,967	2,077	2,020	2,018	1,809	1,753	1,537
				Group 2					
H00979	1,552	1,766	1,650	1,698	1,736	1,718	1,682	1,894	1,571
H00980	1,755	1,731	1,845	1,775	1,836	2,042	1,670	1,733	1,549
H00981	2,216	1,624	2,030	1,965	2,080	2,079	1,554	1,998	1,557
H00982	1,781	1,673	1,548	1,432	1,260	1,570	1,814	1,985	1,480
H00983	1,909	2,007	1,942	1,709	2,094	1,913	1,831	1,455	1,580
H00984	1,619	1,667	1,316	1,380	1,628	1,504	1,449	1,411	1,224
				Group 3					
H00991	1,591	1,834	1,492	1,665	1,726	1,845	1,667	1,676	1,658
H00992	1,958	1,616	1,576	1,508	1,951	1,767	1,285	1,453	1,792
H00993	1,725	2,020	1,899	1,613	2,166	2,043	2,115	1,888	1,673
H00994	1,593	1,761	1,500	1,672	1,921	1,820	1,699	1,632	1,730
H00995	1,784	2,118	1,771	1,815	1,969	1,970	1,652	1,712	1,892
H00996	1,483	1,761	1,649	1,711	1,844	1,854	1,752	1,610	1,714
				Group 4					
H00004	2,146	1,952	2,184	1,978	2,170	2,108	1,787	1,866	2,007
H00005	1,581	1,984	1,899	1,786	1,988	1,953	1,981	1,805	1,959
H00006	1,988	2,127	1,873	1,860	2,053	1,908	1,973	1,840	1,781
H00007	1,963	2,102	2,004	1,818	2,065	1,902	1,810	1,877	1,732
H00008	1,369	1,403	1,492	1,557	1,499	1,732	1,418	1,699	1,530
H00009	1,772	2,149	1,823	1,622	1,838	1,854	1,685	1,613	1,569

Study No. 6127-111

Individual Food Consumptions (g)

Females

Animal Number	Week 18	19	20	21	22	23	24	25	26
				Group 1					
H00967	2,060	2,006	1,799	2,369	2,092	2,322	2,011	1,678	1,658
H00968	1,935	2,094	2,195	2,331	2,092	2,122	2,234	1,788	1,869
H00969	1,679	1,571	1,604	1,881	1,622	1,651	987	1,104	1,324
H00970	2,007	2,006	1,773	2,046	1,869	1,587	1,018	1,404	1,326
H00971	1,883	1,726	1,837	2,154	1,876	1,741	1,726	1,699	1,760
H00972	1,824	1,959	1,977	2,282	1,855	1,767	1,954	1,811	1,755
				Group 2					
H00979	1,504	1,690	1,260	1,609	1,383	1,354	1,671	1,677	1,154
H00980	1,571	1,556	1,529	1,915	1,617	1,685	1,702	1,637	1,208
H00981	1,624	1,885	1,807	2,028	1,827	1,930	1,589	1,988	1,523
H00982	1,416	1,595	1,527	1,595	988	1,577	1,448	1,678	1,448
H00983	1,663	1,417	1,754	1,838	1,723	1,963	1,539	1,628	1,376
H00984	1,476	1,416	1,381	1,656	1,204	1,543	1,339	1,372	1,024
				Group 3					
H00991	1,409	1,694	1,499	1,656	1,549	1,643	1,630	1,672	1,231
H00992	1,707	2,051	1,756	1,905	1,828	2,038	1,515	1,656	1,251
H00993	1,907	1,906	1,749	2,097	1,695	2,073	1,800	1,568	1,586
H00994	1,667	1,550	1,663	1,827	1,645	1,571	1,555	1,616	1,601
H00995	1,879	1,695	1,513	1,936	1,613	1,289	1,080	1,001	1,191
H00996	1,372	1,521	1,867	1,991	1,495	1,684	1,341	1,146	847
				Group 4					
H00004	1,767	2,151	1,912	2,140	1,850	2,217	1,891	1,555	951
H00005	1,568	1,762	1,762	2,139	1,858	2,034	1,873	1,996	1,620
H00006	1,636	1,950	1,644	1,868	1,710	1,868	1,719	1,637	1,645
H00007	1,736	1,808	1,928	1,972	1,916	1,927	1,661	2,063	1,724
H00008	1,485	1,677	1,191	1,279	1,164	1,431	1,188	880	880
H00009	1,607	1,889	1,444	1,712	1,593	1,729	1,416	1,414	1,535

Study No. 6127111

Individual Food Consumptions (g)
Recovery Study

Females

Animal Number	Week 27	28	29	30
		Group 1		
H00971	1,859	1,973	2,090	1,844
H00972	1,579	1,622	1,880	1,770
		Group 2		
H00979	1,315	1,419	1,855	1,243
H00981	1,219	1,918	2,139	1,997
		Group 3		
H00995	1,108	1,347	1,869	1,777
H00996	1,278	1,428	1,682	1,746
		Group 4		
H00005	1,628	1,923	2,137	1,948
H00006	1,105	1,756	1,691	1,699

APPENDIX D

Individual Food Consumptions on Pharmacokinetic Blood Sampling Days

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Study No. 6127-111

Individual Food Consumptions (g) on Pharmacokinetic Blood Sampling Days

Males

Animal Number	Week 1	Week 12	Week 26
	Group 1		
H00961	223	286	471
H00962	241	285	225
H00963	106	155	279
H00964	204	169	301
H00965	302	209	382
H00966	164	106	218
	Group 2		
H00973	184	175	242
H00974	132	197	245
H00975	148	215	287
H00976	189	233	390
H00977	156	246	219
H00978	165	96	129
	Group 3		
H00985	257	135	431
H00986	229	247	235
H00987	136	138	261
H00988	80	97	271
H00989	200	124	276
H00990	195	182	338
	Group 4		
H00997	265	239	244
H00998	181	314	412
H00999	246	356	223
H00001	191	297	250
H00002	174	175	243
H00003	161	296	396

Study No. 6127-111

Individual Food Consumptions (g) on Pharmacokinetic Blood Sampling Days

Females

Animal Number	Week 1	Week 12	Week 26
	Group 1		
H00967	147	237	278
H00968	189	219	287
H00969	247	168	210
H00970	242	266	219
H00971	285	144	300
H00972	168	184	190
	Group 2		
H00979	162	141	164
H00980	185	206	293
H00981	197	184	321
H00982	193	254	335
H00983	95	187	282
H00984	173	166	167
	Group 3		
H00991	126	207	206
H00992	256	217	187
H00993	121	19	327
H00994	69	233	192
H00995	96	210	159
H00996	161	166	168
	Group 4		
H00004	207	309	190
H00005	212	178	289
H00006	192	213	239
H00007	243	169	183
H00008	180	118	167
H00009	130	149	254

APPENDIX E

Individual Physical Examinations

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Study No. 6127-111

Individual Physical Examinations

Males - Baseline

Animal Number	Rectal Temperature (°F)	Heart Rate (Beats/Min)	Respiration (Breaths/Min)	General Condition	Head/ Neck	Thorax/ Abdomen	Anal/ Genital	Extremities	Comments
					Group 1				
H00961	101.3	120	36	Good	NAO	NAO	NAO	NAO	-
H00962	100.9	144	60	Good	NAO	NAO	NAO	NAO	-
H00963	102.4	128	32	Good	NAO	NAO	NAO	NAO	-
H00964	102.0	144	36	Good	NAO	NAO	NAO	NAO	-
H00965	100.2	104	32	Good	NAO	NAO	NAO	NAO	-
H00966	101.5	120	52	Good	Ptyalism	NAO	NAO	NAO	-
Mean	101.4	127	41						
SD	0.78	15.5	11.8						
					Group 2				
H00973	101.6	124	36	Good	NAO	NAO	NAO	NAO	-
H00974	101.4	128	36	Good	NAO	NAO	NAO	NAO	-
H00975	102.5	144	36	Good	Slight ocular discharge - OU	NAO	NAO	NAO	-
H00976	101.0	156	48	Good	Small laceration between eyes	NAO	NAO	NAO	NAO
H00977	101.7	140	44	Good	NAO	NAO	NAO	NAO	-
H00978	101.7	156	42	Good	NAO	NAO	NAO	NAO	-
Mean	101.6	141	40						
SD	0.49	13.5	5.1						

NAO = No abnormal observation.

Study No. 6127-111

Individual Physical Examinations

Males - Baseline

Animal Number	Rectal Temperature (°F)	Heart Rate (Beats/Min)	Respiration (Breaths/Min)	General Condition	Head/ Neck	Thorax/ Abdomen	Anal/ Genital	Extremities	Comments
					Group 3				
H00985	102.0	156	40	Good	NAO	NAO	NAO	NAO	-
H00986	101.7	152	42	Good	NAO	NAO	NAO	NAO	-
H00987	101.0	112	40	Good	NAO	NAO	NAO	NAO	-
H00988	101.4	136	32	Good	NAO	NAO	NAO	NAO	-
H00989	101.9	124	40	Good	NAO	NAO	NAO	NAO	-
H00990	100.1	148	38	Good	NAO	NAO	NAO	NAO	-
Mean	101.4	138	39						
SD	0.71	17.3	3.5						
					Group 4				
H00997	101.9	140	44	Good	NAO	NAO	NAO	NAO	-
H00998	101.6	148	40	Good	NAO	NAO	NAO	NAO	-
H00999	101.4	136	44	Good	NAO	NAO	NAO	NAO	-
H00001	101.7	136	40	Good	NAO	NAO	NAO	NAO	-
H00002	102.5	160	40	Good	NAO	NAO	NAO	NAO	-
H00003	101.4	140	44	Good	Small laceration on top of head	NAO	NAO	NAO	-
Mean	101.8	143	42						
SD	0.41	9.3	2.2						

NAO = No abnormal observation.

Study No. 6127-111

Individual Physical Examinations

Males - Week 8

Animal Number	Rectal Temperature (°F)	Heart Rate (Beats/Min)	Respiration (Breaths/Min)	General Condition	Head/ Neck	Thorax/ Abdomen	Anal/ Genital	Extremities	Comments
				Group 1					
H00961	100.5	120	44	Good	NAO	NAO	NAO	NAO	-
H00962	100.2	124	46	Good	NAO	NAO	NAO	NAO	-
H00963	100.0	120	40	Good	NAO	NAO	NAO	NAO	-
H00964	100.4	120	32	Good	NAO	NAO	NAO	NAO	-
H00965	100.1	132	28	Good	NAO	NAO	NAO	NAO	Erythema
H00966	100.5	100	40	Good	NAO	NAO	NAO	NAO	-
Mean	100.3	119	38						
SD	0.21	10.6	7.0						
				Group 2					
H00973	100.2	124	47	Good	NAO	NAO	NAO	NAO	-
H00974	100.8	140	36	Good	NAO	NAO	NAO	NAO	-
H00975	100.5	136	28	Good	NAO	NAO	NAO	NAO	Erythema
H00976	100.5	136	36	Good	NAO	NAO	NAO	NAO	-
H00977	100.9	124	40	Good	NAO	NAO	NAO	NAO	-
H00978	102.0	108	32	Good	NAO	NAO	NAO	NAO	-
Mean	100.8	128	36						
SD	0.63	11.8	6.6						

NAO = No abnormal observation.

Study No. 6127-111

Individual Physical Examinations

Males - Week 8

Animal Number	Rectal Temperature (°F)	Heart Rate (Beats/Min)	Respiration (Breaths/Min)	General Condition	Head/ Neck	Thorax/ Abdomen	Anal/ Genital	Extremities	Comments
				Group 3					
H00985	100.2	140	36	Good	NAO	NAO	NAO	NAO	Erythema
H00986	101.1	152	40	Good	a	NAO	NAO	NAO	-
H00987	100.1	100	48	Good	NAO	NAO	NAO	NAO	-
H00988	100.5	116	32	Good	NAO	NAO	NAO	NAO	-
H00989	101.4	116	36	Good	NAO	NAO	NAO	NAO	Erythema
H00990	100.0	108	36	Good	NAO	NAO	NAO	NAO	-
Mean	100.5	122	38						
SD	0.58	19.8	5.5						
				Group 4					
H00997	100.5	124	28	Good	NAO	NAO	NAO	NAO	-
H00998	100.5	140	64[b]	Good	NAO	NAO	NAO	NAO	-
H00999	100.3	116	36	Good	NAO	NAO	NAO	NAO	-
H00001	100.3	140	28	Good	NAO	NAO	NAO	NAO	-
H00002	100.6	104	32	Good	NAO	NAO	NAO	NAO	-
H00003	100.5	112	48	Good	Alopecia - tips of ear flaps	NAO	NAO	NAO	-
Mean	100.4	123	39						
SD	0.12	14.9	14.2						

NAO = No abnormal observation.

[a]Slight alopecia-right ear flap; erythema both ear flaps.
[b]Panting.

Study No. 6127-111

Individual Physical Examinations

Males - Week 17

Animal Number	Rectal Temperature (°F)	Heart Rate (Beats/Min)	Respiration (Breaths/Min)	General Condition	Head/ Neck	Thorax/ Abdomen	Anal/ Genital	Extremities	Comments
					Group 1				
H00961	99.5	110	34	Good	NAO	NAO	NAO	NAO	-
H00962	100.7	110	40	Good	NAO	NAO	NAO	NAO	-
H00963	101.0	108	38	Good	NAO	NAO	NAO	NAO	-
H00964	100.5	100	44	Good	NAO	NAO	NAO	NAO	-
H00965	100.2	112	48	Good	NAO	NAO	NAO	Alopecia - legs and paws	Generalized erythema
H00966	100.5	104	40	Good	NAO	NAO	NAO	NAO	-
Mean	100.4	107	41						
SD	0.51	4.5	4.8						
					Group 2				
H00973	100.3	100	34	Good	NAO	NAO	NAO	NAO	-
H00974	101.6	120	42	Good	NAO	NAO	NAO	NAO	-
H00975	100.5	120	36	Good	Alopecia - ear flaps	NAO	NAO	NAO	Erythema - entire body
H00976	100.1	136	42	Good	NAO	NAO	NAO	NAO	-
H00977	101.3	120	40	Good	NAO	NAO	NAO	NAO	-
H00978	101.9	140	40	Good	NAO	NAO	NAO	NAO	-
Mean	101.0	123	39						
SD	0.75	14.2	3.3						

NAO = No abnormal observation.

Study No. 6127-111

Individual Physical Examinations

Males - Week 17

Animal Number	Rectal Temperature (°F)	Heart Rate (Beats/Min)	Respiration (Breaths/Min)	General Condition	Head/ Neck	Thorax/ Abdomen	Anal/ Genital	Extremities	Comments
					Group 3				
H00985	101.5	130	36	Good	Ocular discharge - OU; alopecia - ear flaps	NAO	NAO	NAO	Erythema - entire body
H00986	101.5	136	42	Good	NAO	NAO	NAO	NAO	-
H00987	100.5	96	32	Good	NAO	NAO	NAO	NAO	-
H00988	101.0	132	32	Good	NAO	NAO	NAO	NAO	-
H00989	101.5	124	42	Good	Abrasion - right outer ear flap; slight alopecia - both ear flaps	NAO	NAO	NAO	Generalized erythema; greasy hair coat
H00990	100.5	136	36	Good	NAO	NAO	NAO	NAO	-
Mean	101.1	126	37						
SD	0.49	15.2	4.5						
					Group 4				
H00997	100.6	116	36	Good	NAO	NAO	NAO	NAO	-
H00998	100.8	120	44	Good	NAO	NAO	NAO	NAO	-
H00999	101.0	116	40	Good	NAO	NAO	NAO	NAO	-
H00001	100.5	130	42	Good	NAO	NAO	NAO	NAO	-
H00002	101.5	84	40	Good	NAO	NAO	NAO	NAO	-
H00003	100.0	92	38	Good	NAO	NAO	NAO	NAO	-
Mean	100.7	110	40						
SD	0.50	17.7	2.8						

NAO = No abnormal observation.
OU = Both eyes.

Study No. 6127-111

Individual Physical Examinations

Males - Week 26

Animal Number	Rectal Temperature (°F)	Heart Rate (Beats/Min)	Respiration (Breaths/Min)	General Condition	Head/ Neck	Thorax/ Abdomen	Anal/ Genital	Extremities	Comments
					Group 1				
H00961	101.3	120	34	Good	Injected sclera - OS	NAO	NAO	NAO	-
H00962	102.1	130	42	Good	NAO	NAO	NAO	NAO	-
H00963	102.4	134	36	Good	NAO	NAO	NAO	NAO	-
H00964	101.0	116	34	Good	NAO	NAO	NAO	NAO	-
H00965	100.7	124	28	Good	NAO	NAO	NAO	NAO	Erythema - entire body; generalized alopecia
H00966	105.0	126	34	Good	NAO	NAO	NAO	NAO	-
Mean	102.1	125	35						
SD	1.57	6.5	4.5						
					Group 2				
H00973	101.4	110	34	Good	NAO	NAO	NAO	NAO	-
H00974	101.9	124	32	Good	NAO	NAO	NAO	NAO	-
H00975	100.6	138	30	Good	Alopecia - ear flaps	NAO	NAO	NAO	Erythema - entire body
H00976	101.2	116	30	Good	NAO	NAO	NAO	NAO	-
H00977	101.5	120	34	[a]	[a]	[a]	[a]	[a]	[a]
H00978	101.4	132	36	Good	NAO	NAO	NAO	NAO	-
Mean	101.3	123	33						
SD	0.43	10.3	2.4						

NAO = No abnormal observation.
OS = Left eye.

[a]Physical done; data not recorded.

Study No. 6127-111

Individual Physical Examinations

Males - Week 26

Animal Number	Rectal Temperature (°F)	Heart Rate (Beats/Min)	Respiration (Breaths/Min)	General Condition	Head/ Neck	Thorax/ Abdomen	Anal/ Genital	Extremities	Comments
					Group 3				
H00985	100.5	138	32	Good	Alopecia - ear flaps; ocular discharge - OU	NAO	NAO	NAO	Erythema - entire body
H00986	101.2	128	52	Good	NAO	NAO	NAO	NAO	-
H00987	100.8	114	34	Good	NAO	NAO	NAO	NAO	-
H00988	101.5	112	28	Good	NAO	NAO	NAO	NAO	-
H00989	100.9	118	36	Good	NAO	NAO	NAO	NAO	Erythema - entire body
H00990	100.7	118	32	Good	NAO	NAO	NAO	NAO	-
Mean	100.9	121	36						
SD	0.36	9.9	8.4						
					Group 4				
H00997	100.5	106	34	Good	NAO	NAO	NAO	NAO	-
H00998	101.0	142	32	Good	NAO	NAO	NAO	NAO	-
H00999	100.9	114	42	Good	NAO	NAO	NAO	NAO	-
H00001	101.6	122	30	Good	NAO	NAO	NAO	NAO	-
H00002	101.5	116	44	Good	NAO	NAO	NAO	NAO	-
H00003	100.2	128	46	Good	NAO	NAO	NAO	NAO	-
Mean	101.0	121	38						
SD	0.55	12.6	6.8						

NAO = No abnormal observation.
OU = Both eyes.

Study No. 6127-111

Individual Physical Examinations
Recovery Study

Males - Week 30

Animal Number	Rectal Temperature (°F)	Heart Rate (Beats/Min)	Respiration (Breaths/Min)	General Condition	Head/ Neck	Thorax/ Abdomen	Anal/ Genital	Extremities	Comments
					Group 1				
H00964	101.0	114	38	Good	NAO	NAO	NAO	NAO	
H00965	100.5	140	34	Good	Slight alopecia - ears	Alopecia - thorax	NAO	NAO	Slight erythema - generalized
Mean	100.8	127	36						
SD	0.35	18.4	2.8						
					Group 2				
H00973	100.2	116	42	Good	NAO	NAO	NAO	NAO	
H00977	100.0	126	38	Good	NAO	NAO	NAO	NAO	
Mean	100.1	121	40						
SD	0.14	7.1	2.8						
					Group 3				
H00988	100.7	116	32	Good	NAO	NAO	NAO	NAO	
H00990	100.1	122	36	Good	NAO	NAO	NAO	NAO	
Mean	100.4	119	34						
SD	0.42	4.2	2.8						
					Group 4				
H00998	101.0	130	40	Good	NAO	NAO	NAO	NAO	
H00001	101.1	136	26	Good	NAO	NAO	NAO	NAO	
Mean	101.0	133	33						
SD	0.07	4.2	9.9						

NAO = No abnormal observation.

Note: Because of the number of animals, statistics were done on combined means only (see Tables 16, 17, and 18).

Study No. 6127-111

Individual Physical Examinations

Females - Baseline

Animal Number	Rectal Temperature (°F)	Heart Rate (Beats/Min)	Respiration (Breaths/Min)	General Condition	Head/ Neck	Thorax/ Abdomen	Anal/ Genital	Extremities	Comments
					Group 1				
H00967	101.7	132	32	Good	NAO	NAO	NAO	NAO	-
H00968	102.0	132	75	Good	NAO	NAO	NAO	NAO	-
H00969	101.4	131	40	Good	NAO	NAO	NAO	NAO	-
H00970	101.6	136	44	Good	NAO	NAO	NAO	NAO	-
H00971	101.0	136	36	Good	NAO	NAO	NAO	NAO	-
H00972	100.5	106	38	Good	NAO	NAO	NAO	NAO	-
Mean	101.4	129	44						
SD	0.54	11.4	15.6						
					Group 2				
H00979	100.0	120	64	Good	NAO	NAO	NAO	NAO	-
H00980	100.6	152	50	Good	NAO	NAO	NAO	Sore, left hock	-
H00981	102.0	136	68	Good	NAO	NAO	NAO	NAO	-
H00982	101.5	156	40	Good	NAO	NAO	NAO	NAO	-
H00983	101.5	164	42	Good	NAO	NAO	NAO	NAO	-
H00984	101.2	116	44	Good	NAO	NAO	NAO	NAO	-
Mean	101.1	141	51						
SD	0.72	19.8	11.9						

NAO = No abnormal observation.

Study No. 6127-111

Individual Physical Examinations

Females - Baseline

Animal Number	Rectal Temperature (°F)	Heart Rate (Beats/Min)	Respiration (Breaths/Min)	General Condition	Head/ Neck	Thorax/ Abdomen	Anal/ Genital	Extremities	Comments
				Group 3					
H00991	101.0	148	52	Good	NAO	NAO	NAO	NAO	-
H00992	101.7	120	42	Good	OS-cherry eye	NAO	NAO	NAO	-
H00993	101.0	136	40	Good	NAO	NAO	NAO	NAO	-
H00994	101.1	132	48	Good	NAO	NAO	NAO	NAO	-
H00995	101.1	112	36	Good	NAO	NAO	NAO	NAO	-
H00996	100.0	132	36	Good	NAO	NAO	NAO	NAO	-
Mean	101.0	130	42						
SD	0.55	12.6	6.5						
				Group 4					
H00004	102.0	140	40	Good	NAO	NAO	NAO	NAO	-
H00005	100.5	132	38	Good	NAO	NAO	NAO	NAO	-
H00006	100.5	108	40	Good	NAO	NAO	NAO	NAO	-
H00007	101.0	124	48	Good	NAO	NAO	NAO	NAO	-
H00008	101.5	152	48	Good	NAO	NAO	NAO	NAO	-
H00009	102.0	128	64	Good	NAO	NAO	NAO	NAO	-
Mean	101.2	131	46						
SD	0.69	14.9	9.7						

NAO = No abnormal observation.
OS = Left eye

Study No. 6127-111

Individual Physical Examinations

Females - Week 8

Animal Number	Rectal Temperature (°F)	Heart Rate (Beats/Min)	Respiration (Breaths/Min)	General Condition	Head/ Neck	Thorax/ Abdomen	Anal/ Genital	Extremities	Comments
					Group 1				
H00967	99.9	128	40	Good	NAO	NAO	NAO	NAO	-
H00968	100.5	140	40	Good	NAO	NAO	NAO	NAO	Erythema
H00969	100.7	128	36	Good	NAO	NAO	NAO	NAO	-
H00970	99.9	140	40	Good	NAO	NAO	NAO	NAO	-
H00971	100.1	112	44	Good	NAO	NAO	NAO	Alopecia - left rear paw	Erythema
H00972	99.8	104	40	Good	Alopecia and lacerations both ears	NAO	NAO	NAO	Erythema
Mean	100.2	125	40						
SD	0.40	14.7	2.5						
					Group 2				
H00979	99.0	132	32	Good	NAO	NAO	NAO	NAO	-
H00980	100.7	152	28	Good	NAO	NAO	NAO	NAO	-
H00981	101.0	120	36	Good	NAO	NAO	NAO	NAO	-
H00982	100.5	128	48	Good	NAO	NAO	NAO	Slight alopecia front limbs	-
H00983	100.0	152	52	Good	NAO	NAO	NAO	NAO	-
H00984	100.5	128	40	Good	NAO	NAO	NAO	Slight alopecia ear tips	-
Mean	100.3	135	39						
SD	0.71	13.5	9.3						

NAO = No abnormal observation.

Study No. 6127-111

Individual Physical Examinations

Females - Week 8

Animal Number	Rectal Temperature (°F)	Heart Rate (Beats/Min)	Respiration (Breaths/Min)	General Condition	Head/ Neck	Thorax/ Abdomen	Anal/ Genital	Extremities	Comments
					Group 3				
H00991	100.5	140	36	Good	NAO	NAO	NAO	NAO	-
H00992	100.6	132	36	Good	NAO	NAO	NAO	NAO	-
H00993	101.4	148	28	Good	NAO	NAO	NAO	NAO	-
H00994	100.1	140	44	Good	NAO	NAO	NAO	NAO	-
H00995	100.4	100	36	Good	NAO	NAO	NAO	NAO	-
H00996	100.1	140	36	Good	NAO	NAO	NAO	NAO	-
Mean	100.5	133	36						
SD	0.48	17.1	5.1						
					Group 4				
H00004	101.5	136	36	Good	NAO	NAO	NAO	NAO	-
H00005	101.9	136	32	Good	NAO	NAO	NAO	NAO	-
H00006	100.6	116	28	Good	NAO	NAO	NAO	NAO	-
H00007	100.0	120	32	Good	NAO	NAO	NAO	NAO	-
H00008	100.8	148	52	Good	NAO	NAO	NAO	NAO	-
H00009	101.5	132	36	Good	NAO	NAO	NAO	NAO	-
Mean	101.0	131	36						
SD	0.71	11.7	8.4						

NAO = No abnormal observation.

Study No. 6127-111

Individual Physical Examinations

Females - Week 17

Animal Number	Rectal Temperature (°F)	Heart Rate (Beats/Min)	Respiration (Breaths/Min)	General Condition	Head/ Neck	Thorax/ Abdomen	Anal/ Genital	Extremities	Comments
					Group 1				
H00967	100.0	132	40	Good	NAO	NAO	NAO	NAO	-
H00968	101.0	120	24	Good	NAO	NAO	NAO	NAO	Generalized erythema and alopecia
H00969	100.5	138	34	Good	NAO	NAO	NAO	NAO	-
H00970	100.0	140	36	Good	NAO	NAO	In heat	NAO	-
H00971	101.0	110	28	Good	Erythema - ear canals	NAO	NAO	NAO	Greasy hair coat; slight erythema
H00972	101.1	110	32	Good	Small laceration - left ear; slight erythema - both ear flaps	NAO	NAO	NAO	-
Mean	100.6	125	32						
SD	0.51	13.5	5.7						
					Group 2				
H00979	100.2	140	42	Good	NAO	NAO	NAO	NAO	-
H00980	101.0	148	42	Good	NAO	NAO	NAO	NAO	-
H00981	101.0	116	44	Good	NAO	NAO	NAO	NAO	-
H00982	100.5	140	32	Good	NAO	NAO	NAO	NAO	-
H00983	100.8	128	44	Good	NAO	NAO	NAO	NAO	-
H00984	101.4	126	42	Good	NAO	NAO	NAO	NAO	-
Mean	100.8	133	41**						
SD	0.42	11.7	4.5						

NAO = No abnormal observation.

Study No. 6127-111

Individual Physical Examinations

Females - Week 17

Animal Number	Rectal Temperature (°F)	Heart Rate (Beats/Min)	Respiration (Breaths/Min)	General Condition	Head/ Neck	Thorax/ Abdomen	Anal/ Genital	Extremities	Comments
					Group 3				
H00991	101.4	108	34	Good	NAO	NAO	NAO	NAO	-
H00992	101.0	124	34	Good	NAO	NAO	NAO	NAO	-
H00993	100.7	132	36	Good	Small abrasions in right ear	NAO	NAO	NAO	Generalized erythema
H00994	100.7	132	36	Good	NAO	NAO	NAO	NAO	-
H00995	100.0	134	36	Good	Slight alopecia - ear flaps	NAO	In heat	NAO	-
H00996	101.5	128	32	Good	NAO	NAO	In heat	NAO	-
Mean	100.9	126	35						
SD	0.55	9.7	1.6						
					Group 4				
H00004	100.6	132	42	Good	NAO	Alopecia - both sides of thorax	NAO	NAO	Oily hair coat
H00005	101.6	120	40	Good	Ocular discharge - OS	NAO	NAO	NAO	-
H00006	100.0	112	38	Good	NAO	NAO	NAO	NAO	-
H00007	100.9	140	38	Good	NAO	NAO	NAO	NAO	-
H00008	101.0	142	38	Good	NAO	NAO	In heat	NAO	-
H00009	101.5	120	38	Good	NAO	NAO	NAO	NAO	-
Mean	100.8	128	39*						
SD	0.58	12.2	1.7						

NAO = No abnormal observation.
OS = Left eye.

Study No. 6127-111

Individual Physical Examinations

Females - Week 26

Animal Number	Rectal Temperature (°F)	Heart Rate (Beats/Min)	Respiration (Breaths/Min)	General Condition	Head/ Neck	Thorax/ Abdomen	Anal/ Genital	Extremities	Comments
					Group 1				
H00967	100.5	126	40	Good	Ocular discharge - OU	NAO	NAO	NAO	-
H00968	101.0	122	32	Good	NAO	NAO	NAO	NAO	Erythema - entire body; generalized alopecia
H00969	101.2	126	28	Good	NAO	NAO	NAO	NAO	-
H00970	100.2	140	36	Good	NAO	NAO	NAO	Small laceration on right paw	-
H00971	100.5	126	34	Good	NAO	NAO	NAO	NAO	Erythema - entire body
H00972	102.0	128	40	Good	Erythema - ear flaps	NAO	NAO	NAO	-
Mean	100.9	128	35						
SD	0.65	6.2	4.7						
					Group 2				
H00979	100.6	146	46	Good	NAO	NAO	NAO	NAO	-
H00980	100.9	138	36	[a]	[a]	[a]	[a]	[a]	[a]
H00981	101.2	128	38	Good	NAO	NAO	NAO	NAO	-
H00982	102.0	138	38	Good	NAO	NAO	NAO	NAO	-
H00983	101.5	136	42	Good	NAO	NAO	NAO	NAO	-
H00984	101.7	128	44	Good	NAO	NAO	NAO	NAO	-
Mean	101.3	136	41						
SD	0.52	6.9	3.9						

NAO = No abnormal observation.
OU = Both eyes.

[a]Physical done; data not recorded.

Study No. 6127-111

Individual Physical Examinations

Females - Week 26

Animal Number	Rectal Temperature (°F)	Heart Rate (Beats/Min)	Respiration (Breaths/Min)	General Condition	Head/ Neck	Thorax/ Abdomen	Anal/ Genital	Extremities	Comments
					Group 3				
H00991	100.6	126	34	Good	NAO	NAO	NAO	NAO	-
H00992	101.0	122	32	Good	NAO	NAO	NAO	NAO	-
H00993	100.5	110	30	Good	NAO	NAO	NAO	NAO	Slight erythema - entire body
H00994	100.5	136	44	Good	NAO	NAO	In heat	NAO	-
H00995	100.5	134	36	Good	NAO	NAO	NAO	NAO	-
H00996	101.2	130	40	Good	NAO	NAO	Clear, fluid-like vaginal discharge	NAO	-
Mean	100.7	126	36						
SD	0.31	9.5	5.2						
					Group 4				
H00004	100.5	128	34	Good	NAO	NAO	NAO	NAO	Greasy hair coat
H00005	100.8	134	44	Good	NAO	NAO	NAO	NAO	-
H00006	100.4	122	36	Good	NAO	NAO	NAO	NAO	-
H00007	101.3	126	38	Good	NAO	NAO	In heat	NAO	-
H00008	101.8	136	34	Good	NAO	NAO	NAO	Small sore - left foot	
H00009	101.5	134	36	Good	NAO	NAO	NAO	NAO	-
Mean	101.0	130	37						
SD	0.57	5.5	3.7						

NAO = No abnormal observation.

Study No. 6127-111

Individual Physical Examinations
Recovery Study

Females - Week 30

Animal Number	Rectal Temperature (°F)	Heart Rate (Beats/Min)	Respiration (Breaths/Min)	General Condition	Head/ Neck	Thorax/ Abdomen	Anal/ Genital	Extremities	Comments
					Group 1				
H00971	100.9	114	26	Good	NAO	Alopecia - thorax	NAO	NAO	Generalized erythema
H00972	101.0	110	34	Good	Slight alopecia - ear flaps; slight erythema - ear flaps	NAO	NAO	NAO	Greasy hair coat
Mean	101.0	112	30						
SD	0.07	2.8	5.7						
					Group 2				
H00979	100.2	122	22	Good	NAO	NAO	NAO	NAO	
H00981	101.5	114	26	Good	NAO	NAO	In heat	NAO	
Mean	100.8	118	24						
SD	0.92	5.7	2.8						
					Group 3				
H00995	101.1	116	30	Good	NAO	NAO	NAO	NAO	
H00996	101.1	138	30	Good	NAO	NAO	NAO	NAO	
Mean	101.1	127	30						
SD	0.00	15.6	0.0						
					Group 4				
H00005	101.5	140	40	Good	Slight ocular discharge - OS	NAO	NAO	NAO	
H00006	100.6	132	30	Good	NAO	NAO	NAO	NAO	
Mean	101.0	136	35						
SD	0.64	5.7	7.1						

NAO = No abnormal observation.
OS = Left eye.

Note: Because of the number of animals, statistics were done on combined means only (see Tables 16, 17, and 18).

APPENDIX F

Individual Electrocardiograph Measurements

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Study No. 6127-111

Individual Electrocardiograph Measurements

Males - Week -2

Animal Number	Heart Rate (Beats/min)	P-R Int (sec)	QRS Int (sec)	QT Int (sec)	Elec Axis	Rhythm	P-Wave (sec/mv)	T-Wave (S-T Seg)	Q Amp (mv)	R Amp (mv)	S Amp (mv)	Comment
Group 1												
H00961	120	0.08	0.03	0.17	30°	NS	0.03/0.1	OK	1.0	1.9	0.0	
H00962	160	0.08	0.04	0.16	90°	NS	0.03/0.4	OK	0.2	1.5	0.0	
H00963	140	0.08	0.04	0.16	60°	NS	0.04/0.2	OK	0.4	2.1	0.0	
H00964	120	0.08	0.05	0.18	60°	NS	0.03/0.2	OK	0.1	2.1	0.0	
H00965	140	0.08	0.04	0.16	60°	NS	0.03/0.2	OK	0.3	1.4	0.0	
H00966	120	0.08	0.04	0.19	60°	NS	0.03/0.4	OK	0.4	1.2	0.4	
N	6	6	6	6	6		6/6		6	6	6	
Mean	133	0.08	0.04	0.17	60		0.03/0.2		0.4	1.7	0.1	
S	16.3	0.000	0.006	0.126	19.0		0.004/0.12		0.32	0.038	0.16	
Group 2												
H00973	140	0.10	0.04	0.19	60°	NS	0.03/0.1	OK	0.2	2.1	0.0	
H00974	100	0.11	0.05	0.18	60°	NS	0.03/0.3	OK	0.4	2.4	0.0	
H00975	180	0.07	0.05	0.16	60°	NS	0.03/0.4	OK	0.9	1.5	0.0	
H00976	200	0.07	0.04	0.16	60°	NS	0.03/0.3	OK	0.9	1.6	0.0	
H00977	160	0.08	0.04	0.17	60°	NS	0.04/0.3	OK	0.7	2.1	0.0	
H00978	140	0.09	0.04	0.15	60°	NS	0.03/0.2	OK	0.4	2.8	0.0	
N	6	6	6	6	6		6/6		6	6	6	
Mean	153	0.09	0.04	0.17	60		0.03/0.3		0.6	2.1	0.0	
S	35.0	0.016	0.005	0.147	0.0		0.004/0.10		0.29	0.49	0.00	
Group 3												
H00985	140	0.08	0.05	0.18	60°	NS	0.03/0.3	OK	0.4	1.9	0.0	
H00986	180	0.08	0.04	0.17	Isoelectric	NS	0.03/0.3	OK	1.3	1.5	0.0	
H00987	100	0.08	0.03	0.18	60°	NS	0.03/0.1	OK	0.2	1.9	0.0	
H00988	200	0.09	0.04	0.16	90°	NS	0.04/0.2	OK	0.2	1.2	0.0	
H00989	100	0.08	0.03	0.17	30°	NS	0.03/0.3	OK	0.2	1.5	0.0	
H00990	160	0.08	0.03	0.16	90°	NS	0.03/0.3	OK	0.5	1.7	0.0	
N	6	6	6	6	5		6/6		6	6	6	
Mean	147	0.08	0.04	0.17	66		0.03/0.2		0.5	1.6	0.0	
S	41.3	0.004	0.008	0.009	25.1		0.004/0.08		0.43	0.27	0.00	

NS = Normal sinus rhythm/arrhythmia.

Study No. 6127-111

Individual Electrocardiograph Measurements (Continued)

Males - Week -2

Animal Number	Heart Rate (Beats/min)	P-R Int (sec)	QRS Int (sec)	QT Int (sec)	Elec Axis	Rhythm	P-Wave (sec/mv)	T-Wave (S-T Seg)	Q Amp (mv)	R Amp (mv)	S Amp (mv)	Comment
						Group 4						
H00997	160	0.08	0.04	0.18	30°	NS	0.02/0.2	OK	0.5	1.1	0.0	
H00998	160	0.08	0.04	0.16	60°	NS	0.03/0.2	OK	0.4	1.6	0.1	
H00999	120	0.09	0.05	0.19	90°	NS	0.03/0.1	OK	0.3	2.4	0.1	
H00001	180	0.08	0.03	0.16	60°	NS	0.03/0.3	OK	0.8	2.0	0.0	
H00002	140	0.08	0.04	0.16	60°	NS	0.02/0.2	OK	0.8	2.5	0.0	
H00003	140	0.03	0.05	0.15	90°	NS	0.03/0.3	OK	0.2	2.5	0.0	
N	6	5	6	6	6		6/6		6	6	6	
Mean	150	0.07	0.04	0.17	65		0.03/0.2		0.5	2.0	0.0	
S	21.0	0.022	0.008	0.151	22.6		0.005/0.08		0.25	0.57	0.05	

NS = Normal sinus rhythm/arrhythmia

Study No. 6127-111

Individual Electrocardiograph Measurements

Males - Week 8

Animal Number	Heart Rate (Beats/min)	P-R Int (sec)	QRS Int (sec)	QT Int (sec)	Elec Axis	Rhythm	P-Wave (sec/mv)	T-Wave (S-T Seg)	Q Amp (mv)	R Amp (mv)	S Amp (mv)	Comment
						Group 1						
H00961	160	0.08	0.03	0.19	60°	NS	0.02/0.2	OK	0.3	2.1	0.0	
H00962	140	0.08	0.04	0.17	60°	NS	0.03/0.3	OK	0.5	1.6	0.0	
H00963	180	0.08	0.04	0.17	75°	NS	0.04/0.3	OK	0.4	2.8	0.0	
H00964	100	0.08	0.03	0.18	75°	NS	0.03/0.2	OK	0.0	2.1	0.0	
H00965	160	0.09	0.04	0.18	60°	NS	0.03/0.3	OK	0.6	1.5	0.1	
H00966	100	0.09	0.05	0.19	75°	NS	0.03/0.3	OK	0.5	1.3	0.4	
N	6	6	6	6	6		6/6		6	6	6	
Mean	140	0.08	0.04	0.18	68		0.03/0.3		0.4	1.9	0.1	
S	33.5	0.005	0.008	0.009	8.2		0.006/0.05		0.21	0.55	0.16	
						Group 2						
H00973	100	0.10	0.05	0.20	75°	NS	0.04/0.2	OK	0.2	3.0	0.0	
H00974	180	0.07	0.04	0.16	60°	NS	0.04/0.3	OK	0.4	2.5	0.0	
H00975	160	0.08	0.05	0.17	60°	NS	0.04/0.4	OK	0.2	2.3	0.0	
H00976	180	0.09	0.03	0.16	90°	NS	0.03/0.3	OK	0.3	1.5	0.0	
H00977	120	0.10	0.05	0.18	60°	NS	0.03/0.2	OK	0.4	2.3	0.0	
H00978	180	0.08	0.05	0.15	75°	NS	0.03/0.3	OK	0.3	2.8	0.0	
N	6	6	6	6	6		6/6		6	6	6	
Mean	153	0.09	0.04	0.17	70		0.04/0.3		0.3	2.4	0.0	
S	35.0	0.012	0.008	0.179	12.2		0.005/0.08		0.09	0.52	0.00	
						Group 3						
H00985	120	0.09	0.05	0.18	60°	NS	0.03/0.3	OK	0.3	2.1	0.0	
H00986	140	0.08	0.04	0.18	120°	NS	0.03/0.2	OK	1.2	1.4	0.0	
H00987	100	0.09	0.04	0.20	60°	NS	0.04/0.2	OK	0.2	2.3	0.1	
H00988	200	0.09	0.04	0.16	90°	NS	0.03/0.2	OK	0.3	1.0	0.0	
H00989	140	0.09	0.05	0.19	60°	NS	0.03/0.3	OK	0.2	1.5	0.0	
H00990	200	0.08	0.03	0.17	60°	NS	0.03/0.3	OK	0.4	0.8	0.3	
N	6	6	6	6	6		6/6		6	6	6	
Mean	150	0.09	0.04	0.18	75		0.03/0.2		0.4	1.5	0.1	
S	41.5	0.005	0.008	0.014	25.1		0.004/0.05		0.38	0.59	0.12	

NS = Normal sinus rhythm/arrhythmia

Study No. 6127-111

Individual Electrocardiograph Measurements (Continued)

Males - Week 8

Animal Number	Heart Rate (Beats/min)	P-R Int (sec)	QRS Int (sec)	QT Int (sec)	Elec Axis	Rhythm	P-Wave (sec/mv)	T-Wave (S-T Seg)	Q Amp (mv)	R Amp (mv)	S Amp (mv)	Comment
						Group 4						
H00997	120	0.09	0.03	0.19	60°	NS	0.03/0.2	OK	0.1	1.5	0.0	
H00998	180	0.08	0.04	0.16	60°	NS	0.03/0.2	OK	0.2	2.0	0.1	
H00999	100	0.09	0.06	0.19	60°	NS	0.03/0.1	OK	0.5	2.4	0.2	
H00001	180	0.06	0.03	0.15	90°	NS	0.03/0.3	OK	0.9	2.0	0.0	
H00002	120	0.09	0.04	0.18	75°	NS	0.02/0.2	OK	0.4	3.0	0.0	
H00003	140	0.08	0.05	0.16	75°	NS	0.03/0.3	OK	0.2	2.8	0.0	
S	6	6	6	6	6		6/6		6	6	6	
Mean	140	0.08	0.04	0.17	70		0.03/0.2		0.4	2.3	0.0	
N	33.5	0.012	0.012	0.017	12.2		0.004/0.08		0.29	0.56	0.08	

NS = Normal sinus rhythm/arrhythmia

Study No. 6127-111

Individual Electrocardiograph Measurements

Males - Week 17

Animal Number	Heart Rate (Beats/min)	P-R Int (sec)	QRS Int (sec)	QT Int (sec)	Elec Axis	Rhythm	P-Wave (sec/mv)	T-Wave (S-T Seg)	Q Amp (mv)	R Amp (mv)	S Amp (mv)	Comment
						Group 1						
H00961	100	0.08	0.03	0.18	60°	NS	0.03/0.2	OK	0.4	2.3	0.0	
H00962	160	0.09	0.04	NA	60°	NS	0.04/0.3	OK	0.7	1.6	0.0	
H00963	160	0.07	0.05	0.17	60°	NS	0.03/0.2	OK	0.7	2.6	0.0	
H00964	140	0.09	0.04	0.18	60°	NS	0.03/0.2	OK	0.1	2.2	0.0	
H00965	160	0.08	0.04	0.18	30°	NS	0.03/0.3	OK	0.6	1.8	0.0	
H00966	120	0.09	0.05	0.19	60°	NS	0.03/0.4	OK	0.2	1.5	0.4	
N	6	6	6	5	6		6/6		6	6	6	
Mean	140	0.08	0.04	0.18	55		0.03/0.3		0.4	2.0	0.1	
SD	25.3	0.008	0.008	0.007	12.2		0.004/0.08		0.26	0.43	0.16	
						Group 2						
H00973	100	0.10	0.04	0.20	60°	NS	0.04/0.1	OK	0.3	2.7	0.0	
H00974	160	0.09	0.04	0.17	75°	NS	0.03/0.3	OK	0.2	2.6	0.0	
H00975	140	0.09	0.05	0.18	60°	NS	0.04/0.3	OK	0.2	2.0	0.0	
H00976	180	0.09	0.04	0.16	90°	NS	0.04/0.4	OK	0.4	1.6	0.0	
H00977	120	0.10	0.05	0.18	60°	NS	0.04/0.3	OK	0.2	2.3	0.0	
H00978	120	0.10	0.06	0.17	60°	NS	0.03/0.2	OK	0.5	3.4	0.0	Left ventricular enlargement
N	6	6	6	6	6		6/6		6	6	6	
Mean	137	0.10	0.05	0.18	68		0.04/0.3		0.3	2.4	0.0	
SD	29.4	0.005	0.008	0.014	12.5		0.005/0.10		0.13	0.62	0.00	
						Group 3						
H00985	140	0.09	0.05	0.16	60°	NS	0.03/0.3	OK	0.4	2.3	0.0	
H00986	160	0.08	0.04	0.17	Iso-electric	NS	0.03/0.2	OK	1.4	1.5	0.2	
H00987	100	0.09	0.05	0.20	45°	NS	0.02/0.2	OK	0.4	2.1	0.0	
H00988	90	0.10	0.04	0.16	90°	NS	0.03/0.3	OK	0.3	1.1	0.0	
H00989	120	0.08	0.04	0.17	60°	NS	0.03/0.3	OK	0.8	1.6	0.2	
H00990	160	0.08	0.04	0.16	60°	NS	0.03/0.3	OK	0.3	1.4	0.1	
N	6	6	6	6	5		6/6		6	6	6	
Mean	128	0.09	0.04	0.17	63		0.03/0.3		0.6	1.7	0.1	
SD	29.9	0.008	0.005	0.015	16.4		0.004/0.05		0.43	0.45	0.10	

NS = Normal sinus rhythm/arrhythmia.
NA = Not applicable (unable to measure).

Study No. 6127-111

Individual Electrocardiograph Measurements (Continued)

Males - Week 17

Animal Number	Heart Rate (Beats/min)	P-R Int (sec)	QRS Int (sec)	QT Int (sec)	Elec Axis	Rhythm	P-Wave (sec/mv)	T-Wave (S-T Seg)	Q Amp (mv)	R Amp (mv)	S Amp (mv)	Comment
						Group 4						
H00997	140	0.10	0.04	0.17	45°	NS	0.03/0.2	OK	0.2	1.4	0.0	
H00998	160	0.08	0.04	0.18	30°	NS	0.04/0.2	OK	0.2	1.8	0.2	
H00999	100	0.09	0.05	0.18	60°	NS	0.04/0.2	OK	0.3	2.3	0.2	
H00001	160	0.06	0.03	0.17	90°	NS	0.03/0.2	OK	0.6	2.1	0.0	
H00002	120	0.07	0.04	0.17	75°	NS	0.03/0.2	OK	0.4	3.0	0.0	
H00003	120	0.08	0.04	0.18	60°	NS	0.03/0.3	OK	0.3	3.0	0.0	Wandering pacemaker
N	6	6	6	6	6		6/6		6	6	6	
Mean	133	0.08	0.04	0.18	60		0.03/0.2		0.3	2.3	0.0	
SD	24.2	0.014	0.006	0.005	21.2		0.005/0.04		0.15	0.64	0.10	

NS = Normal sinus rhythm/arrhythmia.

Study No. 6127-111

Individual Electrocardiograph Measurements

Males - Week 26

Animal Number	Heart Rate (beats/min)	P-R Int (sec)	QRS Int (sec)	Q-T Int (sec)	Elec Axis	Rhythm	P-Wave (sec/mV)	T-Wave (S-T seg)	Q Amp (mV)	R Amp (mV)	S Amp (mV)	Comment
						Group 1						
H00961	120	0.07	0.05	0.20	60°	NS	0.03/0.2	OK	0.6	2.3	0.0	
H00962	160	0.09	0.05	0.16	60°	NS	0.03/0.3	OK	0.8	1.7	0.0	
H00963	180	0.07	0.03	0.17	120°	NS	0.02/0.1	OK	0.2	1.0	0.0	
H00964	140	0.08	0.04	0.20	60°	NS	0.03/0.2	OK	0.0	2.0	0.0	
H00965	140	0.09	0.05	0.17	60°	NS	0.03/0.3	OK	0.3	1.4	0.2	
H00966	100	0.08	0.05	0.20	60°	NS	0.03/0.3	OK	0.3	1.5	0.4	
N	6	6	6	6	6		6/6		6	6	6	
Mean	140	0.08	0.04	0.18	70		0.03/0.2		0.4	1.6	0.1	
SD	28.3	0.009	0.008	0.019	24.5		0.004/0.08		0.29	0.46	0.17	
						Group 2						
H00973	140	0.10	0.05	0.17	60°	NS	0.03/0.2	OK	0.4	2.6	0.0	
H00974	160	0.09	0.05	0.18	75°	NS	0.03/0.3	OK	0.1	2.6	0.0	
H00975	140	0.08	0.06	0.20	60°	NS	0.03/0.4	OK	0.3	2.4	0.0	
H00976	160	0.08	0.04	0.17	90°	NS	0.03/0.3	OK	0.5	1.8	0.0	
H00977	140	0.10	0.05	0.18	60°	NS	0.03/0.3	OK	0.2	2.3	0.0	
H00978	180	0.09	0.05	0.15	60°	NS	0.04/0.2	OK	0.4	3.4	0.0	Left ventricular enlargement
N	6	6	6	6	6		6/6		6	6	6	
Mean	153	0.09	0.05	0.18	68		0.03/0.3		0.3	2.5*	0.0	
SD	16.3	0.009	0.006	0.016	12.5		0.004/0.08		0.15	0.52	0.00	

NS = Normal sinus rhythm/arrhythmia.

Study No. 6127-111

Individual Electrocardiograph Measurements

Males - Week 26

Animal Number	Heart Rate (beats/min)	P-R Int (sec)	QRS Int (sec)	Q-T Int (sec)	Elec Axis	Rhythm	P-Wave (sec/mV)	T-Wave (S-T seg)	Q Amp (mV)	R Amp (mV)	S Amp (mV)	Comment
						Group 3						
H00985	140	0.08	0.05	0.18	60°	NS	0.03/0.3	OK	0.5	2.5	0.0	
H00986	140	0.08	0.04	0.16	Iso-electric	NS	0.03/0.2	OK	1.6	1.9	0.0	
H00987	120	0.10	0.05	0.19	60°	NS	0.03/0.2	OK	0.3	2.4	0.0	
H00988	180	0.09	0.04	0.16	90°	NS	0.03/0.2	OK	0.2	1.3	0.1	
H00989	120	0.08	0.05	0.18	60°	NS	0.03/0.3	OK	0.2	1.6	0.2	
H00990	140	0.08	0.05	0.18	60°	NS	0.03/0.3	OK	0.3	1.6	0.1	
N	6	6	6	6	5		6/6		6	6	6	
Mean	140	0.08	0.05	0.18	66		0.03/0.2		0.5	1.9	0.1	
SD	21.9	0.008	0 005	0.012	13.4		0.000/0.05		0.54	0.48	0.08	
						Group 4						
H00001	140	0.07	0.03	0.18	90°	NS	0.03/0.2	OK	0.6	2.2	0.0	
H00002	80	0.07	0.04	0.20	75°	NS	0.03/0.2	OK	0.3	3.1	0.0	Left ventricular enlargement
H00003	100	0.09	0.04	0.17	75°	NS	0.03/0.3	OK	0.3	3.1	0.0	Left ventricular enlargement
H00997	160	0.10	0.03	0.19	60°	NS	0.02/0.2	OK	0.3	1.3	0.0	
H00998	140	0.08	0.04	0.17	60°	NS	0.03/0.2	OK	0.3	1.9	0.0	
H00999	100	0.08	0.04	0.18	60°	NS	0.03/0.2	OK	0.5	2.5	0.0	
N	6	6	6	6	6		6/6		6	6	6	
Mean	120	0.08	0.04	0.18	70		0.03/0.2		0.4	2.4	0.0	
SD	31.0	0.012	0.005	0.012	12.2		0.004/0.04		0.13	0.70	0.00	

NS = Normal sinus rhythm/arrhythmia.

Study No. 6127-111

Individual Electrocardiograph Measurements

Recovery Study

Males - Week 30

Animal Number	Heart Rate (beats/min)	P-R Int (sec)	QRS Int (sec)	Q-T Int (sec)	Elec Axis	Rhythm	P-Wave (sec/mV)	T-Wave (S-T seg)	Q Amp (mV)	R Amp (mV)	S Amp (mV)	Comment
						Group 1						
H00964	120	0.08	0.04	0.18	75°	NS	0.02/0.2	OK	0.1	2.2	0.0	
H00965	140	0.09	0.05	0.18	75°	NS	0.04/0.3	OK	0.2	1.5	1.5	
N	2	2	2	2	2		2/2		2	2	2	
Mean	130	0.08	0.04	0.18	75		0.03/0.2		0.2	1.8	0.8	
SD	14.1	0.007	0.007	0.000	0.0		0.014/0.07		0.07	0.49	1.06	
						Group 2						
H00973	140	0.10	0.05	0.19	75°	NS	0.03/0.2	OK	0.2	2.7	0.0	
H00977	120	0.11	0.05	0.18	90°	NS	0.04/0.4	OK	0.1	2.3	0.0	Wandering pacemaker
N	2	2	2	2	2		2/2		2	2	2	
Mean	130	0.10	0.05	0.18	82		0.04/0.3		0.2	2.5	0.0	
SD	14.1	0.007	0.000	0.007	10.6		0.007/0.14		0.07	0.28	0.00	
						Group 3						
H00988	160	0.09	0.04	0.18	90°	NS	0.03/0.2	OK	0.1	1.5	0.1	
H00990	160	0.09	0.05	0.16	60°	NS	0.03/0.3	OK	0.2	1.5	0.2	
N	2	2	2	2	2		2/2		2	2	2	
Mean	160	0.09	0.04	0.17	75		0.03/0.2		0.2	1.5	0.2	
SD	0.0	0.000	0.007	0.014	21.2		0.000/0.07		0.07	0.00	0.07	
						Group 4						
H00998	160	0.08	0.04	0.18	60°	NS	0.03/0.2	OK	0.1	1.8	0.2	
H00001	160	0.07	0.04	0.16	90°	NS	0.03/0.3	OK	0.5	2.2	0.1	
N	2	2	2	2	2		2/2		2	2	2	
Mean	160	0.08	0.04	0.17	75		0.03/0.2		0.3	2.0	0.2	
SD	0.0	0.007	0.000	0.014	21.2		0.000/0.07		0.28	0.28	0.07	

NS = Normal sinus rhythm/arrhythmia.

Study No. 6127-111

Individual Electrocardiograph Measurements

Females - Week -2

Animal Number	Heart Rate (Beats/min)	P-R Int (sec)	QRS Int (sec)	QT Int (sec)	Elec Axis	Rhythm	P-Wave (sec/mv)	T-Wave (S-T Seg)	Q Amp (mv)	R Amp (mv)	S Amp (mv)	Comment
Group 1												
H00967	140	0.09	0.04	0.16	60°	NS	0.03/0.2	OK	0.8	2.0	0.0	
H00968	180	0.08	0.04	0.16	60°	NS	0.03/0.2	OK	0.2	1.5	0.0	
H00969	160	0.09	0.03	0.16	60°	NS	0.02/0.1	OK	0.2	1.3	0.1	
H00970	180	0.08	0.04	0.16	60°	NS	0.04/0.2	OK	0.6	2.4	0.0	
H00971	120	0.09	0.04	0.18	90°	NS	0.03/0.2	OK	0.2	1.6	0.1	
H00972	100	0.09	0.03	0.19	90°	NS	0.03/0.2	OK	0.1	2.5	0.0	
N	6	6	6	6	6		6/6		6	6	6	
Mean	147	0.09	0.04	0.17	70		0.03/0.2		0.4	1.9	0.0	
S	32.7	0.005	0.005	0.013	15.5		0.006/0.04		0.28	0.50	0.05	
Group 2												
H00975	140	0.08	0.04	0.16	90°	NS	0.03/0.3	OK	0.2	1.8	0.0	
H00980	120	0.07	0.05	0.18	90°	NS	0.03/0.2	OK	0.2	2.1	0.0	
H00981	140	0.08	0.05	0.16	60°	NS	0.03/0.2	OK	1.6	2.7	0.0	
H00982	160	0.07	0.05	0.16	60°	NS	0.02/0.2	OK	0.4	2.0	0.0	
H00983	160	0.10	0.04	0.17	60°	NS	0.03/0.2	OK	0.4	1.8	0.0	
H00984	140	0.08	0.05	0.17	60°	NS	0.03/0.3	OK	0.7	2.4	0.0	
N	6	6	6	6	6		6/6		6	6	6	
Mean	143	0.08	0.05	0.17	70		0.03/0.2		0.6	2.1	0.0	
S	15.1	0.011	0.005	0.008	15.5		0.004/0.05		0.53	0.36	0.00	
Group 3												
H00991	140	0.10	0.03	0.17	90°	NS	0.03/0.3	OK	0.1	2.0	0.0	
H00992	140	0.09	0.05	0.17	-15°	NS	0.03/0.3	OK	0.0	1.4	0.7	
H00993	140	0.08	0.03	0.18	75°	NS	0.04/0.4	OK	0.3	2.0	0.0	
H00994	160	0.08	0.04	0.18	60°	NS	0.03.0.3	OK	0.5	1.9	0.0	
H00995	120	0.08	0.05	0.18	60°	NS	0.03/0.2	OK	0.2	1.4	0.2	
H00996	140	0.08	0.05	0.18	75°	NS	0.03/0.2	OK	0.4	2.7	0.0	
N	6	6	6	6	6		6/6		6	6	6	
Mean	140	0.09	0.04	0.18	58		0.03/0.3		0.2	1.9	0.2	
S	12.6	0.008	0.010	0.005	37.2		0.004/0.08		0.19	0.48	0.28	

NS = Normal sinus rhythm/arrhythmia

Study No. 6127-111

Individual Electrocardiograph Measurements (Continued)

Females - Week -2

Animal Number	Heart Rate (Beats/min)	P-R Int (sec)	QRS Int (sec)	QT Int (sec)	Elec Axis	Rhythm	P-Wave (sec/mv)	T-Wave (S-T Seg)	Q Amp (mv)	R Amp (mv)	S Amp (mv)	Comment
						Group 4						
H00004	140	0.09	0.04	0.17	30°	NS	0.03/0.2	OK	0.2	2.5	0.0	
H00005	140	0.08	0.04	0.18	60°	NS	0.03/0.2	OK	0.8	1.8	0.0	
H00006	140	0.09	0.03	0.17	60°	NS	0.03/0.1	OK	0.3	1.4	0.3	
H00007	140	0.09	0.03	0.18	60°	NS	0.03/0.4	OK	0.4	2.0	0.0	
H00008	180	0.08	0.05	0.14	60°	NS	0.03/0.4	OK	0.7	2.6	0.0	
H00009	100	0.08	0.04	0.19	90°	NS	0.02/0.2	OK	0.1	1.1	0.2	
N	6	6	6	6	6		6/6		6	6	6	
Mean	140	0.08	0.04	0.17	60		0.03/0.2		0.4	1.9	0.1	
S	25.3	0.005	0.008	0.017	19.0		0.004/0.13		0.28	0.59	0.13	

NS = Normal sinus rhythm/arrhythmia

Study No. 6127-111

Individual Electrocardiograph Measurements

Females - Week 8

Animal Number	Heart Rate (Beats/min)	P-R Int (sec)	QRS Int (sec)	QT Int (sec)	Elec Axis	Rhythm	P-Wave (sec/mv)	T-Wave (S-T Seg)	Q Amp (mv)	R Amp (mv)	S Amp (mv)	Comment
Group 1												
H00967	140	0.07	0.04	0.17	60°	NS	0.03/0.2	OK	0.6	2.3	0.0	
H00968	160	0.08	0.04	0.17	60°	NS	0.02/0.2	OK	0.2	2.2	0.0	
H00969	140	0.11	0.04	0.17	60°	NS	0.03/0.2	OK	0.2	1.5	0.2	
H00970	160	0.09	0.03	0.16	90°	NS	0.03/0.3	OK	0.1	2.3	0.0	
H00971	120	0.10	0.05	0.20	60°	NS	0.04/0.2	OK	0.3	1.5	0.3	
H00972	100	0.08	0.03	0.18	90°	NS	0.03/0.2	OK	0.5	2.8	0.0	
N	6	6	6	6	6		6/6		6	6	6	
Mean	137	0.09	0.04	0.18	70		0.03/0.2		0.3	2.1	0.1	
S	23.4	0.015	0.008	0.014	15.5		0.006/0.04		0.19	0.51	0.13	
Group 2												
H00979	160	0.07	0.03	0.18	90°	NS	0.03/0.3	OK	0.2	1.8	0.0	
H00980	140	0.08	0.05	0.17	90°	NS	0.03/0.3	OK	0.4	2.0	0.0	
H00981	140	0.09	0.04	0.17	90°	NS	0.03/0.2	OK	1.1	2.9	0.0	
H00982	160	0.09	0.05	0.18	60°	NS	0.03/0.2	OK	0.5	2.6	0.0	
H00983	160	0.08	0.04	0.17	75°	NS	0.03/0.3	OK	0.3	2.1	0.0	
H00984	120	0.08	0.04	0.17	60°	NS	0.04/0.4	OK	0.6	2.2	0.0	
N	6	6	6	6	6		6/6		6	6	6	
Mean	147	0.08	0.04	0.17	78		0.03/0.3		0.5	2.3	0.0	
S	16.3	0.008	0.008	0.005	14.7		0.004/0.08		0.32	0.41	0.00	
Group 3												
H00991	160	0.10	0.04	0.15	90°	NS	0.03/0.3	OK	0.5	2.2	0.0	
H00992	160	0.09	0.05	0.17	60°	NS	0.03/0.2	OK	0.0	1.8	0.7	
H00993	160	0.07	0.04	0.16	90°	NS	0.03/0.3	OK	0.6	1.7	0.0	
H00994	160	0.08	0.03	0.18	60°	NS	0.03/0.4	OK	0.4	1.7	0.0	
H00995	120	0.09	0.05	0.18	60°	NS	0.03/0.3	OK	0.1	1.2	0.1	
H00996	160	0.08	0.05	0.18	75°	NS	0.04/0.2	OK	0.6	3.0	0.0	
N	6	6	6	6	6			6/6	6	6	6	
Mean	153	0.08	0.04	0.17	72		0.03/0.3		0.4	1.9	0.1	
S	16.3	0.010	0.008	0.013	14.7		0.004/0.08		0.26	0.61	0.28	

NS = Normal sinus rhythm/arrhythmia

Study No. 6127-111

Individual Electrocardiograph Measurements (Continued)

Females - Week 8

Animal Number	Heart Rate (Beats/min)	P-R Int (sec)	QRS Int (sec)	QT Int (sec)	Elec Axis	Rhythm	P-Wave (sec/mv)	T-Wave (S-T Seg)	Q Amp (mv)	R Amp (mv)	S Amp (mv)	Comment
						Group 4						
H00004	140	0.01	0.04	0.20	60°	NS	0.03/0.3	OK	0.3	3.1	0.0	
H00005	140	0.09	0.03	0.17	90°	NS	0.03/0.2	OK	0.6	2.0	0.1	
H00006	140	0.08	0.04	0.19	60°	NS	0.03/0.2	OK	0.2	1.6	0.0	
H00007	140	0.10	0.04	0.18	60°	NS	0.04/0.4	OK	0.2	2.2	0.0	
H00008	180	0.08	0.04	0.16	80°	NS	0.03/0.3	OK	0.5	2.5	0.0	
H00009	160	0.07	0.03	0.16	90°	NS	0.03/0.4	OK	0.2	1.1	0.0	
N	6	6	6	6	6		6/6		6	6	6	
Mean	150	0.07	0.04	0.18	73		0.03/0.3		0.3	2.1	0.0	
S	16.7	0.032	0.005	0.016	15.1		0.004/0.09		0.18	0.70	0.04	

NS = Normal sinus rhythm/arrhythmia

Study No. 6127-111

Individual Electrocardiograph Measurements

Females - Week 17

Animal Number	Heart Rate (Beats/min)	P-R Int (sec)	QRS Int (sec)	QT Int (sec)	Elec Axis	Rhythm	P-Wave (sec/mv)	T-Wave (S-T Seg)	Q Amp (mv)	R Amp (mv)	S Amp (mv)	Comment
						Group 1						
H00967	160	0.10	0.04	0.16	40°	NS	0.04/0.3	OK	1.0	2.1	0.0	
H00968	140	0.10	0.04	0.18	60°	NS	0.03/0.3	OK	0.2	2.0	0.0	
H00969	120	0.12	0.03	0.18	45°	NS	0.03/0.2	OK	0.3	1.4	0.0	
H00970	160	0.10	0.05	0.18	60°	NS	0.03/0.3	OK	0.7	2.2	0.0	
H00971	100	0.10	0.05	0.18	80°	NS	0.03/0.3	OK	0.2	1.5	0.3	
H00972	120	0.08	0.04	0.20	60°	NS	0.03/0.3	OK	0.5	2.5	0.0	
N	6	6	6	6	6		6/6		6	6	6	
Mean	133	0.10	0.04	0.18	58		0.03/0.3		0.5	2.0	0.1	
SD	24.2	0.013	0.008	0.013	14.1		0.004/0.04		0.32	0.42	0.12	
						Group 2						
H00979	140	0.08	0.04	0.20	90°	NS	0.03/0.3	OK	0.1	1.9	0.0	
H00980	160	0.08	0.06	0.16	60°	NS	0.03/0.3	OK	0.5	1.9	0.0	
H00981	120	0.08	0.05	0.18	90°	NS	0.03/0.3	OK	0.9	2.6	0.0	Ventricular premature contractions
H00982	160	0.10	0.05	0.19	60°	NS	0.03/0.2	OK	0.4	2.2	0.0	
H00983	180	0.10	0.05	0.18	60°	NS	0.04/0.4	OK	0.3	1.9	0.0	
H00984	120	0.09	0.05	0.18	60°	NS	0.03/0.3	OK	0.8	2.8	0.0	
N	6	6	6	6	6		6/6		6	6	6	
Mean	147	0.09	0.05	0.18	70		0.03/0.3		0.5	2.2	0.0	
SD	24.2	0.010	0.006	0.013	15.5		0.004/0.06		0.30	0.40	0.00	
						Group 3						
H00991	140	0.10	0.04	0.17	90°	NS	0.03/0.2	OK	0.2	1.8	0.0	
H00992	180	0.09	0.05	0.17	45°	NS	0.04/0.3	OK	NA	1.0	0.5	
H00993	160	0.08	0.04	0.17	60°	NS	0.04/0.4	OK	1.1	2.1	0.0	ST cove
H00994	160	0.08	0.04	0.18	60°	NS	0.04/0.4	OK	0.8	2.3	0.0	
H00995	140	0.08	0.03	0.18	60°	NS	0.04/0.3	OK	0.1	1.6	0.0	
H00996	160	0.08	0.05	0.18	60°	NS	0.03/0.2	OK	0.7	3.0	0.0	
N	6	6	6	6	6		6/6		5	6	6	
Mean	157	0.08	0.04	0.18	62		0.04/0.3		0.9	2.0	0.1	
SD	15.1	0.008	0.008	0.005	14.7		0.005/0.09		0.69	0.68	0.20	

NS = Normal sinus rhythm/arrhythmia.
NA = Not applicable (unable to measure).

Study No. 6127-111

Individual Electrocardiograph Measurements

Females - Week 17

Animal Number	Heart Rate (Beats/min)	P-R Int (sec)	QRS Int (sec)	QT Int (sec)	Elec Axis	Rhythm	P-Wave (sec/mv)	T-Wave (S-T Seg)	Q Amp (mv)	R Amp (mv)	S Amp (mv)	Comment
						Group 4						
H00004	140	0.09	0.05	0.18	30°	NS	0.04/0.4	OK	0.4	2.6	0.1	
H00005	140	0.10	0.05	0.17	60°	NS	0.04/0.2	OK	0.7	1.7	0.1	
H00006	180	0.08	0.04	0.15	60°	NS	0.03/0.2	OK	0.4	1.3	0.0	
H00007	140	0.10	0.03	0.17	60°	NS	0.03/0.3	OK	0.5	2.5	0.0	
H00008	160	0.08	0.05	0.17	90°	NS	0.03/0.4	OK	0.6	2.7	0.0	
H00009	140	0.08	0.05	0.18	75°	NS	0.03/0.2	OK	0.2	1.0	0.1	
N	6	6	6	6	6		6/6		6	6	6	
Mean	150	0.09	0.04	0.17	62		0.03/0.3		0.5	2.0	0.1	
SD	16.7	0.010	0.008	0.011	19.9		0.005/0.10		0.18	0.73	0.55	

NS = Normal sinus rhythm/arrhythmia.

Study No. 6127-111

Individual Electrocardiograph Measurements

Females - Week 26

Animal Number	Heart Rate (beats/min)	P-R Int (sec)	QRS Int (sec)	Q-T Int (sec)	Elec Axis	Rhythm	P-Wave (sec/mV)	T-Wave (S-T seg)	Q Amp (mV)	R Amp (mV)	S Amp (mV)	Comment
						Group 1						
H00967	160	NA	0.04	0.16	-30°	NS	NA/NA	OK	0.9	0.8	0.0	
H00968	160	0.10	0.04	0.17	60°	NS	0.03/0.3	OK	0.1	1.9	0.0	
H00969	140	0.12	0.04	0.18	30°	NS	0.03/0.1	OK	0.3	1.5	0.0	
H00970	160	0.06	0.04	0.16	90°	NS	0.03/0.3	OK	0.3	2.5	0.0	
H00971	120	0.08	0.04	0.20	90°	NS	0.03/0.2	OK	0.2	1.5	0.0	
H00972	140	0.09	0.04	0.18	60°	NS	0.03/0.3	OK	0.2	2.5	0.0	
N	6	5	6	6	6		5/5		6	6	6	
Mean	147	0.09	0.04	0.18	50		0.03/0.2		0.3	1.8	0.0	
SD	16.3	0.022	0.000	0.015	45.2		0.000/0.09		0.29	0.66	0.00	
						Group 2						
H00979	140	0.08	0.05	0.16	60°	NS	0.03/0.3	OK	0.2	1.8	0.0	
H00980	140	0.08	0.05	0.16	60°	NS	0.03/0.2	OK	0.7	2.4	0.0	
H00981	140	0.08	0.05	0.20	75°	NS	0.03/0.5	OK	1.4	3.2	0.0	Left ventricular enlargement; right ventricular premature contraction
H00982	140	0.08	0.05	0.16	60°	NS	0.03/0.2	OK	0.4	2.3	0.0	
H00983	160	0.10	0.05	0.17	60°	NS	0.03/0.4	OK	0.2	2.0	0.0	
H00984	140	0.09	0.05	0.18	60°	NS	0.03/0.3	OK	0.5	2.6	0.0	
N	6	6	6	6	6		6/6		6	6	6	
Mean	143	0.08	0.05	0.17	62		0.03/0.3		0.6	2.4	0.0	
SD	8.2	0.008	0.000	0.016	6.1		0.000/0.12		0.45	0.49	0.00	

NS = Normal sinus rhythm/arrhythmia.
NA = Not able to measure.

Individual Electrocardiograph Measurements (Continued)

Females - Week 26

Animal Number	Heart Rate (beats/min)	P-R Int (sec)	QRS Int (sec)	Q-T Int (sec)	Elec Axis	Rhythm	P-Wave (sec/mV)	T-Wave (S-T seg)	Q Amp (mV)	R Amp (mV)	S Amp (mV)	Comment
						Group 3						
H00991	140	0.10	0.05	0.16	60°	NS	0.03/0.4	OK	0.7	2.4	0.0	
H00992	140	0.09	0.05	0.20	30°	NS	0.03/0.3	OK	0.0	1.4	0.5	
H00993	120	0.09	0.05	0.17	60°	NS	0.03/0.3	OK	0.3	1.9	0.0	
H00994	140	0.08	0.04	0.18	60°	NS	0.03/0.3	OK	0.4	1.8	0.0	
H00995	140	0.09	0.05	0.16	75°	NS	0.03/0.2	OK	0.1	1.2	0.2	
H00996	160	0.08	0.06	0.18	75°	NS	0.03/0.2	OK	0.3	2.7	0.0	
N	6	6	6	6	6		6/6		6	6	6	
Mean	140	0.09	0.05*	0.18	60		0.03/0.3		0.3	1.9	0.1	
SD	12.6	0.008	0.006	0.015	16.4		0.000/0.08		0.24	0.57	0.20	
						Group 4						
H00004	180	0.09	0.05	0.17	30°	NS	0.03/0.3	OK	0.2	2.5	0.2	
H00005	140	0.08	0.04	0.16	60°	NS	0.03/0.2	OK	1.1	2.0	0.0	
H00006	140	0.08	0.04	0.18	60°	NS	0.04/0.3	OK	0.5	1.9	0.0	
H00007	160	0.10	0.04	0.17	60°	NS	0.03/0.4	OK	0.4	2.4	0.0	
H00008	180	0.09	0.05	0.17	90°	NS	0.04/0.4	OK	0.5	2.5	0.0	
H00009	120	0.08	0.04	0.16	120°	NS	0.03/0.3	OK	0.5	1.2	0.0	
N	6	6	6	6	6		6/6		6	6	6	
Mean	153	0.09	0.04	0.17	70		0.03/0.3		0.5	2.1	0.0	
SD	24.2	0.008	0.005	0.008	31.0		0.005/0.08		0.30	0.50	0.08	

NS = Normal sinus rhythm/arrhythmia.

Study No. 6127-111

Individual Electrocardiograph Measurements

Recovery Study

Females - Week 30

Animal Number	Heart Rate (beats/min)	P-R Int (sec)	QRS Int (sec)	Q-T Int (sec)	Elec Axis	Rhythm	P-Wave (sec/mV)	T-Wave (S-T seg)	Q Amp (mV)	R Amp (mV)	S Amp (mV)	Comment
						Group 1						
H00971	100	0.09	0.05	0.20	90°	NS	0.03/0.3	OK	0.2	1.8	0.4	
H00972	120	0.08	0.03	0.20	80°	NS	0.03/0.3	OK	0.3	2.8	0.0	
N	2	2	2	2	2		2/2		2	2	2	
Mean	110	0.08	0.04	0.20	85		0.03/0.3		0.2	2.3	0.2	
SD	14.1	0.007	0.014	0.000	7.07		0.000/0.00		0.07	0.71	0.28	
						Group 2						
H00979	140	0.07	0.03	0.18	90°	NS	0.03/0.3	OK	0.2	1.8	0.0	
H00981	100	0.08	0.04	0.19	90°	NS	0.04/0.2	OK	0.8	2.5	0.0	
N	2	2	2	2	2		2/2		2	2	2	
Mean	120	0.08	0.04	0.18	90		0.04/0.2		0.5	2.2	0.0	
SD	28.3	0.007	0.007	0.007	0.0		0.007/0.07		0.42	0.49	0.00	
						Group 3						
H00995	120	0.09	0.06	0.19	75°	NS	0.03/0.2	OK	0.1	1.3	0.4	Positive T-wave in Lead V_{10}.
H00996	140	0.07	0.05	0.18	75°	NS	0.03/0.2	OK	0.5	2.9	0.0	
N	2	2	2	2	2		2/2		2	2	2	
Mean	130	0.08	0.06	0.18	75		0.03/0.2		0.3	2.1	0.2	
SD	14.1	0.014	0.007	0.007	0.0		0.000/0.00		0.28	1.13	0.28	
						Group 4						
H00005	140	0.08	0.05	0.17	60°	NS	0.03/0.3	OK	0.5	1.9	0.3	
H00006	160	0.08	0.03	0.16	75°	NS	0.03/0.2	OK	0.2	1.7	0.0	
N	2	2	2	2	2		2/2		2	2	1	
Mean	150	0.08	0.04	0.16*	68		0.03/0.2		0.4	1.8	0.2	
SD	14.1	0.000	0.014	0.007	10.6		0.000/0.07		0.21	0.14	0.21	

NS = Normal sinus rhythm/arrhythmia.

APPENDIX G

Individual Hematology Data

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CODES FOR CLINICAL CHEMISTRY AND HEMATOLOGY FOOTNOTES

F	=	Fibrin strands
C	=	Clotted sample
NS	=	No sample
QNS	=	Quantity not sufficient
H	=	Hemolyzed
SH	=	Slightly hemolyzed
I	=	Icteric
SI	=	Slightly icteric
L	=	Lipemic
SL	=	Slightly lipemic
QR	=	QNS to repeat
SE	=	Substrate exhaust
DDB	=	Died during bleeding
DOT	=	Died on test
M	=	Moribund

Chemistry samples that were hemolyzed, icteric, or lipemic were not included in statistical analyses.

APPENDIX
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 AD MIXED IN DIET

ANIMAL NUMBER	RBC E6/CU MM	HGB G/DL	HCT %	MCV FL	MCH PICO GMS	MCHC %	PLT E3/CU MM	NRBC /100 WBC
GROUP & SEX: 1M DOSE LEVEL: 0				DOSAGE UNIT: MG/KG				
H00961	5.82	12.0	41.4	71	20.6	29.0	435	0
H00962	6.29	12.0	42.7	68	19.1	28.1	489	0
H00963	6.11	12.7	43.6	71	20.8	29.1	370	1
H00964	5.99	12.0	42.2	70	20.0	28.4	429	0
H00965	6.38	12.5	45.2	71	19.6	27.7	309	0
H00966	7.22	13.9	49.1	68	19.3	28.3	335	0
N=	6	6	6	6	6	6	6	6
MEAN	6.30	12.5	44.0	70	19.9	28.4	394	0
S.D.	.493	.74	2.80	1.5	.69	.54	68.1	.4
GROUP & SEX: 1F DOSE LEVEL: 0				DOSAGE UNIT: MG/KG				
H00967	6.20	10.6	39.4	64	17.1	26.9	360	0
H00968	6.51	12.2	44.3	68	18.7	27.5	489	0
H00969	5.94	11.2	41.0	69	18.9	27.3	310	0
H00970	6.23	11.7	44.1	71	18.8	26.5	399	0
H00971	6.52	12.2	44.9	69	18.7	27.2	528	0
H00972	6.31	12.0	43.9	70	19.0	27.3	417	0
N=	6	6	6	6	6	6	6	6
MEAN	6.28	11.6	42.9	68	18.5	27.1	417	0
S.D.	.217	.64	2.20	2.4	.71	.36	80.6	.0
POOLED M+F GROUP: 1								
N=	12	12	12	12	12	12	12	12
MEAN M+F	6.29	12.1	43.5	69	19.2	27.8	406	0
S.D. M+F	.363	.80	2.47	2.0	.98	.81	72.2	.3

S6127111 DOG POOL M+F WEEK: -02

APPENDIX
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 AD MIXED IN DIET

ANIMAL NUMBER	RBC E6/CU MM	HGB G/DL	HCT %	MCV FL	MCH PICO GMS	MCHC %	PLT E3/CU MM	NRBC /100 WBC
GROUP & SEX: 2M	DOSE LEVEL: 250			DOSAGE UNIT: MG/KG				
H00973	6.19	12.1	43.1	70	19.5	28.1	397	0
H00974	6.39	12.0	44.1	69	18.8	27.2	435	0
H00975	6.93	13.0	47.0	68	18.8	27.7	326	1
H00976	6.27	11.9	42.3	67	19.0	28.1	495	0
H00977	7.10	11.1	39.6	56	15.6	28.0	487	0
H00978	6.60	13.3	46.5	70	20.2	28.6	339	0
N=	6	6	6	6	6	6	6	6
MEAN	6.58	12.2	43.8	67	18.6	27.9	413	0
S.D.	.368	.80	2.76	5.4	1.59	.47	72.1	.4
GROUP & SEX: 2F	DOSE LEVEL: 250			DOSAGE UNIT: MG/KG				
H00979	6.37	12.2	44.8	70	19.2	27.2	269	0
H00980	6.57	12.6	46.6	71	19.2	27.0	346	0
H00981	6.14	10.6	39.7	65	17.3	26.7	328	0
H00982	6.22	11.8	43.1	69	19.0	27.4	413	0
H00983	6.84	12.6	46.5	68	18.4	27.1	314	0
H00984	6.61	11.2	39.9	60	16.9	28.1	283	0
N=	6	6	6	6	6	6	6	6
MEAN	6.46	11.8	43.4	67	18.3	27.2	326	0
S.D.	.263	.80	3.09	4.1	1.01	.48	51.4	.0
POOLED M+F GROUP: 2								
N=	12	12	12	12	12	12	12	12
MEAN M+F	6.52	12.0	43.6	67	18.5	27.6	369	0
S.D. M+F	.312	.79	2.80	4.5	1.28	.58	75.2	.3

APPENDIX
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 AD MIXED IN DIET

ANIMAL NUMBER	RBC E6/CU MM	HGB G/DL	HCT %	MCV FL	MCH PICO GMS	MCHC %	PLT E3/CU MM	NRBC /100 WBC
GROUP & SEX: 3M DOSE LEVEL: 500 DOSAGE UNIT: MG/KG								
H00985	6.78	12.6	46.6	69	18.6	27.0	322	0
H00986	5.95	11.7	41.9	70	19.7	27.9	358	0
H00987	7.01	12.6	46.7	67	18.0	27.0	463	1
H00988	6.28	12.2	44.1	70	19.4	27.7	311	0
H00989	6.42	11.6	44.1	69	18.1	26.3	337	0
H00990	6.12	12.1	43.8	72	19.8	27.6	310	1
N=	6	6	6	6	6	6	6	6
MEAN	6.43	12.1	44.5	70	18.9	27.2	350	0
S.D.	.402	.43	1.83	1.6	.80	.60	58.1	.5
GROUP & SEX: 3F DOSE LEVEL: 500 DOSAGE UNIT: MG/KG								
H00991	6.72	13.2	47.4	71	19.6	27.8	443	0
H00992	5.90	10.9	40.8	69	18.5	26.7	396	0
H00993	6.69	12.7	47.1	70	19.0	27.0	402	0
H00994	6.24	11.0	39.4	63	17.6	27.9	549	0
H00995	6.79	12.0	47.0	69	17.7	25.5	399	0
H00996	5.71	12.1	41.5	73	21.2	29.2	410	0
N=	6	6	6	6	6	6	6	6
MEAN	6.34	12.0	43.9	69	18.9	27.4	433	0
S.D.	.462	.91	3.68	3.4	1.35	1.26	59.3	.0
POOLED M+F GROUP: 3								
N=	12	12	12	12	12	12	12	12
MEAN M+F	6.38	12.0	44.2	69	18.9	27.3	392	0
S.D. M+F	.416	.68	2.79	2.5	1.06	.94	70.8	.4

S6127111 DOG POOL M+F WEEK: -02

APPENDIX
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 AD MIXED IN DIET

ANIMAL NUMBER	RBC E6/CU MM	HGB G/DL	HCT %	MCV FL	MCH PICO GMS	MCHC %	PLT E3/CU MM	NRBC /100 WBC
GROUP & SEX: 4M DOSE LEVEL: 1000 DOSAGE UNIT: MG/KG								
H00001	6.35	12.3	44.4	70	19.4	27.7	406	0
H00002	6.73	12.6	43.4	64	18.7	29.0	455	0
H00003	6.35	11.3	41.1	65	17.8	27.5	435	0
H00997	6.60	11.7	41.4	63	17.7	28.3	378	0
H00998	5.97	12.0	42.1	71	20.1	28.5	386	0
H00999	6.63	12.7	46.0	69	19.2	27.6	350	0
N=	6	6	6	6	6	6	6	6
MEAN	6.44	12.1	43.1	67	18.8	28.1	402	0
S.D.	.277	.54	1.90	3.4	.94	.60	38.6	.0
GROUP & SEX: 4F DOSE LEVEL: 1000 DOSAGE UNIT: MG/KG								
H00004	6.48	12.4	45.0	69	19.1	27.6	423	0
H00005	6.48	12.2	44.5	69	18.8	27.4	422	0
H00006	6.48	12.4	45.6	70	19.1	27.2	275	0
H00007	6.38	11.6	40.8	64	18.2	28.4	409	0
H00008	6.74	12.9	46.9	70	19.1	27.5	283	0
H00009	6.29	10.5	38.3	61	16.7	27.4	563	0
N=	6	6	6	6	6	6	6	6
MEAN	6.48	12.0	43.5	67	18.5	27.6	396	0
S.D.	.151	.85	3.27	3.8	.95	.42	106.6	.0
POOLED M+F GROUP: 4								
N=	12	12	12	12	12	12	12	12
MEAN M+F	6.46	12.0	43.3	67	18.6	27.8	399	0
S.D. M+F	.213	.68	2.56	3.4	.92	.56	76.5	.0

APPENDIX
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 AD MIXED IN DIET

ANIMAL NUMBER	WBC E3/CU MM	N-SEG E3/CU MM	L E3/CU MM	M E3/CU MM	E E3/CU MM	B E3/CU MM	N-SEG %	L %	M %	E %	B %	BANDS-N %
GROUP & SEX: 1M DOSE LEVEL: 0					DOSAGE UNIT: MG/KG							
H00961	6.1	2.68	2.81	.43	.18	.00	44	46	7	3	0	0
H00962	8.5	5.02	3.06	.17	.26	.00	59	36	2	3	0	0
H00963	9.6	3.55	5.66	.19	.19	.00	37	59	2	2	0	0
H00964	6.5	3.06	2.73	.52	.20	.00	47	42	8	3	0	0
H00965	6.7	3.28	2.68	.54	.20	.00	49	40	8	3	0	0
H00966	8.4	3.86	3.78	.50	.25	.00	46	45	6	3	0	0
N=	6	6	6	6	6	6	6	6	6	6	6	6
MEAN	7.6	3.58	3.45	.39	.21	.00	47	45	6	3	0	0
S.D.	1.39	.815	1.155	.168	.033	.000	7.2	7.9	2.8	.4	.0	.0
GROUP & SEX: 1F DOSE LEVEL: 0					DOSAGE UNIT: MG/KG							
H00967	10.0	6.20	3.40	.20	.20	.00	62	34	2	2	0	0
H00968	8.3	4.98	2.41	.25	.66	.00	60	29	3	8	0	0
H00969	7.0	4.48	2.31	.21	.00	.00	64	33	3	0	0	0
H00970	10.8	8.10	2.27	.22	.22	.00	75	21	2	2	0	0
H00971	7.9	4.27	2.84	.63	.16	.00	54	36	8	2	0	0
H00972	8.2	5.17	2.71	.33	.00	.00	63	33	4	0	0	0
N=	6	6	6	6	6	6	6	6	6	6	6	6
MEAN	8.7	5.53	2.66	.31	.21	.00	63	31	4	2	0	0
S.D.	1.42	1.427	.429	.165	.242	.000	6.9	5.4	2.2	2.9	.0	.0
POOLED M+F GROUP: 1												
N=	12	12	12	12	12	12	12	12	12	12	12	12
MEAN M+F	8.2	4.55	3.06	.35	.21	.00	55	38	4	2	0	0
S.D. M+F	1.45	1.508	.929	.165	.165	.000	10.7	9.6	2.6	2.0	.0	.0

APPENDIX
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 AD MIXED IN DIET

ANIMAL NUMBER	WBC E3/CU MM	N-SEG E3/CU MM	L E3/CU MM	M E3/CU MM	E E3/CU MM	B E3/CU MM	N-SEG %	L %	M %	E %	B %	BANDS-N %
GROUP & SEX: 2M DOSE LEVEL: 250 DOSAGE UNIT: MG/KG												
H00973	9.6	5.57	3.84	.10	.10	.00	58	40	1	1	0	0
H00974	9.9	6.63	2.57	.50	.20	.00	67	26	5	2	0	0
H00975	6.5	3.90	2.34	.20	.06	.00	60	36	3	1	0	0
H00976	11.0	7.15	3.30	.33	.22	.00	65	30	3	2	0	0
H00977	8.8	5.37	3.08	.18	.18	.00	61	35	2	2	0	0
H00978	9.7	4.36	4.66	.48	.19	.00	45	48	5	2	0	0
N=	6	6	6	6	6	6	6	6	6	6	6	6
MEAN	9.2	5.50	3.30	.30	.16	.00	59	36	3	2	0	0
S.D.	1.52	1.255	.854	.168	.063	.000	7.8	7.7	1.6	.5	.0	.0
GROUP & SEX: 2F DOSE LEVEL: 250 DOSAGE UNIT: MG/KG												
H00979	9.6	6.05	2.88	.38	.29	.00	63	30	4	3	0	0
H00980	8.5	4.76	3.66	.08	.00	.00	56	43	1	0	0	0
H00981	7.7	4.24	3.08	.23	.15	.00	55	40	3	2	0	0
H00982	8.2	4.35	3.44	.25	.16	.00	53	42	3	2	0	0
H00983	7.2	4.82	1.80	.36	.14	.07	67	25	5	2	1	0
H00984	5.5	4.29	.82	.22	.16	.00	78	15	4	3	0	0
N=	6	6	6	6	6	6	6	6	6	6	6	6
MEAN	7.8	4.75	2.61	.25	.15	.01	62	32	3	2	0	0
S.D.	1.38	.682	1.090	.109	.092	.028	9.5	11.2	1.4	1.1	.4	.0
POOLED M+F GROUP: 2												
N=	12	12	12	12	12	12	12	12	12	12	12	12
MEAN M+F	8.5	5.12	2.96	.28	.15	.00	61	34	3	2	0	0
S.D. M+F	1.58	1.039	1.000	.136	.075	.020	8.4	9.3	1.4	.8	.3	.0

APPENDIX
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 AD MIXED IN DIET

ANIMAL NUMBER	WBC E3/CU MM	N-SEG E3/CU MM	L E3/CU MM	M E3/CU MM	E E3/CU MM	B E3/CU MM	N-SEG %	L %	M %	E %	B %	BANDS-N %
GROUP & SEX: 3M DOSE LEVEL: 500 DOSAGE UNIT: MG/KG												
H00985	5.8	3.19	2.38	.12	.12	.00	55	41	2	2	0	0
H00986	8.1	4.29	3.24	.16	.40	.00	53	40	2	5	0	0
H00987	6.9	2.76	3.59	.21	.34	.00	40	52	3	5	0	0
H00988	8.1	5.67	1.94	.24	.24	.00	70	24	3	3	0	0
H00989	8.7	3.74	4.09	.26	.52	.09	43	47	3	6	1	0
H00990	7.2	3.67	2.59	.43	.36	.14	51	36	6	5	2	0
N=	6	6	6	6	6	6	6	6	6	6	6	6
MEAN	7.5	3.89	2.97	.24	.33	.04	52	40	3	4	0	0
S.D.	1.05	1.016	.808	.108	.137	.061	10.6	9.6	1.5	1.5	.8	.0
GROUP & SEX: 3F DOSE LEVEL: 500 DOSAGE UNIT: MG/KG												
H00991	8.0	4.08	3.76	.16	.00	.00	51	47	2	0	0	0
H00992	6.2	3.22	2.67	.19	.12	.00	52	43	3	2	0	0
H00993	6.3	3.21	2.65	.13	.32	.00	51	42	2	5	0	0
H00994	5.4	3.29	1.78	.22	.11	.00	61	33	4	2	0	0
H00995	6.5	4.29	2.02	.13	.06	.00	66	31	2	1	0	0
H00996	7.3	3.58	3.28	.29	.15	.00	49	45	4	2	0	0
N=	6	6	6	6	6	6	6	6	6	6	6	6
MEAN	6.6	3.61	2.69	.19	.13	.00	55	40	3	2	0	0
S.D.	.91	.469	.744	.062	.108	.000	6.8	6.6	1.0	1.7	.0	.0
POOLED M+F GROUP: 3												
N=	12	12	12	12	12	12	12	12	12	12	12	12
MEAN M+F	7.0	3.75	2.83	.21	.23	.02	54	40	3	3	0	0
S.D. M+F	1.04	.768	.755	.088	.159	.046	8.6	7.9	1.2	1.9	.6	.0

S6127111 DOG POOL M+F WEEK: -02

APPENDIX
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 AD MIXED IN DIET

ANIMAL NUMBER	WBC E3/CU MM	N-SEG E3/CU MM	L E3/CU MM	M E3/CU MM	E E3/CU MM	B E3/CU MM	N-SEG %	L %	M %	E %	B %	BANDS-N %
GROUP & SEX: 4M DOSE LEVEL: 1000 DOSAGE UNIT: MG/KG												
H00001	5.6	3.25	1.96	.28	.11	.00	58	35	5	2	0	0
H00002	6.2	3.41	2.36	.25	.19	.00	55	38	4	3	0	0
H00003	7.9	5.61	1.82	.08	.40	.00	71	23	1	5	0	0
H00997	6.5	3.32	2.60	.32	.26	.00	51	40	5	4	0	0
H00998	8.0	3.52	3.60	.40	.48	.00	44	45	5	6	0	0
H00999	9.5	5.98	2.47	.38	.66	.00	63	26	4	7	0	0
N=	6	6	6	6	6	6	6	6	6	6	6	6
MEAN	7.3	4.18	2.47	.28	.35	.00	57	34	4	4	0	0
S.D.	1.44	1.258	.631	.116	.203	.000	9.4	8.4	1.5	1.9	.0	.0
GROUP & SEX: 4F DOSE LEVEL: 1000 DOSAGE UNIT: MG/KG												
H00004	7.6	4.48	2.51	.38	.23	.00	59	33	5	3	0	0
H00005	6.3	3.21	2.71	.00	.38	.00	51	43	0	6	0	0
H00006	5.6	3.81	1.62	.11	.06	.00	68	29	2	1	0	0
H00007	7.4	4.59	2.59	.22	.00	.00	62	35	3	0	0	0
H00008	10.8	7.34	2.81	.54	.11	.00	68	26	5	1	0	0
H00009	9.5	5.32	4.08	.00	.10	.00	56	43	0	1	0	0
N=	6	6	6	6	6	6	6	6	6	6	6	6
MEAN	7.9	4.79	2.72	.21	.15	.00	61	35	2	2	0	0
S.D.	1.96	1.440	.791	.217	.137	.000	6.7	7.0	2.2	2.2	.0	.0
POOLED M+F GROUP: 4												
N=	12	12	12	12	12	12	12	12	12	12	12	12
MEAN M+F	7.6	4.49	2.59	.25	.25	.00	59	35	3	3	0	0
S.D. M+F	1.67	1.328	.695	.171	.196	.000	8.0	7.4	2.0	2.3	.0	.0

APPENDIX
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 AD MIXED IN DIET

ANIMAL NUMBER	BANDS-N E3/CU MM	PT SEC	PTT SEC
GROUP & SEX: 1M	DOSE LEVEL: 0		DOSAGE UNIT: MG/KG
H00961	.00	11.9	10.3
H00962	.00	5.8	11.4
H00963	.00	10.4	11.0
H00964	.00	10.9	9.8
H00965	.00	5.4	11.4
H00966	.00	5.8	10.8
N=	6	6	6
MEAN	.00	8.4	10.8
S.D.	.000	3.00	.63
GROUP & SEX: 1F	DOSE LEVEL: 0		DOSAGE UNIT: MG/KG
H00967	.00	6.9	11.9
H00968	.00	6.4	11.9
H00969	.00	6.9	10.8
H00970	.00	5.9	10.4
H00971	.00	6.4	11.8
H00972	.00	6.8	10.9
N=	6	6	6
MEAN	.00	6.6	11.3
S.D.	.000	.39	.66
POOLED M+F GROUP: 1			
N=	12	12	12
MEAN M+F	.00	7.4	11.0
S.D. M+F	.000	2.25	.67

S6127111 DOG POOL M+F WEEK: -02

APPENDIX
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 AD MIXED IN DIET

ANIMAL NUMBER	BANDS-N E3/CU MM	PT SEC	PTT SEC
GROUP & SEX: 2M	DOSE LEVEL: 250		DOSAGE UNIT: MG/KG
H00973	.00	10.8	10.8
H00974	.00	6.4	10.3
H00975	.00	5.8	12.9
H00976	.00	6.4	10.1
H00977	.00	8.9	15.9
H00978	.00	6.4	11.3
N=	6	6	6
MEAN	.00	7.4	11.9
S.D.	.000	1.97	2.21
GROUP & SEX: 2F	DOSE LEVEL: 250		DOSAGE UNIT: MG/KG
H00979	.00	6.4	12.3
H00980	.00	10.4	10.4
H00981	.00	6.4	12.4
H00982	.00	6.9	12.9
H00983	.00	6.9	10.8
H00984	.00	14.5	11.4
N=	6	6	6
MEAN	.00	8.6	11.7
S.D.	.000	3.27	.99
POOLED M+F GROUP: 2			
N=	12	12	12
MEAN M+F	.00	8.0	11.8
S.D. M+F	.000	2.64	1.63

APPENDIX
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 AD MIXED IN DIET

ANIMAL NUMBER	BANDS-N E3/CU MM	PT SEC	PTT SEC
GROUP & SEX: 3M	DOSE LEVEL: 500		DOSAGE UNIT: MG/KG
H00985	.00	5.9	11.8
H00986	.00	11.9	13.9
H00987	.00	7.9	11.8
H00988	.00	6.9	11.3
H00989	.00	6.4	11.9
H00990	.00	9.9	13.8
N=	6	6	6
MEAN	.00	8.2	12.4
S.D.	.000	2.32	1.13
GROUP & SEX: 3F	DOSE LEVEL: 500		DOSAGE UNIT: MG/KG
H00991	.00	10.4	10.9
H00992	.00	6.9	11.4
H00993	.00	6.9	11.3
H00994	.00	6.8	11.9
H00995	.00	6.4	12.4
H00996	.00	6.4	10.4
N=	6	6	6
MEAN	.00	7.3	11.4
S.D.	.000	1.54	.71
POOLED M+F GROUP: 3			
N=	12	12	12
MEAN M+F	.00	7.7	11.9
S.D. M+F	.000	1.93	1.05

APPENDIX
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 AD MIXED IN DIET

ANIMAL NUMBER	BANDS-N E3/CU MM	PT SEC	PTT SEC
GROUP & SEX: 4M	DOSE LEVEL: 1000		DOSAGE UNIT: MG/KG
H00001	.00	5.9	10.9
H00002	.00	5.8	11.3
H00003	.00	6.3	11.4
H00997	.00	6.4	11.3
H00998	.00	7.4	11.8
H00999	.00	8.9	12.6
N=	6	6	6
MEAN	.00	6.8	11.6
S.D.	.000	1.18	.59
GROUP & SEX: 4F	DOSE LEVEL: 1000		DOSAGE UNIT: MG/KG
H00004	.00	6.9	14.3
H00005	.00	6.4	10.3
H00006	.00	5.9	10.4
H00007	.00	6.3	11.3
H00008	.00	6.9	10.8
H00009	.00	5.9	11.3
N=	6	6	6
MEAN	.00	6.4	11.4
S.D.	.000	.45	1.48
POOLED M+F GROUP: 4			
N=	12	12	12
MEAN M+F	.00	6.6	11.5
S.D. M+F	.000	.88	1.08

APPENDIX
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	RBC E6/CU MM	HGB G/DL	HCT %	MCV FL	MCH PICO GMS	MCHC %	PLT E3/CU MM	NRBC /100 WBC
GROUP & SEX: 1M	DOSE LEVEL: 0			DOSAGE UNIT: MG/KG				
H00961	6.43	12.7	43.6	68	19.8	29.1	488	0
H00962	6.96	12.8	42.9	62	18.4	29.8	439	0
H00963	6.76	13.3	46.8	69	19.7	28.4	372	0
H00964	6.77	12.9	44.4	66	19.1	29.1	433	0
H00965	7.00	13.1	46.9	67	18.7	27.9	328	0
H00966	7.45	14.1	47.3	63	18.9	29.8	329	0
N=	6	6	6	6	6	6	6	6
MEAN	6.90	13.2	45.3	66	19.1	29.0	398	0
S.D.	.339	.51	1.91	2.8	.55	.76	65.3	.0
GROUP & SEX: 1F	DOSE LEVEL: 0			DOSAGE UNIT: MG/KG				
H00967	7.78	12.8	45.6	59	16.5	28.1	307	0
H00968	7.40	13.5	46.0	62	18.2	29.3	387	0
H00969	7.47	13.2	45.6	61	17.7	28.9	333	1
H00970	7.67	13.9	49.8	65	18.1	27.9	338	1
H00971	6.79	12.4	43.0	63	18.3	28.8	502	0
H00972	7.68	14.0	50.6	66	18.2	27.7	209	0
N=	6	6	6	6	6	6	6	6
MEAN	7.46	13.3	46.8	63	17.8	28.4	346	0
S.D.	.360	.63	2.88	2.6	.69	.64	96.5	.5
POOLED M+F GROUP: 1								
N=	12	12	12	12	12	12	12	12
MEAN M+F	7.18	13.2	46.0	64	18.5	28.7	372	0
S.D. M+F	.447	.55	2.45	3.0	.89	.73	83.1	.4

APPENDIX
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	RBC E6/CU MM	HGB G/DL	HCT %	MCV FL	MCH PICO GMS	MCHC %	PLT E3/CU MM	NRBC /100 WBC
GROUP & SEX: 2M	DOSE LEVEL: 250		DOSAGE UNIT: MG/KG					
H00973	6.64	12.6	43.0	65	19.0	29.3	400	0
H00974	7.19	13.1	44.2	61	18.2	29.6	357	0
H00975	6.85	12.5	43.0	63	18.2	29.1	266	0
H00976	7.01	12.7	43.1	61	18.1	29.5	390	0
H00977	7.34	11.7	39.5	54	15.9	29.6	405	0
H00978	7.56	14.3	49.7	66	18.9	28.8	340	0
N=	6	6	6	6	6	6	6	6
MEAN	7.10	12.8	43.7	62	18.0	29.3	360	0
S.D.	.334	.86	3.32	4.3	1.12	.32	52.5	.0
GROUP & SEX: 2F	DOSE LEVEL: 250		DOSAGE UNIT: MG/KG					
H00979	7.93	14.5	52.3	66	18.3	27.7	157	0
H00980	6.61	12.8	43.6	66	19.4	29.4	302	0
H00981	8.35	14.2	50.4	60	17.0	28.2	279	0
H00982	7.58	14.2	49.9	66	18.7	28.5	331	1
H00983	7.94	14.3	49.1	62	18.0	29.1	246	0
H00984	8.44	13.3	43.8	52	15.8	30.4	317	0
N=	6	6	6	6	6	6	6	6
MEAN	7.81	13.9	48.2	62	17.9	28.9	272	0
S.D.	.665	.67	3.63	5.5	1.29	.96	63.8	.4
POOLED M+F GROUP: 2								
N=	12	12	12	12	12	12	12	12
MEAN M+F	7.45	13.4	46.0	62	18.0	29.1	316	0
S.D. M+F	.624	.92	4.04	4.7	1.15	.72	72.1	.3

S6127111 DOG POOL M+F WEEK: 008

APPENDIX
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	RBC E6/CU MM	HGB G/DL	HCT %	MCV FL	MCH PICO GMS	MCHC %	PLT E3/CU MM	NRBC /100 WBC
GROUP & SEX: 3M DOSE LEVEL: 500 DOSAGE UNIT: MG/KG								
H00985	7.47	13.5	46.0	62	18.1	29.3	263	1
H00986	6.52	11.9	42.1	65	18.3	28.3	369	0
H00987	7.34	13.2	45.3	62	18.0	29.1	409	0
H00988	7.34	13.4	47.0	64	18.3	28.5	275	0
H00989	7.16	12.7	45.7	64	17.7	27.8	324	0
H00990	6.68	12.4	45.4	68	18.6	27.3	304	2
N=	6	6	6	6	6	6	6	6
MEAN	7.08	12.8	45.2	64	18.2	28.4	324	0
S.D.	.392	.63	1.66	2.2	.31	.76	56.2	.8
GROUP & SEX: 3F DOSE LEVEL: 500 DOSAGE UNIT: MG/KG								
H00991	7.02	13.5	45.8	65	19.2	29.5	379	0
H00992	6.91	12.6	43.4	63	18.2	29.0	380	0
H00993	7.40	13.5	47.4	64	18.2	28.5	422	0
H00994	7.74	13.2	44.7	58	17.1	29.5	400	0
H00995	7.64	13.5	48.7	64	17.7	27.7	271	0
H00996	6.69	13.3	46.3	69	19.9	28.7	349	0
N=	6	6	6	6	6	6	6	6
MEAN	7.23	13.3	46.0	64	18.4	28.8	367	0
S.D.	.423	.35	1.89	3.5	1.01	.68	52.8	.0
POOLED M+F GROUP: 3								
N=	12	12	12	12	12	12	12	12
MEAN M+F	7.16	13.0	45.6	64	18.3	28.6	345	0
S.D. M+F	.396	.53	1.74	2.8	.72	.72	56.6	.6

S6127111 DOG POOL M+F WEEK: 008

APPENDIX
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	RBC E6/CU MM	HGB G/DL	HCT %	MCV FL	MCH PICO GMS	MCHC %	PLT E3/CU MM	NRBC /100 WBC
GROUP & SEX: 4M	DOSE LEVEL: 1000			DOSAGE UNIT: MG/KG				
H00001	6.99	12.6	43.9	63	18.0	28.7	366	0
H00002	7.37	12.9	43.7	59	17.5	29.5	483	0
H00003	6.40	11.5	40.0	63	18.0	28.8	348	1
H00997	7.13	12.6	43.4	61	17.7	29.0	366	0
H00998	6.73	13.0	45.0	67	19.3	28.9	385	0
H00999	6.04	10.9	38.4	64	18.0	28.4	295	0
N=	6	6	6	6	6	6	6	6
MEAN	6.78	12.2	42.4	63	18.1	28.9	374	0
S.D.	.492	.85	2.59	2.7	.63	.36	61.7	.4
GROUP & SEX: 4F	DOSE LEVEL: 1000			DOSAGE UNIT: MG/KG				
H00004	7.33	13.5	47.3	65	18.4	28.5	313	0
H00005	7.35	13.3	45.8	62	18.1	29.0	422	0
H00006	8.21	14.3	51.4	63	17.4	27.8	321	1
H00007	7.30	12.9	44.3	61	17.7	29.1	349	0
H00008	8.05	14.4	50.8	63	17.9	28.3	270	0
H00009	7.91	13.1	46.0	58	16.6	28.5	376	0
N=	6	6	6	6	6	6	6	6
MEAN	7.69	13.6	47.6	62	17.7	28.5	342	0
S.D.	.411	.63	2.88	2.4	.63	.48	53.0	.4
POOLED M+F GROUP: 4								
N=	12	12	12	12	12	12	12	12
MEAN M+F	7.23	12.9	45.0	62	17.9	28.7	358	0
S.D. M+F	.644	1.00	3.77	2.5	.64	.44	57.4	.4

S6127111 DOG POOL M+F WEEK: 008

APPENDIX
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	WBC E3/CU MM	N-SEG E3/CU MM	L E3/CU MM	M E3/CU MM	E E3/CU MM	B E3/CU MM	N-SEG %	L %	M %	E %	B %	BANDS-N %
GROUP & SEX: 1M DOSE LEVEL: 0 DOSAGE UNIT: MG/KG												
H00961	7.0	3.57	2.73	.28	.42	.00	51	39	4	6	0	0
H00962	6.7	4.02	2.34	.13	.20	.00	60	35	2	3	0	0
H00963	9.7	4.46	4.75	.39	.10	.00	46	49	4	1	0	0
H00964	6.7	2.88	3.48	.27	.07	.00	43	52	4	1	0	0
H00965	6.8	3.88	2.72	.14	.07	.00	57	40	2	1	0	0
H00966	8.4	4.87	3.28	.08	.17	.00	58	39	1	2	0	0
N=	6	6	6	6	6	6	6	6	6	6	6	6
MEAN	7.6	3.95	3.22	.22	.17	.00	52	42	3	2	0	0
S.D.	1.24	.694	.858	.117	.133	.000	6.9	6.6	1.3	2.0	.0	.0
GROUP & SEX: 1F DOSE LEVEL: 0 DOSAGE UNIT: MG/KG												
H00967	8.3	3.15	4.73	.08	.33	.00	38	57	1	4	0	0
H00968	7.3	3.21	3.72	.29	.07	.00	44	51	4	1	0	0
H00969	7.5	3.68	3.52	.30	.00	.00	49	47	4	0	0	0
H00970	8.8	4.22	4.05	.00	.53	.00	48	46	0	6	0	0
H00971	9.5	4.75	4.08	.38	.28	.00	50	43	4	3	0	0
H00972	7.7	4.08	3.31	.08	.23	.00	53	43	1	3	0	0
N=	6	6	6	6	6	6	6	6	6	6	6	6
MEAN	8.2	3.85	3.90	.19	.24	.00	47	48	2	3	0	0
S.D.	.85	.621	.504	.154	.190	.000	5.3	5.4	1.9	2.1	.0	.0
POOLED M+F GROUP: 1												
N=	12	12	12	12	12	12	12	12	12	12	12	12
MEAN M+F	7.9	3.90	3.56	.20	.20	.00	50	45	2	2	0	0
S.D. M+F	1.06	.630	.760	.131	.160	.000	6.6	6.4	1.6	2.0	.0	.0

S6127111 DOG POOL M+F WEEK: 008

APPENDIX
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	WBC E3/CU MM	N-SEG E3/CU MM	L E3/CU MM	M E3/CU MM	E E3/CU MM	B E3/CU MM	N-SEG %	L %	M %	E %	B %	BANDS-N %
GROUP & SEX: 2M DOSE LEVEL: 250 DOSAGE UNIT: MG/KG												
H00973	9.1	5.28	3.82	.00	.00	.00	58	42	0	0	0	0
H00974	8.5	4.34	3.66	.08	.42	.00	51	43	1	5	0	0
H00975	8.7	4.87	2.96	.44	.35	.00	56	34	5	4	0	1
H00976	11.9	7.85	3.21	.24	.60	.00	66	27	2	5	0	0
H00977	8.6	5.76	2.67	.00	.17	.00	67	31	0	2	0	0
H00978	8.4	4.79	3.28	.17	.17	.00	57	39	2	2	0	0
N=	6	6	6	6	6	6	6	6	6	6	6	6
MEAN	9.2	5.48	3.27	.16	.28	.00	59	36	2	3	0	0
S.D.	1.34	1.256	.428	.169	.214	.000	6.2	6.4	1.9	2.0	.0	.4
GROUP & SEX: 2F DOSE LEVEL: 250 DOSAGE UNIT: MG/KG												
H00979	6.5	3.90	2.28	.06	.26	.00	60	35	1	4	0	0
H00980	9.5	4.37	4.75	.19	.19	.00	46	50	2	2	0	0
H00981	7.8	3.35	3.98	.16	.31	.00	43	51	2	4	0	0
H00982	7.4	3.63	3.26	.07	.44	.00	49	44	1	6	0	0
H00983	7.4	4.51	2.52	.30	.07	.00	61	34	4	1	0	0
H00984	6.7	4.42	1.94	.20	.13	.00	66	29	3	2	0	0
N=	6	6	6	6	6	6	6	6	6	6	6	6
MEAN	7.6	4.03	3.12	.16	.23	.00	54	40	2	3	0	0
S.D.	1.07	.477	1.084	.090	.133	.000	9.4	9.1	1.2	1.8	.0	.0
POOLED M+F GROUP: 2												
N=	12	12	12	12	12	12	12	12	12	12	12	12
MEAN M+F	8.4	4.76	3.19	.16	.26	.00	57	38	2	3	0	0
S.D. M+F	1.44	1.181	.789	.129	.172	.000	8.0	7.9	1.5	1.8	.0	.3

APPENDIX
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	WBC E3/CU MM	N-SEG E3/CU MM	L E3/CU MM	M E3/CU MM	E E3/CU MM	B E3/CU MM	N-SEG %	L %	M %	E %	B %	BANDS-N %
GROUP & SEX: 3M DOSE LEVEL: 500 DOSAGE UNIT: MG/KG												
H00985	5.5	3.24	2.09	.00	.16	.00	59	38	0	3	0	0
H00986	11.1	6.77	3.55	.00	.78	.00	61	32	0	7	0	0
H00987	7.7	3.85	3.46	.31	.08	.00	50	45	4	1	0	0
H00988	7.3	4.16	2.85	.22	.07	.00	57	39	3	1	0	0
H00989	10.7	7.06	2.78	.32	.54	.00	66	26	3	5	0	0
H00990	8.1	4.86	2.75	.16	.32	.00	60	34	2	4	0	0
N=	6	6	6	6	6	6	6	6	6	6	6	6
MEAN	8.4	4.99	2.91	.17	.32	.00	59	36	2	4	0	0
S.D.	2.13	1.582	.535	.143	.285	.000	5.3	6.5	1.7	2.3	.0	.0
GROUP & SEX: 3F DOSE LEVEL: 500 DOSAGE UNIT: MG/KG												
H00991	7.9	2.76	4.58	.47	.08	.00	35	58	6	1	0	0
H00992	7.5	3.82	3.22	.15	.30	.00	51	43	2	4	0	0
H00993	7.5	4.42	2.62	.22	.22	.00	59	35	3	3	0	0
H00994	6.8	3.67	2.86	.20	.07	.00	54	42	3	1	0	0
H00995	5.6	3.14	2.13	.11	.22	.00	56	38	2	4	0	0
H00996	8.0	5.20	2.64	.16	.00	.00	65	33	2	0	0	0
N=	6	6	6	6	6	6	6	6	6	6	6	6
MEAN	7.2	3.84	3.01	.22	.15	.00	53	42	3	2	0	0
S.D.	.90	.880	.848	.129	.115	.000	10.2	9.0	1.5	1.7	.0	.0
POOLED M+F GROUP: 3												
N=	12	12	12	12	12	12	12	12	12	12	12	12
MEAN M+F	7.8	4.41	2.96	.19	.24	.00	56	38	2	3	0	0
S.D. M+F	1.68	1.362	.678	.133	.227	.000	8.2	8.1	1.6	2.1	.0	.0

S6127111 DOG POOL M+F WEEK: 008

APPENDIX
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	WBC E3/CU MM	N-SEG E3/CU MM	L E3/CU MM	M E3/CU MM	E E3/CU MM	B E3/CU MM	N-SEG %	L %	M %	E %	B %	BANDS-N %
GROUP & SEX: 4M DOSE LEVEL: 1000 DOSAGE UNIT: MG/KG												
H00001	6.1	3.42	2.20	.30	.18	.00	56	36	5	3	0	0
H00002	6.8	4.15	2.04	.20	.41	.00	61	30	3	6	0	0
H00003	7.1	3.98	2.34	.36	.43	.00	56	33	5	6	0	0
H00997	6.7	2.75	3.55	.13	.20	.00	41	53	2	3	0	1
H00998	9.4	4.61	4.61	.19	.00	.00	49	49	2	0	0	0
H00999	8.1	4.62	2.19	.57	.73	.00	57	27	7	9	0	0
N=	6	6	6	6	6	6	6	6	6	6	6	6
MEAN	7.4	3.92	2.82	.29	.32	.00	53	38	4	4	0	0
S.D.	1.19	.727	1.035	.159	.255	.000	7.2	10.6	2.0	3.1	.0	.4
GROUP & SEX: 4F DOSE LEVEL: 1000 DOSAGE UNIT: MG/KG												
H00004	8.4	4.87	2.86	.34	.34	.00	58	34	4	4	0	0
H00005	6.9	3.38	3.17	.21	.14	.00	49	46	3	2	0	0
H00006	7.9	4.74	2.84	.32	.00	.00	60	36	4	0	0	0
H00007	7.9	5.37	2.21	.24	.08	.00	68	28	3	1	0	0
H00008	13.1	8.78	3.41	.26	.66	.00	67	26	2	5	0	0
H00009	11.0	5.50	4.95	.22	.33	.00	50	45	2	3	0	0
N=	6	6	6	6	6	6	6	6	6	6	6	6
MEAN	9.2	5.44	3.24	.26	.26	.00	59	36	3	2	0	0
S.D.	2.36	1.801	.930	.054	.239	.000	8.1	8.4	.9	1.9	.0	.0
POOLED M+F GROUP: 4												
N=	12	12	12	12	12	12	12	12	12	12	12	12
MEAN M+F	8.3	4.68	3.03	.28	.29	.00	56	37	4	4	0	0
S.D. M+F	2.02	1.531	.963	.114	.238	.000	7.8	9.2	1.6	2.7	.0	.3

APPENDIX
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	BANDS-N E3/CU MM	PT SEC	PTT SEC
GROUP & SEX: 1M	DOSE LEVEL: 0		DOSAGE UNIT: MG/KG
H00961	.00	12.4	10.4
H00962	.00	6.4	10.9
H00963	.00	6.4	11.4
H00964	.00	11.9	9.4
H00965	.00	6.4	10.9
H00966	.00	5.9	10.9
N=	6	6	6
MEAN	.00	8.2	10.6
S.D.	.000	3.04	.69
GROUP & SEX: 1F	DOSE LEVEL: 0		DOSAGE UNIT: MG/KG
H00967	.00	5.9	12.9
H00968	.00	5.9	11.9
H00969	.00	5.9	10.2
H00970	.00	5.9	9.9
H00971	.00	6.9	12.4
H00972	.00	7.4	11.4
N=	6	6	6
MEAN	.00	6.3	11.4
S.D.	.000	.66	1.20
POOLED M+F GROUP: 1			
N=	12	12	12
MEAN M+F	.00	7.3	11.0
S.D. M+F	.000	2.33	1.02

APPENDIX
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	BANDS-N E3/CU MM	PT SEC	PTT SEC
GROUP & SEX: 2M	DOSE LEVEL: 250		DOSAGE UNIT: MG/KG
H00973	.00	10.4	10.9
H00974	.00	6.4	10.4
H00975	.09	6.4	10.9
H00976	.00	5.4	10.9
H00977	.00	6.4	10.9
H00978	.00	8.9 H	11.9 H
N=	6	6	6
MEAN	.02	7.3	11.0
S.D.	.037	1.91	.49
GROUP & SEX: 2F	DOSE LEVEL: 250		DOSAGE UNIT: MG/KG
H00979	.00	5.9	12.4
H00980	.00	11.9	11.4
H00981	.00	5.9	11.9
H00982	.00	6.4	11.9
H00983	.00	6.2	11.4
H00984	.00	5.9	11.9
N=	6	6	6
MEAN	.00	7.0	11.8
S.D.	.000	2.39	.38
POOLED M+F GROUP: 2			
N=	12	12	12
MEAN M+F	.01	7.2	11.4
S.D. M+F	.026	2.07	.60

APPENDIX
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	BANDS-N E3/CU MM	PT SEC	PTT SEC
GROUP & SEX: 3M	DOSE LEVEL: 500		DOSAGE UNIT: MG/KG
H00985	.00	5.9	9.9
H00986	.00	5.9	10.9
H00987	.00	5.9	10.1
H00988	.00	5.9	10.9
H00989	.00	6.9	10.9
H00990	.00	5.9	10.9
N=	6	6	6
MEAN	.00	6.1	10.6
S.D.	.000	.41	.47
GROUP & SEX: 3F	DOSE LEVEL: 500		DOSAGE UNIT: MG/KG
H00991	.00	13.4	11.4
H00992	.00	6.4	11.9
H00993	.00	6.4	11.4
H00994	.00	6.4	11.9
H00995	.00	5.9 H	11.9 H
H00996	.00	5.9	11.4
N=	6	6	6
MEAN	.00	7.4	11.6
S.D.	.000	2.95	.27
POOLED M+F GROUP: 3			
N=	12	12	12
MEAN M+F	.00	6.7	11.1
S.D. M+F	.000	2.12	.66

APPENDIX
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	BANDS-N E3/CU MM	PT SEC	PTT SEC
GROUP & SEX: 4M	DOSE LEVEL: 1000		DOSAGE UNIT: MG/KG
H00001	.00	6.4	11.4
H00002	.00	5.9	11.4
H00003	.00	6.4	11.9
H00997	.07	5.9	10.9
H00998	.00	6.9	10.9
H00999	.00	6.4	10.9
N=	6	6	6
MEAN	.01	6.3	11.2
S.D.	.028	.38	.41
GROUP & SEX: 4F	DOSE LEVEL: 1000		DOSAGE UNIT: MG/KG
H00004	.00	5.9	11.9
H00005	.00	6.4	9.9
H00006	.00	5.9	10.9
H00007	.00	5.9	10.4
H00008	.00	5.9	10.9
H00009	.00	6.4	10.9
N=	6	6	6
MEAN	.00	6.1	10.8
S.D.	.000	.26	.66
POOLED M+F GROUP: 4			
N=	12	12	12
MEAN M+F	.00	6.2	11.0
S.D. M+F	.020	.33	.57

S6127111 DOG POOL M+F WEEK: 017

APPENDIX
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	RBC E6/CU MM	HGB G/DL	HCT %	MCV FL	MCH PICO GMS	MCHC %	PLT E3/CU MM	NRBC /100 WBC
GROUP & SEX: 1M DOSE LEVEL: 0				DOSAGE UNIT: MG/KG				
H00961	6.87	12.8	43.9	64	18.6	29.2	455	0
H00962	7.84	13.4	45.6	58	17.1	29.4	430	0
H00963	6.99	13.1	46.4	66	18.7	28.2	319	0
H00964	6.66	12.0	41.2	62	18.0	29.1	387	0
H00965	7.62	13.9	49.9	65	18.2	27.9	356	0
H00966	7.78	13.8	46.7	60	17.7	29.6	341	0
N=	6	6	6	6	6	6	6	6
MEAN	7.29	13.2	45.6	62	18.0	28.9	381	0
S.D.	.513	.71	2.92	3.1	.60	.69	52.9	.0
GROUP & SEX: 1F DOSE LEVEL: 0				DOSAGE UNIT: MG/KG				
H00967	8.55	13.5	49.1	57	15.8	27.5	359	0
H00968	8.20	13.7	49.3	60	16.7	27.8	418	0
H00969	8.25	13.9	49.0	59	16.8	28.4	323	0
H00970	7.75	13.2	47.2	61	17.0	28.0	382	0
H00971	7.71	13.0	47.3	61	16.9	27.5	507	0
H00972	7.90	13.5	48.9	62	17.1	27.6	376	0
N=	6	6	6	6	6	6	6	6
MEAN	8.06	13.5	48.5	60	16.7	27.8	394	0
S.D.	.329	.33	.95	1.8	.47	.35	63.4	.0
POOLED M+F GROUP: 1								
N=	12	12	12	12	12	12	12	12
MEAN M+F	7.68	13.3	47.0	61	17.4	28.4	388	0
S.D. M+F	.574	.55	2.55	2.7	.86	.78	56.0	.0

APPENDIX
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	RBC E6/CU MM	HGB G/DL	HCT %	MCV FL	MCH PICO GMS	MCHC %	PLT E3/CU MM	NRBC /100 WBC
GROUP & SEX: 2M	DOSE LEVEL: 250		DOSAGE UNIT: MG/KG					
H00973	7.49	13.7	47.0	63	18.3	29.1	351	0
H00974	8.20	13.8	48.3	59	16.8	28.6	382	0
H00975	7.92	13.9	47.3	60	17.6	29.4	314	0
H00976	7.71	13.4	45.1	58	17.4	29.7	445	0
H00977	8.02	12.9	43.1	54	16.1	29.9	380	0
H00978	8.15	14.7	49.3	60	18.0	29.8	372	0
N=	6	6	6	6	6	6	6	6
MEAN	7.92	13.7	46.7	59	17.4	29.4	374	0
S.D.	.272	.60	2.25	3.0	.81	.50	43.1	.0
GROUP & SEX: 2F	DOSE LEVEL: 250		DOSAGE UNIT: MG/KG					
H00979	8.10	14.4	50.8	63	17.8	28.3	255	0
H00980	7.76	13.8	48.9	63	17.8	28.2	319	0
H00981	7.83	12.5	45.8	58	16.0	27.3	326	0
H00982	7.15	12.6	45.9	64	17.6	27.5	392	0
H00983	8.89	14.8	53.7	60	16.6	27.6	272	0
H00984	8.46	13.9	47.0	56	16.4	29.6	325	0
N=	6	6	6	6	6	6	6	6
MEAN	8.03	13.7	48.7	61	17.0	28.1	315	0
S.D.	.603	.94	3.12	3.2	.79	.84	48.2	.0
POOLED M+F GROUP: 2								
N=	12	12	12	12	12	12	12	12
MEAN M+F	7.97	13.7	47.7	60	17.2	28.8	344	0
S.D. M+F	.450	.75	2.79	3.1	.78	.96	53.4	.0

S6127111 DOG POOL M+F WEEK: 017

APPENDIX
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	RBC E6/CU MM	HGB G/DL	HCT %	MCV FL	MCH PICO GMS	MCHC %	PLT E3/CU MM	NRBC /100 WBC
GROUP & SEX: 3M DOSE LEVEL: 500 DOSAGE UNIT: MG/KG								
H00985	7.93	13.9	48.0	61	17.5	29.0	325	0
H00986	6.78	12.2	42.2	62	18.0	28.9	373	0
H00987	8.00	14.1	47.3	59	17.6	29.8	355	0
H00988	7.97	13.8	48.4	61	17.3	28.5	331	0
H00989	7.78	13.5	49.1	63	17.4	27.5	331	0
H00990	7.31	13.1	46.1	63	17.9	28.4	312	0
N=	6	6	6	6	6	6	6	6
MEAN	7.63	13.4	46.8	62	17.6	28.7	338	0
S.D.	.488	.70	2.50	1.5	.28	.76	22.2	.0
GROUP & SEX: 3F DOSE LEVEL: 500 DOSAGE UNIT: MG/KG								
H00991	8.41	14.7	52.0	62	17.5	28.3	384	0
H00992	7.66	12.7	46.4	61	16.6	27.4	414	0
H00993	7.72	13.2	47.0	61	17.1	28.1	442	0
H00994	7.91	13.3	46.9	59	16.8	28.4	457	0
H00995	8.01	13.6	51.1	64	17.0	26.6	373	0
H00996	6.95	12.6	45.2	65	18.1	27.9	421	0
N=	6	6	6	6	6	6	6	6
MEAN	7.78	13.4	48.1	62	17.2	27.8	415	0
S.D.	.484	.76	2.76	2.2	.54	.68	32.4	.0
POOLED M+F GROUP: 3								
N=	12	12	12	12	12	12	12	12
MEAN M+F	7.70	13.4	47.5	62	17.4	28.2	376	0
S.D. M+F	.470	.70	2.59	1.8	.47	.83	48.3	.0

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APPENDIX
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	RBC E6/CU MM	HGB G/DL	HCT %	MCV FL	MCH PICO GMS	MCHC %	PLT E3/CU MM	NRBC /100 WBC
GROUP & SEX: 4M	DOSE LEVEL: 1000		DOSAGE UNIT: MG/KG					
H00001	7.78	13.3	46.0	59	17.1	28.9	384	0
H00002	8.03	13.3	45.1	56	16.6	29.5	420	0
H00003	6.73	11.7	41.1	61	17.4	28.5	428	0
H00997	7.59	13.0	44.7	59	17.1	29.1	311	0
H00998	7.47	13.5	46.6	62	18.1	29.0	349	0
H00999	7.66	13.3	45.2	59	17.4	29.4	320	0
N=	6	6	6	6	6	6	6	6
MEAN	7.54	13.0	44.8	59	17.3	29.1	369	0
S.D.	.442	.66	1.93	2.1	.50	.36	49.9	.0
GROUP & SEX: 4F	DOSE LEVEL: 1000		DOSAGE UNIT: MG/KG					
H00004	8.02	13.8	48.4	60	17.2	28.5	450	1
H00005	8.12	13.2	46.6	57	16.3	28.3	394	0
H00006	8.78	14.1	51.2	58	16.1	27.5	403	0
H00007	7.47	12.6	43.8	59	16.9	28.8	422	0
H00008	8.49	14.3	50.7	60	16.8	28.2	315	0
H00009	7.53	12.5	44.3	59	16.6	28.2	541	0
N=	6	6	6	6	6	6	6	6
MEAN	8.07	13.4	47.5	59	16.6	28.2	421	0
S.D.	.517	.77	3.14	1.2	.40	.43	74.2	.4
POOLED M+F GROUP: 4								
N=	12	12	12	12	12	12	12	12
MEAN M+F	7.80	13.2	46.1	59	17.0	28.6	395	0
S.D. M+F	.534	.72	2.86	1.6	.54	.57	66.2	.3

APPENDIX
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	WBC E3/CU MM	N-SEG E3/CU MM	L E3/CU MM	M E3/CU MM	E E3/CU MM	B E3/CU MM	N-SEG %	L %	M %	E %	B %	BANDS-N %
GROUP & SEX: 1M DOSE LEVEL: 0 DOSAGE UNIT: MG/KG												
H00961	6.4	3.14	2.30	.45	.51	.00	49	36	7	8	0	0
H00962	8.3	5.73	1.91	.33	.33	.00	69	23	4	4	0	0
H00963	8.1	3.97	3.24	.40	.49	.00	49	40	5	6	0	0
H00964	6.2	4.77	.99	.19	.25	.00	77	16	3	4	0	0
H00965	6.8	4.22	2.11	.27	.20	.00	62	31	4	3	0	0
H00966	15.8	12.16	2.53	.79	.32	.00	77	16	5	2	0	0
N=	6	6	6	6	6	6	6	6	6	6	6	6
MEAN	8.6	5.66	2.18	.40	.35	.00	64	27	5	4	0	0
S.D.	3.63	3.296	.742	.210	.126	.000	12.8	10.2	1.4	2.2	.0	.0
GROUP & SEX: 1F DOSE LEVEL: 0 DOSAGE UNIT: MG/KG												
H00967	8.2	4.84	2.87	.33	.16	.00	59	35	4	2	0	0
H00968	7.6	4.71	2.51	.30	.08	.00	62	33	4	1	0	0
H00969	7.8	4.91	2.50	.39	.00	.00	63	32	5	0	0	0
H00970	10.1	6.46	2.93	.71	.00	.00	64	29	7	0	0	0
H00971	9.0	6.39	1.98	.54	.09	.00	71	22	6	1	0	0
H00972	9.0	6.84	1.35	.27	.54	.00	76	15	3	6	0	0
N=	6	6	6	6	6	6	6	6	6	6	6	6
MEAN	8.6	5.69	2.36	.42	.14	.00	66	28	5	2	0	0
S.D.	.93	.969	.598	.170	.203	.000	6.4	7.7	1.5	2.2	.0	.0
POOLED M+F GROUP: 1												
N=	12	12	12	12	12	12	12	12	12	12	12	12
MEAN M+F	8.6	5.68	2.27	.41	.25	.00	65	27	5	3	0	0
S.D. M+F	2.53	2.316	.649	.182	.193	.000	9.7	8.6	1.4	2.6	.0	.0

APPENDIX
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	WBC E3/CU MM	N-SEG E3/CU MM	L E3/CU MM	M E3/CU MM	E E3/CU MM	B E3/CU MM	N-SEG %	L %	M %	E %	B %	BANDS-N %
GROUP & SEX: 2M DOSE LEVEL: 250 DOSAGE UNIT: MG/KG												
H00973	8.2	4.92	2.62	.25	.41	.00	60	32	3	5	0	0
H00974	8.9	5.70	2.58	.18	.44	.00	64	29	2	5	0	0
H00975	8.0	5.20	2.24	.32	.24	.00	65	28	4	3	0	0
H00976	9.9	7.23	2.18	.20	.30	.00	73	22	2	3	0	0
H00977	9.3	6.42	1.95	.00	.93	.00	69	21	0	10	0	0
H00978	9.2	4.88	3.77	.18	.37	.00	53	41	2	4	0	0
N=	6	6	6	6	6	6	6	6	6	6	6	6
MEAN	8.9	5.72	2.56	.19	.45	.00	64	29	2	5	0	0
S.D.	.71	.937	.646	.107	.247	.000	7.0	7.3	1.3	2.6	.0	.0
GROUP & SEX: 2F DOSE LEVEL: 250 DOSAGE UNIT: MG/KG												
H00979	7.3	5.33	1.61	.15	.22	.00	73	22	2	3	0	0
H00980	6.8	4.76	1.63	.34	.07	.00	70	24	5	1	0	0
H00981	7.2	4.18	2.38	.36	.29	.00	58	33	5	4	0	0
H00982	7.9	5.13	2.29	.24	.24	.00	65	29	3	3	0	0
H00983	7.6	5.24	2.05	.08	.15	.00	69	27	1	2	0	1
H00984	6.9	4.97	1.59	.21	.07	.00	72	23	3	1	0	1
N=	6	6	6	6	6	6	6	6	6	6	6	6
MEAN	7.3	4.94	1.92	.23	.17	.00	68	26	3	2	0	0
S.D.	.42	.422	.362	.108	.092	.000	5.6	4.2	1.6	1.2	.0	.5
POOLED M+F GROUP: 2												
N=	12	12	12	12	12	12	12	12	12	12	12	12
MEAN M+F	8.1	5.33	2.24	.21	.31	.00	66	28	3	4	0	0
S.D. M+F	1.02	.806	.598	.105	.228	.000	6.3	5.8	1.5	2.4	.0	.4

APPENDIX
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	WBC E3/CU MM	N-SEG E3/CU MM	L E3/CU MM	M E3/CU MM	E E3/CU MM	B E3/CU MM	N-SEG %	L %	M %	E %	B %	BANDS-N %
GROUP & SEX: 3M DOSE LEVEL: 500 DOSAGE UNIT: MG/KG												
H00985	6.9	5.04	1.59	.07	.21	.00	73	23	1	3	0	1
H00986	8.6	5.50	2.75	.09	.26	.00	64	32	1	3	0	0
H00987	6.6	3.76	2.44	.33	.07	.00	57	37	5	1	0	0
H00988	9.1	6.19	1.73	.27	.91	.00	68	19	3	10	0	0
H00989	11.1	8.10	2.00	.33	.67	.00	73	18	3	6	0	0
H00990	7.0	3.99	2.24	.21	.56	.00	57	32	3	8	0	0
N=	6	6	6	6	6	6	6	6	6	6	6	6
MEAN	8.2	5.43	2.12	.22	.45	.00	65	27	3	5	0	0
S.D.	1.74	1.595	.438	.115	.319	.000	7.3	7.9	1.5	3.4	.0	.4
GROUP & SEX: 3F DOSE LEVEL: 500 DOSAGE UNIT: MG/KG												
H00991	8.4	5.21	2.94	.17	.08	.00	62	35	2	1	0	0
H00992	6.6	3.76	2.51	.07	.20	.00	57	38	1	3	0	1
H00993	8.4	5.04	2.94	.17	.25	.00	60	35	2	3	0	0
H00994	6.5	4.48	1.56	.20	.26	.00	69	24	3	4	0	0
H00995	7.6	5.70	1.22	.23	.46	.00	75	16	3	6	0	0
H00996	10.3	8.03	1.85	.41	.00	.00	78	18	4	0	0	0
N=	6	6	6	6	6	6	6	6	6	6	6	6
MEAN	8.0	5.37	2.17	.21	.21	.00	67	28	2	3	0	0
S.D.	1.41	1.463	.732	.112	.160	.000	8.5	9.6	1.0	2.1	.0	.4
POOLED M+F GROUP: 3												
N=	12	12	12	12	12	12	12	12	12	12	12	12
MEAN M+F	8.1	5.40	2.15	.21	.33	.00	66	27	2	4	0	0
S.D. M+F	1.51	1.460	.576	.108	.271	.000	7.6	8.4	1.2	3.0	.0	.4

S6127111 DOG POOL M+F WEEK: 017

APPENDIX
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	WBC E3/CU MM	N-SEG E3/CU MM	L E3/CU MM	M E3/CU MM	E E3/CU MM	B E3/CU MM	N-SEG %	L %	M %	E %	B %	BANDS-N %
GROUP & SEX: 4M DOSE LEVEL: 1000 DOSAGE UNIT: MG/KG												
H00001	6.0	2.82	2.52	.24	.42	.00	47	42	4	7	0	0
H00002	7.2	5.04	1.37	.36	.43	.00	70	19	5	6	0	0
H00003	8.2	6.48	1.31	.16	.25	.00	79	16	2	3	0	0
H00997	6.1	3.42	2.32	.24	.12	.00	56	38	4	2	0	0
H00998	10.9	6.76	3.38	.44	.33	.00	62	31	4	3	0	1
H00999	7.4	4.00	2.66	.22	.52	.00	54	36	3	7	0	0
N=	6	6	6	6	6	6	6	6	6	6	6	6
MEAN	7.6	4.75	2.26	.28	.34	.00	61	30	4	5	0	0
S.D.	1.80	1.623	.798	.103	.144	.000	11.6	10.6	1.0	2.2	.0	.4
GROUP & SEX: 4F DOSE LEVEL: 1000 DOSAGE UNIT: MG/KG												
H00004	13.0	9.88	2.47	.26	.26	.00	76	19	2	2	0	1
H00005	7.8	4.84	2.18	.08	.70	.00	62	28	1	9	0	0
H00006	8.2	5.90	1.97	.25	.08	.00	72	24	3	1	0	0
H00007	8.2	6.07	1.64	.41	.08	.00	74	20	5	1	0	0
H00008	12.0	9.12	2.16	.36	.36	.00	76	18	3	3	0	0
H00009	14.2	6.82	7.24	.14	.00	.00	48	51	1	0	0	0
N=	6	6	6	6	6	6	6	6	6	6	6	6
MEAN	10.6	7.10	2.94	.25	.25	.00	68	27	2	3	0	0
S.D.	2.83	1.975	2.123	.126	.259	.000	11.1	12.5	1.5	3.3	.0	.4
POOLED M+F GROUP: 4												
N=	12	12	12	12	12	12	12	12	12	12	12	12
MEAN M+F	9.1	5.93	2.60	.26	.30	.00	65	28	3	4	0	0
S.D. M+F	2.73	2.116	1.570	.110	.206	.000	11.4	11.2	1.4	2.9	.0	.4

APPENDIX
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	BANDS-N E3/CU MM	PT SEC	PTT SEC
GROUP & SEX: 1M	DOSE LEVEL: 0		DOSAGE UNIT: MG/KG
H00961	.00	10.9	9.2
H00962	.00	6.9	10.9
H00963	.00	6.4	10.9
H00964	.00	11.4	9.9
H00965	.00	5.9	10.9
H00966	.00	5.9	10.9
N=	6	6	6
MEAN	.00	7.9	10.4
S.D.	.000	2.55	.73
GROUP & SEX: 1F	DOSE LEVEL: 0		DOSAGE UNIT: MG/KG
H00967	.00	6.4	9.4
H00968	.00	5.9	9.4
H00969	.00	6.4	8.9
H00970	.00	5.9	8.9
H00971	.00	6.4	8.4
H00972	.00	6.9	9.7
N=	6	6	6
MEAN	.00	6.3	9.1
S.D.	.000	.38	.47
POOLED M+F GROUP: 1			
N=	12	12	12
MEAN M+F	.00	7.1	9.8
S.D. M+F	.000	1.92	.91

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TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	BANDS-N E3/CU MM	PT SEC	PTT SEC
GROUP & SEX: 2M	DOSE LEVEL: 250		DOSAGE UNIT: MG/KG
H00973	.00	10.9	10.4
H00974	.00	6.4	10.8
H00975	.00	6.4	11.4
H00976	.00	5.9	10.9
H00977	.00	6.4	11.3
H00978	.00	6.4	10.9
N=	6	6	6
MEAN	.00	7.1	10.9
S.D.	.000	1.89	.36
GROUP & SEX: 2F	DOSE LEVEL: 250		DOSAGE UNIT: MG/KG
H00979	.00	6.4	11.9
H00980	.00	11.4	9.9
H00981	.00	6.4	10.4
H00982	.00	6.4	9.4
H00983	.08	6.4	9.9
H00984	.07	6.4	9.9
N=	6	6	6
MEAN	.02	7.2	10.2
S.D.	.039	2.04	.88
POOLED M+F GROUP: 2			
N=	12	12	12
MEAN M+F	.01	7.2	10.6
S.D. M+F	.029	1.88	.74

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INDIVIDUAL CLINICAL HEMATOLOGY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	BANDS-N E3/CU MM	PT SEC	PTT SEC
GROUP & SEX: 3M	DOSE LEVEL: 500		DOSAGE UNIT: MG/KG
H00985	.07	5.9	10.9
H00986	.00	5.9	10.4
H00987	.00	6.9	9.9
H00988	.00	5.9	9.9
H00989	.00	6.9	9.4
H00990	.00	5.9	9.9
N=	6	6	6
MEAN	.01	6.2	10.1
S.D.	.028	.52	.52
GROUP & SEX: 3F	DOSE LEVEL: 500		DOSAGE UNIT: MG/KG
H00991	.00	10.9	9.4
H00992	.07	5.9	9.4
H00993	.00	5.9	9.9
H00994	.00	5.9	9.9
H00995	.00	5.9	9.4
H00996	.00	5.9	9.4
N=	6	6	6
MEAN	.01	6.7	9.6
S.D.	.028	2.04	.26
POOLED M+F GROUP: 3			
N=	12	12	12
MEAN M+F	.01	6.5	9.8
S.D. M+F	.027	1.44	.47

APPENDIX
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	BANDS-N E3/CU MM	PT SEC	PTT SEC
GROUP & SEX: 4M	DOSE LEVEL: 1000		DOSAGE UNIT: MG/KG
H00001	.00	5.9	9.4
H00002	.00	5.9	9.4
H00003	.00	6.4	10.4
H00997	.00	6.4	8.4
H00998	.11	6.9	8.9
H00999	.00	6.4	9.9
N=	6	6	6
MEAN	.02	6.3	9.4
S.D.	.045	.38	.71
GROUP & SEX: 4F	DOSE LEVEL: 1000		DOSAGE UNIT: MG/KG
H00004	.13	5.9	9.9
H00005	.00	6.1	9.4
H00006	.00	6.4	10.4
H00007	.00	5.9	10.4
H00008	.00	5.9	9.9
H00009	.00	6.4	9.9
N=	6	6	6
MEAN	.02	6.1	10.0
S.D.	.053	.24	.38
POOLED M+F GROUP: 4			
N=	12	12	12
MEAN M+F	.02	6.2	9.7
S.D. M+F	.047	.32	.62

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INDIVIDUAL CLINICAL HEMATOLOGY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	RBC E6/CU MM	HGB G/DL	HCT %	MCV FL	MCH PICO GMS	MCHC %	PLT E3/CU MM	NRBC /100 WBC
GROUP & SEX: 1M DOSE LEVEL: 0				DOSAGE UNIT: MG/KG				
H00961	8.22	14.7	48.9	59	17.9	30.1	515	0
H00962	9.17	15.6	50.5	55	17.0	30.9	450	0
H00963	7.86	14.8	47.2	60	18.8	31.4	376	0
H00964	7.95	14.6	44.7	56	18.4	32.7	457	0
H00965	8.29	16.1	49.3	59	19.4	32.7	326	0
H00966	8.57	15.7	48.7	57	18.3	32.2	344	0
N=	6	6	6	6	6	6	6	6
MEAN	8.34	15.2	48.2	58	18.3	31.7	411	0
S.D.	.478	.63	2.02	2.0	.81	1.05	74.0	.0
GROUP & SEX: 1F DOSE LEVEL: 0				DOSAGE UNIT: MG/KG				
H00967	9.43	14.8	50.5	54	15.7	29.3	429	0
H00968	8.88	15.1	51.1	58	17.0	29.5	447	0
H00969	9.15	15.8	52.7	58	17.3	30.0	417	0
H00970	7.82	14.0	47.4	61	17.9	29.5	452	1
H00971	8.75	14.9	49.2	56	17.0	30.3	494	0
H00972	9.35	16.5	55.1	59	17.6	29.9	364	0
N=	6	6	6	6	6	6	6	6
MEAN	8.90	15.2	51.0	58	17.1	29.8	434	0
S.D.	.589	.86	2.69	2.4	.76	.38	43.1	.4
POOLED M+F GROUP: 1								
N=	12	12	12	12	12	12	12	12
MEAN M+F	8.62	15.2	49.6	58	17.7	30.7	422	0
S.D. M+F	.587	.72	2.69	2.1	.98	1.25	58.9	.3

APPENDIX
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	RBC E6/CU MM	HGB G/DL	HCT %	MCV FL	MCH PICO GMS	MCHC %	PLT E3/CU MM	NRBC /100 WBC
GROUP & SEX: 2M DOSE LEVEL: 250 DOSAGE UNIT: MG/KG								
H00973	8.53	15.7	49.2	58	18.4	31.9	364	0
H00974	9.08	16.2	51.1	56	17.8	31.7	364	1
H00975	8.78	15.5	49.2	56	17.7	31.5	345	0
H00976	8.61	15.3	46.6	54	17.8	32.8	449	0
H00977	9.48	15.7	49.1	52	16.6	32.0	350	0
H00978	8.99	16.3	50.5	56	18.1	32.3	367	0
N=	6	6	6	6	6	6	6	6
MEAN	8.91	15.8	49.3	55	17.7	32.0	373	0
S.D.	.350	.39	1.55	2.1	.61	.46	38.2	.4
GROUP & SEX: 2F DOSE LEVEL: 250 DOSAGE UNIT: MG/KG								
H00979	8.69	14.9	52.6	61	17.1	28.3	301	0
H00980	8.54	15.6	52.3	61	18.3	29.8	353	0
H00981	9.56	15.2	53.0	55	15.9	28.7	411	0
H00982	8.61	15.7	50.9	59	18.2	30.8	453	0
H00983	10.44	17.5	59.4	57	16.8	29.5	298	0
H00984	9.89	16.8	56.8	57	17.0	29.6	374	0
N=	6	6	6	6	6	6	6	6
MEAN	9.29	16.0	54.2	58	17.2	29.4	365	0
S.D.	.792	1.00	3.23	2.4	.91	.88	61.1	.0
POOLED M+F GROUP: 2								
N=	12	12	12	12	12	12	12	12
MEAN M+F	9.10	15.9	51.7	57	17.5	30.7	369	0
S.D. M+F	.616	.73	3.51	2.6	.78	1.51	48.8	.3

APPENDIX
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	RBC E6/CU MM	HGB G/DL	HCT %	MCV FL	MCH PICO GMS	MCHC %	PLT E3/CU MM	NRBC /100 WBC
GROUP & SEX: 3M DOSE LEVEL: 500				DOSAGE UNIT: MG/KG				
H00985	8.62	15.2	47.5	55	17.6	32.0	321	0
H00986	7.57	13.4	44.3	59	17.7	30.2	424	0
H00987	9.10	15.6	48.9	54	17.1	31.9	409	0
H00988	8.99	15.4	52.9	59	17.1	29.1	342	0
H00989	8.10	14.0	47.3	58	17.3	29.6	351	0
H00990	8.81	16.1	52.9	60	18.3	30.4	327	0
N=	6	6	6	6	6	6	6	6
MEAN	8.53	15.0	49.0	58	17.5	30.5	362	0
S.D.	.588	1.03	3.40	2.4	.46	1.19	43.5	.0
GROUP & SEX: 3F DOSE LEVEL: 500				DOSAGE UNIT: MG/KG				
H00991	9.17	16.5	55.2	60	18.0	29.9	419	0
H00992	8.76	15.4	49.5	57	17.6	31.1	450	1
H00993	8.80	15.3	49.8	57	17.4	30.7	456	1
H00994	8.35	14.3	46.0	55	17.1	31.1	348	0
H00995	7.84	14.0	47.5	61	17.9	29.5	363	0
H00996	7.39	13.8	47.2	64	18.7	29.2	475	0
N=	6	6	6	6	6	6	6	6
MEAN	8.38	14.9	49.2	59	17.8	30.2	418	0
S.D.	.666	1.03	3.27	3.3	.56	.83	52.2	.5
POOLED M+F GROUP: 3								
N=	12	12	12	12	12	12	12	12
MEAN M+F	8.46	14.9	49.1	58	17.6	30.4	390	0
S.D. M+F	.604	.98	3.18	2.9	.50	.99	54.4	.4

S6127111 DOG POOL M+F WEEK: 026

APPENDIX
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	RBC E6/CU MM	HGB G/DL	HCT %	MCV FL	MCH PICO GMS	MCHC %	PLT E3/CU MM	NRBC /100 WBC
GROUP & SEX: 4M DOSE LEVEL: 1000 DOSAGE UNIT: MG/KG								
H00001	8.89	15.4	51.3	58	17.3	30.0	419	0
H00002	8.84	14.7	46.0	52	16.6	32.0	528	0
H00003	7.65	13.5	43.7	57	17.6	30.9	388	0
H00997	8.60	14.4	46.9	55	16.7	30.7	382	0
H00998	8.44	16.1	50.9	60	19.1	31.6	369	0
H00999	8.83	15.1	48.3	55	17.1	31.3	350	0
N=	6	6	6	6	6	6	6	6
MEAN	8.54	14.9	47.8	56	17.4	31.1	406	0
S.D.	.470	.89	2.93	2.8	.91	.71	64.0	.0
GROUP & SEX: 4F DOSE LEVEL: 1000 DOSAGE UNIT: MG/KG								
H00004	8.28	14.7	48.7	59	17.8	30.2	447	1
H00005	9.03	15.3	49.6	55	16.9	30.8	433	0
H00006	9.01	15.1	50.6	56	16.8	29.8	377	0
H00007	8.53	14.2	48.4	57	16.6	29.3	390	0
H00008	8.93	15.1	52.4	59	16.9	28.8	369	0
H00009	8.64	14.4	47.8	55	16.7	30.1	485	0
N=	6	6	6	6	6	6	6	6
MEAN	8.74	14.8	49.6	57	17.0	29.8	417	0
S.D.	.303	.44	1.69	1.8	.43	.71	45.6	.4
POOLED M+F GROUP: 4								
N=	12	12	12	12	12	12	12	12
MEAN M+F	8.64	14.8	48.7	56	17.2	30.4	411	0
S.D. M+F	.390	.67	2.45	2.3	.72	.94	53.3	.3

S6127111 DOG POOL M+F WEEK: 026

APPENDIX
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	WBC E3/CU MM	N-SEG E3/CU MM	L E3/CU MM	M E3/CU MM	E E3/CU MM	B E3/CU MM	N-SEG %	L %	M %	E %	B %	BANDS-N %
GROUP & SEX: 1M DOSE LEVEL: 0						DOSAGE UNIT: MG/KG						
H00961	7.2	4.46	2.38	.29	.07	.00	62	33	4	1	0	0
H00962	7.0	5.18	1.26	.56	.00	.00	74	18	8	0	0	0
H00963	7.2	4.61	1.80	.65	.14	.00	64	25	9	2	0	0
H00964	6.3	4.28	1.64	.19	.19	.00	68	26	3	3	0	0
H00965	6.2	3.97	2.05	.19	.00	.00	64	33	3	0	0	0
H00966	10.5	7.66	2.52	.32	.00	.00	73	24	3	0	0	0
N=	6	6	6	6	6	6	6	6	6	6	6	6
MEAN	7.4	5.03	1.94	.37	.07	.00	68	26	5	1	0	0
S.D.	1.58	1.351	.472	.194	.082	.000	5.0	5.8	2.8	1.3	.0	.0
GROUP & SEX: 1F DOSE LEVEL: 0						DOSAGE UNIT: MG/KG						
H00967	9.4	6.96	1.69	.66	.09	.00	74	18	7	1	0	0
H00968	7.9	5.37	1.90	.55	.08	.00	68	24	7	1	0	0
H00969	7.1	5.04	1.70	.36	.00	.00	71	24	5	0	0	0
H00970	8.7	5.74	2.00	.52	.44	.00	66	23	6	5	0	0
H00971	7.6	4.86	2.28	.30	.15	.00	64	30	4	2	0	0
H00972	9.8	7.35	1.57	.59	.29	.00	75	16	6	3	0	0
N=	6	6	6	6	6	6	6	6	6	6	6	6
MEAN	8.4	5.89	1.86	.50	.18	.00	70	22	6	2	0	0
S.D.	1.06	1.035	.259	.139	.162	.000	4.4	5.0	1.2	1.8	.0	.0
POOLED M+F GROUP: 1												
N=	12	12	12	12	12	12	12	12	12	12	12	12
MEAN M+F	7.9	5.46	1.90	.43	.12	.00	68	24	5	2	0	0
S.D. M+F	1.39	1.232	.366	.174	.135	.000	4.7	5.5	2.1	1.6	.0	.0

S6127111 DOG POOL M+F WEEK: 026

APPENDIX
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	WBC E3/CU MM	N-SEG E3/CU MM	L E3/CU MM	M E3/CU MM	E E3/CU MM	B E3/CU MM	N-SEG %	L %	M %	E %	B %	BANDS-N %
GROUP & SEX: 2M DOSE LEVEL: 250 DOSAGE UNIT: MG/KG												
H00973	8.5	6.29	1.87	.17	.17	.00	74	22	2	2	0	0
H00974	6.6	4.75	1.52	.26	.07	.00	72	23	4	1	0	0
H00975	6.5	4.68	1.04	.52	.26	.00	72	16	8	4	0	0
H00976	8.4	6.30	1.01	.67	.42	.00	75	12	8	5	0	0
H00977	9.2	7.45	1.38	.09	.28	.00	81	15	1	3	0	0
H00978	9.3	6.32	2.23	.56	.19	.00	68	24	6	2	0	0
N=	6	6	6	6	6	6	6	6	6	6	6	6
MEAN	8.1	5.96	1.51	.38	.23	.00	74	19	5	3	0	0
S.D.	1.24	1.066	.477	.236	.118	.000	4.3	5.0	3.0	1.5	.0	.0
GROUP & SEX: 2F DOSE LEVEL: 250 DOSAGE UNIT: MG/KG												
H00979	5.7	3.76	1.54	.28	.11	.00	66	27	5	2	0	0
H00980	6.6	3.96	2.51	.13	.00	.00	60	38	2	0	0	0
H00981	6.9	4.69	1.59	.28	.34	.00	68	23	4	5	0	0
H00982	7.7	5.47	1.62	.08	.54	.00	71	21	1	7	0	0
H00983	7.7	5.39	2.00	.23	.08	.00	70	26	3	1	0	0
H00984	7.6	6.16	.91	.53	.00	.00	81	12	7	0	0	0
N=	6	6	6	6	6	6	6	6	6	6	6	6
MEAN	7.0	4.90	1.70	.26	.18	.00	69	24	4	2	0	0
S.D.	.80	.936	.532	.157	.217	.000	6.9	8.5	2.2	2.9	.0	.0
POOLED M+F GROUP: 2												
N=	12	12	12	12	12	12	12	12	12	12	12	12
MEAN M+F	7.6	5.44	1.60	.32	.20	.00	72	22	4	3	0	0
S.D. M+F	1.14	1.105	.491	.202	.169	.000	5.9	7.3	2.6	2.2	.0	.0

S6127111 DOG POOL M+F WEEK: 026

APPENDIX
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	WBC E3/CU MM	N-SEG E3/CU MM	L E3/CU MM	M E3/CU MM	E E3/CU MM	B E3/CU MM	N-SEG %	L %	M %	E %	B %	BANDS-N %
GROUP & SEX: 3M DOSE LEVEL: 500 DOSAGE UNIT: MG/KG												
H00985	7.2	5.40	1.51	.14	.14	.00	75	21	2	2	0	0
H00986	9.1	6.82	2.00	.18	.09	.00	75	22	2	1	0	0
H00987	8.1	5.67	2.02	.32	.08	.00	70	25	4	1	0	0
H00988	7.5	5.55	1.50	.22	.22	.00	74	20	3	3	0	0
H00989	12.5	9.38	2.00	.50	.62	.00	75	16	4	5	0	0
H00990	7.2	5.04	1.66	.22	.29	.00	70	23	3	4	0	0
N=	6	6	6	6	6	6	6	6	6	6	6	6
MEAN	8.6	6.31	1.78	.26	.24	.00	73	21	3	3	0	0
S.D.	2.04	1.619	.253	.130	.203	.000	2.5	3.1	.9	1.6	.0	.0
GROUP & SEX: 3F DOSE LEVEL: 500 DOSAGE UNIT: MG/KG												
H00991	6.7	4.15	2.08	.34	.13	.00	62	31	5	2	0	0
H00992	6.9	4.90	1.86	.00	.14	.00	71	27	0	2	0	0
H00993	8.6	6.36	1.81	.26	.17	.00	74	21	3	2	0	0
H00994	5.8	3.83	1.62	.23	.12	.00	66	28	4	2	0	0
H00995	6.8	4.62	1.70	.14	.34	.00	68	25	2	5	0	0
H00996	7.4	5.25	1.63	.37	.15	.00	71	22	5	2	0	0
N=	6	6	6	6	6	6	6	6	6	6	6	6
MEAN	7.0	4.85	1.78	.22	.18	.00	69	26	3	2	0	0
S.D.	.93	.897	.174	.137	.083	.000	4.3	3.8	1.9	1.2	.0	.0
POOLED M+F GROUP: 3												
N=	12	12	12	12	12	12	12	12	12	12	12	12
MEAN M+F	7.8	5.58	1.78	.24	.21	.00	71	23	3	2	0	0
S.D. M+F	1.72	1.462	.207	.129	.151	.000	4.1	4.0	1.4	1.4	.0	.0

S6127111 DOG POOL M+F WEEK: 026

APPENDIX
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	WBC E3/CU MM	N-SEG E3/CU MM	L E3/CU MM	M E3/CU MM	E E3/CU MM	B E3/CU MM	N-SEG %	L %	M %	E %	B %	BANDS-N %
GROUP & SEX: 4M DOSE LEVEL: 1000 DOSAGE UNIT: MG/KG												
H00001	7.4	5.77	1.18	.22	.22	.00	78	16	3	3	0	0
H00002	7.3	5.77	1.31	.15	.07	.00	79	18	2	1	0	0
H00003	7.4	5.77	1.11	.07	.44	.00	78	15	1	6	0	0
H00997	6.3	4.16	1.58	.44	.13	.00	66	25	7	2	0	0
H00998	7.1	4.05	2.20	.57	.28	.00	57	31	8	4	0	0
H00999	7.2	5.62	1.08	.14	.36	.00	78	15	2	5	0	0
N=	6	6	6	6	6	6	6	6	6	6	6	6
MEAN	7.1	5.19	1.41	.26	.25	.00	73	20	4	4	0	0
S.D.	.42	.843	.428	.196	.139	.000	9.1	6.6	2.9	1.9	.0	.0
GROUP & SEX: 4F DOSE LEVEL: 1000 DOSAGE UNIT: MG/KG												
H00004	8.0	5.84	1.92	.16	.08	.00	73	24	2	1	0	0
H00005	7.0	4.69	1.54	.56	.21	.00	67	22	8	3	0	0
H00006	7.6	5.24	1.98	.23	.15	.00	69	26	3	2	0	0
H00007	6.4	4.48	1.86	.06	.00	.00	70	29	1	0	0	0
H00008	8.5	6.12	1.62	.17	.60	.00	72	19	2	7	0	0
H00009	9.4	4.70	4.04	.19	.47	.00	50	43	2	5	0	0
N=	6	6	6	6	6	6	6	6	6	6	6	6
MEAN	7.8	5.18	2.16	.23	.25	.00	67	27	3	3	0	0
S.D.	1.07	.676	.937	.172	.234	.000	8.5	8.5	2.5	2.6	.0	.0
POOLED M+F GROUP: 4												
N=	12	12	12	12	12	12	12	12	12	12	12	12
MEAN M+F	7.5	5.18	1.78	.25	.25	.00	70	24	3	3	0	0
S.D. M+F	.86	.728	.797	.177	.184	.000	8.9	8.1	2.6	2.2	.0	.0

APPENDIX
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	BANDS-N E3/CU MM	PT SEC	PTT SEC
GROUP & SEX: 1M	DOSE LEVEL: 0		DOSAGE UNIT: MG/KG
H00961	.00	10.9	9.9
H00962	.00	5.9	10.4
H00963	.00	6.4	10.4
H00964	.00	10.9	9.4
H00965	.00	5.9	10.8
H00966	.00	5.9	10.9
N=	6	6	6
MEAN	.00	7.6	10.3
S.D.	.000	2.52	.56
GROUP & SEX: 1F	DOSE LEVEL: 0		DOSAGE UNIT: MG/KG
H00967	.00	6.4	11.4
H00968	.00	6.4	12.4
H00969	.00	6.4	11.9
H00970	.00	6.4	11.4
H00971	.00	6.4	11.9
H00972	.00	6.9	11.8
N=	6	6	6
MEAN	.00	6.5	11.8
S.D.	.000	.20	.37
POOLED M+F GROUP: 1			
N=	12	12	12
MEAN M+F	.00	7.1	11.0
S.D. M+F	.000	1.81	.91

APPENDIX
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	BANDS-N E3/CU MM	PT SEC	PTT SEC
GROUP & SEX: 2M	DOSE LEVEL: 250		DOSAGE UNIT: MG/KG
H00973	.00	10.9	10.9
H00974	.00	6.4	10.3
H00975	.00	6.4	13.4
H00976	.00	6.4	12.9
H00977	.00	6.4	11.3
H00978	.00	6.4	11.9
N=	6	6	6
MEAN	.00	7.2	11.8
S.D.	.000	1.84	1.19
GROUP & SEX: 2F	DOSE LEVEL: 250		DOSAGE UNIT: MG/KG
H00979	.00	6.4	12.9
H00980	.00	11.4	11.4
H00981	.00	6.4	11.4
H00982	.00	6.9	13.9
H00983	.00	6.4	14.4
H00984	.00	5.9	12.9
N=	6	6	6
MEAN	.00	7.2	12.8
S.D.	.000	2.06	1.24
POOLED M+F GROUP: 2			
N=	12	12	12
MEAN M+F	.00	7.2	12.3
S.D. M+F	.000	1.86	1.28

APPENDIX
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	BANDS-N E3/CU MM	PT SEC	PTT SEC
GROUP & SEX: 3M	DOSE LEVEL: 500		DOSAGE UNIT: MG/KG
H00985	.00	6.4	10.8
H00986	.00	6.4	11.9
H00987	.00	6.9	9.9
H00988	.00	6.9	14.4
H00989	.00	7.4	13.9
H00990	.00	6.4	12.4
N=	6	6	6
MEAN	.00	6.7	12.2
S.D.	.000	.41	1.74
GROUP & SEX: 3F	DOSE LEVEL: 500		DOSAGE UNIT: MG/KG
H00991	.00	10.9	11.4
H00992	.00	5.9	11.9
H00993	.00	6.4	11.9
H00994	.00	6.4	11.4
H00995	.00	6.3	11.9
H00996	.00	6.3	10.9
N=	6	6	6
MEAN	.00	7.0	11.6
S.D.	.000	1.90	.41
POOLED M+F GROUP: 3			
N=	12	12	12
MEAN M+F	.00	6.9	11.9
S.D. M+F	.000	1.32	1.25

APPENDIX
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	BANDS-N E3/CU MM	PT SEC	PTT SEC
GROUP & SEX: 4M	DOSE LEVEL: 1000		DOSAGE UNIT: MG/KG
H00001	.00	6.4	10.9
H00002	.00	5.9	11.4
H00003	.00	6.4	11.9
H00997	.00	6.4	10.9
H00998	.00	7.4	11.4
H00999	.00	6.4	11.4
N=	6	6	6
MEAN	.00	6.5	11.3
S.D.	.000	.49	.38
GROUP & SEX: 4F	DOSE LEVEL: 1000		DOSAGE UNIT: MG/KG
H00004	.00	6.3	12.4
H00005	.00	6.3	11.9
H00006	.00	6.9	11.9
H00007	.00	6.4	11.4
H00008	.00	5.9	11.4
H00009	.00	6.4	11.4
N=	6	6	6
MEAN	.00	6.4	11.7
S.D.	.000	.32	.41
POOLED M+F GROUP: 4			
N=	12	12	12
MEAN M+F	.00	6.4	11.5
S.D. M+F	.000	.40	.43

S6127111 DOG POOL M+F WEEK: 031

APPENDIX
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	RBC E6/CU MM	HGB G/DL	HCT %	MCV FL	MCH PICO GMS	MCHC %	PLT E3/CU MM	NRBC /100 WBC
GROUP & SEX: 1M DOSE LEVEL: 0				DOSAGE UNIT: MG/KG				
H00964	5.80	13.8	41.3	71	23.8	33.4	431	0
H00965	6.35	14.9	45.4	71	23.5	32.8	366	0
N=	2	2	2	2	2	2	2	2
MEAN	6.08	14.3	43.4	71	23.6	33.1	398	0
S.D.	.389	.78	2.90	.0	.21	.42	46.0	.0
GROUP & SEX: 1F DOSE LEVEL: 0				DOSAGE UNIT: MG/KG				
H00971	6.43	14.6	44.8	70	22.7	32.6	456	0
H00972	6.98	16.4	49.3	71	23.5	33.3	382	0
N=	2	2	2	2	2	2	2	2
MEAN	6.70	15.5	47.0	70	23.1	33.0	419	0
S.D.	.389	1.27	3.18	.7	.56	.49	52.3	.0
POOLED M+F GROUP: 1								
N=	4	4	4	4	4	4	4	4
MEAN M+F	6.39	14.9	45.2	71	23.4	33.0	409	0
S.D. M+F	.483	1.09	3.28	.5	.47	.39	41.9	.0

S6127111 DOG POOL M+F WEEK: 031

APPENDIX
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	RBC E6/CU MM	HGB G/DL	HCT %	MCV FL	MCH PICO GMS	MCHC %	PLT E3/CU MM	NRBC /100 WBC
GROUP & SEX: 2M DOSE LEVEL: 250 DOSAGE UNIT: MG/KG								
H00973	6.60	15.4	46.9	71	23.3	32.8	350	0
H00977	6.84	14.9	45.2	66	21.8	33.0	317	0
N=	2	2	2	2	2	2	2	2
MEAN	6.72	15.2	46.0	68	22.5	32.9	334	0
S.D.	.170	.35	1.20	3.5	1.06	.14	23.3	.0
GROUP & SEX: 2F DOSE LEVEL: 250 DOSAGE UNIT: MG/KG								
H00979	5.95	13.8	43.3	73	23.2	31.9	266	0
H00981	6.53	14.9	44.4	68	22.8	33.6	322	0
N=	2	2	2	2	2	2	2	2
MEAN	6.24	14.3	43.8	70	23.0	32.8	294	0
S.D.	.410	.78	.78	3.5	.28	1.20	39.6	.0
POOLED M+F GROUP: 2								
N=	4	4	4	4	4	4	4	4
MEAN M+F	6.48	14.8	45.0	70	22.8	32.8	314	0
S.D. M+F	.377	.68	1.52	3.1	.68	.70	35.0	.0

APPENDIX
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	RBC E6/CU MM	HGB G/DL	HCT %	MCV FL	MCH PICO GMS	MCHC %	PLT E3/CU MM	NRBC /100 WBC
GROUP & SEX: 3M DOSE LEVEL: 500 DOSAGE UNIT: MG/KG								
H00988	6.70	15.3	47.5	71	22.8	32.2	326	0
H00990	6.57	15.5	47.2	72	23.6	32.8	288	0
N=	2	2	2	2	2	2	2	2
MEAN	6.64	15.4	47.3	72	23.2	32.5	307	0
S.D.	.092	.14	.21	.7	.56	.42	26.9	.0
GROUP & SEX: 3F DOSE LEVEL: 500 DOSAGE UNIT: MG/KG								
H00995	6.33	14.6	44.8	71	23.1	32.6	338	0
H00996	5.85	14.6	43.0	74	25.0	34.0	398	0
N=	2	2	2	2	2	2	2	2
MEAN	6.09	14.6	43.9	72	24.0	33.3	368	0
S.D.	.339	.00	1.27	2.1	1.34	.99	42.4	.0
POOLED M+F GROUP: 3								
N=	4	4	4	4	4	4	4	4
MEAN M+F	6.36	15.0	45.6	72	23.6	32.9	338	0
S.D. M+F	.374	.47	2.13	1.4	.97	.77	45.6	.0

S6127111 DOG POOL M+F WEEK: 031

APPENDIX
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	RBC E6/CU MM	HGB G/DL	HCT %	MCV FL	MCH PICO GMS	MCHC %	PLT E3/CU MM	NRBC /100 WBC
GROUP & SEX: 4M DOSE LEVEL: 1000 DOSAGE UNIT: MG/KG								
H00001	6.40	15.2	44.7	70	23.8	34.0	343	0
H00998	6.17	14.8	43.8	71	24.0	33.8	340	0
N=	2	2	2	2	2	2	2	2
MEAN	6.28	15.0	44.2	70	23.9	33.9	342	0
S.D.	.163	.28	.64	.7	.14	.14	2.1	.0
GROUP & SEX: 4F DOSE LEVEL: 1000 DOSAGE UNIT: MG/KG								
H00005	6.67	15.0	45.7	69	22.5	32.8	365	0
H00006	7.22	16.3	50.3	70	22.6	32.4	364	0
N=	2	2	2	2	2	2	2	2
MEAN	6.94	15.6	48.0	70	22.5	32.6	364	0
S.D.	.389	.92	3.25	.7	.07	.28	.7	.0
POOLED M+F GROUP: 4								
N=	4	4	4	4	4	4	4	4
MEAN M+F	6.62	15.3	46.1	70	23.2	33.2	353	0
S.D. M+F	.452	.67	2.89	.8	.78	.77	13.3	.0

APPENDIX
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	WBC E3/CU MM	N-SEG E3/CU MM	L E3/CU MM	M E3/CU MM	E E3/CU MM	B E3/CU MM	N-SEG %	L %	M %	E %	B %	BANDS-N %
GROUP & SEX: 1M DOSE LEVEL: 0 DOSAGE UNIT: MG/KG												
H00964	8.2	5.41	2.05	.41	.33	.00	66	25	5	4	0	0
H00965	9.7	5.63	3.40	.19	.48	.00	58	35	2	5	0	0
N=	2	2	2	2	2	2	2	2	2	2	2	2
MEAN	9.0	5.52	2.72	.30	.40	.00	62	30	4	4	0	0
S.D.	1.06	.156	.954	.156	.106	.000	5.6	7.1	2.1	.7	.0	.0
GROUP & SEX: 1F DOSE LEVEL: 0 DOSAGE UNIT: MG/KG												
H00971	9.9	6.53	3.07	.20	.10	.00	66	31	2	1	0	0
H00972	12.5	8.50	2.62	.88	.50	.00	68	21	7	4	0	0
N=	2	2	2	2	2	2	2	2	2	2	2	2
MEAN	11.2	7.52	2.84	.54	.30	.00	67	26	4	2	0	0
S.D.	1.84	1.393	.318	.481	.283	.000	1.4	7.1	3.5	2.1	.0	.0
POOLED M+F GROUP: 1												
N=	4	4	4	4	4	4	4	4	4	4	4	4
MEAN M+F	10.1	6.52	2.78	.42	.35	.00	64	28	4	4	0	0
S.D. M+F	1.78	1.408	.585	.323	.185	.000	4.4	6.2	2.4	1.7	.0	.0

APPENDIX
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	WBC E3/CU MM	N-SEG E3/CU MM	L E3/CU MM	M E3/CU MM	E E3/CU MM	B E3/CU MM	N-SEG %	L %	M %	E %	B %	BANDS-N %
GROUP & SEX: 2M DOSE LEVEL: 250 DOSAGE UNIT: MG/KG												
H00973	11.7	8.19	2.81	.70	.00	.00	70	24	6	0	0	0
H00977	13.5	9.04	3.64	.40	.40	.00	67	27	3	3	0	0
N=	2	2	2	2	2	2	2	2	2	2	2	2
MEAN	12.6	8.62	3.22	.55	.20	.00	68	26	4	2	0	0
S.D.	1.27	.601	.587	.212	.283	.000	2.1	2.1	2.1	2.1	.0	.0
GROUP & SEX: 2F DOSE LEVEL: 250 DOSAGE UNIT: MG/KG												
H00979	8.6	5.59	2.41	.34	.26	.00	65	28	4	3	0	0
H00981	8.9	5.70	2.58	.36	.27	.00	64	29	4	3	0	0
N=	2	2	2	2	2	2	2	2	2	2	2	2
MEAN	8.8	5.64	2.50	.35	.26	.00	64	28	4	3	0	0
S.D.	.21	.078	.120	.014	.007	.000	.7	.7	.0	.0	.0	.0
POOLED M+F GROUP: 2												
N=	4	4	4	4	4	4	4	4	4	4	4	4
MEAN M+F	10.7	7.13	2.86	.45	.23	.00	66	27	4	2	0	0
S.D. M+F	2.34	1.750	.545	.168	.168	.000	2.6	2.2	1.2	1.5	.0	.0

APPENDIX
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	WBC E3/CU MM	N-SEG E3/CU MM	L E3/CU MM	M E3/CU MM	E E3/CU MM	B E3/CU MM	N-SEG %	L %	M %	E %	B %	BANDS-N %
GROUP & SEX: 3M DOSE LEVEL: 500 DOSAGE UNIT: MG/KG												
H00988	10.3	7.00	2.37	.41	.52	.00	68	23	4	5	0	0
H00990	8.3	5.73	1.91	.33	.33	.00	69	23	4	4	0	0
N=	2	2	2	2	2	2	2	2	2	2	2	2
MEAN	9.3	6.36	2.14	.37	.42	.00	68	23	4	4	0	0
S.D.	1.41	.898	.325	.056	.134	.000	.7	.0	.0	.7	.0	.0
GROUP & SEX: 3F DOSE LEVEL: 500 DOSAGE UNIT: MG/KG												
H00995	9.0	5.85	2.43	.27	.45	.00	65	27	3	5	0	0
H00996	9.4	6.39	2.63	.28	.09	.00	68	28	3	1	0	0
N=	2	2	2	2	2	2	2	2	2	2	2	2
MEAN	9.2	6.12	2.53	.28	.27	.00	66	28	3	3	0	0
S.D.	.28	.382	.141	.007	.254	.000	2.1	.7	.0	2.8	.0	.0
POOLED M+F GROUP: 3												
N=	4	4	4	4	4	4	4	4	4	4	4	4
MEAN M+F	9.2	6.24	2.34	.32	.35	.00	68	25	4	4	0	0
S.D. M+F	.83	.581	.304	.064	.189	.000	1.7	2.6	.6	1.9	.0	.0

APPENDIX
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	WBC E3/CU MM	N-SEG E3/CU MM	L E3/CU MM	M E3/CU MM	E E3/CU MM	B E3/CU MM	N-SEG %	L %	M %	E %	B %	BANDS-N %
GROUP & SEX: 4M DOSE LEVEL: 1000 DOSAGE UNIT: MG/KG												
H00001	7.8	4.76	2.18	.31	.55	.00	61	28	4	7	0	0
H00998	11.1	5.88	4.33	.56	.33	.00	53	39	5	3	0	0
N=	2	2	2	2	2	2	2	2	2	2	2	2
MEAN	9.4	5.32	3.26	.44	.44	.00	57	34	4	5	0	0
S.D.	2.33	.792	1.520	.177	.156	.000	5.6	7.8	.7	2.8	.0	.0
GROUP & SEX: 4F DOSE LEVEL: 1000 DOSAGE UNIT: MG/KG												
H00005	8.7	6.09	1.74	.61	.26	.00	70	20	7	3	0	0
H00006	9.8	7.06	2.45	.00	.29	.00	72	25	0	3	0	0
N=	2	2	2	2	2	2	2	2	2	2	2	2
MEAN	9.2	6.58	2.10	.30	.28	.00	71	22	4	3	0	0
S.D.	.78	.686	.502	.431	.021	.000	1.4	3.5	4.9	.0	.0	.0
POOLED M+F GROUP: 4												
N=	4	4	4	4	4	4	4	4	4	4	4	4
MEAN M+F	9.4	5.95	2.68	.37	.36	.00	64	28	4	4	0	0
S.D. M+F	1.42	.944	1.141	.279	.131	.000	8.8	8.0	2.9	2.0	.0	.0

APPENDIX
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	BANDS-N E3/CU MM	PT SEC	PTT SEC
GROUP & SEX: 1M	DOSE LEVEL: 0		DOSAGE UNIT: MG/KG
H00964	.00	10.9	9.4
H00965	.00	5.9	10.9
N=	2	2	2
MEAN	.00	8.4	10.2
S.D.	.000	3.54	1.06
GROUP & SEX: 1F	DOSE LEVEL: 0		DOSAGE UNIT: MG/KG
H00971	.00	6.4	11.9
H00972	.00	6.9	12.3
N=	2	2	2
MEAN	.00	6.6	12.1
S.D.	.000	.35	.28
POOLED M+F GROUP: 1			
N=	4	4	4
MEAN M+F	.00	7.5	11.1
S.D. M+F	.000	2.29	1.29

APPENDIX
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	BANDS-N E3/CU MM	PT SEC	PTT SEC
GROUP & SEX: 2M	DOSE LEVEL: 250		DOSAGE UNIT: MG/KG
H00973	.00	10.4	10.8
H00977	.00	6.4	11.8
N=	2	2	2
MEAN	.00	8.4	11.3
S.D.	.000	2.83	.71
GROUP & SEX: 2F	DOSE LEVEL: 250		DOSAGE UNIT: MG/KG
H00979	.00	6.4	9.9
H00981	.00	6.4	12.9
N=	2	2	2
MEAN	.00	6.4	11.4
S.D.	.000	.00	2.12
POOLED M+F GROUP: 2			
N=	4	4	4
MEAN M+F	.00	7.4	11.3
S.D. M+F	.000	2.00	1.29

APPENDIX
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	BANDS-N E3/CU MM	PT SEC	PTT SEC
GROUP & SEX: 3M	DOSE LEVEL: 500		DOSAGE UNIT: MG/KG
H00988	.00	5.9	11.3
H00990	.00	5.9	10.9
N=	2	2	2
MEAN	.00	5.9	11.1
S.D.	.000	.00	.28
GROUP & SEX: 3F	DOSE LEVEL: 500		DOSAGE UNIT: MG/KG
H00995	.00	6.4	12.4
H00996	.00	6.4	11.3
N=	2	2	2
MEAN	.00	6.4	11.8
S.D.	.000	.00	.78
POOLED M+F GROUP: 3			
N=	4	4	4
MEAN M+F	.00	6.2	11.5
S.D. M+F	.000	.29	.64

APPENDIX
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	BANDS-N E3/CU MM	PT SEC	PTT SEC
GROUP & SEX: 4M	DOSE LEVEL: 1000		DOSAGE UNIT: MG/KG
H00001	.00	5.9	9.8
H00998	.00	6.8	10.4
N=	2	2	2
MEAN	.00	6.4	10.1
S.D.	.000	.64	.42
GROUP & SEX: 4F	DOSE LEVEL: 1000		DOSAGE UNIT: MG/KG
H00005	.00	5.9	9.9
H00006	.00	6.4	11.9
N=	2	2	2
MEAN	.00	6.2	10.9
S.D.	.000	.35	1.41
POOLED M+F GROUP: 4			
N=	4	4	4
MEAN M+F	.00	6.2	10.5
S.D. M+F	.000	.44	.97

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APPENDIX H

Individual Clinical Chemistry Data

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S6127111 DOG POOL M+F WEEK: -02

APPENDIX
INDIVIDUAL CLINICAL CHEMISTRY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 AD MIXED IN DIET

ANIMAL NUMBER	GLU MG/DL	T PRO G/DL	ALB G/DL	GLOB G/DL	A/G	T BILI MG/DL	CHOL MG/DL	AST/SGOT IU/L	ALT/SGPT IU/L	ALK PHOS IU/L
GROUP & SEX: 1M DOSE LEVEL: 0				DOSAGE UNIT: MG/KG						
H00961	106.7	5.2	3.2	1.9	1.7	.0	151	20	18	85
H00962	101.2	5.2	3.0	2.2	1.4	.0	113	23	20	59
H00963	106.5	5.3	3.5	1.8	1.9	.0	174	20	27	80
H00964	104.2	5.1	2.9	2.2	1.4	.0	161	22	22	82
H00965	108.8	5.0	3.3	1.7	1.9	.0	106	18	21	99
H00966	97.5	5.1	3.2	1.9	1.7	.0	121	18	23	71
N=	6	6	6	6	6	6	6	6	6	6
MEAN	104.1	5.2	3.2	2.0	1.7	.0	138	20	22	79
S.D.	4.16	.10	.21	.21	.22	.00	28.0	2.0	3.1	13.5
GROUP & SEX: 1F DOSE LEVEL: 0				DOSAGE UNIT: MG/KG						
H00967	114.6	5.4	3.3	2.1	1.5	.0	115	20	27	61
H00968	105.8	5.2	3.5	1.8	1.9	.0	107	19	20	77
H00969	103.3	4.9	3.2	1.7	1.9	.0	121	18	18	70
H00970	116.1	5.4	3.4	2.0	1.7	.0	116	17	23	92
H00971	101.4	5.4	3.1	2.2	1.4	.1	85	22	25	107
H00972	108.2	5.8	3.6	2.2	1.6	.0	106	23	21	101
N=	6	6	6	6	6	6	6	6	6	6
MEAN	108.2	5.4	3.4	2.0	1.7	.0	108	20	22	85
S.D.	5.99	.29	.19	.21	.21	.04	12.8	2.3	3.3	18.2
POOLED M+F GROUP: 1										
N=	12	12	12	12	12	12	12	12	12	12
MEAN M+F	106.2	5.2	3.3	2.0	1.7	.0	123	20	22	82
S.D. M+F	5.36	.24	.21	.20	.20	.03	25.8	2.1	3.0	15.5

S6127111 DOG POOL M+F WEEK: -02

APPENDIX
INDIVIDUAL CLINICAL CHEMISTRY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 AD MIXED IN DIET

ANIMAL NUMBER	GLU MG/DL	T PRO G/DL	ALB G/DL	GLOB G/DL	A/G	T BILI MG/DL	CHOL MG/DL	AST/SGOT IU/L	ALT/SGPT IU/L	ALK PHOS IU/L
GROUP & SEX: 2M DOSE LEVEL: 250 DOSAGE UNIT: MG/KG										
H00973	103.1	5.7	3.4	2.4	1.4	.0	156	21	21	111
H00974	112.8	6.0	3.7	2.3	1.6	.0	192	23	21	68
H00975	113.4	6.0	3.3	2.8	1.2	.0	125	18	26	65
H00976	115.2	6.0	3.4	2.6	1.3	.0	114	25	26	69
H00977	105.0	5.7	3.2	2.5	1.3	.0	129	19	22	67
H00978	111.2	5.8	3.8	2.1	1.8	.0	144	16	22	54
N=	6	6	6	6	6	6	6	6	6	6
MEAN	110.1	5.9	3.5	2.4	1.4	.0	143	20	23	72
S.D.	4.91	.15	.23	.24	.22	.00	28.0	3.3	2.4	19.7
GROUP & SEX: 2F DOSE LEVEL: 250 DOSAGE UNIT: MG/KG										
H00979	109.6	5.2	3.1	2.1	1.5	.2	122	20	23	63
H00980	107.4	5.7	3.6	2.1	1.8	.0	159	20	22	101
H00981	114.1	5.5	3.3	2.2	1.5	.0	116	20	21	53
H00982	105.1	5.5	3.5	2.0	1.7	.0	139	24	26	79
H00983	104.2	5.4	3.5	1.9	1.8	.0	104	15	21	83
H00984	111.6	5.6	3.5	2.1	1.6	.1	155	17	24	59
N=	6	6	6	6	6	6	6	6	6	6
MEAN	108.7	5.5	3.4	2.1	1.6	.0	132	19	23	73
S.D.	3.83	.17	.18	.10	.14	.08	22.1	3.1	1.9	18.0
POOLED M+F GROUP: 2										
N=	12	12	12	12	12	12	12	12	12	12
MEAN M+F	109.4	5.7	3.4	2.2	1.5	.0	138	20	23	73
S.D. M+F	4.26	.25	.20	.27	.21	.06	24.7	3.1	2.1	18.0

S6127111 DOG POOL M+F WEEK: -02

APPENDIX
INDIVIDUAL CLINICAL CHEMISTRY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 AD MIXED IN DIET

ANIMAL NUMBER	GLU MG/DL	T PRO G/DL	ALB G/DL	GLOB G/DL	A/G	T BILI MG/DL	CHOL MG/DL	AST/SGOT IU/L	ALT/SGPT IU/L	ALK PHOS IU/L
GROUP & SEX: 3M DOSE LEVEL: 500					DOSAGE UNIT: MG/KG					
H00985	114.3	5.0	3.2	1.9	1.7	.0	136	19	20	58
H00986	107.6	5.0	3.2	1.8	1.7	.0	89	20	24	75
H00987	111.9	5.4	3.4	2.0	1.7	.0	136	17	21	89
H00988	108.8	5.4	3.6	1.7	2.1	.0	138	19	20	54
H00989	112.7	5.8	3.2	2.6	1.2	.3	92	23	24	111
H00990	94.1	4.9	3.2	1.7	1.9	.0	111	19	22	82
N=	6	6	6	6	6	6	6	6	6	6
MEAN	108.2	5.2	3.3	2.0	1.7	.0	117	20	22	78
S.D.	7.36	.34	.17	.34	.30	.12	22.8	2.0	1.8	21.0
GROUP & SEX: 3F DOSE LEVEL: 500					DOSAGE UNIT: MG/KG					
H00991	103.8	5.9	3.8	2.2	1.7	.1	194	19	24	122
H00992	113.3	5.2	3.4	1.8	1.9	.0	94	19	24	84
H00993	103.2	5.5	3.4	2.1	1.7	.0	113	22	23	86
H00994	108.7	5.8	3.6	2.2	1.7	.4	104	24	22	65
H00995	108.7	5.8	3.7	2.1	1.7	.1	118	19	21	67
H00996	103.7	5.3	3.0	2.3	1.3	.0	147	19	22	70
N=	6	6	6	6	6	6	6	6	6	6
MEAN	106.9	5.6	3.5	2.1	1.7	.1	128	20	23	82
S.D.	4.02	.29	.28	.17	.20	.15	36.8	2.2	1.2	21.3
POOLED M+F GROUP: 3										
N=	12	12	12	12	12	12	12	12	12	12
MEAN M+F	107.6	5.4	3.4	2.0	1.7	.1	123	20	22	80
S.D. M+F	5.70	.35	.24	.27	.24	.14	29.8	2.0	1.5	20.3

S6127111 DOG POOL M+F WEEK: -02

APPENDIX
INDIVIDUAL CLINICAL CHEMISTRY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 AD MIXED IN DIET

ANIMAL NUMBER	GLU MG/DL	T PRO G/DL	ALB G/DL	GLOB G/DL	A/G	T BILI MG/DL	CHOL MG/DL	AST/SGOT IU/L	ALT/SGPT IU/L	ALK PHOS IU/L
GROUP & SEX: 4M DOSE LEVEL: 1000 DOSAGE UNIT: MG/KG										
H00001	105.4	5.0	3.2	1.8	1.8	.0	174	17	32	77
H00002	102.2	5.1	3.0	2.1	1.4	.0	155	21	33	83
H00003	115.4	5.8	3.1	2.8	1.1	.0	129	18	26	64
H00997	115.8	5.5	3.3	2.3	1.4	.0	129	20	29	89
H00998	107.4	5.3	3.3	2.0	1.6	.0	156	18	24	86
H00999	106.6	5.5	3.1	2.4	1.3	.0	108	18	27	73
N=	6	6	6	6	6	6	6	6	6	6
MEAN	108.8	5.4	3.2	2.2	1.4	.0	142	19	28	79
S.D.	5.56	.29	.12	.35	.24	.00	24.0	1.5	3.5	9.3
GROUP & SEX: 4F DOSE LEVEL: 1000 DOSAGE UNIT: MG/KG										
H00004	104.1	5.5	3.2	2.3	1.4	.0	94	18	18	62
H00005	103.8	5.2	3.2	2.0	1.6	.0	168	17	28	91
H00006	107.0	5.5	3.6	1.9	1.9	.2	114	19	23	74
H00007	104.8	5.3	3.2	2.1	1.5	.0	128	21	23	71
H00008	120.2	5.5	3.2	2.2	1.4	.2	141	19	21	81
H00009	114.1	5.5	3.3	2.3	1.5	.0	126	22	22	92
N=	6	6	6	6	6	6	6	6	6	6
MEAN	109.0	5.4	3.3	2.1	1.6	.1	128	19	22	78
S.D.	6.70	.13	.16	.16	.19	.10	25.0	1.9	3.3	11.8
POOLED M+F GROUP: 4										
N=	12	12	12	12	12	12	12	12	12	12
MEAN M+F	108.9	5.4	3.2	2.2	1.5	.0	135	19	26	78
S.D. M+F	5.87	.22	.15	.26	.22	.08	24.4	1.6	4.5	10.1

S6127111 DOG POOL M+F WEEK: -02

APPENDIX
INDIVIDUAL CLINICAL CHEMISTRY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 AD MIXED IN DIET

ANIMAL NUMBER	UN MG/DL	CREAT MG/DL	CA MG/DL	NA MMOL/L	K MMOL/L	CL MMOL/L
GROUP & SEX: 1M	DOSE LEVEL: 0			DOSAGE UNIT: MG/KG		
H00961	11.5	.7	11.3	142	4.7	105
H00962	10.6	.8	10.5	140	4.6	105
H00963	9.4	.7	10.7	144	4.5	107
H00964	10.5	.7	11.3	145	5.0	107
H00965	9.2	.9	10.6	143	4.7	106
H00966	8.8	.6	10.7	143	4.5	106
N=	6	6	6	6	6	6
MEAN	10.0	.7	10.8	143	4.7	106
S.D.	1.03	.10	.36	1.7	.19	.9
GROUP & SEX: 1F	DOSE LEVEL: 0			DOSAGE UNIT: MG/KG		
H00967	8.8	.7	10.7	141	4.7	109
H00968	9.5	.7	10.8	141	4.5	108
H00969	11.6	.8	11.4	142	4.7	109
H00970	7.8	.9	10.8	142	4.4	111
H00971	11.2	.7	11.0	144	4.5	112
H00972	10.8	.8	11.0	145	5.2	113
N=	6	6	6	6	6	6
MEAN	10.0	.8	11.0	142	4.7	110
S.D.	1.49	.08	.25	1.6	.29	2.0
POOLED M+F GROUP: 1						
N=	12	12	12	12	12	12
MEAN M+F	10.0	.8	10.9	143	4.7	108
S.D. M+F	1.22	.09	.30	1.6	.23	2.7

S6127111 DOG POOL M+F WEEK: -02

APPENDIX
INDIVIDUAL CLINICAL CHEMISTRY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 AD MIXED IN DIET

ANIMAL NUMBER	UN MG/DL	CREAT MG/DL	CA MG/DL	NA MMOL/L	K MMOL/L	CL MMOL/L
GROUP & SEX: 2M	DOSE LEVEL: 250		DOSAGE UNIT: MG/KG			
H00973	10.9	.8	10.8	144	4.8	106
H00974	10.9	.8	11.0	143	4.7	104
H00975	9.4	.7	10.9	141	5.2	105
H00976	11.3	.7	10.6	144	4.6	105
H00977	8.5	.8	10.6	143	4.8	106
H00978	11.5	.8	11.0	144	4.8	104
N=	6	6	6	6	6	6
MEAN	10.4	.8	10.8	143	4.8	105
S.D.	1.19	.05	.18	1.2	.20	.9
GROUP & SEX: 2F	DOSE LEVEL: 250		DOSAGE UNIT: MG/KG			
H00979	15.7	.7	11.1	144	4.9	111
H00980	14.6	.9	11.2	143	5.1	110
H00981	9.5	.7	11.3	144	4.7	111
H00982	8.5	.7	11.0	141	4.6	108
H00983	9.1	.7	10.7	143	4.7	110
H00984	9.4	.7	11.2	141	4.4	108
N=	6	6	6	6	6	6
MEAN	11.1	.7	11.1	143	4.7	110
S.D.	3.15	.08	.21	1.4	.24	1.4
POOLED M+F GROUP: 2						
N=	12	12	12	12	12	12
MEAN M+F	10.8	.8	11.0	143	4.8	107
S.D. M+F	2.30	.07	.24	1.2	.22	2.7

APPENDIX
INDIVIDUAL CLINICAL CHEMISTRY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 AD MIXED IN DIET

ANIMAL NUMBER	UN MG/DL	CREAT MG/DL	CA MG/DL	NA MMOL/L	K MMOL/L	CL MMOL/L
GROUP & SEX: 3M DOSE LEVEL: 500 DOSAGE UNIT: MG/KG						
H00985	8.4	.7	10.7	141	4.4	105
H00986	11.9	.7	10.7	143	4.6	106
H00987	8.0	.8	10.6	142	5.0	107
H00988	9.8	.8	10.5	143	4.6	105
H00989	10.1	.8	11.1	145	5.7	107
H00990	11.0	.6	10.7	143	4.7	107
N=	6	6	6	6	6	6
MEAN	9.9	.7	10.7	143	4.8	106
S.D.	1.49	.08	.20	1.3	.47	1.0
GROUP & SEX: 3F DOSE LEVEL: 500 DOSAGE UNIT: MG/KG						
H00991	8.9	.8	11.3	143	4.8	108
H00992	8.4	.6	11.1	142	4.4	109
H00993	15.2	.8	11.2	144	4.5	111
H00994	12.6	.7	11.3	143	4.8	111
H00995	13.5	.8	11.0	144	4.7	110
H00996	10.9	.9	10.9	143	5.1	110
N=	6	6	6	6	6	6
MEAN	11.6	.8	11.1	143	4.7	110
S.D.	2.67	.10	.16	.8	.25	1.2
POOLED M+F GROUP: 3						
N=	12	12	12	12	12	12
MEAN M+F	10.7	.8	10.9	143	4.8	108
S.D. M+F	2.25	.09	.28	1.0	.36	2.2

S6127111 DOG POOL M+F WEEK: -02

APPENDIX
INDIVIDUAL CLINICAL CHEMISTRY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 AD MIXED IN DIET

ANIMAL NUMBER	UN MG/DL	CREAT MG/DL	CA MG/DL	NA MMOL/L	K MMOL/L	CL MMOL/L
GROUP & SEX: 4M	DOSE LEVEL: 1000		DOSAGE UNIT: MG/KG			
H00001	8.9	.7	10.5	144	4.9	106
H00002	9.6	.7	10.6	142	4.9	105
H00003	7.2	.8	10.4	143	4.6	106
H00997	11.9	.8	11.4	145	5.2	106
H00998	10.6	.8	11.0	143	5.0	106
H00999	8.7	.7	10.5	143	4.6	107
N=	6	6	6	6	6	6
MEAN	9.5	.8	10.7	143	4.9	106
S.D.	1.63	.05	.39	1.0	.23	.6
GROUP & SEX: 4F	DOSE LEVEL: 1000		DOSAGE UNIT: MG/KG			
H00004	9.3	.7	10.7	143	5.2	109
H00005	9.8	.8	10.9	143	4.8	110
H00006	10.4	.6	10.9	141	4.6	110
H00007	10.2	.7	11.2	143	4.9	109
H00008	13.6	.9	10.6	144	4.7	110
H00009	12.6	.8	10.8	143	5.4	111
N=	6	6	6	6	6	6
MEAN	11.0	.8	10.8	143	4.9	110
S.D.	1.71	.10	.21	1.0	.31	.8
POOLED M+F GROUP: 4						
N=	12	12	12	12	12	12
MEAN M+F	10.2	.8	10.8	143	4.9	108
S.D. M+F	1.78	.08	.30	1.0	.26	2.1

S6127111 DOG POOL M+F WEEK: 008

APPENDIX
INDIVIDUAL CLINICAL CHEMISTRY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	GLU MG/DL	T PRO G/DL	ALB G/DL	GLOB G/DL	A/G	T BILI MG/DL	CHOL MG/DL	AST/SGOT IU/L	ALT/SGPT IU/L	ALK PHOS IU/L
GROUP & SEX: 1M DOSE LEVEL: 0				DOSAGE UNIT: MG/KG						
H00961	105.8	5.9	3.0	2.9	1.1	.1	142	24	29	55
H00962	94.6	6.2	3.3	3.0	1.1	.2	101	23	28	34
H00963	101.9	5.9	3.7	2.2	1.7	.2	135	20	35	50
H00964	93.7	6.1	3.2	2.9	1.1	.1	120	24	22	57
H00965	85.3	5.7	3.2	2.4	1.3	.2	102	25	25	63
H00966	98.9	5.8	3.5	2.4	1.5	.1	112	21	25	44
N=	6	6	6	6	6	6	6	6	6	6
MEAN	96.7	5.9	3.3	2.6	1.3	.2	119	23	27	50
S.D.	7.18	.19	.25	.34	.25	.05	17.0	1.9	4.5	10.3
GROUP & SEX: 1F DOSE LEVEL: 0				DOSAGE UNIT: MG/KG						
H00967	102.2	5.4	2.9	2.5	1.2	.2	89	22	39	37
H00968	97.4	6.2	3.5	2.7	1.3	.2	70	21	21	44
H00969	100.8	5.9	3.2	2.7	1.2	.2	114	23	23	55
H00970	105.5	5.8	3.4	2.4	1.4	.2	95	17	20	59
H00971	95.7	7.1	3.5	3.6	1.0	.2	100	23	28	85
H00972	100.2	5.6	2.8	2.9	1.0	.5	72	21	20	42
N=	6	6	6	6	6	6	6	6	6	6
MEAN	100.3	6.0	3.2	2.8	1.2	.2	90	21	25	54
S.D.	3.48	.60	.31	.43	.16	.12	16.9	2.2	7.4	17.4
POOLED M+F GROUP: 1										
N=	12	12	12	12	12	12	12	12	12	12
MEAN M+F	98.5	6.0	3.3	2.7	1.2	.2	104	22	26	52
S.D. M+F	5.70	.43	.27	.38	.21	.10	22.0	2.2	6.0	13.8

APPENDIX
INDIVIDUAL CLINICAL CHEMISTRY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	GLU MG/DL	T PRO G/DL	ALB G/DL	GLOB G/DL	A/G	T BILI MG/DL	CHOL MG/DL	AST/SGOT IU/L	ALT/SGPT IU/L	ALK PHOS IU/L
GROUP & SEX: 2M DOSE LEVEL: 250 DOSAGE UNIT: MG/KG										
H00973	92.8	5.7	3.2	2.5	1.3	.1	144	22	25	78
H00974	96.9	5.9	3.5	2.4	1.4	.4	150	30	30	42
H00975	98.8	6.0	3.3	2.7	1.2	.1	87	18	31	40
H00976	98.2	5.6	3.2	2.4	1.3	.1	101	24	36	45
H00977	91.7	6.3	3.1	3.2	1.0	.2	109	24	30	48
H00978	92.6	6.1	3.8	2.3	1.7	.2	119	18	24	32
N=	6	6	6	6	6	6	6	6	6	6
MEAN	95.2	5.9	3.4	2.6	1.3	.2	118	23	29	48
S.D.	3.15	.26	.26	.33	.23	.12	24.6	4.5	4.4	15.9
GROUP & SEX: 2F DOSE LEVEL: 250 DOSAGE UNIT: MG/KG										
H00979 SH	106.3	6.1	3.5	2.6	1.3	1.3	103	22	27	32
H00980	95.0	5.6	3.1	2.5	1.3	.2	115	20	24	62
H00981	105.1	5.3	3.1	2.2	1.5	.3	76	21	23	37
H00982	93.2	5.8	3.5	2.3	1.5	.2	105	21	29	47
H00983	98.9	5.4	3.3	2.1	1.6	.2	92	17	26	55
H00984	104.1	5.6	3.2	2.4	1.3	.2	101	20	24	37
N=	6	6	6	6	6	6	6	6	6	6
MEAN	100.4	5.6	3.3	2.4	1.4	.4	99	20	26	45
S.D.	5.55	.29	.18	.19	.13	.44	13.3	1.7	2.2	11.7
POOLED M+F GROUP: 2										
N=	12	12	12	12	12	12	12	12	12	12
MEAN M+F	97.8	5.8	3.3	2.5	1.4	.3	108	21	27	46
S.D. M+F	5.10	.30	.22	.28	.19	.33	21.5	3.5	3.9	13.4

S6127111 DOG POOL M+F WEEK: 008

APPENDIX
INDIVIDUAL CLINICAL CHEMISTRY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	GLU MG/DL	T PRO G/DL	ALB G/DL	GLOB G/DL	A/G	T BILI MG/DL	CHOL MG/DL	AST/SGOT IU/L	ALT/SGPT IU/L	ALK PHOS IU/L
GROUP & SEX: 3M DOSE LEVEL: 500 DOSAGE UNIT: MG/KG										
H00985	104.1	5.3	3.2	2.1	1.6	.2	110	24	31	38
H00986	105.2	5.6	3.1	2.6	1.2	.2	101	23	28	42
H00987	102.7	5.8	3.5	2.3	1.5	.2	120	16	23	51
H00988	109.0	5.6	3.4	2.2	1.5	.3	95	23	22	33
H00989	110.5	6.2	3.3	2.9	1.1	.2	97	18	30	71
H00990	104.7	5.8	3.3	2.5	1.3	.4	111	22	27	51
N=	6	6	6	6	6	6	6	6	6	6
MEAN	106.0	5.7	3.3	2.4	1.4	.2	106	21	27	48
S.D.	3.04	.30	.14	.29	.20	.08	9.6	3.2	3.6	13.5
GROUP & SEX: 3F DOSE LEVEL: 500 DOSAGE UNIT: MG/KG										
H00991	90.4	5.8	3.4	2.4	1.4	.1	155	15	21	75
H00992	100.7	5.4	3.2	2.2	1.4	.1	84	20	27	53
H00993	93.1	6.0	3.5	2.5	1.4	.2	104	20	24	66
H00994	97.1	6.2	3.7	2.5	1.5	.3	114	20	24	51
H00995	95.9	5.4	3.2	2.3	1.4	.2	81	17	21	45
H00996	95.6	6.0	3.0	3.0	1.0	.2	95	20	24	45
N=	6	6	6	6	6	6	6	6	6	6
MEAN	95.5	5.8	3.3	2.5	1.4	.2	106	19	24	56
S.D.	3.51	.33	.25	.28	.18	.08	27.2	2.2	2.2	12.1
POOLED M+F GROUP: 3										
N=	12	12	12	12	12	12	12	12	12	12
MEAN M+F	100.8	5.8	3.3	2.4	1.4	.2	106	20	25	52
S.D. M+F	6.34	.30	.19	.27	.18	.08	19.4	2.9	3.4	12.9

APPENDIX
INDIVIDUAL CLINICAL CHEMISTRY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	GLU MG/DL	T PRO G/DL	ALB G/DL	GLOB G/DL	A/G	T BILI MG/DL	CHOL MG/DL	AST/SGOT IU/L	ALT/SGPT IU/L	ALK PHOS IU/L
GROUP & SEX: 4M DOSE LEVEL: 1000 DOSAGE UNIT: MG/KG										
H00001	91.7	5.8	3.5	2.4	1.5	.1	179	18	34	50
H00002	94.8	5.8	3.4	2.4	1.4	.1	145	19	41	63
H00003	98.5	6.4	3.1	3.3	1.0	.1	114	20	29	51
H00997	101.1	5.4	2.8	2.6	1.1	.1	106	20	46	50
H00998	99.7	5.6	3.4	2.2	1.5	.2	140	19	28	61
H00999	89.3	6.3	3.2	3.1	1.0	.1	96	20	28	48
N=	6	6	6	6	6	6	6	6	6	6
MEAN	95.8	5.9	3.2	2.7	1.2	.1	130	19	34	54
S.D.	4.70	.39	.26	.44	.24	.04	30.7	.8	7.6	6.4
GROUP & SEX: 4F DOSE LEVEL: 1000 DOSAGE UNIT: MG/KG										
H00004	92.8	6.0	3.1	2.9	1.1	.1	90	15	19	37
H00005	99.6	6.3	3.4	3.0	1.1	.2	210	17	27	87
H00006	97.3	5.9	3.5	2.4	1.4	.2	100	18	25	52
H00007	97.8	5.8	3.0	2.8	1.0	.2	101	20	32	51
H00008	102.5	6.1	3.2	2.9	1.1	.1	117	17	26	48
H00009	101.6	6.0	3.1	3.0	1.0	.2	98	19	25	59
N=	6	6	6	6	6	6	6	6	6	6
MEAN	98.6	6.0	3.2	2.8	1.1	.2	119	18	26	56
S.D.	3.50	.17	.19	.22	.15	.05	45.3	1.8	4.2	16.9
POOLED M+F GROUP: 4										
N=	12	12	12	12	12	12	12	12	12	12
MEAN M+F	97.2	6.0	3.2	2.8	1.2	.1	125	18	30	55
S.D. M+F	4.20	.30	.22	.34	.20	.05	37.3	1.6	7.4	12.2

S6127111 DOG POOL M+F WEEK: 008

APPENDIX
INDIVIDUAL CLINICAL CHEMISTRY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	UN MG/DL	CREAT MG/DL	CA MG/DL	NA MMOL/L	K MMOL/L	CL MMOL/L
GROUP & SEX: 1M DOSE LEVEL: 0			DOSAGE UNIT: MG/KG			
H00961	11.9	.9	11.6	147	4.8	110
H00962	9.4	.8	11.0	142	4.4	108
H00963	11.9	.8	10.9	146	4.6	110
H00964	12.3	.9	11.4	146	5.1	109
H00965	11.5	.8	11.1	144	4.4	109
H00966	11.1	.7	11.2	147	4.2	113
N=	6	6	6	6	6	6
MEAN	11.4	.8	11.2	145	4.6	110
S.D.	1.04	.08	.26	2.0	.32	1.7
GROUP & SEX: 1F DOSE LEVEL: 0			DOSAGE UNIT: MG/KG			
H00967	13.4	1.0	10.4	145	4.9	108
H00968	10.1	.9	10.7	145	4.6	107
H00969	12.6	1.0	11.2	148	4.6	110
H00970	9.8	1.0	10.7	145	4.3	110
H00971	13.2	.9	10.9	148	5.5	113
H00972	14.4	.8	10.6	144	4.8	112
N=	6	6	6	6	6	6
MEAN	12.2	.9	10.8	146	4.8	110
S.D.	1.88	.08	.27	1.7	.41	2.3
POOLED M+F GROUP: 1						
N=	12	12	12	12	12	12
MEAN M+F	11.8	.9	11.0	146	4.7	110
S.D. M+F	1.52	.10	.35	1.8	.37	1.9

APPENDIX
INDIVIDUAL CLINICAL CHEMISTRY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	UN MG/DL	CREAT MG/DL	CA MG/DL	NA MMOL/L	K MMOL/L	CL MMOL/L
GROUP & SEX: 2M DOSE LEVEL: 250 DOSAGE UNIT: MG/KG						
H00973	12.6	.8	11.3	145	4.8	111
H00974	10.8	.7	11.3	144	4.7	108
H00975	10.1	.7	10.8	143	5.2	108
H00976	12.8	.7	11.2	145	5.0	106
H00977	11.4	.8	11.0	145	4.6	107
H00978	11.4	.9	11.5	146	4.8	108
N=	6	6	6	6	6	6
MEAN	11.5	.8	11.2	145	4.8	108
S.D.	1.04	.08	.25	1.0	.22	1.7
GROUP & SEX: 2F DOSE LEVEL: 250 DOSAGE UNIT: MG/KG						
H00979 SH	13.7	.7	11.1	147	5.2	109
H00980	13.5	1.0	10.6	146	4.6	110
H00981	12.8	.9	10.3	143	4.9	107
H00982	9.3	.9	10.3	143	4.8	110
H00983	12.2	.9	10.5	147	4.7	111
H00984	10.5	.8	10.5	144	4.5	109
N=	6	6	6	6	6	6
MEAN	12.0	.9	10.6	145	4.8	109
S.D.	1.75	.10	.29	1.9	.25	1.4
POOLED M+F GROUP: 2						
N=	12	12	12	12	12	12
MEAN M+F	11.8	.8	10.9	145	4.8	109
S.D. M+F	1.40	.10	.42	1.5	.22	1.6

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INDIVIDUAL CLINICAL CHEMISTRY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	UN MG/DL	CREAT MG/DL	CA MG/DL	NA MMOL/L	K MMOL/L	CL MMOL/L
GROUP & SEX: 3M DOSE LEVEL: 500 DOSAGE UNIT: MG/KG						
H00985	10.2	.8	11.0	145	4.6	111
H00986	14.4	.9	11.2	145	5.0	108
H00987	11.0	.8	11.6	148	4.7	113
H00988	13.0	1.0	11.0	145	4.4	109
H00989	10.8	.8	11.2	147	4.5	111
H00990	13.9	.7	11.5	144	4.4	108
N=	6	6	6	6	6	6
MEAN	12.2	.8	11.2	146	4.6	110
S.D.	1.78	.10	.25	1.5	.23	2.0
GROUP & SEX: 3F DOSE LEVEL: 500 DOSAGE UNIT: MG/KG						
H00991	10.6	.9	10.7	147	4.6	111
H00992	10.8	.8	10.4	144	4.6	108
H00993	13.1	.9	10.2	146	4.4	110
H00994	14.0	1.0	11.1	147	4.6	111
H00995	13.2	1.0	10.2	144	4.7	106
H00996	12.7	.9	10.4	145	4.9	111
N=	6	6	6	6	6	6
MEAN	12.4	.9	10.5	146	4.6	110
S.D.	1.38	.08	.35	1.4	.16	2.1
POOLED M+F GROUP: 3						
N=	12	12	12	12	12	12
MEAN M+F	12.3	.9	10.9	146	4.6	110
S.D. M+F	1.52	.10	.49	1.4	.19	2.0

APPENDIX
INDIVIDUAL CLINICAL CHEMISTRY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	UN MG/DL	CREAT MG/DL	CA MG/DL	NA MMOL/L	K MMOL/L	CL MMOL/L
GROUP & SEX: 4M	DOSE LEVEL: 1000		DOSAGE UNIT: MG/KG			
H00001	12.9	.9	11.3	145	5.4	109
H00002	10.2	.8	11.1	146	5.0	109
H00003	9.4	.8	11.0	144	4.4	108
H00997	15.6	.9	11.2	144	4.9	110
H00998	11.6	.9	10.9	146	4.9	110
H00999	11.2	.8	10.9	145	4.5	111
N=	6	6	6	6	6	6
MEAN	11.8	.8	11.1	145	4.8	110
S.D.	2.21	.05	.16	.9	.36	1.0
GROUP & SEX: 4F	DOSE LEVEL: 1000		DOSAGE UNIT: MG/KG			
H00004	13.0	.9	10.2	144	4.8	109
H00005	11.5	.9	10.7	145	4.7	110
H00006	11.4	1.0	10.5	146	4.7	109
H00007	12.6	.9	10.4	145	4.7	110
H00008	12.4	1.0	10.5	145	4.8	112
H00009	14.4	1.0	10.5	147	4.9	113
N=	6	6	6	6	6	6
MEAN	12.6	1.0	10.5	145	4.8	110
S.D.	1.10	.05	.16	1.0	.08	1.6
POOLED M+F GROUP: 4						
N=	12	12	12	12	12	12
MEAN M+F	12.2	.9	10.8	145	4.8	110
S.D. M+F	1.71	.07	.35	.9	.25	1.4

S6127111 DOG POOL M+F WEEK: 017

APPENDIX
INDIVIDUAL CLINICAL CHEMISTRY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	GLU MG/DL	T PRO G/DL	ALB G/DL	GLOB G/DL	A/G	T BILI MG/DL	CHOL MG/DL	AST/SGOT IU/L	ALT/SGPT IU/L	ALK PHOS IU/L
GROUP & SEX: 1M DOSE LEVEL: 0				DOSAGE UNIT: MG/KG						
H00961	102.0	6.9	3.4	3.5	1.0	.3	114	22	30	43
H00962	91.9	6.8	3.3	3.5	.9	.2	98	22	27	31
H00963	98.7	6.2	3.8	2.4	1.6	.3	140	21	35	42
H00964	92.2	6.5	3.2	3.3	1.0	.3	108	26	28	43
H00965	97.8	6.4	3.6	2.9	1.2	.4	112	20	29	49
H00966	93.6	6.3	3.6	2.7	1.3	.3	114	20	25	38
N=	6	6	6	6	6	6	6	6	6	6
MEAN	96.0	6.5	3.5	3.0	1.2	.3	114	22	29	41
S.D.	4.09	.28	.22	.45	.26	.06	13.9	2.2	3.4	6.8
GROUP & SEX: 1F DOSE LEVEL: 0				DOSAGE UNIT: MG/KG						
H00967	102.6	6.9	3.8	3.1	1.2	.2	111	22	32	29
H00968	108.0	6.5	3.7	2.8	1.3	.2	90	20	24	32
H00969	95.5	6.1	3.3	2.7	1.2	.5	104	20	20	34
H00970	107.2	6.0	3.5	2.6	1.3	.3	113	18	25	42
H00971	95.7	7.1	3.4	3.7	.9	.4	79	27	32	62
H00972	101.9	6.3	3.3	3.0	1.1	.3	82	24	24	41
N=	6	6	6	6	6	6	6	6	6	6
MEAN	101.8	6.5	3.5	3.0	1.2	.3	96	22	26	40
S.D.	5.39	.44	.21	.40	.15	.12	14.8	3.2	4.8	11.9
POOLED M+F GROUP: 1										
N=	12	12	12	12	12	12	12	12	12	12
MEAN M+F	98.9	6.5	3.5	3.0	1.2	.3	105	22	28	40
S.D. M+F	5.47	.35	.21	.41	.20	.09	18.8	2.6	4.2	9.0

APPENDIX
INDIVIDUAL CLINICAL CHEMISTRY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	GLU MG/DL	T PRO G/DL	ALB G/DL	GLOB G/DL	A/G	T BILI MG/DL	CHOL MG/DL	AST/SGOT IU/L	ALT/SGPT IU/L	ALK PHOS IU/L
GROUP & SEX: 2M DOSE LEVEL: 250 DOSAGE UNIT: MG/KG										
H00973	87.6	6.4	3.7	2.7	1.4	.4	156	22	26	57
H00974	91.9	6.6	3.6	2.9	1.2	.3	138	25	23	30
H00975	100.9	7.1	3.7	3.4	1.1	.3	97	20	30	35
H00976	91.2	6.5	3.5	3.0	1.2	.3	107	25	33	39
H00977	88.7	7.3	3.4	4.0	.9	.3	112	22	27	46
H00978	96.6	6.9	4.0	2.9	1.4	.3	115	17	23	26
N=	6	6	6	6	6	6	6	6	6	6
MEAN	92.8	6.8	3.6	3.2	1.2	.3	121	22	27	39
S.D.	5.04	.36	.21	.48	.19	.04	21.9	3.1	3.9	11.3
GROUP & SEX: 2F DOSE LEVEL: 250 DOSAGE UNIT: MG/KG										
H00979	102.7	5.8	3.5	2.3	1.5	.3	117	20	25	31
H00980	93.3	6.2	3.7	2.5	1.5	.4	150	21	25	55
H00981	101.6	6.0	3.6	2.4	1.5	.2	101	24	23	28
H00982	93.3	6.1	3.6	2.5	1.4	.2	127	21	24	44
H00983	86.8	6.0	3.5	2.5	1.4	.3	74	17	24	44
H00984	94.9	6.1	3.4	2.7	1.3	.4	103	20	27	31
N=	6	6	6	6	6	6	6	6	6	6
MEAN	95.4	6.0	3.6	2.5	1.4	.3	112	20	25	39
S.D.	5.91	.14	.10	.13	.08	.09	25.8	2.2	1.4	10.5
POOLED M+F GROUP: 2										
N=	12	12	12	12	12	12	12	12	12	12
MEAN M+F	94.1	6.4	3.6	2.8	1.3	.3	116	21	26	39
S.D. M+F	5.42	.48	.16	.48	.18	.07	23.3	2.6	3.1	10.4

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TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	GLU MG/DL	T PRO G/DL	ALB G/DL	GLOB G/DL	A/G	T BILI MG/DL	CHOL MG/DL	AST/SGOT IU/L	ALT/SGPT IU/L	ALK PHOS IU/L
GROUP & SEX: 3M DOSE LEVEL: 500 DOSAGE UNIT: MG/KG										
H00985	96.5	6.2	3.7	2.5	1.5	.3	117	21	28	36
H00986	97.0	6.4	3.4	2.9	1.2	.3	109	24	24	36
H00987	95.9	6.2	3.9	2.3	1.7	.3	127	19	24	49
H00988	93.5	6.3	3.7	2.6	1.5	.3	102	20	21	25
H00989	100.1	6.3	3.6	2.7	1.3	.3	90	22	31	66
H00990	95.2	6.2	3.4	2.8	1.2	.0	106	21	26	53
N=	6	6	6	6	6	6	6	6	6	6
MEAN	96.4	6.3	3.6	2.6	1.4	.2	108	21	26	44
S.D.	2.20	.08	.19	.22	.20	.12	12.7	1.7	3.5	14.7
GROUP & SEX: 3F DOSE LEVEL: 500 DOSAGE UNIT: MG/KG										
H00991	92.5	6.6	4.0	2.6	1.5	.3	179	18	25	62
H00992	104.8	5.7	3.6	2.2	1.7	.3	91	22	28	37
H00993	88.0	6.2	3.4	2.8	1.2	.2	101	31	34	59
H00994	93.5	6.0	3.5	2.5	1.4	.3	101	20	29	37
H00995	97.8	5.9	3.6	2.4	1.5	.2	113	20	26	38
H00996	99.8	5.8	3.3	2.5	1.3	.2	120	16	26	39
N=	6	6	6	6	6	6	6	6	6	6
MEAN	96.1	6.0	3.6	2.5	1.4	.2	118	21	28	45
S.D.	5.96	.33	.24	.20	.18	.05	31.8	5.2	3.3	11.8
POOLED M+F GROUP: 3										
N=	12	12	12	12	12	12	12	12	12	12
MEAN M+F	96.2	6.2	3.6	2.6	1.4	.2	113	21	27	45
S.D. M+F	4.28	.26	.21	.21	.18	.09	23.6	3.7	3.4	12.7

S6127111 DOG POOL M+F WEEK: 017

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TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	GLU MG/DL	T PRO G/DL	ALB G/DL	GLOB G/DL	A/G	T BILI MG/DL	CHOL MG/DL	AST/SGOT IU/L	ALT/SGPT IU/L	ALK PHOS IU/L
GROUP & SEX: 4M DOSE LEVEL: 1000 DOSAGE UNIT: MG/KG										
H00001	84.8	6.1	3.6	2.5	1.4	.2	169	20	32	47
H00002	93.7	6.0	3.5	2.5	1.4	.3	133	19	38	55
H00003	96.6	7.1	3.3	3.8	.9	.1	108	22	32	48
H00997	95.3	6.4	3.3	3.2	1.0	.2	101	20	37	54
H00998	96.4	6.0	3.5	2.6	1.3	.2	139	19	28	54
H00999	94.8	6.6	3.4	3.2	1.0	.2	99	22	33	42
N=	6	6	6	6	6	6	6	6	6	6
MEAN	93.6	6.4	3.4	3.0	1.2	.2	125	20	33	50
S.D.	4.44	.43	.12	.52	.22	.06	27.3	1.4	3.7	5.2
GROUP & SEX: 4F DOSE LEVEL: 1000 DOSAGE UNIT: MG/KG										
H00004	91.3	6.2	3.1	3.1	1.0	.2	95	16	20	30
H00005	94.9	6.0	3.5	2.5	1.4	.5	175	15	29	69
H00006	103.3	5.9	3.6	2.2	1.6	.6	99	22	31	36
H00007	98.5	6.1	3.3	2.7	1.2	.2	111	20	28	46
H00008	102.5	6.2	3.2	3.0	1.1	.1	139	14	22	43
H00009	98.2	6.1	3.1	3.0	1.1	.2	118	20	27	53
N=	6	6	6	6	6	6	6	6	6	6
MEAN	98.1	6.1	3.3	2.8	1.2	.3	123	18	26	46
S.D.	4.54	.12	.21	.35	.22	.20	30.0	3.2	4.3	13.7
POOLED M+F GROUP: 4										
N=	12	12	12	12	12	12	12	12	12	12
MEAN M+F	95.8	6.2	3.4	2.8	1.2	.2	124	19	30	48
S.D. M+F	4.89	.34	.18	.44	.22	.15	27.4	2.7	5.3	10.1

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TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	UN MG/DL	CREAT MG/DL	CA MG/DL	NA MMOL/L	K MMOL/L	CL MMOL/L
GROUP & SEX: 1M DOSE LEVEL: 0				DOSAGE UNIT: MG/KG		
H00961	10.9	1.0	10.9	143	4.8	110
H00962	10.7	.8	10.3	141	4.4	108
H00963	12.2	.9	10.8	142	4.4	110
H00964	13.1	.9	10.9	143	4.4	110
H00965	8.4	.9	11.0	144	4.3	110
H00966	8.5	.8	10.5	142	4.2	108
N=	6	6	6	6	6	6
MEAN	10.6	.9	10.7	142	4.4	109
S.D.	1.90	.08	.27	1.0	.20	1.0
GROUP & SEX: 1F DOSE LEVEL: 0				DOSAGE UNIT: MG/KG		
H00967	12.3	.9	11.3	142	4.6	109
H00968	10.6	1.0	10.8	141	4.3	107
H00969	13.9	.8	11.0	141	4.2	108
H00970	12.5	.9	11.1	143	4.0	110
H00971	10.7	.8	10.9	143	4.7	109
H00972	12.2	.8	10.8	142	3.9	109
N=	6	6	6	6	6	6
MEAN	12.0	.9	11.0	142	4.3	109
S.D.	1.24	.08	.19	.9	.32	1.0
POOLED M+F GROUP: 1						
N=	12	12	12	12	12	12
MEAN M+F	11.3	.9	10.8	142	4.4	109
S.D. M+F	1.70	.08	.26	1.0	.26	1.0

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TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	UN MG/DL	CREAT MG/DL	CA MG/DL	NA MMOL/L	K MMOL/L	CL MMOL/L
GROUP & SEX: 2M DOSE LEVEL: 250 DOSAGE UNIT: MG/KG						
H00973	12.8	1.0	10.6	143	4.5	110
H00974	10.4	1.0	10.9	142	4.4	108
H00975	9.9	.9	11.1	140	4.4	108
H00976	12.8	.8	10.8	142	4.4	105
H00977	10.2	1.0	11.1	142	4.3	109
H00978	12.1	.9	11.2	142	4.2	107
N=	6	6	6	6	6	6
MEAN	11.4	.9	11.0	142	4.4	108
S.D.	1.35	.08	.22	1.0	.10	1.7
GROUP & SEX: 2F DOSE LEVEL: 250 DOSAGE UNIT: MG/KG						
H00979	12.5	1.0	10.0	142	4.3	110
H00980	12.8	1.0	10.9	143	4.1	109
H00981	11.2	.9	11.0	142	4.1	108
H00982	14.7	.8	10.7	141	4.1	107
H00983	11.5	.9	10.5	143	4.0	109
H00984	10.6	.8	10.8	140	3.8	106
N=	6	6	6	6	6	6
MEAN	12.2	.9	10.6	142	4.1	108
S.D.	1.47	.09	.36	1.2	.16	1.5
POOLED M+F GROUP: 2						
N=	12	12	12	12	12	12
MEAN M+F	11.8	.9	10.8	142	4.2	108
S.D. M+F	1.41	.08	.33	1.0	.20	1.5

S6127111 DOG POOL M+F WEEK: 017

APPENDIX
INDIVIDUAL CLINICAL CHEMISTRY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	UN MG/DL	CREAT MG/DL	CA MG/DL	NA MMOL/L	K MMOL/L	CL MMOL/L
GROUP & SEX: 3M DOSE LEVEL: 500 DOSAGE UNIT: MG/KG						
H00985	8.7	.9	10.9	142	4.2	109
H00986	11.9	1.0	10.8	142	4.2	108
H00987	12.1	.9	11.5	145	4.7	111
H00988	12.2	1.0	11.0	142	4.1	108
H00989	10.3	.8	11.3	144	4.2	111
H00990	15.2	.9	11.0	143	4.3	109
N=	6	6	6	6	6	6
MEAN	11.7	.9	11.1	143	4.3	109
S.D.	2.18	.08	.26	1.3	.21	1.4
GROUP & SEX: 3F DOSE LEVEL: 500 DOSAGE UNIT: MG/KG						
H00991	11.6	1.0	11.2	144	4.1	108
H00992	10.8	.9	10.3	144	3.9	109
H00993	13.9	.9	10.6	142	4.1	108
H00994	12.4	.9	10.8	142	4.3	112
H00995	14.6	1.1	11.3	142	4.3	109
H00996	9.2	.9	10.3	141	4.4	109
N=	6	6	6	6	6	6
MEAN	12.1	1.0	10.8	142	4.2	109
S.D.	2.00	.08	.43	1.2	.18	1.5
POOLED M+F GROUP: 3						
N=	12	12	12	12	12	12
MEAN M+F	11.9	.9	10.9	143	4.2	109
S.D. M+F	2.00	.08	.38	1.2	.20	1.4

APPENDIX
INDIVIDUAL CLINICAL CHEMISTRY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	UN MG/DL	CREAT MG/DL	CA MG/DL	NA MMOL/L	K MMOL/L	CL MMOL/L
GROUP & SEX: 4M DOSE LEVEL: 1000 DOSAGE UNIT: MG/KG						
H00001	11.5	.9	10.9	143	4.4	110
H00002	10.5	.9	10.7	143	4.4	110
H00003	9.0	.8	10.8	141	4.4	108
H00997	13.0	1.0	11.3	143	4.2	109
H00998	11.9	1.0	10.8	143	4.5	111
H00999	10.1	.9	10.8	142	4.3	111
N=	6	6	6	6	6	6
MEAN	11.0	.9	10.9	142	4.4	110
S.D.	1.42	.08	.21	.8	.10	1.2
GROUP & SEX: 4F DOSE LEVEL: 1000 DOSAGE UNIT: MG/KG						
H00004	9.9	.9	9.9	141	4.4	109
H00005	10.9	.9	10.6	142	4.1	108
H00006	11.2	.9	10.8	143	4.2	109
H00007	10.2	.9	10.6	143	4.3	109
H00008	11.0	1.0	10.5	144	4.2	111
H00009	13.8	1.0	10.5	141	4.1	110
N=	6	6	6	6	6	6
MEAN	11.2	.9	10.5	142	4.2	109
S.D.	1.38	.05	.31	1.2	.12	1.0
POOLED M+F GROUP: 4						
N=	12	12	12	12	12	12
MEAN M+F	11.1	.9	10.7	142	4.3	110
S.D. M+F	1.34	.06	.33	1.0	.13	1.1

S6127111 DOG POOL M+F WEEK: 026

APPENDIX
INDIVIDUAL CLINICAL CHEMISTRY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	GLU MG/DL	T PRO G/DL	ALB G/DL	GLOB G/DL	A/G	T BILI MG/DL	CHOL MG/DL	AST/OT IU/L	ALT/PT IU/L	ALK PHOS IU/L
GROUP & SEX: 1M DOSE LEVEL: 0				DOSAGE UNIT: MG/KG						
H00961	111.6	6.9	3.1	3.8	.8	.4	106	21	28	32
H00962	96.0	6.5	3.2	3.3	1.0	.2	94	18	25	24
H00963	106.0	6.2	3.7	2.6	1.4	.4	136	20	33	39
H00964	101.7	6.9	3.2	3.7	.9	.2	110	24	25	34
H00965	99.0	6.3	3.5	2.8	1.3	.4	95	19	28	36
H00966	114.5	6.0	3.2	2.8	1.1	.3	91	17	22	30
N=	6	6	6	6	6	6	6	6	6	6
MEAN	104.8	6.5	3.3	3.2	1.1	.3	105	20	27	32
S.D.	7.24	.37	.23	.51	.23	.10	16.8	2.5	3.8	5.2
GROUP & SEX: 1F DOSE LEVEL: 0				DOSAGE UNIT: MG/KG						
H00967	106.7	6.1	3.5	2.6	1.4	.2	122	18	26	23
H00968	111.0	6.2	3.6	2.6	1.4	.1	102	18	22	27
H00969	99.0	6.6	3.5	3.1	1.2	1.0	131	22	25	28
H00970	103.5	6.0	3.2	2.7	1.2	.2	119	14	21	38
H00971	96.0	7.2	3.4	3.8	.9	.2	88	24	40	56
H00972	106.3	6.5	3.6	2.9	1.3	.9	109	23	27	25
N=	6	6	6	6	6	6	6	6	6	6
MEAN	103.8	6.4	3.5	3.0	1.2	.4	112	20	27	33
S.D.	5.48	.44	.15	.46	.19	.40	15.4	3.8	6.8	12.5
POOLED M+F GROUP: 1										
N=	12	12	12	12	12	12	12	12	12	12
MEAN M+F	104.3	6.4	3.4	3.0	1.2	.4	108	20	27	33
S.D. M+F	6.15	.39	.20	.48	.22	.29	15.7	3.1	5.3	9.1

S6127111 DOG POOL M+F WEEK: 026

APPENDIX
INDIVIDUAL CLINICAL CHEMISTRY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	GLU MG/DL	T PRO G/DL	ALB G/DL	GLOB G/DL	A/G	T BILI MG/DL	CHOL MG/DL	AST/OT IU/L	ALT/PT IU/L	ALK PHOS IU/L
GROUP & SEX: 2M DOSE LEVEL: 250 DOSAGE UNIT: MG/KG										
H00973	96.6	6.4	3.6	2.8	1.3	.2	137	21	24	40
H00974	105.5	6.3	3.8	2.5	1.5	.5	129	38	28	17
H00975	105.8	6.8	3.6	3.2	1.1	.2	85	23	39	26
H00976	105.8	6.5	3.5	3.0	1.2	.1	97	22	32	30
H00977	98.5	7.4	3.4	3.9	.9	.3	116	20	29	43
H00978	105.8	6.6	3.9	2.7	1.4	.3	105	15	21	22
N=	6	6	6	6	6	6	6	6	6	6
MEAN	103.0	6.7	3.6	3.0	1.2	.3	112	23	29	30
S.D.	4.26	.40	.19	.50	.22	.14	19.6	7.8	6.3	10.2
GROUP & SEX: 2F DOSE LEVEL: 250 DOSAGE UNIT: MG/KG										
H00979	102.0	5.7	3.4	2.3	1.5	.2	173	14	21	23
H00980	99.3	6.8	3.9	2.8	1.4	.2	174	18	27	48
H00981	100.8	6.1	3.6	2.4	1.5	.3	129	19	25	22
H00982	103.6	6.2	3.8	2.4	1.6	.2	117	18	30	37
H00983	96.0	6.0	3.7	2.3	1.6	.2	116	16	28	35
H00984	102.6	6.4	3.6	2.9	1.3	.3	125	18	26	24
N=	6	6	6	6	6	6	6	6	6	6
MEAN	100.7	6.2	3.7	2.5	1.5	.2	139	17	26	32
S.D.	2.75	.37	.18	.26	.12	.05	27.2	1.8	3.1	10.3
POOLED M+F GROUP: 2										
N=	12	12	12	12	12	12	12	12	12	12
MEAN M+F	101.8	6.4	3.6	2.8	1.4	.2	125	20	28	30
S.D. M+F	3.62	.44	.17	.46	.21	.10	26.8	6.2	4.9	9.8

APPENDIX
INDIVIDUAL CLINICAL CHEMISTRY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	GLU MG/DL	T PRO G/DL	ALB G/DL	GLOB G/DL	A/G	T BILI MG/DL	CHOL MG/DL	AST/OT IU/L	ALT/PT IU/L	ALK PHOS IU/L
GROUP & SEX: 3M DOSE LEVEL: 500 DOSAGE UNIT: MG/KG										
H00985	107.2	5.5	3.5	2.0	1.8	.2	108	18	26	30
H00986	109.9	6.1	3.3	2.8	1.2	.3	82	22	26	32
H00987	106.1	6.0	3.7	2.3	1.6	.2	95	18	24	36
H00988	117.5	5.1	3.3	1.9	1.8	.3	77	19	23	13
H00989	108.2	5.7	3.2	2.5	1.3	.2	85	17	29	44
H00990	136.7	5.9	3.5	2.4	1.4	.3	123	16	26	42
N=	6	6	6	6	6	6	6	6	6	6
MEAN	114.3	5.7	3.4	2.3	1.5	.2	95	18	26	33
S.D.	11.72	.37	.18	.33	.26	.05	17.6	2.1	2.1	11.1
GROUP & SEX: 3F DOSE LEVEL: 500 DOSAGE UNIT: MG/KG										
H00991	93.6	6.3	3.8	2.5	1.5	.2	204	16	25	49
H00992	108.2	5.9	3.6	2.3	1.6	.2	93	20	32	32
H00993	102.2	6.4	3.5	2.9	1.2	.1	122	19	29	64
H00994	102.1	6.3	3.6	2.7	1.3	.3	116	20	27	34
H00995	107.8	5.7	3.4	2.3	1.5	.2	142	16	23	30
H00996	110.0	6.1	3.4	2.7	1.3	.2	132	18	25	31
N=	6	6	6	6	6	6	6	6	6	6
MEAN	104.0	6.1	3.6	2.6	1.4	.2	135	18	27	40
S.D.	6.05	.27	.15	.24	.15	.06	37.7	1.8	3.2	13.7
POOLED M+F GROUP: 3										
N=	12	12	12	12	12	12	12	12	12	12
MEAN M+F	109.1	5.9	3.5	2.4	1.4	.2	115	18	26	36
S.D. M+F	10.38	.37	.17	.30	.21	.06	34.9	1.9	2.7	12.5

S6127111 DOG POOL M+F WEEK: 026

APPENDIX
INDIVIDUAL CLINICAL CHEMISTRY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	GLU MG/DL	T PRO G/DL	ALB G/DL	GLOB G/DL	A/G	T BILI MG/DL	CHOL MG/DL	AST/OT IU/L	ALT/PT IU/L	ALK PHOS IU/L
GROUP & SEX: 4M DOSE LEVEL: 1000 DOSAGE UNIT: MG/KG										
H00001	102.7	5.8	3.6	2.2	1.7	.3	173	18	35	30
H00002	106.3	5.5	3.1	2.4	1.3	.2	159	15	37	47
H00003	113.0	6.5	3.3	3.2	1.0	.2	106	19	32	40
H00997	110.2	6.2	3.2	2.9	1.1	.3	149	17	35	49
H00998	110.2	5.9	3.6	2.3	1.6	.2	157	17	31	39
H00999	106.8	6.5	3.3	3.2	1.0	.3	120	18	29	34
N=	6	6	6	6	6	6	6	6	6	6
MEAN	108.2	6.1	3.4	2.7	1.3	.2	144	17	33	40
S.D.	3.66	.40	.21	.46	.31	.05	25.6	1.4	3.0	7.3
GROUP & SEX: 4F DOSE LEVEL: 1000 DOSAGE UNIT: MG/KG										
H00004	109.7	6.2	3.2	3.0	1.1	.2	125	16	24	25
H00005	109.6	6.7	3.6	3.1	1.1	.2	213	17	30	69
H00006	105.5	5.8	3.6	2.3	1.6	.6	123	20	31	23
H00007	97.7	6.3	3.3	3.0	1.1	.2	164	19	24	37
H00008	112.5	6.5	3.2	3.3	1.0	.2	161	14	37	31
H00009	110.2	6.0	3.3	2.7	1.2	.5	147	20	30	35
N=	6	6	6	6	6	6	6	6	6	6
MEAN	107.5	6.2	3.4	2.9	1.2	.3	156	18	29	37
S.D.	5.32	.33	.19	.35	.21	.18	33.1	2.4	4.9	16.8
POOLED M+F GROUP: 4										
N=	12	12	12	12	12	12	12	12	12	12
MEAN M+F	107.9	6.2	3.4	2.8	1.2	.3	150	18	31	38
S.D. M+F	4.37	.36	.19	.40	.26	.13	28.8	1.9	4.4	12.4

S6127111 DOG POOL M+F WEEK: 026

APPENDIX
INDIVIDUAL CLINICAL CHEMISTRY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	UN MG/DL	CREAT MG/DL	CA MG/DL	NA MMOL/L	K MMOL/L	CL MMOL/L
GROUP & SEX: 1M DOSE LEVEL: 0				DOSAGE UNIT: MG/KG		
H00961	10.8	.9	10.8	142	5.0	110
H00962	12.3	.9	10.1	143	4.9	110
H00963	12.0	.9	10.4	144	4.9	114
H00964	11.1	1.0	10.5	144	5.1	112
H00965	10.6	1.0	10.7	143	4.8	109
H00966	10.0	.8	10.1	141	5.2	110
N=	6	6	6	6	6	6
MEAN	11.1	.9	10.4	143	5.0	111
S.D.	.87	.08	.29	1.2	.15	1.8
GROUP & SEX: 1F DOSE LEVEL: 0				DOSAGE UNIT: MG/KG		
H00967	9.7	1.0	10.4	143	4.4	111
H00968	9.8	.8	10.2	141	4.4	108
H00969	10.0	.8	11.4	145	4.7	112
H00970	8.9	1.0	10.6	142	4.4	109
H00971	9.9	.8	11.0	143	4.6	110
H00972	11.3	.7	11.1	143	4.8	110
N=	6	6	6	6	6	6
MEAN	9.9	.8	10.8	143	4.6	110
S.D.	.78	.12	.46	1.3	.18	1.4
POOLED M+F GROUP: 1						
N=	12	12	12	12	12	12
MEAN M+F	10.5	.9	10.6	143	4.8	110
S.D. M+F	1.00	.10	.41	1.2	.27	1.6

S6127111 DOG POOL M+F WEEK: 026

APPENDIX
INDIVIDUAL CLINICAL CHEMISTRY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	UN MG/DL	CREAT MG/DL	CA MG/DL	NA MMOL/L	K MMOL/L	CL MMOL/L
GROUP & SEX: 2M DOSE LEVEL: 250 DOSAGE UNIT: MG/KG						
H00973	13.4	1.0	10.8	143	5.0	111
H00974	12.1	1.1	10.4	143	4.6	112
H00975	9.7	1.0	10.5	141	5.3	110
H00976	12.5	.9	10.2	143	5.1	109
H00977	10.7	1.1	10.7	143	4.6	111
H00978	10.2	1.0	10.6	142	4.7	111
N=	6	6	6	6	6	6
MEAN	11.4	1.0	10.5	142	4.9	111
S.D.	1.45	.08	.22	.8	.29	1.0
GROUP & SEX: 2F DOSE LEVEL: 250 DOSAGE UNIT: MG/KG						
H00979	9.4	1.0	10.3	141	5.0	111
H00980	16.2	1.2	10.9	145	5.5	111
H00981	9.6	.9	10.7	142	4.7	109
H00982	11.3	1.0	10.8	143	4.5	110
H00983	10.2	1.0	10.3	145	4.6	111
H00984	9.0	.9	10.6	142	4.8	108
N=	6	6	6	6	6	6
MEAN	11.0	1.0	10.6	143	4.8	110
S.D.	2.69	.11	.25	1.7	.36	1.3
POOLED M+F GROUP: 2						
N=	12	12	12	12	12	12
MEAN M+F	11.2	1.0	10.6	143	4.9	110
S.D. M+F	2.08	.09	.23	1.3	.31	1.2

APPENDIX
INDIVIDUAL CLINICAL CHEMISTRY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	UN MG/DL	CREAT MG/DL	CA MG/DL	NA MMOL/L	K MMOL/L	CL MMOL/L
GROUP & SEX: 3M	DOSE LEVEL: 500		DOSAGE UNIT: MG/KG			
H00985	9.4	1.0	10.3	143	4.5	112
H00986	11.6	1.0	10.3	142	4.6	110
H00987	10.4	.9	10.8	144	5.2	112
H00988	13.3	1.1	9.9	142	4.4	112
H00989	9.5	.8	10.3	144	4.5	111
H00990	15.0	.9	10.8	143	4.7	110
N=	6	6	6	6	6	6
MEAN	11.5	1.0	10.4	143	4.6	111
S.D.	2.24	.10	.35	.9	.29	1.0
GROUP & SEX: 3F	DOSE LEVEL: 500		DOSAGE UNIT: MG/KG			
H00991	10.5	1.1	10.9	144	4.5	110
H00992	13.0	.9	10.3	142	4.5	108
H00993	11.1	1.0	10.6	144	4.4	110
H00994	13.3	1.1	10.6	144	4.5	110
H00995	15.6	1.2	10.6	142	4.4	108
H00996	10.1	1.0	10.3	143	4.7	110
N=	6	6	6	6	6	6
MEAN	12.3	1.0	10.6	143	4.5	109
S.D.	2.09	.10	.22	1.0	.11	1.0
POOLED M+F GROUP: 3						
N=	12	12	12	12	12	12
MEAN M+F	11.9	1.0	10.5	143	4.6	110
S.D. M+F	2.10	.11	.29	.9	.22	1.4

APPENDIX
INDIVIDUAL CLINICAL CHEMISTRY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	UN MG/DL	CREAT MG/DL	CA MG/DL	NA MMOL/L	K MMOL/L	CL MMOL/L
GROUP & SEX: 4M DOSE LEVEL: 1000 DOSAGE UNIT: MG/KG						
H00001	10.2	1.0	10.3	144	5.0	110
H00002	10.2	.9	9.9	143	5.1	110
H00003	8.7	.9	10.5	141	4.8	109
H00997	12.2	1.0	10.6	143	4.6	110
H00998	15.0	1.2	10.3	145	5.0	114
H00999	11.3	1.0	10.5	143	4.7	113
N=	6	6	6	6	6	6
MEAN	11.3	1.0	10.4	143	4.9	111
S.D.	2.18	.11	.25	1.3	.20	2.0
GROUP & SEX: 4F DOSE LEVEL: 1000 DOSAGE UNIT: MG/KG						
H00004	10.8	1.0	9.6	143	4.7	110
H00005	11.8	1.0	10.5	144	4.6	110
H00006	13.3	.9	10.5	144	4.5	110
H00007	12.7	.9	10.6	144	4.6	110
H00008	16.5	1.1	10.2	143	4.4	112
H00009	14.7	1.0	10.4	142	4.5	110
N=	6	6	6	6	6	6
MEAN	13.3	1.0	10.3	143	4.6	110
S.D.	2.05	.08	.37	.8	.10	.8
POOLED M+F GROUP: 4						
N=	12	12	12	12	12	12
MEAN M+F	12.3	1.0	10.3	143	4.7	111
S.D. M+F	2.28	.09	.30	1.0	.22	1.5

APPENDIX
INDIVIDUAL CLINICAL CHEMISTRY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	GLU MG/DL	T PRO G/DL	ALB G/DL	GLOB G/DL	A/G	T BILI MG/DL	CHOL MG/DL	AST/OT IU/L	ALT/PT IU/L	ALK PHOS IU/L
GROUP & SEX: 1M DOSE LEVEL: 0 DOSAGE UNIT: MG/KG										
H00964	100.8	6.4	2.9	3.5	.8	.2	133	24	24	42
H00965	96.3	5.9	3.2	2.8	1.1	.2	95	21	28	40
N=	2	2	2	2	2	2	2	2	2	2
MEAN	98.6	6.2	3.0	3.2	1.0	.2	114	22	26	41
S.D.	3.18	.35	.21	.49	.21	.00	26.9	2.1	2.8	1.4
GROUP & SEX: 1F DOSE LEVEL: 0 DOSAGE UNIT: MG/KG										
H00971	103.7	6.6	3.3	3.3	1.0	.2	86	23	29	65
H00972	104.8	5.6	3.3	2.3	1.4	.2	91	20	22	32
N=	2	2	2	2	2	2	2	2	2	2
MEAN	104.2	6.1	3.3	2.8	1.2	.2	88	22	26	48
S.D.	.78	.71	.00	.71	.28	.00	3.5	2.1	4.9	23.3
POOLED M+F GROUP: 1										
N=	4	4	4	4	4	4	4	4	4	4
MEAN M+F	101.4	6.1	3.2	3.0	1.1	.2	101	22	26	45
S.D. M+F	3.80	.46	.19	.54	.25	.00	21.5	1.8	3.3	14.2

S6127111 DOG POOL M+F WEEK: 031

APPENDIX
INDIVIDUAL CLINICAL CHEMISTRY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	GLU MG/DL	T PRO G/DL	ALB G/DL	GLOB G/DL	A/G	T BILI MG/DL	CHOL MG/DL	AST/OT IU/L	ALT/PT IU/L	ALK PHOS IU/L
GROUP & SEX: 2M DOSE LEVEL: 250 DOSAGE UNIT: MG/KG										
H00973	99.1	6.3	3.5	2.9	1.2	.3	154	23	24	41
H00977	98.9	6.8	3.1	3.7	.9	.2	110	26	37	38
N=	2	2	2	2	2	2	2	2	2	2
MEAN	99.0	6.6	3.3	3.3	1.0	.2	132	24	30	40
S.D.	.14	.35	.28	.56	.21	.07	31.1	2.1	9.2	2.1
GROUP & SEX: 2F DOSE LEVEL: 250 DOSAGE UNIT: MG/KG										
H00979	107.8	5.4	3.3	2.1	1.6	.2	153	19	22	29
H00981	107.6	5.7	3.5	2.2	1.6	.2	116	24	23	26
N=	2	2	2	2	2	2	2	2	2	2
MEAN	107.7	5.6	3.4	2.2	1.6	.2	134	22	22	28
S.D.	.14	.21	.14	.07	.00	.00	26.2	3.5	.7	2.1
POOLED M+F GROUP: 2										
N=	4	4	4	4	4	4	4	4	4	4
MEAN M+F	103.4	6.0	3.4	2.7	1.3	.2	133	23	26	34
S.D. M+F	5.02	.62	.19	.74	.34	.05	23.5	2.9	7.0	7.1

S6127111 DOG POOL M+F WEEK: 031

APPENDIX
INDIVIDUAL CLINICAL CHEMISTRY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	GLU MG/DL	T PRO G/DL	ALB G/DL	GLOB G/DL	A/G	T BILI MG/DL	CHOL MG/DL	AST/OT IU/L	ALT/PT IU/L	ALK PHOS IU/L
GROUP & SEX: 3M DOSE LEVEL: 500 DOSAGE UNIT: MG/KG										
H00988	105.0	5.7	3.4	2.3	1.5	.2	98	20	24	11
H00990	94.4	5.6	3.4	2.2	1.5	.2	107	18	27	33
N=	2	2	2	2	2	2	2	2	2	2
MEAN	99.7	5.6	3.4	2.2	1.5	.2	102	19	26	22
S.D.	7.50	.07	.00	.07	.00	.00	6.4	1.4	2.1	15.6
GROUP & SEX: 3F DOSE LEVEL: 500 DOSAGE UNIT: MG/KG										
H00995	102.3	5.7	3.5	2.2	1.6	.2	104	19	25	39
H00996	111.1	5.8	3.4	2.4	1.5	.2	105	20	25	31
N=	2	2	2	2	2	2	2	2	2	2
MEAN	106.7	5.8	3.4	2.3	1.6	.2	104	20	25	35
S.D.	6.22	.07	.07	.14	.07	.00	.7	.7	.0	5.6
POOLED M+F GROUP: 3										
N=	4	4	4	4	4	4	4	4	4	4
MEAN M+F	103.2	5.7	3.4	2.3	1.5	.2	104	19	25	28
S.D. M+F	6.92	.08	.05	.10	.05	.00	3.9	1.0	1.2	12.2

S6127111 DOG POOL M+F WEEK: 031

APPENDIX
INDIVIDUAL CLINICAL CHEMISTRY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	GLU MG/DL	T PRO G/DL	ALB G/DL	GLOB G/DL	A/G	T BILI MG/DL	CHOL MG/DL	AST/OT IU/L	ALT/PT IU/L	ALK PHOS IU/L
GROUP & SEX: 4M DOSE LEVEL: 1000 DOSAGE UNIT: MG/KG										
H00001	96.7	5.7	3.4	2.2	1.5	.2	147	21	32	39
H00998	108.2	5.5	3.4	2.1	1.6	.2	149	18	25	39
N=	2	2	2	2	2	2	2	2	2	2
MEAN	102.4	5.6	3.4	2.2	1.6	.2	148	20	28	39
S.D.	8.13	.14	.00	.07	.07	.00	1.4	2.1	4.9	.0
GROUP & SEX: 4F DOSE LEVEL: 1000 DOSAGE UNIT: MG/KG										
H00005	101.2	6.0	3.6	2.5	1.4	.2	172	18	31	89
H00006	113.0	5.5	3.7	1.9	1.9	.2	94	21	27	27
N=	2	2	2	2	2	2	2	2	2	2
MEAN	107.1	5.8	3.6	2.2	1.6	.2	133	20	29	58
S.D.	8.34	.35	.07	.42	.35	.00	55.2	2.1	2.8	43.8
POOLED M+F GROUP: 4										
N=	4	4	4	4	4	4	4	4	4	4
MEAN M+F	104.8	5.7	3.5	2.2	1.6	.2	140	20	29	48
S.D. M+F	7.24	.24	.15	.25	.22	.00	33.0	1.7	3.3	27.6

APPENDIX
INDIVIDUAL CLINICAL CHEMISTRY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	UN MG/DL	CREAT MG/DL	CA MG/DL	NA MMOL/L	K MMOL/L	CL MMOL/L
GROUP & SEX: 1M DOSE LEVEL: 0				DOSAGE UNIT: MG/KG		
H00964	10.9	1.1	10.2	146	4.8	114
H00965	9.6	1.0	10.4	144	4.3	112
N=	2	2	2	2	2	2
MEAN	10.2	1.0	10.3	145	4.6	113
S.D.	.92	.07	.14	1.4	.35	1.4
GROUP & SEX: 1F DOSE LEVEL: 0				DOSAGE UNIT: MG/KG		
H00971	10.1	.9	11.0	142	4.3	113
H00972	12.1	1.0	10.6	145	4.4	115
N=	2	2	2	2	2	2
MEAN	11.1	1.0	10.8	144	4.4	114
S.D.	1.41	.07	.28	2.1	.07	1.4
POOLED M+F GROUP: 1						
N=	4	4	4	4	4	4
MEAN M+F	10.7	1.0	10.6	144	4.4	114
S.D. M+F	1.09	.08	.34	1.7	.24	1.3

APPENDIX
INDIVIDUAL CLINICAL CHEMISTRY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	UN MG/DL	CREAT MG/DL	CA MG/DL	NA MMOL/L	K MMOL/L	CL MMOL/L
GROUP & SEX: 2M	DOSE LEVEL: 250		DOSAGE UNIT: MG/KG			
H00973	11.5	1.1	10.6	145	4.6	114
H00977	8.8	1.0	10.7	144	4.3	114
N=	2	2	2	2	2	2
MEAN	10.2	1.0	10.6	144	4.4	114
S.D.	1.91	.07	.07	.7	.21	.0
GROUP & SEX: 2F	DOSE LEVEL: 250		DOSAGE UNIT: MG/KG			
H00979	11.9	1.0	10.3	142	4.7	114
H00981	14.0	.9	10.6	142	4.4	112
N=	2	2	2	2	2	2
MEAN	13.0	1.0	10.4	142	4.6	113
S.D.	1.48	.07	.21	.0	.21	1.4
POOLED M+F GROUP: 2						
N=	4	4	4	4	4	4
MEAN M+F	11.6	1.0	10.6	143	4.5	114
S.D. M+F	2.14	.08	.17	1.5	.18	1.0

S6127111 DOG POOL M+F WEEK: 031

APPENDIX
INDIVIDUAL CLINICAL CHEMISTRY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	UN MG/DL	CREAT MG/DL	CA MG/DL	NA MMOL/L	K MMOL/L	CL MMOL/L
GROUP & SEX: 3M DOSE LEVEL: 500 DOSAGE UNIT: MG/KG						
H00988	9.7	.9	10.2	144	4.3	117
H00990	12.1	1.0	10.9	145	4.2	114
N=	2	2	2	2	2	2
MEAN	10.9	1.0	10.6	144	4.2	116
S.D.	1.70	.07	.49	.7	.07	2.1
GROUP & SEX: 3F DOSE LEVEL: 500 DOSAGE UNIT: MG/KG						
H00995	14.3	1.2	10.7	143	4.4	112
H00996	10.0	1.2	10.5	142	4.8	114
N=	2	2	2	2	2	2
MEAN	12.2	1.2	10.6	142	4.6	113
S.D.	3.04	.00	.14	.7	.28	1.4
POOLED M+F GROUP: 3						
N=	4	4	4	4	4	4
MEAN M+F	11.5	1.1	10.6	144	4.4	114
S.D. M+F	2.14	.15	.30	1.3	.26	2.1

S6127111 DOG POOL M+F WEEK: 031

APPENDIX
INDIVIDUAL CLINICAL CHEMISTRY VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	UN MG/DL	CREAT MG/DL	CA MG/DL	NA MG/DL	K MG/DL	CL MMOL/L
GROUP & SEX: 4M	DOSE LEVEL: 1000		DOSAGE UNIT: MG/KG			
H00001	12.0	1.1	10.6	142	4.4	114
H00998	11.0	1.1	10.6	144	4.4	115
N=	2	2	2	2	2	2
MEAN	11.5	1.1	10.6	143	4.4	114
S.D.	.71	.00	.00	1.4	.00	.7
GROUP & SEX: 4F	DOSE LEVEL: 1000		DOSAGE UNIT: MG/KG			
H00005	12.8	1.2	10.9	144	4.4	112
H00006	13.6	1.1	10.8	144	4.5	113
N=	2	2	2	2	2	2
MEAN	13.2	1.2	10.8	144	4.4	112
S.D.	.56	.07	.07	.0	.07	.7
POOLED M+F GROUP: 4						
N=	4	4	4	4	4	4
MEAN M+F	12.4	1.1	10.7	144	4.4	114
S.D. M+F	1.11	.05	.15	1.0	.05	1.3

APPENDIX I

Individual Urinalysis Data

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CODES FOR INDIVIDUAL URINE EXAMINATIONS

URINE APPEARANCE

Color

A - Pale
B - Straw
C - Yellow
D - Dark Yellow
E - Amber
F - Brown
G - Red
H - Green
I - Black

Clarity

J - Clear
K - Hazy
L - Cloudy
M - Debris
N - Sediment
O - Feces

URINE MICROSCOPIC†

Cells, Crystals, and Casts

0 - Not present
1 - Rare, 1-3 per field
2 - Occasional, 4-5 per field
3 - Few, 6-10 per field
4 - Many, 11-20 per field
5 - Packed, > 20 per field

A - Amorphous urates
B - Amorphous phosphates
C - Uric acid
D - Triple phosphates
E - Clacium oxalate
F - Hyaline casts
G - Finely granular casts
H - Granular casts
I - Coarsely granular casts
J - Calcium carbonate

Bacteria

0 - Not present
I - Few
II - Moderate
III - Many

Special Comments

P - Mucous threads
Q - Sperm
R - Fecal contamination
S - Pinworm ova found
T - Pinworm larvae found
U - Parasite ova found
V - Flagellate
* - See footnote

†Casts and crystals were examined at 10X and all other parameters at 40X

Codes for General Footnotes

NS = No sample
QNS = Quantity not sufficient
COL = Color interferes with stick
DOT = Diet on test
M = Moribund
TE = Technician error

APPENDIX
INDIVIDUAL CLINICAL URINALYSIS VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 AD MIXED IN DIET

ANIMAL NUMBER	SP GR	PH	U. VOL ML
GROUP & SEX: 1M	DOSE LEVEL: 0		DOSAGE UNIT: MG/KG
H00961	1.015	8.5	518.0
H00962	1.027	8.5	202.0
H00963	1.017	8.5	433.0
H00964	1.012	8.5	290.0
H00965	1.023	8.5	356.0
H00966	1.020	8.5	231.0
N=	6	6	6
MEAN	1.019	8.5	338.3
S.D.	.0055	.00	121.65
GROUP & SEX: 1F	DOSE LEVEL: 0		DOSAGE UNIT: MG/KG
H00967	1.012	8.5	713.0
H00968	1.026	8.5	252.0
H00969	1.020	8.5	335.0
H00970	1.026	8.5	211.0
H00971	1.026	8.5	231.0
H00972	1.020	8.0	341.0
N=	6	6	6
MEAN	1.022	8.4	347.2
S.D.	.0056	.20	187.14
POOLED M+F GROUP: 1			
N=	12	12	12
MEAN M+F	1.020	8.4	342.8
S.D. M+F	.0054	.14	150.56

APPENDIX
INDIVIDUAL CLINICAL URINALYSIS VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 AD MIXED IN DIET

ANIMAL NUMBER	SP GR	PH	U. VOL ML
GROUP & SEX: 2M	DOSE LEVEL: 250		DOSAGE UNIT: MG/KG
H00973	1.014	8.5	572.0
H00974	1.025	8.5	320.0
H00975	1.024	8.0	231.0
H00976	1.028	8.5	200.0
H00977	1.013	8.5	468.0
H00978	1.029	8.5	220.0
N=	6	6	6
MEAN	1.022	8.4	335.2
S.D.	.0070	.20	152.54
GROUP & SEX: 2F	DOSE LEVEL: 250		DOSAGE UNIT: MG/KG
H00979	1.016	8.5	682.0
H00980	1.011	8.5	718.0
H00981	1.024	8.5	275.0
H00982	1.032	8.5	155.0
H00983	1.021	8.5	268.0
H00984	1.024	8.5	248.0
N=	6	6	6
MEAN	1.021	8.5	391.0
S.D.	.0072	.00	243.45
POOLED M+F GROUP: 2			
N=	12	12	12
MEAN M+F	1.022	8.4	363.1
S.D. M+F	.0068	.14	195.88

S6127111 DOG POOL M+F WEEK: -02

APPENDIX
INDIVIDUAL CLINICAL URINALYSIS VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 AD MIXED IN DIET

ANIMAL NUMBER	SP GR	PH	U. VOL ML
GROUP & SEX: 3M	DOSE LEVEL: 500		DOSAGE UNIT: MG/KG
H00985	1.015	8.5	730.0
H00986	1.015	8.5	684.0
H00987	1.022	7.5	300.0
H00988	1.031	8.5	154.0
H00989	1.025	8.5	267.0
H00990	1.017	8.5	444.0
N=	6	6	6
MEAN	1.021	8.3	429.8
S.D.	.0064	.41	234.25
GROUP & SEX: 3F	DOSE LEVEL: 500		DOSAGE UNIT: MG/KG
H00991	1.011	8.5	680.0
H00992	1.032	8.5	183.0
H00993 TE	-	-	305.0
H00994	1.023	8.5	266.0
H00995	1.046	8.5	102.0
H00996	1.014	8.5	541.0
N=	5	5	6
MEAN	1.025	8.5	346.2
S.D.	.0142	.00	220.80
POOLED M+F GROUP: 3			
N=	11	11	12
MEAN M+F	1.023	8.4	388.0
S.D. M+F	.0103	.30	221.38

APPENDIX
INDIVIDUAL CLINICAL URINALYSIS VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 AD MIXED IN DIET

ANIMAL NUMBER	SP GR	PH	U. VOL ML
GROUP & SEX: 4M	DOSE LEVEL: 1000		DOSAGE UNIT: MG/KG
H00001	1.015	8.5	429.0
H00002	1.014	8.5	586.0
H00003	1.018	8.5	345.0
H00997	1.018	8.5	491.0
H00998	1.015	8.5	600.0
H00999	1.022	8.5	610.0
N=	6	6	6
MEAN	1.017	8.5	510.2
S.D.	.0030	.00	107.72
GROUP & SEX: 4F	DOSE LEVEL: 1000		DOSAGE UNIT: MG/KG
H00004	1.017	8.5	425.0
H00005	1.012	8.5	557.0
H00006	1.022	8.5	341.0
H00007	1.019	8.5	250.0
H00008	1.023	8.5	364.0
H00009	1.019	8.0	309.0
N=	6	6	6
MEAN	1.019	8.4	374.3
S.D.	.0039	.20	106.66
POOLED M+F GROUP: 4			
N=	12	12	12
MEAN M+F	1.018	8.4	442.2
S.D. M+F	.0034	.14	124.41

S6127111 DOG POOL M+F WEEK: -02

APPENDIX
INDIVIDUAL CLINICAL URINALYSIS VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 AD MIXED IN DIET

ANIMAL NUMBER	U PRO MG/DL	U GLU	U KET	U BILI	U BLOOD	UROBILI	URINE APP.
GROUP & SEX: 1M	DOSE LEVEL: 0		DOSAGE UNIT: MG/KG				
H00961	10	0	0	0	0	0	B,K,M
H00962	100	0	0	0	0	0	C,L,N
H00963	30	0	0	0	0	0	B,L,M,N
H00964	30	0	0	0	0	0	B,J
H00965	10	0	0	0	0	0	B,J,N
H00966	100	0	0	0	0	0	B,K,M
GROUP & SEX: 1F	DOSE LEVEL: 0		DOSAGE UNIT: MG/KG				
H00967	10	0	0	0	0	0	B,K,N
H00968	100	0	0	0	0	0	B,L,N
H00969	300	0	0	0	0	0	B,K,N
H00970	300	0	0	0	0	0	B,K,M,N
H00971	>2000	0	0	0	0	0	B,K,M
H00972	30	0	0	0	0	0	B,K,M,N

S6127111 DOG POOL M+F WEEK: -02

APPENDIX
INDIVIDUAL CLINICAL URINALYSIS VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 AD MIXED IN DIET

ANIMAL NUMBER	U PRO MG/DL	U GLU	U KET	U BILI	U BLOOD	UROBILI	URINE APP.
GROUP & SEX: 2M	DOSE LEVEL: 250			DOSAGE UNIT: MG/KG			
H00973	30	0	0	0	0	0	B,L,M
H00974	300	0	0	0	0	0	B,K,N
H00975	10	0	0	0	0	0	B,J,N
H00976	)2000	0	0	0	0	0	C,K,M
H00977	10	0	0	0	0	0	B,L,N
H00978	)2000	0	0	0	0	0	B,K,M
GROUP & SEX: 2F	DOSE LEVEL: 250			DOSAGE UNIT: MG/KG			
H00979	100	0	0	0	0	0	B,K,M,N
H00980	30	0	0	0	0	0	B,K,N
H00981	)2000	0	0	0	0	0	B,L,N
H00982	)2000	0	0	0	0	0	C,J,N
H00983	100	0	0	0	0	0	B,J,M
H00984	)2000	0	0	0	0	0	B,K,M,N

APPENDIX
INDIVIDUAL CLINICAL URINALYSIS VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 AD MIXED IN DIET

ANIMAL NUMBER	U PRO MG/DL	U GLU	U KET	U BILI	U BLOOD	UROBILI	URINE APP.
GROUP & SEX: 3M	DOSE LEVEL: 500		DOSAGE UNIT: MG/KG				
H00985	30	0	0	0	0	0	B,J,N
H00986	30	0	0	0	0	0	B,L,N
H00987	0	0	0	0	0	0	C,J,M
H00988	100	0	0	0	0	0	B,K,M
H00989	>2000	0	0	0	0	0	C,K,N
H00990	30	0	0	0	0	0	B,L,M,N
GROUP & SEX: 3F	DOSE LEVEL: 500		DOSAGE UNIT: MG/KG				
H00991	100	0	0	0	0	0	B,K,N
H00992	100	0	0	0	0	0	C,J,M
H00993 TE	-	-	-	-	-	-	-
H00994	100	0	0	0	0	0	B,L,N
H00995	>2000	0	0	0	0	0	B,J,M,N
H00996	300	0	0	0	0	0	B,K,N

S6127111 DOG POOL M+F WEEK: -02

APPENDIX
INDIVIDUAL CLINICAL URINALYSIS VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 AD MIXED IN DIET

ANIMAL NUMBER	U PRO MG/DL	U GLU	U KET	U BILI	U BLOOD	UROBILI	URINE APP.
GROUP & SEX: 4M	DOSE LEVEL: 1000		DOSAGE UNIT: MG/KG				
H00001	300	0	0	0	0	0	B,L,M
H00002	>2000	0	0	0	0	0	B,L,M,N
H00003	100	0	0	0	0	0	B,L,N
H00997	30	0	0	0	0	0	B,L,M,N
H00998	30	0	0	0	0	0	B,L,M
H00999	10	0	0	0	0	0	B,J,M
GROUP & SEX: 4F	DOSE LEVEL: 1000		DOSAGE UNIT: MG/KG				
H00004	100	0	0	0	0	0	B,K,N
H00005	100	0	0	0	0	0	B,L,M
H00006	>2000	0	0	0	0	0	B,K,M,N
H00007	300	0	0	0	0	0	B,K,N
H00008	300	0	0	0	0	0	B,K,M
H00009	30	0	0	0	0	0	B,K,M,N

S6127111 DOG POOL M+F WEEK: -02

APPENDIX
INDIVIDUAL CLINICAL URINALYSIS VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 AD MIXED IN DIET

ANIMAL NUMBER	RBC PER HPF	WBC PER HPF	EPITH PER HPF	BACT PER HPF	CASTS PER LPF	CRYSTALS PER LPF	SPECIAL COMMENTS
GROUP & SEX: 1M	DOSE LEVEL: 0		DOSAGE UNIT: MG/KG				
H00961	0	0	0	III	0	1D	-
H00962	0	0	0	III	0	3B,5D	-
H00963	0	0	0	III	0	1D	-
H00964	0	0	0	III	0	2B	-
H00965	0	0	0	III	0	5D	-
H00966	0	0	0	III	0	5D	-
GROUP & SEX: 1F	DOSE LEVEL: 0		DOSAGE UNIT: MG/KG				
H00967	0	0	1	III	0	5D	-
H00968	0	0	0	III	0	5D,5B	-
H00969	0	0	0	III	0	5D,1B	-
H00970	0	0	0	III	0	0	-
H00971	0	0	0	III	0	5D	-
H00972	0	0	1	III	0	5D	-

S6127111 DOG POOL M+F WEEK: -02

APPENDIX
INDIVIDUAL CLINICAL URINALYSIS VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 AD MIXED IN DIET

ANIMAL NUMBER	RBC PER HPF	WBC PER HPF	EPITH PER HPF	BACT PER HPF	CASTS PER LPF	CRYSTALS PER LPF	SPECIAL COMMENTS
GROUP & SEX: 2M	DOSE LEVEL: 250			DOSAGE UNIT: MG/KG			
H00973	0	1	0	III	0	1D	-
H00974	0	0	0	III	0	5D,5B	-
H00975	0	0	0	I	0	5D	P
H00976	0	0	0	III	0	5D	-
H00977	0	0	0	III	0	1D,5B	-
H00978	0	0	0	III	0	3D	-
GROUP & SEX: 2F	DOSE LEVEL: 250			DOSAGE UNIT: MG/KG			
H00979	0	0	0	III	0	5D	-
H00980	0	0	0	III	0	5D	-
H00981	0	0	0	III	0	5D	-
H00982	0	0	0	III	0	5D	-
H00983	0	0	0	III	0	5D	-
H00984	0	0	0	III	0	5D	-

APPENDIX
INDIVIDUAL CLINICAL URINALYSIS VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 AD MIXED IN DIET

ANIMAL NUMBER	RBC PER HPF	WBC PER HPF	EPITH PER HPF	BACT PER HPF	CASTS PER LPF	CRYSTALS PER LPF	SPECIAL COMMENTS
GROUP & SEX: 3M	DOSE LEVEL: 500			DOSAGE UNIT: MG/KG			
H00985	0	1	0	III	0	1D,2B	-
H00986	0	0	0	III	0	5B	-
H00987	0	0	0	III	0	5D	-
H00988	0	0	0	III	0	5D	-
H00989	0	0	0	III	0	5B.5D	-
H00990	0	0	0	II	0	5D,5B	-
GROUP & SEX: 3F	DOSE LEVEL: 500			DOSAGE UNIT: MG/KG			
H00991	0	0	0	III	0	5B	-
H00992	0	0	0	III	0	5D,1B	-
H00993 TE	-	-	-	-	-	-	-
H00994	0	0	0	III	0	5D,5B	-
H00995	0	0	0	III	0	5D	-
H00996	0	0	0	III	0	5D	-

APPENDIX
INDIVIDUAL CLINICAL URINALYSIS VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 AD MIXED IN DIET

ANIMAL NUMBER	RBC PER HPF	WBC PER HPF	EPITH PER HPF	BACT PER HPF	CASTS PER LPF	CRYSTALS PER LPF	SPECIAL COMMENTS
GROUP & SEX: 4M	DOSE LEVEL: 1000		DOSAGE UNIT: MG/KG				
H00001	0	0	0	III	0	3B	-
H00002	0	0	0	III	0	5B	-
H00003	0	0	1	III	0	4B,5D	-
H00997	0	0	1	III	0	5D,1B	-
H00998	0	0	0	III	0	5D	-
H00999	0	0	1	III	0	5D	-
GROUP & SEX: 4F	DOSE LEVEL: 1000		DOSAGE UNIT: MG/KG				
H00004	0	0	0	III	0	5D	-
H00005	0	0	0	III	0	5D,5B	-
H00006	0	0	0	III	0	5D	-
H00007	0	0	0	III	0	4D,1B	-
H00008	0	0	0	III	0	5D	-
H00009	0	0	0	III	0	5D,3B	-

S6127111 DOG POOL M+F WEEK: 008

APPENDIX
INDIVIDUAL CLINICAL URINALYSIS VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	SP GR	PH	U. VOL ML
GROUP & SEX: 1M	DOSE LEVEL: 0		DOSAGE UNIT: MG/KG
H00961	1.009	8.5	980.0
H00962	1.022	8.5	420.0
H00963	1.015	8.5	620.0
H00964	1.011	8.5	800.0
H00965	1.016	8.5	620.0
H00966	1.011	8.5	555.0
N=	6	6	6
MEAN	1.014	8.5	665.8
S.D.	.0047	.00	196.78
GROUP & SEX: 1F	DOSE LEVEL: 0		DOSAGE UNIT: MG/KG
H00967	1.012	7.5	800.0
H00968	1.023	8.5	270.0
H00969	1.011	8.5	1000.0
H00970	1.014	8.5	730.0
H00971	1.026	8.5	200.0
H00972	1.018	7.5	360.0
N=	6	6	6
MEAN	1.017	8.2	560.0
S.D.	.0061	.52	326.74
POOLED M+F GROUP: 1			
N=	12	12	12
MEAN M+F	1.016	8.3	612.9
S.D. M+F	.0055	.39	263.03

APPENDIX
INDIVIDUAL CLINICAL URINALYSIS VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	SP GR	PH	U. VOL ML
GROUP & SEX: 2M	DOSE LEVEL: 250		DOSAGE UNIT: MG/KG
H00973	1.025	8.5	305.0
H00974	1.018	8.5	565.0
H00975	1.014	8.5	690.0
H00976	1.030	8.5	630.0
H00977	1.017	8.5	530.0
H00978	1.027	8.5	195.0
N=	6	6	6
MEAN	1.022	8.5	485.8
S.D.	.0064	.00	193.89
GROUP & SEX: 2F	DOSE LEVEL: 250		DOSAGE UNIT: MG/KG
H00979	1.048	8.0	60.0
H00980	1.012	7.0	590.0
H00981	1.019	7.5	240.0
H00982 **	1.001	7.5	2990.0
H00983	1.006	8.5	1220.0
H00984	1.017	8.5	430.0
N=	5	5	5
MEAN	1.020	7.9	508.0
S.D.	.0162	.65	445.05
POOLED M+F GROUP: 2			
N=	11	11	11
MEAN M+F	1.021	8.2	495.9
S.D. M+F	.0112	.52	313.30

** = POSSIBLE WATER CONTAMINATION, DATA EXCLUDED FROM STATISTICS

S6127111 DOG POOL M+F WEEK: 008

APPENDIX
INDIVIDUAL CLINICAL URINALYSIS VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	SP GR	PH	U. VOL ML
GROUP & SEX: 3M	DOSE LEVEL: 500		DOSAGE UNIT: MG/KG
H00985	1.011	8.5	820.0
H00986	1.013	8.5	760.0
H00987	1.014	8.5	220.0
H00988	1.013	8.5	305.0
H00989	1.019	8.5	450.0
H00990	1.025	8.5	250.0
N=	6	6	6
MEAN	1.016	8.5	467.5
S.D.	.0052	.00	262.71
GROUP & SEX: 3F	DOSE LEVEL: 500		DOSAGE UNIT: MG/KG
H00991	1.012	7.5	650.0
H00992	1.014	8.5	580.0
H00993	1.025	8.5	350.0
H00994	1.023	8.5	365.0
H00995	1.027	7.5	150.0
H00996	1.022	7.5	240.0
N=	6	6	6
MEAN	1.020	8.0	389.2
S.D.	.0061	.55	192.88
POOLED M+F GROUP: 3			
N=	12	12	12
MEAN M+F	1.018	8.2	428.3
S.D. M+F	.0059	.45	223.51

APPENDIX
INDIVIDUAL CLINICAL URINALYSIS VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	SP GR	PH	U. VOL ML
GROUP & SEX: 4M	DOSE LEVEL: 1000		DOSAGE UNIT: MG/KG
H00001	1.021	8.5	375.0
H00002	1.007	8.0	1195.0
H00003	1.021	8.0	320.0
H00997	1.022	8.5	480.0
H00998	1.014	8.5	790.0
H00999	1.008	8.5	720.0
N=	6	6	6
MEAN	1.016	8.3	646.7
S.D.	.0068	.26	327.07
GROUP & SEX: 4F	DOSE LEVEL: 1000		DOSAGE UNIT: MG/KG
H00004	1.023	8.5	330.0
H00005	1.014	8.5	605.0
H00006	1.025	8.5	280.0
H00007	1.018	8.5	405.0
H00008	1.025	8.0	210.0
H00009	1.025	8.0	170.0
N=	6	6	6
MEAN	1.022	8.3	333.3
S.D.	.0046	.26	157.28
POOLED M+F GROUP: 4			
N=	12	12	12
MEAN M+F	1.018	8.3	490.0
S.D. M+F	.0064	.25	294.36

S6127111 DOG POOL M+F WEEK: 008

APPENDIX
INDIVIDUAL CLINICAL URINALYSIS VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	U PRO MG/DL	U GLU	U KET	U BILI	U BLOOD	UROBILI	URINE APP.
GROUP & SEX: 1M	DOSE LEVEL: 0		DOSAGE UNIT: MG/KG				
H00961	100	0	0	0	0	0	B,L,M
H00962	300	0	0	0	0	0	C,L,M
H00963	)2000	0	0	0	0	0	B,K,N
H00964	)2000	0	0	0	0	0	B,L,M
H00965	)2000	0	0	0	0	0	B,L,M
H00966	)2000	0	0	0	0	0	B,K,M
GROUP & SEX: 1F	DOSE LEVEL: 0		DOSAGE UNIT: MG/KG				
H00967	30	0	0	0	0	0	A,K,M
H00968	)2000	0	0	0	0	0	C,L
H00969	30	0	0	0	0	0	A,L,M
H00970	)2000	0	0	0	0	0	B,L,M
H00971	300	0	0	0	0	0	B,L,M
H00972	30	0	0	0	+	0	C,L,M

APPENDIX
INDIVIDUAL CLINICAL URINALYSIS VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	U PRO MG/DL	U GLU	U KET	U BILI	U BLOOD	UROBILI	URINE APP.
GROUP & SEX: 2M	DOSE LEVEL: 250		DOSAGE UNIT: MG/KG				
H00973	)2000	0	0	0	0	0	D,L,M
H00974	)2000	0	0	0	0	0	D,L,M
H00975	)2000	0	0	0	0	0	B,L,M
H00976	)2000	0	0	0	0	0	B,L,M,N
H00977	)2000	0	0	0	0	0	B,L,M
H00978	)2000	0	0	0	0	0	D,J,M
GROUP & SEX: 2F	DOSE LEVEL: 250		DOSAGE UNIT: MG/KG				
H00979	100	0	0	0	0	0	D,J,M
H00980	10	0	0	0	0	0	A,K,M
H00981	10	0	0	0	0	0	B,J
H00982 **	0	0	0	0	0	0	A,J
H00983	)2000	0	0	0	0	0	A,L,M
H00984	)2000	0	0	0	0	0	B,L,M

** = POSSIBLE WATER CONTAMINATION

APPENDIX
INDIVIDUAL CLINICAL URINALYSIS VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	U PRO MG/DL	U GLU	U KET	U BILI	U BLOOD	UROBILI	URINE APP.
GROUP & SEX: 3M	DOSE LEVEL: 500		DOSAGE UNIT: MG/KG				
H00985	)2000	0	0	0	0	0	B,L,M
H00986	)2000	0	0	0	0	0	B,L,M
H00987	)2000	0	0	0	0	0	C,J,M
H00988	)2000	0	0	0	0	0	B,J,M
H00989	30	0	0	0	0	0	C,J,M
H00990	)2000	0	0	0	0	0	C,K
GROUP & SEX: 3F	DOSE LEVEL: 500		DOSAGE UNIT: MG/KG				
H00991	10	0	0	0	0	0	B,L,M
H00992	)2000	0	0	0	0	0	B,L,M
H00993	)2000	0	0	0	0	0	B,J
H00994	)2000	0	0	0	0	0	B,L,M
H00995	)2000	0	0	0	0	0	A,J
H00996	30	0	0	0	0	0	B,L,M

S6127111 DOG POOL M+F WEEK: 008

APPENDIX
INDIVIDUAL CLINICAL URINALYSIS VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	U PRO MG/DL	U GLU	U KET	U BILI	U BLOOD	UROBILI	URINE APP.
GROUP & SEX: 4M	DOSE LEVEL: 1000		DOSAGE UNIT: MG/KG				
H00001	>2000	0	0	0	0	0	C,L,M
H00002	10	0	0	0	0	0	A,K,M
H00003	100	0	0	0	0	0	B,L,M
H00997	>2000	0	0	0	0	0	B,L,N
H00998	>2000	0	0	0	0	0	B,L,M
H00999	30	0	0	0	0	0	B,L,M
GROUP & SEX: 4F	DOSE LEVEL: 1000		DOSAGE UNIT: MG/KG				
H00004	100	0	0	0	0	0	B,K,M
H00005	30	0	0	0	0	0	B,L,M
H00006	>2000	0	0	0	0	0	B,L,M
H00007	>2000	0	0	0	0	0	B,L,M
H00008	10	0	+	0	0	0	B,J,M
H00009	30	0	0	0	0	0	B,L,M

S6127111 DOG POOL M+F WEEK: 008

APPENDIX
INDIVIDUAL CLINICAL URINALYSIS VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	RBC PER HPF	WBC PER HPF	EPITH PER HPF	BACT PER HPF	CASTS PER LPF	CRYSTALS PER LPF	SPECIAL COMMENTS
GROUP & SEX: 1M	DOSE LEVEL: 0			DOSAGE UNIT: MG/KG			
H00961	0	0	0	III	0	5D	-
H00962	0	0	0	III	0	5D	-
H00963	0	1	0	III	0	5D	-
H00964	0	0	0	III	0	5D	-
H00965	0	0	0	III	0	5D	-
H00966	0	0	0	III	0	5D	-
GROUP & SEX: 1F	DOSE LEVEL: 0			DOSAGE UNIT: MG/KG			
H00967	0	0	0	III	0	5D	-
H00968	0	0	0	III	0	5D	-
H00969	0	0	0	III	0	5D	-
H00970	0	0	0	III	0	5D	-
H00971	0	0	0	III	0	5D	-
H00972	0	0	0	III	0	5D	R

S6127111 DOG POOL M+F WEEK: 008

APPENDIX
INDIVIDUAL CLINICAL URINALYSIS VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	RBC PER HPF	WBC PER HPF	EPITH PER HPF	BACT PER HPF	CASTS PER LPF	CRYSTALS PER LPF	SPECIAL COMMENTS
GROUP & SEX: 2M	DOSE LEVEL: 250			DOSAGE UNIT: MG/KG			
H00973	0	0	0	III	0	5D	-
H00974	0	0	0	III	0	5D	-
H00975	0	0	0	III	0	5D	-
H00976	0	0	0	III	0	5D	-
H00977	0	0	0	III	0	5D	-
H00978	0	0	0	III	0	5D	-
GROUP & SEX: 2F	DOSE LEVEL: 250			DOSAGE UNIT: MG/KG			
H00979	1	0	0	II	0	5D	-
H00980	0	0	0	III	0	2D,2B	*
H00981	0	0	0	III	0	5D	-
H00982 **	0	0	0	II	0	1D,2A	-
H00983	0	0	0	III	0	3D	-
H00984	0	0	1	III	0	5D	-

* = TRICHOMONAS PRESENT
** = POSSIBLE WATER CONTAMINATION

APPENDIX
INDIVIDUAL CLINICAL URINALYSIS VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	RBC PER HPF	WBC PER HPF	EPITH PER HPF	BACT PER HPF	CASTS PER LPF	CRYSTALS PER LPF	SPECIAL COMMENTS
GROUP & SEX: 3M	DOSE LEVEL: 500		DOSAGE UNIT: MG/KG				
H00985	0	0	0	III	0	5D,5B	-
H00986	0	0	0	III	0	5D	-
H00987	0	0	0	III	0	5D	-
H00988	0	0	0	III	0	5D	-
H00989	0	0	0	III	0	5D,5B	-
H00990	0	1	0	III	0	5D	-
GROUP & SEX: 3F	DOSE LEVEL: 500		DOSAGE UNIT: MG/KG				
H00991	0	0	0	III	0	4D,1A	-
H00992	0	0	0	III	0	5D,5B	-
H00993	0	0	1	III	0	5D	-
H00994	0	0	0	III	0	5D	-
H00995	0	1	0	II	0	1D	-
H00996	0	0	0	III	0	5D,2A	

S6127111 DOG POOL M+F WEEK: 008

APPENDIX
INDIVIDUAL CLINICAL URINALYSIS VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	RBC PER HPF	WBC PER HPF	EPITH PER HPF	BACT PER HPF	CASTS PER LPF	CRYSTALS PER LPF	SPECIAL COMMENTS
GROUP & SEX: 4M	DOSE LEVEL: 1000			DOSAGE UNIT: MG/KG			
H00001	0	0	0	III	0	5D	-
H00002	0	0	0	III	0	5D	-
H00003	0	0	0	III	0	5D	-
H00997	0	0	0	III	0	5D	-
H00998	0	0	0	III	0	5D,5B	-
H00999	0	0	0	III	0	5D	R
GROUP & SEX: 4F	DOSE LEVEL: 1000			DOSAGE UNIT: MG/KG			
H00004	0	0	0	III	0	5D	-
H00005	0	0	0	III	0	5D	-
H00006	0	0	0	III	0	5D	-
H00007	0	0	0	III	0	1D	-
H00008	0	0	0	III	0	5D	-
H00009	0	0	0	III	0	5D	P

S6127111 DOG POOL M+F WEEK: 017

APPENDIX
INDIVIDUAL CLINICAL URINALYSIS VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	SP GR	PH	U. VOL ML
GROUP & SEX: 1M	DOSE LEVEL: 0		DOSAGE UNIT: MG/KG
H00961	1.021	8.5	220.0
H00962	1.015	8.5	530.0
H00963	1.021	8.5	230.0
H00964	1.017	8.5	480.0
H00965	1.018	8.5	430.0
H00966	1.017	8.5	445.0
N=	6	6	6
MEAN	1.018	8.5	389.2
S.D.	.0024	.00	131.77
GROUP & SEX: 1F	DOSE LEVEL: 0		DOSAGE UNIT: MG/KG
H00967	1.013	8.5	830.0
H00968	1.016	8.5	600.0
H00969	1.018	8.5	440.0
H00970	1.016	8.5	615.0
H00971	1.019	7.5	420.0
H00972	1.020	7.5	410.0
N=	6	6	6
MEAN	1.017	8.2	552.5
S.D.	.0025	.52	163.52
POOLED M+F GROUP: 1			
N=	12	12	12
MEAN M+F	1.018	8.3	470.8
S.D. M+F	.0024	.39	165.29

APPENDIX
INDIVIDUAL CLINICAL URINALYSIS VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	SP GR	PH	U. VOL ML
GROUP & SEX: 2M	DOSE LEVEL: 250		DOSAGE UNIT: MG/KG
H00973	1.015	8.5	445.0
H00974	1.020	8.5	230.0
H00975	1.008	8.5	840.0
H00976	1.015	8.5	685.0
H00977	1.013	8.5	615.0
H00978	1.018	8.5	440.0
N=	6	6	6
MEAN	1.015	8.5	542.5
S.D.	.0042	.00	215.28
GROUP & SEX: 2F	DOSE LEVEL: 250		DOSAGE UNIT: MG/KG
H00979	1.022	8.5	275.0
H00980	1.013	8.5	605.0
H00981	1.018	8.5	500.0
H00982	1.028	8.5	285.0
H00983	1.010	8.5	605.0
H00984	1.028	8.5	190.0
N=	6	6	6
MEAN	1.020	8.5	410.0
S.D.	.0075	.00	182.43
POOLED M+F GROUP: 2			
N=	12	12	12
MEAN M+F	1.017	8.5	476.2
S.D. M+F	.0064	.00	202.44

APPENDIX
INDIVIDUAL CLINICAL URINALYSIS VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	SP GR	PH	U. VOL ML
GROUP & SEX: 3M	DOSE LEVEL: 500		DOSAGE UNIT: MG/KG
H00985	1.014	8.5	860.0
H00986	1.018	8.5	450.0
H00987	1.024	8.5	225.0
H00988	1.028	8.5	150.0
H00989	1.022	8.0	455.0
H00990	1.016	8.0	690.0
N=	6	6	6
MEAN	1.020	8.3	471.7
S.D.	.0053	.26	269.64
GROUP & SEX: 3F	DOSE LEVEL: 500		DOSAGE UNIT: MG/KG
H00991	1.020	8.5	350.0
H00992	1.025	8.5	255.0
H00993	1.024	8.5	355.0
H00994	1.014	8.5	140.0
H00995	1.048	8.5	110.0
H00996	1.014	8.5	400.0
N=	6	6	6
MEAN	1.024	8.5	268.3
S.D.	.0126	.00	121.02
POOLED M+F GROUP: 3			
N=	12	12	12
MEAN M+F	1.022	8.4	370.0
S.D. M+F	.0094	.19	225.79

APPENDIX
INDIVIDUAL CLINICAL URINALYSIS VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	SP GR	PH	U. VOL ML
GROUP & SEX: 4M	DOSE LEVEL: 1000		DOSAGE UNIT: MG/KG
H00001	1.011	8.5	880.0
H00002	1.009	8.5	795.0
H00003	1.020	8.0	330.0
H00997	1.013	8.5	575.0
H00998	1.012	8.5	1145.0
H00999	1.007	8.5	1300.0
N=	6	6	6
MEAN	1.012	8.4	837.5
S.D.	.0045	.20	357.36
GROUP & SEX: 4F	DOSE LEVEL: 1000		DOSAGE UNIT: MG/KG
H00004	1.029	8.5	250.0
H00005	1.014	8.5	365.0
H00006	1.014	8.5	620.0
H00007	1.014	8.5	535.0
H00008	1.031	8.5	215.0
H00009	1.024	8.5	300.0
N=	6	6	6
MEAN	1.021	8.5	380.8
S.D.	.0080	.00	162.71
POOLED M+F GROUP: 4			
N=	12	12	12
MEAN M+F	1.016	8.4	609.2
S.D. M+F	.0078	.14	356.31

S6127111 DOG POOL M+F WEEK: 017

APPENDIX
INDIVIDUAL CLINICAL URINALYSIS VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	U PRO MG/DL	U GLU	U KET	U BILI	U BLOOD	UROBILI	URINE APP.
GROUP & SEX: 1M	DOSE LEVEL: 0		DOSAGE UNIT: MG/KG				
H00961	>2000	0	0	0	0	0	D,K,M,N
H00962	>2000	0	0	0	0	0	B,K,M,N
H00963	>2000	0	0	0	0	0	C,K,M,N
H00964	300	0	0	0	0	0	B,K,M,N
H00965	>2000	0	0	0	0	0	B,K,N
H00966	300	0	0	0	0	0	C,K,M,N
GROUP & SEX: 1F	DOSE LEVEL: 0		DOSAGE UNIT: MG/KG				
H00967	>2000	0	0	0	0	0	B,K,N
H00968	>2000	0	0	0	0	0	B,K,N
H00969	>2000	0	0	0	0	0	B,K,M,N
H00970	>2000	0	0	0	0	0	B,K,M,N
H00971	0	0	0	0	0	0	B,K,M,N
H00972	30	0	0	0	0	0	B,K,M,N

S6127111 DOG POOL M+F WEEK: 017

APPENDIX
INDIVIDUAL CLINICAL URINALYSIS VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	U PRO MG/DL	U GLU	U KET	U BILI	U BLOOD	UROBILI	URINE APP.
GROUP & SEX: 2M	DOSE LEVEL: 250		DOSAGE UNIT: MG/KG				
H00973	300	0	0	0	0	0	B,K,M,N
H00974	100	0	0	0	0	0	C,J,M,N
H00975	300	0	0	0	0	0	B,K,M,N
H00976	100	0	0	0	0	0	B,K,M,N
H00977	30	0	0	0	0	0	C,K,N
H00978	30	0	0	0	0	0	C,K,N
GROUP & SEX: 2F	DOSE LEVEL: 250		DOSAGE UNIT: MG/KG				
H00979	)2000	0	0	0	0	0	C,K,M,N
H00980	30	0	0	0	0	0	B,K,N
H00981	)2000	0	0	0	0	0	B,J,N
H00982	)2000	0	0	0	0	0	C,J,M,N
H00983	100	0	0	0	0	0	B,K,N
H00984	)2000	0	0	0	0	0	C,K,M,N

S6127111 DOG POOL M+F WEEK: 017

APPENDIX
INDIVIDUAL CLINICAL URINALYSIS VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	U PRO MG/DL	U GLU	U KET	U BILI	U BLOOD	UROBILI	URINE APP.
GROUP & SEX: 3M	DOSE LEVEL: 500			DOSAGE UNIT: MG/KG			
H00985	>2000	0	0	0	0	0	B,K,M,N
H00986	>2000	0	0	0	0	0	B,K,M,N
H00987	100	0	0	0	0	0	C,J,M,N
H00988	100	0	0	0	0	0	C,J,N
H00989	30	0	0	0	0	0	C,K,M,N
H00990	0	0	0	0	0	0	B,K,M,N
GROUP & SEX: 3F	DOSE LEVEL: 500			DOSAGE UNIT: MG/KG			
H00991	>2000	0	0	0	0	0	B,K,M,N
H00992	300	0	0	0	0	0	C,K,N
H00993	>2000	0	0	0	0	0	B,K,M,N
H00994	>2000	0	0	0	0	0	C,J
H00995	>2000	0	0	0	0	0	D,K,M,N
H00996	30	0	0	0	+	0	B,K,N

S6127111 DOG POOL M+F WEEK: 017

APPENDIX
INDIVIDUAL CLINICAL URINALYSIS VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	U PRO MG/DL	U GLU	U KET	U BILI	U BLOOD	UROBILI	URINE APP.
GROUP & SEX: 4M	DOSE LEVEL: 1000		DOSAGE UNIT: MG/KG				
H00001	>2000	0	0	0	0	0	B,K,M,N
H00002	30	0	0	0	0	0	B,K,M,N
H00003	30	0	0	0	0	0	B,K,M,N
H00997	30	0	0	0	0	0	B,K,M,N
H00998	300	0	0	0	0	0	B,L,M,N
H00999	100	0	0	0	0	0	B,K,M,N
GROUP & SEX: 4F	DOSE LEVEL: 1000		DOSAGE UNIT: MG/KG				
H00004	100	0	0	0	+	0	B,K,M,N
H00005	100	0	0	0	0	0	B,J,N
H00006	100	0	0	0	0	0	B,K,N
H00007	100	0	0	0	0	0	B,K,M,N
H00008	>2000	0	0	0	0	0	C,K,M,N
H00009	>2000	0	0	0	0	0	C,K,M,N

S6127111 DOG POOL M+F WEEK: 017

APPENDIX
INDIVIDUAL CLINICAL URINALYSIS VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	RBC PER HPF	WBC PER HPF	EPITH PER HPF	BACT PER HPF	CASTS PER LPF	CRYSTALS PER LPF	SPECIAL COMMENTS
GROUP & SEX: 1M	DOSE LEVEL: 0		DOSAGE UNIT: MG/KG				
H00961	1	0	0	III	0	3B	-
H00962	0	0	1	III	0	2B	-
H00963	0	0	0	II	0	3B	-
H00964	1	0	0	III	0	2D,2B	-
H00965	1	0	0	III	0	2D,3B	R
H00966	0	0	0	III	0	3B	-
GROUP & SEX: 1F	DOSE LEVEL: 0		DOSAGE UNIT: MG/KG				
H00967	0	0	1	III	0	2B,2D	-
H00968	0	0	0	III	0	3B	-
H00969	1	0	0	III	0	4D,2B	-
H00970	0	0	0	III	0	3B,1D	-
H00971	0	0	0	III	0	3D,3B	-
H00972	0	0	0	III	0	2D,2B	-

APPENDIX
INDIVIDUAL CLINICAL URINALYSIS VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	RBC PER HPF	WBC PER HPF	EPITH PER HPF	BACT PER HPF	CASTS PER LPF	CRYSTALS PER LPF	SPECIAL COMMENTS
GROUP & SEX: 2M	DOSE LEVEL: 250		DOSAGE UNIT: MG/KG				
H00973	0	0	0	III	0	2B,1D	-
H00974	1	0	1	II	0	3D,2B	-
H00975	1	0	0	III	0	3B,2D	-
H00976	0	0	0	III	0	3B,3D	-
H00977	0	0	0	III	0	3B,2D	R
H00978	0	0	0	III	0	3B,3D	-
GROUP & SEX: 2F	DOSE LEVEL: 250		DOSAGE UNIT: MG/KG				
H00979	0	0	0	III	0	5D	-
H00980	0	0	0	II	0	3D,1B	-
H00981	0	0	2	III	0	4D,2B	-
H00982	0	0	2	II	0	4D	-
H00983	0	0	0	III	0	3D,3B	-
H00984	0	0	1	III	0	4D	-

APPENDIX
INDIVIDUAL CLINICAL URINALYSIS VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	RBC PER HPF	WBC PER HPF	EPITH PER HPF	BACT PER HPF	CASTS PER LPF	CRYSTALS PER LPF	SPECIAL COMMENTS
GROUP & SEX: 3M	DOSE LEVEL: 500			DOSAGE UNIT: MG/KG			
H00985	0	0	0	III	0	3B,2D	-
H00986	0	0	0	III	0	3B,1D	-
H00987	0	0	0	II	0	3D,2B	-
H00988	0	0	0	II	0	3D,1B	-
H00989	0	0	0	II	0	4D,2B	-
H00990	0	0	0	III	0	2D,2B	-
GROUP & SEX: 3F	DOSE LEVEL: 500			DOSAGE UNIT: MG/KG			
H00991	0	0	0	III	0	4D,2B	-
H00992	0	0	1	II	0	4D,2B	-
H00993	0	0	0	III	0	3D,4B	-
H00994	0	0	0	I	0	3D	-
H00995	0	0	0	III	0	4D,2B	-
H00996	0	0	1	III	0	4D	-

APPENDIX
INDIVIDUAL CLINICAL URINALYSIS VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	RBC PER HPF	WBC PER HPF	EPITH PER HPF	BACT PER HPF	CASTS PER LPF	CRYSTALS PER LPF	SPECIAL COMMENTS
GROUP & SEX: 4M	DOSE LEVEL: 1000		DOSAGE UNIT: MG/KG				
H00001	0	0	0	III	0	3B	R
H00002	0	0	0	III	0	3D,3B	-
H00003	0	0	0	III	0	1B	-
H00997	0	0	0	II	0	4D,3B	-
H00998	0	0	0	III	0	3B	-
H00999	1	0	1	III	0	3B	R
GROUP & SEX: 4F	DOSE LEVEL: 1000		DOSAGE UNIT: MG/KG				
H00004	0	0	0	III	0	4D,3B	-
H00005	0	0	0	II	0	3D,1B	-
H00006	0	0	0	III	0	4D,4B	-
H00007	0	0	0	II	0	4D,2B	-
H00008	0	0	0	III	0	3B,1D	-
H00009	0	0	0	III	0	2B,1D	-

S6127111 DOG POOL M+F WEEK: 026

APPENDIX
INDIVIDUAL CLINICAL URINALYSIS VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	SP GR	PH	U. VOL ML
GROUP & SEX: 1M	DOSE LEVEL: 0		DOSAGE UNIT: MG/KG
H00961	1.016	8.0	315.0
H00962	1.017	8.5	760.0
H00963	1.027	8.5	330.0
H00964	1.014	8.5	670.0
H00965	1.027	8.5	235.0
H00966	1.016	8.5	455.0
N=	6	6	6
MEAN	1.020	8.4	460.8
S.D.	.0059	.20	211.03
GROUP & SEX: 1F	DOSE LEVEL: 0		DOSAGE UNIT: MG/KG
H00967	1.018	8.5	345.0
H00968	1.017	8.5	460.0
H00969	1.015	8.5	430.0
H00970	1.009	8.0	630.0
H00971	1.022	8.5	350.0
H00972	1.011	8.0	720.0
N=	6	6	6
MEAN	1.015	8.3	489.2
S.D.	.0048	.26	153.38
POOLED M+F GROUP: 1			
N=	12	12	12
MEAN M+F	1.017	8.4	475.0
S.D. M+F	.0056	.23	176.51

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INDIVIDUAL CLINICAL URINALYSIS VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	SP GR	PH	U. VOL ML
GROUP & SEX: 2M	DOSE LEVEL: 250		DOSAGE UNIT: MG/KG
H00973	1.020	8.5	360.0
H00974	1.016	8.5	415.0
H00975	1.006	7.5	600.0
H00976	1.028	8.5	220.0
H00977	1.026	8.5	230.0
H00978	1.029	8.0	105.0
N=	6	6	6
MEAN	1.021	8.2	321.7
S.D.	.0088	.42	175.12
GROUP & SEX: 2F	DOSE LEVEL: 250		DOSAGE UNIT: MG/KG
H00979	>1.090	6.0	30.0
H00980	1.070	6.5	21.0
H00981	1.018	8.5	520.0
H00982	1.033	8.5	25.0
H00983	1.008	8.5	865.0
H00984	1.028	7.0	190.0
N=	5	6	6
MEAN	1.031	7.5	275.2
S.D.	.0236	1.14	347.10
POOLED M+F GROUP: 2			
N=	11	12	12
MEAN M+F	1.026	7.9	298.4
S.D. M+F	.0171	.91	263.23

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INDIVIDUAL CLINICAL URINALYSIS VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	SP GR	PH	U. VOL ML
GROUP & SEX: 3M	DOSE LEVEL: 500		DOSAGE UNIT: MG/KG
H00985	1.013	8.5	1095.0
H00986	1.017	8.5	580.0
H00987	1.021	8.5	290.0
H00988	1.029	7.0	110.0
H00989	1.023	7.5	205.0
H00990	1.011	8.0	810.0
N=	6	6	6
MEAN	1.019	8.0	515.0
S.D.	.0067	.63	384.29
GROUP & SEX: 3F	DOSE LEVEL: 500		DOSAGE UNIT: MG/KG
H00991	1.034	7.5	63.0
H00992	1.030	8.0	81.0
H00993	1.031	8.5	205.0
H00994	1.027	8.0	280.0
H00995	1.023	8.5	100.0
H00996	1.015	7.5	230.0
N=	6	6	6
MEAN	1.027	8.0	159.8
S.D.	.0068	.45	90.08
POOLED M+F GROUP: 3			
N=	12	12	12
MEAN M+F	1.023	8.0	337.4
S.D. M+F	.0076	.52	324.37

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TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	SP GR	PH	U. VOL ML
GROUP & SEX: 4M	DOSE LEVEL: 1000		DOSAGE UNIT: MG/KG
H00001	1.012	8.5	490.0
H00002	1.021	6.0	275.0
H00003	1.015	6.5	555.0
H00997	1.020	8.5	560.0
H00998	1.015	7.0	545.0
H00999	1.016	8.0	585.0
N=	6	6	6
MEAN	1.016	7.4	501.7
S.D.	.0034	1.07	115.40
GROUP & SEX: 4F	DOSE LEVEL: 1000		DOSAGE UNIT: MG/KG
H00004	1.033	6.5	53.0
H00005	1.021	7.0	335.0
H00006	1.024	8.5	425.0
H00007	1.017	8.5	450.0
H00008	1.022	8.5	225.0
H00009	1.060	6.5	69.0
N=	6	6	6
MEAN	1.030	7.6	259.5
S.D.	.0158	1.02	172.92
POOLED M+F GROUP: 4			
N=	12	12	12
MEAN M+F	1.023	7.5	380.6
S.D. M+F	.0129	1.00	188.78

S6127111 DOG POOL M+F WEEK: 026

APPENDIX
INDIVIDUAL CLINICAL URINALYSIS VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	U PRO MG/DL	U GLU	U KET	U BILI	U BLOOD	UROBILI	URINE APP.
GROUP & SEX: 1M	DOSE LEVEL: 0		DOSAGE UNIT: MG/KG				
H00961	10	0	0	0	0	0	C,L,M,N
H00962	100	0	0	0	0	0	C,L,M,N
H00963	>2000	0	0	0	0	0	C,L,M,N
H00964	300	0	0	0	0	0	B,K
H00965	30	0	0	0	0	0	D,L,M,N
H00966	100	0	0	0	0	0	B,L,M,N
GROUP & SEX: 1F	DOSE LEVEL: 0		DOSAGE UNIT: MG/KG				
H00967	>2000	0	0	0	0	0	B,J
H00968	>2000	0	0	0	0	0	B,K,M,N
H00969	30	0	0	0	0	0	B,K,M,N
H00970	10	0	0	0	0	0	B,J,M,N
H00971	30	0	0	0	0	0	B,K,N
H00972	10	0	0	0	0	0	B,J,N

S6127111 DOG POOL M+F WEEK: 026

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INDIVIDUAL CLINICAL URINALYSIS VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	U PRO MG/DL	U GLU	U KET	U BILI	U BLOOD	UROBILI	URINE APP.
GROUP & SEX: 2M	DOSE LEVEL: 250			DOSAGE UNIT: MG/KG			
H00973	30	0	0	0	0	0	C,K,M,N
H00974	30	0	0	0	0	0	C,K,M,N
H00975	10	0	0	0	0	0	B,J
H00976	30	0	0	0	0	0	D,L,M,N
H00977	300	0	0	0	0	0	C,K,N
H00978	30	0	0	0	0	0	C,J,M,N
GROUP & SEX: 2F	DOSE LEVEL: 250			DOSAGE UNIT: MG/KG			
H00979	>2000	0	0	0	0	0	E,L,M,N
H00980	100	0	0	0	0	0	D,J
H00981	30	0	0	0	+	0	B,K,M,N
H00982	>2000	0	0	0	0	0	D,K,N
H00983	30	0	0	0	0	0	B,K,N
H00984	30	0	0	0	0	0	C,K,M,N

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INDIVIDUAL CLINICAL URINALYSIS VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	U PRO MG/DL	U GLU	U KET	U BILI	U BLOOD	UROBILI	URINE APP.
GROUP & SEX: 3M	DOSE LEVEL: 500			DOSAGE UNIT: MG/KG			
H00985	30	0	0	0	0	0	B,L,M,N
H00986	30	0	0	0	0	0	B,K,N
H00987	100	0	0	0	0	0	B,K,N
H00988	30	0	0	0	+++	0	D,L,M
H00989	30	0	0	0	0	0	B,J,M,N
H00990	30	0	0	0	0	0	B,K,M,N
GROUP & SEX: 3F	DOSE LEVEL: 500			DOSAGE UNIT: MG/KG			
H00991	30	0	0	0	0	0	D,K,N
H00992	30	0	0	0	0	0	D,K,N
H00993	>2000	0	0	0	0	0	B,K,M,N
H00994	30	0	0	0	0	0	B,J,M,N
H00995	>2000	0	0	0	0	0	C,K,N
H00996	10	0	0	0	0	0	B,J,M,N

S6127111 DOG POOL M+F WEEK: 026

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INDIVIDUAL CLINICAL URINALYSIS VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	U PRO MG/DL	U GLU	U KET	U BILI	U BLOOD	UROBILI	URINE APP.
GROUP & SEX: 4M	DOSE LEVEL: 1000		DOSAGE UNIT: MG/KG				
H00001	30	0	0	0	0	0	B,K,M,N
H00002	30	0	0	0	+	0	B,K,M,N
H00003	10	0	0	0	0	0	B,J,M,N
H00997	100	0	0	0	0	0	B,K,M,N
H00998	30	0	0	0	0	0	B,L,M,N
H00999	10	0	0	0	0	0	B,K,M,N
GROUP & SEX: 4F	DOSE LEVEL: 1000		DOSAGE UNIT: MG/KG				
H00004	30	0	0	0	0	0	C,J,M
H00005	10	0	0	0	0	0	B,J,M,N
H00006	>2000	0	0	0	0	0	B,K,M,N
H00007	100	0	0	0	0	0	B,J,M
H00008	100	0	0	0	0	0	B,K,M,N
H00009	30	0	0	0	0	0	C,J,M,N

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INDIVIDUAL CLINICAL URINALYSIS VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	RBC PER HPF	WBC PER HPF	EPITH PER HPF	BACT PER HPF	CASTS PER LPF	CRYSTALS PER LPF	SPECIAL COMMENTS
GROUP & SEX: 1M	DOSE LEVEL: 0		DOSAGE UNIT: MG/KG				
H00961	0	0	1	III	0	5D	-
H00962	0	0	0	III	0	3D,2B	-
H00963	0	0	0	III	0	5D,3B	-
H00964	0	0	0	III	0	3D	-
H00965	0	0	0	III	0	2D	-
H00966	0	0	0	III	0	5D,4B	-
GROUP & SEX: 1F	DOSE LEVEL: 0		DOSAGE UNIT: MG/KG				
H00967	0	0	0	III	0	3D	-
H00968	0	0	0	III	0	5D,4B	-
H00969	0	0	0	III	0	5D	-
H00970	0	0	0	III	0	5D,4B	-
H00971	0	0	1	III	0	4B,2D	-
H00972	0	0	0	III	0	4B,5D	-

S6127111 DOG POOL M+F WEEK: 026

APPENDIX
INDIVIDUAL CLINICAL URINALYSIS VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	RBC PER HPF	WBC PER HPF	EPITH PER HPF	BACT PER HPF	CASTS PER LPF	CRYSTALS PER LPF	SPECIAL COMMENTS
GROUP & SEX: 2M	DOSE LEVEL: 250		DOSAGE UNIT: MG/KG				
H00973	0	0	0	III	0	3D,4B	-
H00974	0	0	1	III	0	5D	-
H00975	0	0	1	III	0	2D	-
H00976	0	0	0	III	0	2D,3B	-
H00977	0	0	0	III	0	5D	-
H00978	0	0	1	III	0	5D	-
GROUP & SEX: 2F	DOSE LEVEL: 250		DOSAGE UNIT: MG/KG				
H00979	4	0	1	I	0	2B,2D	-
H00980	1	1	1	I	0	2D	-
H00981	1	0	2	III	0	3B,3D	-
H00982	3	0	1	III	0	5D	-
H00983	1	0	0	III	0	3B,3D	-
H00984	4	1	1	III	0	2B,1D	-

APPENDIX
INDIVIDUAL CLINICAL URINALYSIS VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	RBC PER HPF	WBC PER HPF	EPITH PER HPF	BACT PER HPF	CASTS PER LPF	CRYSTALS PER LPF	SPECIAL COMMENTS
GROUP & SEX: 3M	DOSE LEVEL: 500			DOSAGE UNIT: MG/KG			
H00985	0	0	0	III	0	3D,3B	-
H00986	0	0	0	III	0	5D,3B	-
H00987	0	0	1	III	0	5D,3B	-
H00988	5	1	1	II	0	0	-
H00989	0	0	1	III	0	5D	-
H00990	0	0	0	III	0	2D,4B	-
GROUP & SEX: 3F	DOSE LEVEL: 500			DOSAGE UNIT: MG/KG			
H00991	1	0	1	I	0	5D	-
H00992	1	0	0	III	0	3B,5D	-
H00993	1	0	1	III	0	2B,1D	-
H00994	0	0	1	III	0	2B,4D	-
H00995	1	0	1	III	0	2B,4D	-
H00996	1	0	1	II	0	3B,5D	-

S6127111 DOG POOL M+F WEEK: 026

APPENDIX

INDIVIDUAL CLINICAL URINALYSIS VALUES

TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	RBC PER HPF	WBC PER HPF	EPITH PER HPF	BACT PER HPF	CASTS PER LPF	CRYSTALS PER LPF	SPECIAL COMMENTS
GROUP & SEX: 4M	DOSE LEVEL: 1000		DOSAGE UNIT: MG/KG				
H00001	0	0	1	III	0	3D,3B	-
H00002	1	0	1	II	0	0	Q
H00003	0	0	1	III	0	2D	-
H00997	0	0	1	III	0	5D	-
H00998	0	0	0	III	0	5B	-
H00999	0	0	0	III	0	5D	-
GROUP & SEX: 4F	DOSE LEVEL: 1000		DOSAGE UNIT: MG/KG				
H00004	0	0	1	I	0	1D	-
H00005	1	0	1	II	0	1B	-
H00006	1	0	1	III	0	2B,1D	-
H00007	0	0	0	II	0	2B,2D	-
H00008	3	0	1	III	0	3B,1D	-
H00009	0	0	1	I	0	2B,5D	-

APPENDIX
INDIVIDUAL CLINICAL URINALYSIS VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	SP GR	PH	U. VOL ML
GROUP & SEX: 1M	DOSE LEVEL: 0		DOSAGE UNIT: MG/KG
H00964	1.008	8.5	1014.0
H00965	1.015	7.5	673.0
N=	2	2	2
MEAN	1.012	8.0	843.5
S.D.	.0050	.71	241.12
GROUP & SEX: 1F	DOSE LEVEL: 0		DOSAGE UNIT: MG/KG
H00971	1.019	8.5	475.0
H00972	1.013	7.5	650.0
N=	2	2	2
MEAN	1.016	8.0	562.5
S.D.	.0042	.71	123.74
POOLED M+F GROUP: 1			
N=	4	4	4
MEAN M+F	1.014	8.0	703.0
S.D. M+F	.0046	.58	225.40

APPENDIX
INDIVIDUAL CLINICAL URINALYSIS VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	SP GR	PH	U. VOL ML
GROUP & SEX: 2M	DOSE LEVEL: 250		DOSAGE UNIT: MG/KG
H00973	1.009	7.5	1090.0
H00977	1.008	7.5	861.0
N=	2	2	2
MEAN	1.008	7.5	975.5
S.D.	.0007	.00	161.93
GROUP & SEX: 2F	DOSE LEVEL: 250		DOSAGE UNIT: MG/KG
H00979	1.011	8.0	592.0
H00981	1.011	7.5	1081.0
N=	2	2	2
MEAN	1.011	7.8	836.5
S.D.	.0000	.35	345.78
POOLED M+F GROUP: 2			
N=	4	4	4
MEAN M+F	1.010	7.6	906.0
S.D. M+F	.0015	.25	234.59

APPENDIX
INDIVIDUAL CLINICAL URINALYSIS VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	SP GR	PH	U. VOL ML
GROUP & SEX: 3M	DOSE LEVEL: 500		DOSAGE UNIT: MG/KG
H00988	1.016	8.0	568.0
H00990	1.015	8.0	500.0
N=	2	2	2
MEAN	1.016	8.0	534.0
S.D.	.0007	.00	48.08
GROUP & SEX: 3F	DOSE LEVEL: 500		DOSAGE UNIT: MG/KG
H00995	1.022	8.0	332.0
H00996	1.010	8.0	723.0
N=	2	2	2
MEAN	1.016	8.0	527.5
S.D.	.0085	.00	276.48
POOLED M+F GROUP: 3			
N=	4	4	4
MEAN M+F	1.016	8.0	530.8
S.D. M+F	.0049	.00	162.06

APPENDIX
INDIVIDUAL CLINICAL URINALYSIS VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	SP GR	PH	U. VOL ML
GROUP & SEX: 4M	DOSE LEVEL: 1000		DOSAGE UNIT: MG/KG
H00001	1.014	8.5	632.0
H00998	1.008	7.0	1203.0
N=	2	2	2
MEAN	1.011	7.8	917.5
S.D.	.0042	1.06	403.76
GROUP & SEX: 4F	DOSE LEVEL: 1000		DOSAGE UNIT: MG/KG
H00005	1.009	8.0	1005.0
H00006	1.014	7.5	631.0
N=	2	2	2
MEAN	1.012	7.8	818.0
S.D.	.0035	.35	264.46
POOLED M+F GROUP: 4			
N=	4	4	4
MEAN M+F	1.011	7.8	867.8
S.D. M+F	.0032	.64	284.52

APPENDIX
INDIVIDUAL CLINICAL URINALYSIS VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	U PRO MG/DL	U GLU	U KET	U BILI	U BLOOD	UROBILI	URINE APP.
GROUP & SEX: 1M	DOSE LEVEL: 0		DOSAGE UNIT: MG/KG				
H00964	0	0	0	0	0	0	B,K,M,N
H00965	0	0	0	0	0	0	C,K,M,N
GROUP & SEX: 1F	DOSE LEVEL: 0		DOSAGE UNIT: MG/KG				
H00971	0	0	0	0	0	0	B,K,N
H00972	0	0	0	0	+++	0	B,K,M,N

APPENDIX
INDIVIDUAL CLINICAL URINALYSIS VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	U PRO MG/DL	U GLU	U KET	U BILI	U BLOOD	UROBILI	URINE APP.
GROUP & SEX: 2M	DOSE LEVEL: 250		DOSAGE UNIT: MG/KG				
H00973	0	0	0	0	0	0	B,K,N
H00977	0	0	0	0	0	0	B,K,M,N
GROUP & SEX: 2F	DOSE LEVEL: 250		DOSAGE UNIT: MG/KG				
H00979	0	0	0	0	0	0	B,J,N
H00981	0	0	0	0	0	0	B,K,M,N

S6127111 DOG POOL M+F WEEK: 031

APPENDIX
INDIVIDUAL CLINICAL URINALYSIS VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	U PRO MG/DL	U GLU	U KET	U BILI	U BLOOD	UROBILI	URINE APP.
GROUP & SEX: 3M	DOSE LEVEL: 500		DOSAGE UNIT: MG/KG				
H00988	0	0	0	0	0	0	C,K,N
H00990	0	0	0	0	0	0	C,K,N
GROUP & SEX: 3F	DOSE LEVEL: 500		DOSAGE UNIT: MG/KG				
H00995	0	0	0	0	0	0	C,J,N
H00996	0	0	0	0	0	0	B,K,N

S6127111 DOG POOL M+F WEEK: 031

APPENDIX
INDIVIDUAL CLINICAL URINALYSIS VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	U PRO MG/DL	U GLU	U KET	U BILI	U BLOOD	UROBILI	URINE APP.
GROUP & SEX: 4M	DOSE LEVEL: 1000		DOSAGE UNIT: MG/KG				
H00001	30	0	0	0	0	0	B,K,M,N
H00998	0	0	0	0	0	0	B,K,M,N
GROUP & SEX: 4F	DOSE LEVEL: 1000		DOSAGE UNIT: MG/KG				
H00005	0	0	0	0	0	0	B,K,M,N
H00006	0	0	0	0	0	0	B,J,N

APPENDIX
INDIVIDUAL CLINICAL URINALYSIS VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	RBC PER HPF	WBC PER HPF	EPITH PER HPF	BACT PER HPF	CASTS PER LPF	CRYSTALS PER LPF	SPECIAL COMMENTS
GROUP & SEX: 1M	DOSE LEVEL: 0			DOSAGE UNIT: MG/KG			
H00964	1	0	0	III	0	4B,5D	-
H00965	1	1	1	III	0	3B,5D	-
GROUP & SEX: 1F	DOSE LEVEL: 0			DOSAGE UNIT: MG/KG			
H00971	1	0	1	III	0	2B,5D	-
H00972	2	0	0	III	0	3B,4D	-

S6127111 DOG POOL M+F WEEK: 031

APPENDIX
INDIVIDUAL CLINICAL URINALYSIS VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	RBC PER HPF	WBC PER HPF	EPITH PER HPF	BACT PER HPF	CASTS PER LPF	CRYSTALS PER LPF	SPECIAL COMMENTS
GROUP & SEX: 2M	DOSE LEVEL: 250			DOSAGE UNIT: MG/KG			
H00973	0	0	0	III	0	2B,4D	-
H00977	0	0	0	III	0	3B,4D	-
GROUP & SEX: 2F	DOSE LEVEL: 250			DOSAGE UNIT: MG/KG			
H00979	2	1	3	II	0	2B,3D	-
H00981	0	0	4	III	0	2B,4D	-

S6127111 DOG POOL M+F WEEK: 031

APPENDIX
INDIVIDUAL CLINICAL URINALYSIS VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	RBC PER HPF	WBC PER HPF	EPITH PER HPF	BACT PER HPF	CASTS PER LPF	CRYSTALS PER LPF	SPECIAL COMMENTS
GROUP & SEX: 3M	DOSE LEVEL: 500			DOSAGE UNIT: MG/KG			
H00988	1	0	0	III	0	3B,5D	-
H00990	1	0	0	III	0	3B,4D	-
GROUP & SEX: 3F	DOSE LEVEL: 500			DOSAGE UNIT: MG/KG			
H00995	1	1	1	II	0	5D	-
H00996	1	0	0	III	0	4B,5D	-

S6127111 DOG POOL M+F WEEK: 031

APPENDIX
INDIVIDUAL CLINICAL URINALYSIS VALUES
TWENTY-SIX WEEK SUBCHRONIC TOXICITY STUDY IN DOGS WITH SC-19129 ADMIXED IN DIET

ANIMAL NUMBER	RBC PER HPF	WBC PER HPF	EPITH PER HPF	BACT PER HPF	CASTS PER LPF	CRYSTALS PER LPF	SPECIAL COMMENTS
GROUP & SEX: 4M	DOSE LEVEL: 1000		DOSAGE UNIT: MG/KG				
H00001	0	0	0	III	0	4B,4D	-
H00998	1	0	0	III	0	3B,3D	-
GROUP & SEX: 4F	DOSE LEVEL: 1000		DOSAGE UNIT: MG/KG				
H00005	0	0	1	III	0	3B,5D	-
H00006	1	2	1	II	0	2B,4D	-

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APPENDIX J

Individual Animal Pathology Data

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APPENDIX J

INDIVIDUAL ANIMAL PATHOLOGY DATA

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

PRINTED: 22-MAY-86
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STUDY NUMBER: 6127111

ANIMAL NUMBER: 000961 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 01/10/86 STUDY DAY OF DEATH: 185 STUDY WEEK OF DEATH: 27 TERMINAL BODY WEIGHT: 12600.0 GRAMS
DATE AND TIME OF NECROPSY: 01/10/86 PROSECTOR: NANCY DIEDRICH RECORDER: JACK SERFORT
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. WILLIAM E. FIELD WEIGHER: JACK SERFORT

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
THYROID(S)/PARA (TPO)	1.215	.0096 %	.0142	WEIGHT TAKEN
HEART (HT)	107.186	.8507 %	1.2527	WEIGHT TAKEN
ADRENAL(S) (AD)	.984	.0078 %	.0115	WEIGHT TAKEN
SPLEEN (SP)	27.232	.2161 %	.3183	WEIGHT TAKEN
THYMUS (TH)	7.823	.0621 %	.0914	WEIGHT TAKEN
SALIVARY GLD(S) (SG)	21.1100	.1675 %	.2467	WEIGHT TAKEN
KIDNEY(S) (KD)	77.320	.6152 %	.9060	WEIGHT TAKEN
LIVER (LI)	341.935	2.7138 %	3.9962	WEIGHT TAKEN
TESTES (TE)	18.940	.1495 %	.2202	WEIGHT TAKEN
EPIDIDYMIDES (EP)	4.6140	.0366 %	.0539	WEIGHT TAKEN
PROSTATE (PR)	8.766	.0696 %	.1024	WEIGHT TAKEN
BRAIN (BR)	85.564	.6791 %	1.0000	WEIGHT TAKEN
PITUITARY (PI)	.054	.0004 %	.0006	WEIGHT TAKEN

*** P A T H O L O G Y O B S E R V A T I O N S ***

ORGAN NAME	KEYWORDS, SEVERITY, DISTRIBUTION	GROSS FREE-TEXT COMMENTS / HISTOPATHOLOGIC FINDINGS
GENERAL COMMENT (GC)		
GROSS:	-ALL TISSUES/ORGANS NORMAL	
KIDNEY, LEFT (KDO)		
MICRO:	-MINIMAL	-MINERALIZATION
KIDNEY, RIGHT (KD1)		
MICRO:	-MINIMAL	-MINERALIZATION
MAMMARY GLAND (MG)		
MICRO:	-TISSUE MISSING	

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INDIVIDUAL ANIMAL PATHOLOGY DATA

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

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STUDY NUMBER: 6127111

ANIMAL NUMBER: 000962 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 01/10/86 STUDY DAY OF DEATH: 185 STUDY WEEK OF DEATH: 27 TERMINAL BODY WEIGHT: 10900.0 GRAMS
DATE AND TIME OF NECROPSY: 01/10/86 PROSECTOR: JANELLE RASCHEIN RECORDER: JACK SERFORT
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. WILLIAM E. FIELD WEIGHER: JACK SERFORT

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
THYROID(S)/PARA (TYO)	.051	.0078 %	.0108	WEIGHT TAKEN
HEART (HT)	85.328	.7828 %	1.0815	WEIGHT TAKEN
ADRENAL(S) (AD)	1.076	.0099 %	.0136	WEIGHT TAKEN
SPLEEN (SP)	53.444	.4903 %	.6774	WEIGHT TAKEN
THYMUS (TH)	7.948	.0729 %	.1007	WEIGHT TAKEN
SALIVARY GLD(S) (SG)	17.2500	.1583 %	.2187	WEIGHT TAKEN
KIDNEY(S) (KD)	62.953	.5776 %	.7979	WEIGHT TAKEN
LIVER (LI)	297.135	2.7260 %	3.7660	WEIGHT TAKEN
TESTES (TE)	15.608	.1439 %	.1988	WEIGHT TAKEN
EPIDIDYMIDES (EP)	4.0150	.0368 %	.0509	WEIGHT TAKEN
PROSTATE (PR)	8.870	.0814 %	.1124	WEIGHT TAKEN
BRAIN (BR)	78.899	.7238 %	1.0000	WEIGHT TAKEN
PITUITARY (PI)	.048	.0004 %	.0006	WEIGHT TAKEN

*** P A T H O L O G Y O B S E R V A T I O N S ***

ORGAN NAME	KEYWORDS, SEVERITY, DISTRIBUTION	GROSS FREE-TEXT COMMENTS / HISTOPATHOLOGIC FINDINGS
GENERAL COMMENT (GC)		
	GROSS: -ALL TISSUES/ORGANS NORMAL	
KIDNEY, RIGHT (KD1)		
	MICRO: -MINIMAL	-MINERALIZATION
MAMMARY GLAND (MG)		
	MICRO: -TISSUE MISSING	
GENERAL INFORMATION (XX)		
	GROSS:	NECROPSY NOTE: >ANIMAL DIED PRIOR TO EXSANGUINATION

APPENDIX J

INDIVIDUAL ANIMAL PATHOLOGY DATA

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

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STUDY NUMBER: 6127111

ANIMAL NUMBER: 000963 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 01/08/86 STUDY DAY OF DEATH: 183 STUDY WEEK OF DEATH: 27 TERMINAL BODY WEIGHT: 0900.0 GRAMS
DATE AND TIME OF NECROPSY: 01/08/86 PROSECTOR: JACK SERFORT RECORDER: RUTH SCHMITZ
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. WILLIAM E. FIELD WEIGHER: RUTH SCHMITZ

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
THYROID(S)/PARA (TYO)	1.098	.0123 %	.0142	WEIGHT TAKEN
HEART (HT)	77.280	.8683 %	1.0010	WEIGHT TAKEN
ADRENAL(S) (AD)	1.192	.0134 %	.0154	WEIGHT TAKEN
SPLEEN (SP)	26.647	.2994 %	.3452	WEIGHT TAKEN
THYMUS (TH)	7.838	.0881 %	.1015	WEIGHT TAKEN
SALIVARY GLD(S) (SG)	16.0900	.1808 %	.2084	WEIGHT TAKEN
KIDNEY(S) (KD)	37.650	.4230 %	.4877	WEIGHT TAKEN
LIVER (LI)	225.949	2.5376 %	2.9255	WEIGHT TAKEN
TESTES (TE)	16.463	.1850 %	.2133	WEIGHT TAKEN
EPIDIDYMIDES (EP)	4.8040	.0540 %	.0622	WEIGHT TAKEN
PROSTATE (PR)	7.798	.0876 %	.1010	WEIGHT TAKEN
BRAIN (BR)	77.199	.8674 %	1.0000	WEIGHT TAKEN
PITUITARY (PI)	.038	.0004 %	.0005	WEIGHT TAKEN

*** P A T H O L O G Y O B S E R V A T I O N S ***

ORGAN NAME	KEYWORDS, SEVERITY, DISTRIBUTION	GROSS FREE-TEXT COMMENTS / HISTOPATHOLOGIC FINDINGS
GENERAL COMMENT (GC)		
GROSS:	-ALL TISSUES/ORGANS NORMAL	
KIDNEY, LEFT (KDO)		
MICRO:	-MINIMAL	-MINERALIZATION
KIDNEY, RIGHT (KD1)		
MICRO:	-MINIMAL	-MINERALIZATION
MAMMARY GLAND (MG)		
MICRO:	-TISSUE MISSING	

APPENDIX J

INDIVIDUAL ANIMAL PATHOLOGY DATA

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

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STUDY NUMBER: 6127111

ANIMAL NUMBER: 000964 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, FIRST POST-RECOV SAC
DATE OF DEATH: 02/07/86 STUDY DAY OF DEATH: 213 STUDY WEEK OF DEATH: 31 TERMINAL BODY WEIGHT: 10200.0 GRAMS
DATE AND TIME OF NECROPSY: 02/07/86 PROSECTOR: JACK SERFORT RECORDER: RUTH SCHMITZ
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. WILLIAM E. FIELD WEIGHER: RUTH SCHMITZ

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
THYROID(S)/PARA (TYO)	1.134	.0111 %	.0137	WEIGHT TAKEN
HEART (HT)	82.264	.8065 %	.9914	WEIGHT TAKEN
ADRENAL(S) (AD)	1.216	.0119 %	.0147	WEIGHT TAKEN
SPLEEN (SP)	20.536	.2013 %	.2475	WEIGHT TAKEN
THYMUS (TH)	8.336	.0817 %	.1005	WEIGHT TAKEN
SALIVARY GLD(S) (SG)	14.0100	.1374 %	.1688	WEIGHT TAKEN
KIDNEY(S) (KD)	47.525	.4659 %	.5727	WEIGHT TAKEN
LIVER (LI)	308.936	3.0288 %	3.7231	WEIGHT TAKEN
TESTES (TE)	14.765	.1448 %	.1779	WEIGHT TAKEN
EPIDIDYMIDES (EP)	3.5010	.0343 %	.0422	WEIGHT TAKEN
PROSTATE (PR)	6.339	.0621 %	.0764	WEIGHT TAKEN
BRAIN (BR)	82.978	.8135 %	1.0000	WEIGHT TAKEN
PITUITARY (PI)	.044	.0004 %	.0005	WEIGHT TAKEN

*** P A T H O L O G Y O B S E R V A T I O N S ***

ORGAN NAME	KEYWORDS, SEVERITY, DISTRIBUTION	GROSS FREE-TEXT COMMENTS / HISTOPATHOLOGIC FINDINGS
MEDIAST/BRONC LN (ML)	. . . . .	. . . . .
GROSS:	-LARGE	-UP TO 10 MM IN DIAMETER (CAP 36)
	-DIFFUSELY RED	
MICRO:	-MODERATELY SEVERE	-CONGESTION

APPENDIX J

INDIVIDUAL ANIMAL PATHOLOGY DATA

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

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STUDY NUMBER: 6127111

ANIMAL NUMBER: 000965 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, FIRST POST-RECOV SAC
DATE OF DEATH: 02/06/86 STUDY DAY OF DEATH: 212 STUDY WEEK OF DEATH: 31 TERMINAL BODY WEIGHT: 11800.0 GRAMS
DATE AND TIME OF NECROPSY: 02/06/86 PROSECTOR: DENNIS HOFFMAN RECORDER: RUTH SCHMITZ
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. WILLIAM E. FIELD WEIGHER: RUTH SCHMITZ

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
THYROID(S)/PARA (TYO)	.864	.0073 %	.0107	WEIGHT TAKEN
HEART (HT)	85.637	.7257 %	1.0565	WEIGHT TAKEN
ADRENAL(S) (AD)	1.037	.0088 %	.0128	WEIGHT TAKEN
SPLEEN (SP)	33.270	.2819 %	.4105	WEIGHT TAKEN
THYMUS (TH)	6.261	.0531 %	.0772	WEIGHT TAKEN
SALIVARY GLD(S) (SG)	20.6260	.1748 %	.2545	WEIGHT TAKEN
KIDNEY(S) (KD)	58.467	.4955 %	.7213	WEIGHT TAKEN
LIVER (LI)	332.387	2.8168 %	4.1007	WEIGHT TAKEN
TESTES (TE)	13.236	.1122 %	.1633	WEIGHT TAKEN
EPIDIDYMIDES (EP)	4.2510	.0360 %	.0524	WEIGHT TAKEN
PROSTATE (PR)	6.358	.0539 %	.0784	WEIGHT TAKEN
BRAIN (BR)	81.057	.6869 %	1.0000	WEIGHT TAKEN
PITUITARY (PI)	.059	.0005 %	.0007	WEIGHT TAKEN

*** P A T H O L O G Y O B S E R V A T I O N S ***

ORGAN NAME	KEYWORDS, SEVERITY, DISTRIBUTION	GROSS FREE-TEXT COMMENTS / HISTOPATHOLOGIC FINDINGS
LUNG (LU)		
	GROSS: -RED FOCUS(I)/AREA(S)	-RIGHT CAUDAL LOBE: 2.5 X 1.5 CM, COLLECTED ON ROUTINE SECTION
	MICRO: -MODERATE	-PNEUMONITIS
	-MODERATE	-CONGESTION/HEMORRHAGE

APPENDIX J

INDIVIDUAL ANIMAL PATHOLOGY DATA

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

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STUDY NUMBER: 6127111

ANIMAL NUMBER: 000966 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 01/10/86 STUDY DAY OF DEATH: 185 STUDY WEEK OF DEATH: 27 TERMINAL BODY WEIGHT: 0400.0 GRAMS
DATE AND TIME OF NECROPSY: 01/10/86 PROSECTOR: DENNIS HOFFMAN RECORDER: JACK SERFORT
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. WILLIAM E. FIELD WEIGHER: JACK SERFORT

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
THYROID(S)/PARA (TYO)	.907	.0168 %	.0131	WEIGHT TAKEN
HEART (HT)	75.527	.8991 %	1.0904	WEIGHT TAKEN
ADRENAL(S) (AD)	.819	.0097 %	.0118	WEIGHT TAKEN
SPLEEN (SP)	28.676	.3414 %	.4140	WEIGHT TAKEN
THYMUS (TH)	4.732	.0563 %	.0683	WEIGHT TAKEN
SALIVARY GLD(S) (SG)	14.8310	.1766 %	.2141	WEIGHT TAKEN
KIDNEY(S) (KD)	63.047	.7506 %	.9102	WEIGHT TAKEN
LIVER (LI)	281.939	3.3564 %	4.0703	WEIGHT TAKEN
TESTES (TE)	12.493	.1487 %	.1804	WEIGHT TAKEN
EPIDIDYMIDES (EP)	3.4260	.0408 %	.0495	WEIGHT TAKEN
PROSTATE (PR)	6.108	.0727 %	.0882	WEIGHT TAKEN
BRAIN (BR)	69.267	.8246 %	1.0000	WEIGHT TAKEN
PITUITARY (PI)	.061	.0007 %	.0009	WEIGHT TAKEN

*** P A T H O L O G Y O B S E R V A T I O N S ***

ORGAN NAME	KEYWORDS, SEVERITY, DISTRIBUTION	GROSS FREE-TEXT COMMENTS / HISTOPATHOLOGIC FINDINGS
COLON (CO)		
	GROSS: -RED FOCUS(I)/AREA(S)	-MUCOSA: MULTIPLE LINEAR AREAS; COLLECTED WITH ROUTINE SECTION
	MICRO: -SLIGHT	-MUCOUS ON MUCOSA
EPIDIDYMIDES (EP)		
	MICRO: -PRESENT	-SPERM GRANULOMA
ILEUM (IL)		
	GROSS: -RED FOCUS(I)/AREA(S)	-MUCOSA: MULTIPLE LINEAR AREAS; COLLECTED WITH ROUTINE SECTION
	MICRO: -MODERATE	-MUCOUS ON MUCOSA
JEJUNUM (JE)		
	GROSS: -RED FOCUS(I)/AREA(S)	-MUCOSA: MULTIPLE LINEAR AREAS; COLLECTED WITH ROUTINE SECTION
	MICRO: -MODERATE	-MUCOUS ON MUCOSA

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INDIVIDUAL ANIMAL PATHOLOGY DATA

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DEPARTMENT OF PATHOLOGY
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STUDY NUMBER: 6127111

ANIMAL NUMBER: 000966 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 01/10/86 STUDY DAY OF DEATH: 185 STUDY WEEK OF DEATH: 27 TERMINAL BODY WEIGHT: 0400.0 GRAMS
DATE AND TIME OF NECROPSY: 01/10/86 PROSECTOR: DENNIS HOFFMAN RECORDER: JACK SERFORT
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. WILLIAM E. FIELD WEIGHER: JACK SERFORT

*** PATHOLOGY OBSERVATIONS (CONTINUED) ***

ORGAN NAME	KEYWORDS, SEVERITY, DISTRIBUTION	GROSS FREE-TEXT COMMENTS / HISTOPATHOLOGIC FINDINGS
KIDNEY, LEFT (KDO)		
	MICRO: -MINIMAL	-MINERALIZATION
KIDNEY, RIGHT (KD1)		
	MICRO: -SLIGHT	-MINERALIZATION
MAMMARY GLAND (MG)		
	MICRO: -TISSUE MISSING	
PARATHYROID(S) (PT)		
	MICRO: -PRESENT	-ONE EXAMINED

APPENDIX J

INDIVIDUAL ANIMAL PATHOLOGY DATA

ANIMAL NUMBER: 000973 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, FIRST POST-RECOV SAC
DATE OF DEATH: 02/07/86 STUDY DAY OF DEATH: 213 STUDY WEEK OF DEATH: 31 TERMINAL BODY WEIGHT: 12400.0 GRAMS
DATE AND TIME OF NECROPSY: 02/07/86 PROSECTOR: JACK SERFORT RECORDER: RUTH SCHMITZ
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. WILLIAM E. FIELD WEIGHER: RUTH SCHMITZ

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
THYROID(S)/PARA (TYO)	1.312	.0106 %	.0164	WEIGHT TAKEN
HEART (HT)	104.603	.8436 %	1.3115	WEIGHT TAKEN
ADRENAL(S) (AD)	1.329	.0107 %	.0167	WEIGHT TAKEN
SPLEEN (SP)	32.456	.2617 %	.4069	WEIGHT TAKEN
THYMUS (TH)	6.016	.0485 %	.0754	WEIGHT TAKEN
SALIVARY GLD(S) (SG)	16.4650	.1328 %	.2064	WEIGHT TAKEN
KIDNEY(S) (KD)	54.062	.4360 %	.6778	WEIGHT TAKEN
LIVER (LI)	335.600	2.7065 %	4.2076	WEIGHT TAKEN
TESTES (TE)	17.098	.1379 %	.2144	WEIGHT TAKEN
EPIDIDYMIDES (EP)	4.3630	.0352 %	.0547	WEIGHT TAKEN
PROSTATE (PR)	7.898	.0637 %	.0990	WEIGHT TAKEN
BRAIN (BR)	79.760	.6432 %	1.0000	WEIGHT TAKEN
PITUITARY (PI)	.055	.0004 %	.0007	WEIGHT TAKEN

*** P A T H O L O G Y O B S E R V A T I O N S ***

ORGAN NAME	KEYWORDS, SEVERITY, DISTRIBUTION	GROSS FREE-TEXT COMMENTS / HISTOPATHOLOGIC FINDINGS
MEDIAST/BRONC LN (ML)	. . . . .	. . . . .
GROSS:	-DIFFUSELY RED	-(CAP 36)
MICRO:	-MODERATE	-CONGESTION

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INDIVIDUAL ANIMAL PATHOLOGY DATA

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
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STUDY NUMBER: 6127111

ANIMAL NUMBER: 000974 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 01/09/86 STUDY DAY OF DEATH: 184 STUDY WEEK OF DEATH: 27 TERMINAL BODY WEIGHT: 10400.0 GRAMS
DATE AND TIME OF NECROPSY: 01/09/86 PROSECTOR: NANCY DIEDRICH RECORDER: RUTH SCHMITZ
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. WILLIAM E. FIELD WEIGHER: RUTH SCHMITZ

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
THYROID(S)/PARA (TYO)	1.009	.0097 %	.0146	WEIGHT TAKEN
HEART (HT)	102.553	.9861 %	1.4816	WEIGHT TAKEN
ADRENAL(S) (AD)	1.104	.0106 %	.0159	WEIGHT TAKEN
SPLEEN (SP)	28.511	.2741 %	.4119	WEIGHT TAKEN
THYMUS (TH)	4.444	.0427 %	.0642	WEIGHT TAKEN
SALIVARY GLD(S) (SG)	14.4890	.1393 %	.2093	WEIGHT TAKEN
KIDNEY(S) (KD)	47.743	.4591 %	.6897	WEIGHT TAKEN
LIVER (LI)	245.272	2.3584 %	3.5434	WEIGHT TAKEN
TESTES (TE)	17.304	.1664 %	.2500	WEIGHT TAKEN
EPIDIDYMIDES (EP)	3.7300	.0359 %	.0539	WEIGHT TAKEN
PROSTATE (PR)	2.761	.0265 %	.0399	WEIGHT TAKEN
BRAIN (BR)	69.220	.6656 %	1.0000	WEIGHT TAKEN
PITUITARY (PI)	.067	.0006 %	.0010	WEIGHT TAKEN

*** P A T H O L O G Y O B S E R V A T I O N S ***

ORGAN NAME	KEYWORDS, SEVERITY, DISTRIBUTION	GROSS FREE-TEXT COMMENTS / HISTOPATHOLOGIC FINDINGS
KIDNEY, LEFT (KDO)		
	MICRO: -MINIMAL	-MINERALIZATION
KIDNEY, RIGHT (KD1)		
	MICRO: -MINIMAL	-MINERALIZATION
LUNG (LU)		
	GROSS: -LIGHT FOCUS(I)/AREA(S)	-LEFT CRANIAL LOBE: SINGLE TAN AREA, 10 MM IN DIAMETER, FIRM AND SLIGHTLY RAISED (CAP 36)
	MICRO: -SLIGHT, FOCAL	-PNEUMONITIS
MAMMARY GLAND (MG)		
	MICRO: -TISSUE MISSING	
PARATHYROID(S) (PT)		
	MICRO: -PRESENT	-ONE EXAMINED

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INDIVIDUAL ANIMAL PATHOLOGY DATA

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
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STUDY NUMBER: 6127111

ANIMAL NUMBER: 000974 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 01/09/86 STUDY DAY OF DEATH: 184 STUDY WEEK OF DEATH: 27 TERMINAL BODY WEIGHT: 10400.0 GRAMS
DATE AND TIME OF NECROPSY: 01/09/86 PROSECTOR: NANCY DIEDRICH RECORDER: RUTH SCHMITZ
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. WILLIAM E. FIELD WEIGHER: RUTH SCHMITZ

*** PATHOLOGY OBSERVATIONS (CONTINUED) ***

ORGAN NAME	KEYWORDS, SEVERITY, DISTRIBUTION	GROSS FREE-TEXT COMMENTS / HISTOPATHOLOGIC FINDINGS
THYMUS (TH)		
	MICRO: -MODERATE	-INVOLUTION

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INDIVIDUAL ANIMAL PATHOLOGY DATA

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DEPARTMENT OF PATHOLOGY
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STUDY NUMBER: 6127111

ANIMAL NUMBER: 000975 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 01/10/86 STUDY DAY OF DEATH: 185 STUDY WEEK OF DEATH: 27 TERMINAL BODY WEIGHT: 10000.0 GRAMS
DATE AND TIME OF NECROPSY: 01/10/86 PROSECTOR: DENNIS HOFFMAN RECORDER: JACK SERFORT
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. WILLIAM E. FIELD WEIGHER: JACK SERFORT

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
THYROID(S)/PARA (TYO)	1.401	.0140 %	.0194	WEIGHT TAKEN
HEART (HT)	86.438	.8644 %	1.1941	WEIGHT TAKEN
ADRENAL(S) (AD)	1.039	.0104 %	.0144	WEIGHT TAKEN
SPLEEN (SP)	36.608	.3661 %	.5057	WEIGHT TAKEN
THYMUS (TH)	7.540	.0754 %	.1042	WEIGHT TAKEN
SALIVARY GLD(S) (SG)	17.8920	.1789 %	.2472	WEIGHT TAKEN
KIDNEY(S) (KD)	56.042	.5604 %	.7742	WEIGHT TAKEN
LIVER (LI)	334.391	3.3439 %	4.6196	WEIGHT TAKEN
TESTES (TE)	19.086	.1909 %	.2637	WEIGHT TAKEN
EPIDIDYMIDES (EP)	3.8690	.0387 %	.0535	WEIGHT TAKEN
PROSTATE (PR)	5.001	.0500 %	.0691	WEIGHT TAKEN
BRAIN (BR)	72.385	.7239 %	1.0000	WEIGHT TAKEN
PITUITARY (PI)	.051	.0005 %	.0007	WEIGHT TAKEN

*** P A T H O L O G Y O B S E R V A T I O N S ***

ORGAN NAME	KEYWORDS, SEVERITY, DISTRIBUTION	GROSS FREE-TEXT COMMENTS / HISTOPATHOLOGIC FINDINGS
KIDNEY, LEFT (KDO)		
MICRO:	-MINIMAL	-MINERALIZATION
KIDNEY, RIGHT (KD1)		
MICRO:	-SLIGHT	-MINERALIZATION
MAMMARY GLAND (MG)		
MICRO:	-TISSUE MISSING	
SKIN (SK)		
GROSS:	-ALOPECIA-FOCAL	-BILATERAL EARS, DISTAL ENDS, AND MID-CERVICAL REGION: MULTIPLE, INDISTINCT AREAS; SECTION COLLECTED FROM RIGHT EAR (CAPSULE 36)
MICRO:	-MODERATE	-ACANTHOSIS
	-SLIGHT	-HYPERKERATOSIS

APPENDIX J

INDIVIDUAL ANIMAL PATHOLOGY DATA

ANIMAL NUMBER: 000975 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 01/10/86 STUDY DAY OF DEATH: 185 STUDY WEEK OF DEATH: 27 TERMINAL BODY WEIGHT: 10000.0 GRAMS
DATE AND TIME OF NECROPSY: 01/10/86 PROSECTOR: DENNIS HOFFMAN RECORDER: JACK SERFORT
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. WILLIAM E. FIELD WEIGHER: JACK SERFORT

*** PATHOLOGY OBSERVATIONS (CONTINUED) ***

ORGAN NAME	KEYWORDS, SEVERITY, DISTRIBUTION	GROSS FREE-TEXT COMMENTS / HISTOPATHOLOGIC FINDINGS
THYROID(S) (TY)		
	GROSS: -DIFFUSELY LIGHT	-BILATERAL: TAN
	MICRO: -MODERATELY SEVERE, DIFFUSE	-"C" CELL HYPERPLASIA

APPENDIX J

INDIVIDUAL ANIMAL PATHOLOGY DATA

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

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STUDY NUMBER: 6127111

ANIMAL NUMBER: 000976 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 01/08/86 STUDY DAY OF DEATH: 183 STUDY WEEK OF DEATH: 27 TERMINAL BODY WEIGHT: 9900.0 GRAMS
DATE AND TIME OF NECROPSY: 01/08/86 PROSECTOR: JACK SERFORT RECORDER: RUTH SCHMITZ
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. WILLIAM E. FIELD WEIGHER: RUTH SCHMITZ

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
THYROID(S)/PARA (TYO)	1.179	.0119 %	.0163	WEIGHT TAKEN
HEART (HT)	72.903	.7364 %	1.0083	WEIGHT TAKEN
ADRENAL(S) (AD)	1.152	.0116 %	.0159	WEIGHT TAKEN
SPLEEN (SP)	23.244	.2348 %	.3215	WEIGHT TAKEN
THYMUS (TH)	5.063	.0511 %	.0700	WEIGHT TAKEN
SALIVARY GLD(S) (SG)	15.6190	.1578 %	.2160	WEIGHT TAKEN
KIDNEY(S) (KD)	61.101	.6172 %	.8451	WEIGHT TAKEN
LIVER (LI)	257.265	2.5986 %	3.5582	WEIGHT TAKEN
TESTES (TE)	13.273	.1341 %	.1836	WEIGHT TAKEN
EPIDIDYMIDES (EP)	3.7910	.0383 %	.0524	WEIGHT TAKEN
PROSTATE (PR)	7.914	.0799 %	.1095	WEIGHT TAKEN
BRAIN (BR)	72.302	.7303 %	1.0000	WEIGHT TAKEN
PITUITARY (PI)	.058	.0006 %	.0008	WEIGHT TAKEN

*** P A T H O L O G Y O B S E R V A T I O N S ***

ORGAN NAME	KEYWORDS, SEVERITY, DISTRIBUTION	GROSS FREE-TEXT COMMENTS / HISTOPATHOLOGIC FINDINGS
KIDNEY, LEFT (KDO)		
	MICRO: -SLIGHT	-MINERALIZATION
KIDNEY, RIGHT (KD1)		
	MICRO: -MINIMAL	-MINERALIZATION
MAMMARY GLAND (MG)		
	MICRO: -TISSUE MISSING	
PARATHYROID(S) (PT)		
	MICRO: -PRESENT	-ONE EXAMINED
SKIN (SK)		
	GROSS: -RED FOCUS(I)/AREA(S)	-ALL SHAVED AREAS: MULTIFOCAL, RED AREAS; SECTION COLLECTED FROM RIGHT LATERAL THORACIC REGION (CAP 36)
	MICRO: -SLIGHT	-ACANTHOSIS

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INDIVIDUAL ANIMAL PATHOLOGY DATA

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STUDY NUMBER: 6127111

ANIMAL NUMBER: 000977 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, FIRST POST-RECOV SAC
DATE OF DEATH: 02/06/86 STUDY DAY OF DEATH: 212 STUDY WEEK OF DEATH: 31 TERMINAL BODY WEIGHT: 10400.0 GRAMS
DATE AND TIME OF NECROPSY: 02/06/86 PROSECTOR: DENNIS HOFFMAN RECORDER: RUTH SCHMITZ
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. WILLIAM E. FIELD WEIGHER: RUTH SCHMITZ

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
THYROID(S)/PARA (TYO)	1.546	.0149 %	.0220	WEIGHT TAKEN
HEART (HT)	74.607	.7174 %	1.0596	WEIGHT TAKEN
ADRENAL(S) (AD)	1.335	.0128 %	.0190	WEIGHT TAKEN
SPLEEN (SP)	26.132	.2513 %	.3712	WEIGHT TAKEN
THYMUS (TM)	7.889	.0759 %	.1120	WEIGHT TAKEN
SALIVARY GLD(S) (SG)	16.3740	.1574 %	.2326	WEIGHT TAKEN
KIDNEY(S) (KD)	48.982	.4710 %	.6957	WEIGHT TAKEN
LIVER (LI)	280.855	2.7005 %	3.9890	WEIGHT TAKEN
TESTES (TE)	12.594	.1211 %	.1789	WEIGHT TAKEN
EPIDIDYMIDES (EP)	3.0290	.0291 %	.0430	WEIGHT TAKEN
PROSTATE (PR)	4.428	.0426 %	.0629	WEIGHT TAKEN
BRAIN (BR)	70.408	.6770 %	1.0000	WEIGHT TAKEN
PITUITARY (PI)	.041	.0004 %	.0006	WEIGHT TAKEN

*** P A T H O L O G Y O B S E R V A T I O N S ***

ORGAN NAME	KEYWORDS, SEVERITY, DISTRIBUTION	GROSS FREE-TEXT COMMENTS / HISTOPATHOLOGIC FINDINGS
GENERAL COMMENT (GC)	. . . . .	
	GROSS: -ALL TISSUES/ORGANS NORMAL	

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STUDY NUMBER: 6127111

ANIMAL NUMBER: 000978 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 01/08/86 STUDY DAY OF DEATH: 183 STUDY WEEK OF DEATH: 27 TERMINAL BODY WEIGHT: 0900.0 GRAMS
DATE AND TIME OF NECROPSY: 01/08/86 PROSECTOR: JACK SERFORT RECORDER: RUTH SCHMITZ
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. WILLIAM E. FIELD WEIGHER: RUTH SCHMITZ

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
THYROID(S)/PARA (TYO)	1.024	.0115 %	.0141	WEIGHT TAKEN
HEART (HT)	90.167	1.0131 %	1.2447	WEIGHT TAKEN
ADRENAL(S) (AD)	.918	.0103 %	.0127	WEIGHT TAKEN
SPLEEN (SP)	23.460	.2636 %	.3238	WEIGHT TAKEN
THYMUS (TH)	14.460	.1625 %	.1996	WEIGHT TAKEN
SALIVARY GLD(S) (SG)	10.7240	.1205 %	.1480	WEIGHT TAKEN
KIDNEY(S) (KD)	41.703	.4686 %	.5757	WEIGHT TAKEN
LIVER (LI)	214.998	2.4157 %	2.9679	WEIGHT TAKEN
TESTES (TE)	13.020	.1463 %	.1797	WEIGHT TAKEN
EPIDIDYMIDES (EP)	2.7610	.0310 %	.0381	WEIGHT TAKEN
PROSTATE (PR)	3.869	.0435 %	.0534	WEIGHT TAKEN
BRAIN (BR)	72.441	.8139 %	1.0000	WEIGHT TAKEN
PITUITARY (PI)	.060	.0007 %	.0008	WEIGHT TAKEN

*** P A T H O L O G Y O B S E R V A T I O N S ***

ORGAN NAME	KEYWORDS, SEVERITY, DISTRIBUTION	GROSS FREE-TEXT COMMENTS / HISTOPATHOLOGIC FINDINGS
KIDNEY, LEFT (KDO)		
	MICRO: -MINIMAL	-MINERALIZATION
KIDNEY, RIGHT (KD1)		
	MICRO: -MINIMAL	-MINERALIZATION
MAMMARY GLAND (MG)		
	MICRO: -TISSUE MISSING	
THYMUS (TH)		
	GROSS: -DIFFUSELY RED	-DARK RED
	MICRO: -SLIGHT	-INVOLUTION
	-MODERATELY SEVERE	-HEMORRHAGE

APPENDIX J

INDIVIDUAL ANIMAL PATHOLOGY DATA

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

PRINTED: 22-MAY-86
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STUDY NUMBER: 6127111

ANIMAL NUMBER: 000985 SEX: MALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 01/09/86 STUDY DAY OF DEATH: 184 STUDY WEEK OF DEATH: 27 TERMINAL BODY WEIGHT: 11900.0 GRAMS
DATE AND TIME OF NECROPSY: 01/09/86 PROSECTOR: JANELLE RASCHEIN RECORDER: RUTH SCHMITZ
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. WILLIAM E. FIELD WEIGHER: RUTH SCHMITZ

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
THYROID(S)/PARA (TYO)	.999	.0084 %	.0132	WEIGHT TAKEN
HEART (HT)	96.093	.8075 %	1.2710	WEIGHT TAKEN
ADRENAL(S) (AD)	1.426	.0120 %	.0189	WEIGHT TAKEN
SPLEEN (SP)	45.019	.3783 %	.5954	WEIGHT TAKEN
THYMUS (TH)	4.785	.0402 %	.0633	WEIGHT TAKEN
SALIVARY GLD(S) (SG)	16.2410	.1365 %	.2148	WEIGHT TAKEN
KIDNEY(S) (KD)	60.549	.5088 %	.8008	WEIGHT TAKEN
LIVER (LI)	332.261	2.7921 %	4.3946	WEIGHT TAKEN
TESTES (TE)	16.889	.1419 %	.2234	WEIGHT TAKEN
EPIDIDYMIDES (EP)	3.5030	.0294 %	.0463	WEIGHT TAKEN
PROSTATE (PR)	2.716	.0228 %	.0359	WEIGHT TAKEN
BRAIN (BR)	75.606	.6353 %	1.0000	WEIGHT TAKEN
PITUITARY (PI)	.065	.0005 %	.0009	WEIGHT TAKEN

*** P A T H O L O G Y O B S E R V A T I O N S ***

ORGAN NAME	KEYWORDS, SEVERITY, DISTRIBUTION	GROSS FREE-TEXT COMMENTS / HISTOPATHOLOGIC FINDINGS
EAR (ER)		
GROSS:	-THICKENED	-BILATERAL, DIFFUSE (CAPSULE 37)
MICRO:	-MODERATE, MULTI-FOCAL	-DERMATITIS
	-MODERATE	-ACANTHOSIS
KIDNEY, LEFT (KDO)		
MICRO:	-MINIMAL	-MINERALIZATION
KIDNEY, RIGHT (KD1)		
MICRO:	-MINIMAL	-MINERALIZATION
MAMMARY GLAND (MG)		
MICRO:	-TISSUE MISSING	
PARATHYROID(S) (PT)		
MICRO:	-PRESENT	-ONE EXAMINED

APPENDIX J

INDIVIDUAL ANIMAL PATHOLOGY DATA

ANIMAL NUMBER: 000985 SEX: MALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 01/09/86 STUDY DAY OF DEATH: 184 STUDY WEEK OF DEATH: 27 TERMINAL BODY WEIGHT: 11900.0 GRAMS
DATE AND TIME OF NECROPSY: 01/09/86 PROSECTOR: JANELLE RASCHEIN RECORDER: RUTH SCHMITZ
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. WILLIAM E. FIELD WEIGHER: RUTH SCHMITZ

*** PATHOLOGY OBSERVATIONS (CONTINUED) ***

ORGAN NAME	KEYWORDS, SEVERITY, DISTRIBUTION	GROSS FREE-TEXT COMMENTS / HISTOPATHOLOGIC FINDINGS
SKIN (SK)		
	GROSS: -RED FOCUS(I)/AREA(S)	-DIFFUSE: AREAS ARE INDISTINCT (CAPSULE 36)
	MICRO: -SLIGHT	-ACANTHOSIS
	-SLIGHT, FOCAL	-DERMATITIS
THYMUS (TH)		
	MICRO: -SLIGHT	-INVOLUTION
	-PRESENT	-CYST(S)

APPENDIX J

INDIVIDUAL ANIMAL PATHOLOGY DATA

ANIMAL NUMBER: 000986 SEX: MALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 01/09/86 STUDY DAY OF DEATH: 184 STUDY WEEK OF DEATH: 27 TERMINAL BODY WEIGHT: 11000.0 GRAMS
DATE AND TIME OF NECROPSY: 01/09/86 PROSECTOR: JANELLE RASCHEIN RECORDER: RUTH SCHMITZ
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. WILLIAM E. FIELD WEIGHER: RUTH SCHMITZ

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
THYROID(S)/PARA (TYO)	1.153	.0105 %	.0180	WEIGHT TAKEN
HEART (HT)	90.596	.8236 %	1.4166	WEIGHT TAKEN
ADRENAL(S) (AD)	1.557	.0142 %	.0243	WEIGHT TAKEN
SPLEEN (SP)	27.554	.2505 %	.4308	WEIGHT TAKEN
THYMUS (TH)	15.378	.1398 %	.2405	WEIGHT TAKEN
SALIVARY GLD(S) (SG)	14.1940	.1290 %	.2219	WEIGHT TAKEN
KIDNEY(S) (KD)	38.341	.3486 %	.5995	WEIGHT TAKEN
LIVER (LI)	265.940	2.4176 %	4.1583	WEIGHT TAKEN
TESTES (TE)	17.636	.1603 %	.2758	WEIGHT TAKEN
EPIDIDYMIDES (EP)	4.4780	.0407 %	.0700	WEIGHT TAKEN
PROSTATE (PR)	10.500	.0955 %	.1642	WEIGHT TAKEN
BRAIN (BR)	63.954	.5814 %	1.0000	WEIGHT TAKEN
PITUITARY (PI)	.084	.0008 %	.0013	WEIGHT TAKEN

*** PATHOLOGY OBSERVATIONS ***

ORGAN NAME	KEYWORDS, SEVERITY, DISTRIBUTION	GROSS FREE-TEXT COMMENTS / HISTOPATHOLOGIC FINDINGS
GENERAL COMMENT (GC)		
	GROSS: -ALL TISSUES/ORGANS NORMAL	
KIDNEY, RIGHT (KD1)		
	MICRO: -MINIMAL	-MINERALIZATION
LIVER (LI)		
	MICRO: -SLIGHT, MULTI-FOCAL	-INFILTRATE,MONONUCLEAR CELL
MAMMARY GLAND (MG)		
	MICRO: -TISSUE MISSING	

APPENDIX J

INDIVIDUAL ANIMAL PATHOLOGY DATA

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

PRINTED: 22-MAY-86
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STUDY NUMBER: 6127111

ANIMAL NUMBER: 000987 SEX: MALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 01/09/86 STUDY DAY OF DEATH: 184 STUDY WEEK OF DEATH: 27 TERMINAL BODY WEIGHT: 9900.0 GRAMS
DATE AND TIME OF NECROPSY: 01/09/86 PROSECTOR: JACK SERFORT RECORDER: RUTH SCHMITZ
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. WILLIAM E. FIELD WEIGHER: RUTH SCHMITZ

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
THYROID(S)/PARA (TYO)	1.045	.0106 %	.0134	WEIGHT TAKEN
HEART (HT)	86.677	.8755 %	1.1088	WEIGHT TAKEN
ADRENAL(S) (AD)	.994	.0100 %	.0127	WEIGHT TAKEN
SPLEEN (SP)	32.037	.3236 %	.4098	WEIGHT TAKEN
THYMUS (TH)	8.990	.0908 %	.1150	WEIGHT TAKEN
SALIVARY GLD(S) (SG)	15.4800	.1564 %	.1980	WEIGHT TAKEN
KIDNEY(S) (KD)	52.479	.5301 %	.6713	WEIGHT TAKEN
LIVER (LI)	269.620	2.7234 %	3.4491	WEIGHT TAKEN
TESTES (TE)	13.846	.1399 %	.1771	WEIGHT TAKEN
EPIDIDYMIDES (EP)	2.6710	.0270 %	.0342	WEIGHT TAKEN
PROSTATE (PR)	3.778	.0382 %	.0483	WEIGHT TAKEN
BRAIN (BR)	78.172	.7896 %	1.0000	WEIGHT TAKEN
PITUITARY (PI)	.068	.0007 %	.0009	WEIGHT TAKEN

*** P A T H O L O G Y O B S E R V A T I O N S ***

ORGAN NAME	KEYWORDS, SEVERITY, DISTRIBUTION	GROSS FREE-TEXT COMMENTS / HISTOPATHOLOGIC FINDINGS
GENERAL COMMENT (GC)		
GROSS:	-ALL TISSUES/ORGANS NORMAL	
KIDNEY, LEFT (KDO)		
MICRO:	-SLIGHT	-MINERALIZATION
KIDNEY, RIGHT (KD1)		
MICRO:	-MINIMAL	-MINERALIZATION
MAMMARY GLAND (MG)		
MICRO:	-TISSUE MISSING	
PARATHYROID(S) (PT)		
MICRO:	-PRESENT	-CYST(S)

APPENDIX J

INDIVIDUAL ANIMAL PATHOLOGY DATA

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

STUDY NUMBER: 6127111

ANIMAL NUMBER: 000908 SEX: MALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, FIRST POST-RECOV SAC
DATE OF DEATH: 02/07/86 STUDY DAY OF DEATH: 213 STUDY WEEK OF DEATH: 31 TERMINAL BODY WEIGHT: 9600.0 GRAMS
DATE AND TIME OF NECROPSY: 02/07/86 PROSECTOR: JACK SERFORT RECORDER: RUTH SCHMITZ
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. WILLIAM E. FIELD WEIGHER: RUTH SCHMITZ

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
THYROID(S)/PARA (TYO)	1.014	.0106 %	.0141	WEIGHT TAKEN
HEART (HT)	87.076	.9070 %	1.2112	WEIGHT TAKEN
ADRENAL(S) (AD)	1.114	.0116 %	.0155	WEIGHT TAKEN
SPLEEN (SP)	27.401	.2854 %	.3811	WEIGHT TAKEN
THYMUS (TH)	3.869	.0403 %	.0538	WEIGHT TAKEN
SALIVARY GLD(S) (SG)	11.7660	.1226 %	.1637	WEIGHT TAKEN
KIDNEY(S) (KD)	46.956	.4891 %	.6531	WEIGHT TAKEN
LIVER (LI)	271.083	2.8238 %	3.7707	WEIGHT TAKEN
TESTES (TE)	12.262	.1277 %	.1706	WEIGHT TAKEN
EPIDIDYMIDES (EP)	2.9300	.0305 %	.0408	WEIGHT TAKEN
PROSTATE (PR)	4.691	.0489 %	.0653	WEIGHT TAKEN
BRAIN (BR)	71.892	.7489 %	1.0000	WEIGHT TAKEN
PITUITARY (PI)	.038	.0004 %	.0005	WEIGHT TAKEN

*** P A T H O L O G Y O B S E R V A T I O N S ***

ORGAN NAME	KEYWORDS, SEVERITY, DISTRIBUTION	GROSS FREE-TEXT COMMENTS / HISTOPATHOLOGIC FINDINGS
KIDNEY(S) (KD)		
GROSS:	-CYST(S)	-LEFT, VISIBLE ON THE CUT SURFACE: SINGLE CYSTS, 6 MM IN DIAMETER, FILLED WITH CLEAR FLUID
KIDNEY, LEFT (KDO)		
MICRO:	-PRESENT	-CYST(S)

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INDIVIDUAL ANIMAL PATHOLOGY DATA

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

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STUDY NUMBER: 6127111

ANIMAL NUMBER: 000989 SEX: MALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 01/08/86 STUDY DAY OF DEATH: 183 STUDY WEEK OF DEATH: 27 TERMINAL BODY WEIGHT: 10700.0 GRAMS
DATE AND TIME OF NECROPSY: 01/08/86 PROSECTOR: JANELLE RASCHEIN RECORDER: RUTH SCHMITZ
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. WILLIAM E. FIELD WEIGHER: RUTH SCHMITZ

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
THYROID(S)/PARA (TYO)	1.280	.0120 %	.0166	WEIGHT TAKEN
HEART (HT)	75.303	.7038 %	.9770	WEIGHT TAKEN
ADRENAL(S) (AD)	1.109	.0104 %	.0144	WEIGHT TAKEN
SPLEEN (SP)	29.552	.2762 %	.3834	WEIGHT TAKEN
THYMUS (TH)	8.294	.0775 %	.1076	WEIGHT TAKEN
SALIVARY GLD(S) (SG)	19.0540	.1781 %	.2472	WEIGHT TAKEN
KIDNEY(S) (KD)	53.373	.4988 %	.6925	WEIGHT TAKEN
LIVER (LI)	268.665	2.5109 %	3.4857	WEIGHT TAKEN
TESTES (TE)	13.735	.1284 %	.1782	WEIGHT TAKEN
EPIDIDYMIDES (EP)	3.6670	.0343 %	.0476	WEIGHT TAKEN
PROSTATE (PR)	3.735	.0349 %	.0485	WEIGHT TAKEN
BRAIN (BR)	77.077	.7203 %	1.0000	WEIGHT TAKEN
PITUITARY (PI)	.008	.0001 %	.0001	WEIGHT TAKEN

*** P A T H O L O G Y O B S E R V A T I O N S ***

ORGAN NAME	KEYWORDS, SEVERITY, DISTRIBUTION	GROSS FREE-TEXT COMMENTS / HISTOPATHOLOGIC FINDINGS
GENERAL COMMENT (GC)		
GROSS:	-ALL TISSUES/ORGANS NORMAL	
KIDNEY, LEFT (KDO)		
MICRO:	-MINIMAL	-MINERALIZATION
KIDNEY, RIGHT (KD1)		
MICRO:	-MINIMAL	-MINERALIZATION
MAMMARY GLAND (MG)		
MICRO:	-TISSUE MISSING	
SALIVARY GLD(S) (SG)		
MICRO:	-SLIGHT, MULTI-FOCAL	-MONONUCLEAR INFILTRATION

APPENDIX J

INDIVIDUAL ANIMAL PATHOLOGY DATA

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

PRINTED: 22-MAY-86
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STUDY NUMBER: 6127111

ANIMAL NUMBER: 000990 SEX: MALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, FIRST POST-RECOV SAC
DATE OF DEATH: 02/06/86 STUDY DAY OF DEATH: 212 STUDY WEEK OF DEATH: 31 TERMINAL BODY WEIGHT: 10800.0 GRAMS
DATE AND TIME OF NECROPSY: 02/06/86 PROSECTOR: DENNIS HOFFMAN RECORDER: RUTH SCHMITZ
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. WILLIAM E. FIELD WEIGHER: RUTH SCHMITZ

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
THYROID(S)/PARA (TYO)	.937	.0087 %	.0111	WEIGHT TAKEN
HEART (HT)	79.636	.7374 %	.9444	WEIGHT TAKEN
ADRENAL(S) (AD)	1.099	.0102 %	.0130	WEIGHT TAKEN
SPLEEN (SP)	38.579	.3572 %	.4575	WEIGHT TAKEN
THYMUS (TH)	8.061	.0746 %	.0956	WEIGHT TAKEN
SALIVARY GLD(S) (SG)	20.1630	.1867 %	.2391	WEIGHT TAKEN
KIDNEY(S) (KD)	49.200	.4556 %	.5835	WEIGHT TAKEN
LIVER (LI)	298.242	2.7615 %	3.5369	WEIGHT TAKEN
TESTES (TE)	17.007	.1575 %	.2017	WEIGHT TAKEN
EPIDIDYMIDES (EP)	4.3760	.0405 %	.0519	WEIGHT TAKEN
PROSTATE (PR)	5.360	.0496 %	.0636	WEIGHT TAKEN
BRAIN (BR)	84.324	.7808 %	1.0000	WEIGHT TAKEN
PITUITARY (PI)	.061	.0006 %	.0007	WEIGHT TAKEN

*** P A T H O L O G Y O B S E R V A T I O N S ***

ORGAN NAME	KEYWORDS, SEVERITY, DISTRIBUTION	GROSS FREE-TEXT COMMENTS / HISTOPATHOLOGIC FINDINGS
ANT.MES/PANC LN (AM)	. . . . .	
GROSS:	-DIFFUSELY RED	-COLLECTED (CAP 36)
MICRO:	-MODERATE	-CONGESTION

APPENDIX J

INDIVIDUAL ANIMAL PATHOLOGY DATA

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

PRINTED: 22-MAY-86
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STUDY NUMBER: 6127111

ANIMAL NUMBER: 000997 SEX: MALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 01/09/86 STUDY DAY OF DEATH: 184 STUDY WEEK OF DEATH: 27 TERMINAL BODY WEIGHT: 11300.0 GRAMS
DATE AND TIME OF NECROPSY: 01/09/86 PROSECTOR: NANCY DIEDRICH RECORDER: RUTH SCHMITZ
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. WILLIAM E. FIELD WEIGHER: RUTH SCHMITZ

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
THYROID(S)/PARA (TYO)	1.278	.0113 %	.0164	WEIGHT TAKEN
HEART (HT)	91.650	.8111 %	1.1730	WEIGHT TAKEN
ADRENAL(S) (AD)	1.244	.0110 %	.0159	WEIGHT TAKEN
SPLEEN (SP)	40.248	.3562 %	.5151	WEIGHT TAKEN
THYMUS (TH)	8.305	.0735 %	.1063	WEIGHT TAKEN
SALIVARY GLD(S) (SG)	18.8560	.1669 %	.2413	WEIGHT TAKEN
KIDNEY(S) (KD)	54.297	.4805 %	.6949	WEIGHT TAKEN
LIVER (LI)	359.294	3.1796 %	4.5980	WEIGHT TAKEN
TESTES (TE)	18.962	.1678 %	.2427	WEIGHT TAKEN
EPIDIDYMIDES (EP)	4.6220	.0409 %	.0591	WEIGHT TAKEN
PROSTATE (PR)	7.544	.0668 %	.0965	WEIGHT TAKEN
BRAIN (BR)	78.142	.6915 %	1.0000	WEIGHT TAKEN
PITUITARY (PI)	.080	.0007 %	.0010	WEIGHT TAKEN

*** P A T H O L O G Y O B S E R V A T I O N S ***

ORGAN NAME	KEYWORDS, SEVERITY, DISTRIBUTION	GROSS FREE-TEXT COMMENTS / HISTOPATHOLOGIC FINDINGS
GENERAL COMMENT (GC)		
GROSS:	-ALL TISSUES/ORGANS NORMAL	
KIDNEY, LEFT (KDO)		
MICRO:	-MINIMAL	-MINERALIZATION
KIDNEY, RIGHT (KD1)		
MICRO:	-MINIMAL	-MINERALIZATION
MAMMARY GLAND (MG)		
MICRO:	-TISSUE MISSING	
GENERAL INFORMATION (XX)		
GROSS:		NECROPSY NOTE: >ANIMAL DIED PRIOR TO EXSANGUINATION

APPENDIX J

INDIVIDUAL ANIMAL PATHOLOGY DATA

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

PRINTED: 22-MAY-86
PAGE: 24

STUDY NUMBER: 6127111

ANIMAL NUMBER: 000998 SEX: MALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, FIRST POST-RECOV SAC
DATE OF DEATH: 02/07/86 STUDY DAY OF DEATH: 213 STUDY WEEK OF DEATH: 31 TERMINAL BODY WEIGHT: 11000.0 GRAMS
DATE AND TIME OF NECROPSY: 02/07/86 PROSECTOR: JACK SERFORT RECORDER: RUTH SCHMITZ
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. WILLIAM E. FIELD WEIGHER: RUTH SCHMITZ

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
THYROID(S)/PARA (TYO)	1.305	.0119 %	.0164	WEIGHT TAKEN
HEART (HT)	87.942	.7995 %	1.1037	WEIGHT TAKEN
ADRENAL(S) (AD)	1.544	.0140 %	.0194	WEIGHT TAKEN
SPLEEN (SP)	32.777	.2980 %	.4114	WEIGHT TAKEN
THYMUS (TH)	15.144	.1377 %	.1901	WEIGHT TAKEN
SALIVARY GLD(S) (SG)	15.7570	.1432 %	.1978	WEIGHT TAKEN
KIDNEY(S) (KD)	43.495	.3954 %	.5459	WEIGHT TAKEN
LIVER (LI)	250.458	2.2769 %	3.1435	WEIGHT TAKEN
TESTES (TE)	9.374	.0852 %	.1177	WEIGHT TAKEN
EPIDIDYMIDES (EP)	4.4080	.0401 %	.0553	WEIGHT TAKEN
PROSTATE (PR)	5.581	.0507 %	.0700	WEIGHT TAKEN
BRAIN (BR)	79.676	.7243 %	1.0000	WEIGHT TAKEN
PITUITARY (PI)	.039	.0004 %	.0005	WEIGHT TAKEN

*** P A T H O L O G Y O B S E R V A T I O N S ***

ORGAN NAME	KEYWORDS, SEVERITY, DISTRIBUTION	GROSS FREE-TEXT COMMENTS / HISTOPATHOLOGIC FINDINGS
GENERAL COMMENT (GC)	. . . . .	
	GROSS: -ALL TISSUES/ORGANS NORMAL	

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INDIVIDUAL ANIMAL PATHOLOGY DATA

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DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

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STUDY NUMBER: 6127111

ANIMAL NUMBER: 000999 SEX: MALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 01/08/86 STUDY DAY OF DEATH: 183 STUDY WEEK OF DEATH: 27 TERMINAL BODY WEIGHT: 10000.0 GRAMS
DATE AND TIME OF NECROPSY: 01/08/86 PROSECTOR: JANELLE RASCHEIN RECORDER: RUTH SCHMITZ
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. WILLIAM E. FIELD WEIGHER: RUTH SCHMITZ

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
THYROID(S)/PARA (TYO)	.900	.0090 %	.0126	WEIGHT TAKEN
HEART (HT)	87.859	.8786 %	1.2253	WEIGHT TAKEN
ADRENAL(S) (AD)	1.003	.0100 %	.0140	WEIGHT TAKEN
SPLEEN (SP)	33.582	.3358 %	.4683	WEIGHT TAKEN
THYMUS (TH)	12.030	.1203 %	.1678	WEIGHT TAKEN
SALIVARY GLD(S) (SG)	18.4740	.1847 %	.2576	WEIGHT TAKEN
KIDNEY(S) (KD)	52.299	.5230 %	.7294	WEIGHT TAKEN
LIVER (LI)	304.456	3.0446 %	4.2460	WEIGHT TAKEN
TESTES (TE)	15.218	.1522 %	.2122	WEIGHT TAKEN
EPIDIDYMIDES (EP)	4.4340	.0443 %	.0618	WEIGHT TAKEN
PROSTATE (PR)	6.997	.0700 %	.0976	WEIGHT TAKEN
BRAIN (BR)	71.704	.7170 %	1.0000	WEIGHT TAKEN
PITUITARY (PI)	.058	.0006 %	.0008	WEIGHT TAKEN

*** P A T H O L O G Y O B S E R V A T I O N S ***

ORGAN NAME	KEYWORDS, SEVERITY, DISTRIBUTION	GROSS FREE-TEXT COMMENTS / HISTOPATHOLOGIC FINDINGS
GENERAL COMMENT (GC)		
GROSS:	-ALL TISSUES/ORGANS NORMAL	
KIDNEY, RIGHT (KD1)		
MICRO:	-MINIMAL	-MINERALIZATION
MAMMARY GLAND (MG)		
MICRO:	-TISSUE MISSING	
PARATHYROID(S) (PT)		
MICRO:	-PRESENT	-ONE EXAMINED

APPENDIX J

INDIVIDUAL ANIMAL PATHOLOGY DATA

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

PRINTED: 22-MAY-86
PAGE: 26

STUDY NUMBER: 6127111

ANIMAL NUMBER: 000001 SEX: MALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, FIRST POST-RECOV SAC
DATE OF DEATH: 02/06/86 STUDY DAY OF DEATH: 212 STUDY WEEK OF DEATH: 31 TERMINAL BODY WEIGHT: 9800.0 GRAMS
DATE AND TIME OF NECROPSY: 02/06/86 PROSECTOR: DENNIS HOFFMAN RECORDER: RUTH SCHMITZ
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. WILLIAM E. FIELD WEIGHER: RUTH SCHMITZ

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
THYROID(S)/PARA (TYO)	.746	.0076 %	.0097	WEIGHT TAKEN
HEART (HT)	77.011	.7856 %	.9980	WEIGHT TAKEN
ADRENAL(S) (AD)	1.108	.0113 %	.0144	WEIGHT TAKEN
SPLEEN (SP)	20.331	.2075 %	.2635	WEIGHT TAKEN
THYMUS (TH)	6.805	.0694 %	.0882	WEIGHT TAKEN
SALIVARY GLD(S) (SG)	14.4750	.1477 %	.1876	WEIGHT TAKEN
KIDNEY(S) (KD)	45.650	.4658 %	.5916	WEIGHT TAKEN
LIVER (LI)	284.333	2.9014 %	3.6847	WEIGHT TAKEN
TESTES (TE)	16.016	.1634 %	.2076	WEIGHT TAKEN
EPIDIDYMIDES (EP)	3.7030	.0378 %	.0480	WEIGHT TAKEN
PROSTATE (PR)	4.456	.0455 %	.0577	WEIGHT TAKEN
BRAIN (BR)	77.165	.7874 %	1.0000	WEIGHT TAKEN
PITUITARY (PI)	.064	.0007 %	.0008	WEIGHT TAKEN

*** P A T H O L O G Y O B S E R V A T I O N S ***

ORGAN NAME	KEYWORDS, SEVERITY, DISTRIBUTION	GROSS FREE-TEXT COMMENTS / HISTOPATHOLOGIC FINDINGS
GENERAL COMMENT (GC)	. . . . .	
	GROSS: -ALL TISSUES/ORGANS NORMAL	

APPENDIX J

INDIVIDUAL ANIMAL PATHOLOGY DATA

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

PRINTED: 22-MAY-86
PAGE: 27

STUDY NUMBER: 6127111

ANIMAL NUMBER: 000002 SEX: MALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 01/09/86 STUDY DAY OF DEATH: 184 STUDY WEEK OF DEATH: 27 TERMINAL BODY WEIGHT: 7800.0 GRAMS
DATE AND TIME OF NECROPSY: 01/09/86 PROSECTOR: JANELLE RASCHEIN RECORDER: RUTH SCHMITZ
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. WILLIAM E. FIELD WEIGHER: RUTH SCHMITZ

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
THYROID(S)/PARA (TYO)	.967	.0124 %	.0133	WEIGHT TAKEN
HEART (HT)	62.501	.8013 %	.8608	WEIGHT TAKEN
ADRENAL(S) (AD)	1.192	.0153 %	.0164	WEIGHT TAKEN
SPLEEN (SP)	17.674	.2266 %	.2434	WEIGHT TAKEN
THYMUS (TH)	2.443	.0313 %	.0336	WEIGHT TAKEN
SALIVARY GLD(S) (SG)	12.5660	.1611 %	.1731	WEIGHT TAKEN
KIDNEY(S) (KD)	44.020	.5644 %	.6063	WEIGHT TAKEN
LIVER (LI)	230.808	2.9591 %	3.1787	WEIGHT TAKEN
TESTES (TE)	15.006	.1924 %	.2067	WEIGHT TAKEN
EPIDIDYMIDES (EP)	3.0110	.0386 %	.0415	WEIGHT TAKEN
PROSTATE (PR)	1.635	.0210 %	.0225	WEIGHT TAKEN
BRAIN (BR)	72.610	.9309 %	1.0000	WEIGHT TAKEN
PITUITARY (PI)	.044	.0006 %	.0006	WEIGHT TAKEN

*** P A T H O L O G Y O B S E R V A T I O N S ***

ORGAN NAME	KEYWORDS, SEVERITY, DISTRIBUTION	GROSS FREE-TEXT COMMENTS / HISTOPATHOLOGIC FINDINGS
KIDNEY, LEFT (KD0)		
	MICRO: -MINIMAL	-MINERALIZATION
KIDNEY, RIGHT (KD1)		
	MICRO: -MINIMAL	-MINERALIZATION
MAMMARY GLAND (MG)		
	MICRO: -TISSUE MISSING	
SKIN (SK)		
	GROSS: -ALOPECIA-DIFFUSE	-VENTRAL CERVICAL REGION: AREA OF 20 MM IN DIAMETER (CAP 36)
	-THICKENED	-VENTRAL CERVICAL REGION: (CAP 36)
	MICRO: -MODERATE	-ACANTHOSIS
	-MODERATE	-HYPERKERATOSIS
	-MODERATE	-ULCERATIVE DERMATITIS

APPENDIX J

INDIVIDUAL ANIMAL PATHOLOGY DATA

ANIMAL NUMBER: 000002 SEX: MALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 01/09/86 STUDY DAY OF DEATH: 184 STUDY WEEK OF DEATH: 27 TERMINAL BODY WEIGHT: 7800.0 GRAMS
DATE AND TIME OF NECROPSY: 01/09/86 PROSECTOR: JANELLE RASCHEIN RECORDER: RUTH SCHMITZ
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. WILLIAM E. FIELD WEIGHER: RUTH SCHMITZ

*** PATHOLOGY OBSERVATIONS (CONTINUED) ***

ORGAN NAME	KEYWORDS, SEVERITY, DISTRIBUTION	GROSS FREE-TEXT COMMENTS / HISTOPATHOLOGIC FINDINGS
THYMUS (TH)		
	MICRO: -MODERATE	-INVOLUTION
	-PRESENT	-CYST(S)

APPENDIX J

INDIVIDUAL ANIMAL PATHOLOGY DATA

ANIMAL NUMBER: 000003 SEX: MALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 01/10/86 STUDY DAY OF DEATH: 185 STUDY WEEK OF DEATH: 27 TERMINAL BODY WEIGHT: 0300.0 GRAMS
DATE AND TIME OF NECROPSY: 01/10/86 PROSECTOR: JANELLE RASCHEIN RECORDER: JACK SERFORT
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. WILLIAM E. FIELD WEIGHER: JACK SERFORT

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
THYROID(S)/PARA (TYO)	.942	.0113 %	.0147	WEIGHT TAKEN
HEART (HT)	74.399	.8908 %	1.1617	WEIGHT TAKEN
ADRENAL(S) (AD)	.938	.0113 %	.0146	WEIGHT TAKEN
SPLEEN (SP)	18.499	.2229 %	.2891	WEIGHT TAKEN
THYMUS (TH)	3.361	.0405 %	.0523	WEIGHT TAKEN
SALIVARY GLD(S) (SG)	13.6140	.1640 %	.2120	WEIGHT TAKEN
KIDNEY(S) (KD)	46.410	.5592 %	.7228	WEIGHT TAKEN
LIVER (LI)	226.933	2.7341 %	3.5341	WEIGHT TAKEN
TESTES (TE)	11.944	.1439 %	.1860	WEIGHT TAKEN
EPIDIDYMIDES (EP)	2.7100	.0327 %	.0422	WEIGHT TAKEN
PROSTATE (PR)	1.763	.0212 %	.0275	WEIGHT TAKEN
BRAIN (BR)	64.213	.7737 %	1.0000	WEIGHT TAKEN
PITUITARY (PI)	.047	.0006 %	.0007	WEIGHT TAKEN

*** P A T H O L O G Y O B S E R V A T I O N S ***

ORGAN NAME	KEYWORDS, SEVERITY, DISTRIBUTION	GROSS FREE-TEXT COMMENTS / HISTOPATHOLOGIC FINDINGS
KIDNEY, LEFT (KDO)		
MICRO:	-MINIMAL	-MINERALIZATION
KIDNEY, RIGHT (KD1)		
MICRO:	-MINIMAL	-MINERALIZATION
MAMMARY GLAND (MG)		
MICRO:	-TISSUE MISSING	
PARATHYROID(S) (PT)		
MICRO:	-PRESENT	-ONE EXAMINED
SKIN (SK)		
GROSS:	-RED FOCUS(I)/AREA(S)	-DIFFUSE: REPRESENTATIVE SECTION COLLECTED FROM RIGHT INGUINAL REGION (CAP 36)
MICRO:	-UNREMARKABLE	

APPENDIX J

INDIVIDUAL ANIMAL PATHOLOGY DATA

ANIMAL NUMBER: 000003 SEX: MALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 01/10/86 STUDY DAY OF DEATH: 185 STUDY WEEK OF DEATH: 27 TERMINAL BODY WEIGHT: 8300.0 GRAMS
DATE AND TIME OF NECROPSY: 01/10/86 PROSECTOR: JANELLE ROSCHEIN RECORDER: JACK SERFORT
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. WILLIAM E. FIELD WEIGHER: JACK SERFORT

*** PATHOLOGY OBSERVATIONS (CONTINUED) ***

ORGAN NAME	KEYWORDS, SEVERITY, DISTRIBUTION	GROSS FREE-TEXT COMMENTS / HISTOPATHOLOGIC FINDINGS
SKIN (SK)		
	MICRO:	HISTOPATHOLOGICAL COMMENT: >NO MICROSCOPIC CORRELATION WITH GROSS FINDING
THYROID(S) (TY)		
	MICRO: -MODERATE, DIFFUSE	-"C" CELL HYPERPLASIA
	-PRESENT	-CYST(S),NOS.

APPENDIX J

INDIVIDUAL ANIMAL PATHOLOGY DATA

ANIMAL NUMBER: 000967 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 01/10/86 STUDY DAY OF DEATH: 185 STUDY WEEK OF DEATH: 27 TERMINAL BODY WEIGHT: 12000.0 GRAMS
DATE AND TIME OF NECROPSY: 01/10/86 PROSECTOR: DENNIS HOFFMAN RECORDER: JACK SERFORT
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. WILLIAM E. FIELD WEIGHER: JACK SERFORT

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
THYROID(S)/PARA (TYO)	.839	.0070 %	.0111	WEIGHT TAKEN
HEART (HT)	94.043	.7837 %	1.2387	WEIGHT TAKEN
ADRENAL(S) (AD)	1.697	.0141 %	.0224	WEIGHT TAKEN
SPLEEN (SP)	42.452	.3538 %	.5592	WEIGHT TAKEN
THYMUS (TH)	15.224	.1269 %	.2005	WEIGHT TAKEN
SALIVARY GLD(S) (SG)	18.5570	.1546 %	.2444	WEIGHT TAKEN
KIDNEY(S) (KD)	42.332	.3528 %	.5576	WEIGHT TAKEN
LIVER (LI)	317.293	2.6441 %	4.1793	WEIGHT TAKEN
UTERUS (UT)	25.1710	.2098 %	.3315	WEIGHT TAKEN
OVARIES (OV)	2.313	.0193 %	.0305	WEIGHT TAKEN
BRAIN (BR)	75.921	.6327 %	1.0000	WEIGHT TAKEN
PITUITARY (PI)	.076	.0006 %	.0010	WEIGHT TAKEN

*** PATHOLOGY OBSERVATIONS ***

ORGAN NAME	KEYWORDS, SEVERITY, DISTRIBUTION	GROSS FREE-TEXT COMMENTS / HISTOPATHOLOGIC FINDINGS
GENERAL COMMENT (GC)		
GROSS:	-ALL TISSUES/ORGANS NORMAL	
KIDNEY, LEFT (KDO)		
MICRO:	-SLIGHT	-MINERALIZATION
KIDNEY, RIGHT (KD1)		
MICRO:	-MINIMAL	-MINERALIZATION
PARATHYROID(S) (PT)		
MICRO:	-TISSUE MISSING	

APPENDIX J

INDIVIDUAL ANIMAL PATHOLOGY DATA

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

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STUDY NUMBER: 6127111

ANIMAL NUMBER: 000968 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 01/09/86 STUDY DAY OF DEATH: 184 STUDY WEEK OF DEATH: 27 TERMINAL BODY WEIGHT: 9900.0 GRAMS
DATE AND TIME OF NECROPSY: 01/09/86 PROSECTOR: JACK SERFORT RECORDER: RUTH SCHMITZ
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. WILLIAM E. FIELD WEIGHER: RUTH SCHMITZ

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
THYROID(S)/PARA (TYO)	.819	.0083 %	.0110	WEIGHT TAKEN
HEART (HT)	79.201	.8000 %	1.0638	WEIGHT TAKEN
ADRENAL(S) (AD)	1.547	.0156 %	.0208	WEIGHT TAKEN
SPLEEN (SP)	27.030	.2730 %	.3631	WEIGHT TAKEN
THYMUS (TH)	5.878	.0594 %	.0790	WEIGHT TAKEN
SALIVARY GLD(S) (SG)	14.6500	.1481 %	.1969	WEIGHT TAKEN
KIDNEY(S) (KD)	42.303	.4273 %	.5682	WEIGHT TAKEN
LIVER (LI)	258.992	2.6161 %	3.4786	WEIGHT TAKEN
UTERUS (UT)	15.7650	.1592 %	.2117	WEIGHT TAKEN
OVARIES (OV)	1.275	.0129 %	.0171	WEIGHT TAKEN
BRAIN (BR)	74.452	.7520 %	1.0000	WEIGHT TAKEN
PITUITARY (PI)	.061	.0006 %	.0008	WEIGHT TAKEN

*** PATHOLOGY OBSERVATIONS ***

ORGAN NAME	KEYWORDS, SEVERITY, DISTRIBUTION	GROSS FREE-TEXT COMMENTS / HISTOPATHOLOGIC FINDINGS
KIDNEY, LEFT (KDO)		
MICRO:	-MINIMAL	-MINERALIZATION
KIDNEY, RIGHT (KD1)		
MICRO:	-MINIMAL	-MINERALIZATION
SKIN (SK)		
GROSS:	-ALOPECIA-DIFFUSE	-DIFFUSE, ALL AREAS: SECTION COLLECTED FROM LEFT LATERAL LUMBAR REGION (CAP 36)
MICRO:	-SLIGHT, MULTI-FOCAL	-FOLLICULITIS,NOS.

APPENDIX J

INDIVIDUAL ANIMAL PATHOLOGY DATA

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

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STUDY NUMBER: 6127111

ANIMAL NUMBER: 000969 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 01/09/86 STUDY DAY OF DEATH: 184 STUDY WEEK OF DEATH: 27 TERMINAL BODY WEIGHT: 9200.0 GRAMS
DATE AND TIME OF NECROPSY: 01/09/86 PROSECTOR: JANELLE RASCHEIN RECORDER: RUTH SCHMITZ
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. WILLIAM E. FIELD WEIGHER: RUTH SCHMITZ

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
THYROID(S)/PARA (TYO)	.764	.0083 %	.0111	WEIGHT TAKEN
HEART (HT)	63.005	.6848 %	.9123	WEIGHT TAKEN
ADRENAL(S) (AD)	1.518	.0165 %	.0220	WEIGHT TAKEN
SPLEEN (SP)	52.883	.5748 %	.7657	WEIGHT TAKEN
THYMUS (TH)	8.155	.0886 %	.1181	WEIGHT TAKEN
SALIVARY GLD(S) (SG)	17.1400	.1863 %	.2482	WEIGHT TAKEN
KIDNEY(S) (KD)	37.238	.4048 %	.5392	WEIGHT TAKEN
LIVER (LI)	248.076	2.6965 %	3.5919	WEIGHT TAKEN
UTERUS (UT)	7.1920	.0782 %	.1041	WEIGHT TAKEN
OVARIES (OV)	1.044	.0113 %	.0151	WEIGHT TAKEN
BRAIN (BR)	69.065	.7507 %	1.0000	WEIGHT TAKEN
PITUITARY (PI)	.048	.0005 %	.0007	WEIGHT TAKEN

*** P A T H O L O G Y O B S E R V A T I O N S ***

ORGAN NAME	KEYWORDS, SEVERITY, DISTRIBUTION	GROSS FREE-TEXT COMMENTS / HISTOPATHOLOGIC FINDINGS
GENERAL COMMENT (GC)		
GROSS:	-ALL TISSUES/ORGANS NORMAL	
KIDNEY, LEFT (KDO)		
MICRO:	-MINIMAL	-MINERALIZATION
KIDNEY, RIGHT (KD1)		
MICRO:	-MINIMAL	-MINERALIZATION
THYROID(S) (TY)		
MICRO:	-MODERATE, DIFFUSE	-"C" CELL HYPERPLASIA
GENERAL INFORMATION (XX)		
GROSS:		NECROPSY NOTE: >ANIMAL DIED PRIOR TO EXSANGUINATION

APPENDIX J

INDIVIDUAL ANIMAL PATHOLOGY DATA

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

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STUDY NUMBER: 6127111

ANIMAL NUMBER: 000970 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 01/09/86 STUDY DAY OF DEATH: 184 STUDY WEEK OF DEATH: 27 TERMINAL BODY WEIGHT: 9200.0 GRAMS
DATE AND TIME OF NECROPSY: 01/09/86 PROSECTOR: JANELLE RASCHEIN RECORDER: RUTH SCHMITZ
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. WILLIAM E. FIELD WEIGHER: RUTH SCHMITZ

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
THYROID(S)/PARA (TYO)	1.018	.0111 %	.0133	WEIGHT TAKEN
HEART (HT)	74.112	.8056 %	.9695	WEIGHT TAKEN
ADRENAL(S) (AD)	1.513	.0164 %	.0198	WEIGHT TAKEN
SPLEEN (SP)	29.235	.3178 %	.3825	WEIGHT TAKEN
THYMUS (TH)	7.665	.0833 %	.1003	WEIGHT TAKEN
SALIVARY GLD(S) (SG)	18.7930	.2043 %	.2459	WEIGHT TAKEN
KIDNEY(S) (KD)	39.647	.4309 %	.5187	WEIGHT TAKEN
LIVER (LI)	250.077	2.7182 %	3.2715	WEIGHT TAKEN
UTERUS (UT)	8.7130	.0947 %	.1140	WEIGHT TAKEN
OVARIES (OV)	1.271	.0138 %	.0166	WEIGHT TAKEN
BRAIN (BR)	76.440	.8309 %	1.0000	WEIGHT TAKEN
PITUITARY (PI)	.069	.0008 %	.0009	WEIGHT TAKEN

*** P A T H O L O G Y O B S E R V A T I O N S ***

ORGAN NAME	KEYWORDS, SEVERITY, DISTRIBUTION	GROSS FREE-TEXT COMMENTS / HISTOPATHOLOGIC FINDINGS
GENERAL COMMENT (GC)		
	GROSS: -ALL TISSUES/ORGANS NORMAL	
KIDNEY, LEFT (KDO)		
	MICRO: -MINIMAL	-MINERALIZATION

APPENDIX J

INDIVIDUAL ANIMAL PATHOLOGY DATA

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

PRINTED: 22-MAY-86
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STUDY NUMBER: 6127111

ANIMAL NUMBER: 000971 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, FIRST POST-RECOV SAC
DATE OF DEATH: 02/07/86 STUDY DAY OF DEATH: 213 STUDY WEEK OF DEATH: 31 TERMINAL BODY WEIGHT: 0900.0 GRAMS
DATE AND TIME OF NECROPSY: 02/07/86 PROSECTOR: DENNIS HOFFMAN RECORDER: RUTH SCHMITZ
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. WILLIAM E. FIELD WEIGHER: RUTH SCHMITZ

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
THYROID(S)/PARA (TYO)	1.085	.0122 %	.0146	WEIGHT TAKEN
HEART (HT)	77.546	.8713 %	1.0415	WEIGHT TAKEN
ADRENAL(S) (AD)	1.007	.0113 %	.0135	WEIGHT TAKEN
SPLEEN (SP)	21.553	.2422 %	.2895	WEIGHT TAKEN
THYMUS (TH)	8.170	.0918 %	.1097	WEIGHT TAKEN
SALIVARY GLD(S) (SG)	14.0310	.1577 %	.1884	WEIGHT TAKEN
KIDNEY(S) (KD)	40.545	.4556 %	.5445	WEIGHT TAKEN
LIVER (LI)	265.245	2.9803 %	3.5623	WEIGHT TAKEN
UTERUS (UT)	3.5560	.0400 %	.0478	WEIGHT TAKEN
OVARIES (OV)	.766	.0086 %	.0103	WEIGHT TAKEN
BRAIN (BR)	74.458	.8366 %	1.0000	WEIGHT TAKEN
PITUITARY (PI)	.070	.0008 %	.0009	WEIGHT TAKEN

*** P A T H O L O G Y O B S E R V A T I O N S ***

ORGAN NAME	KEYWORDS, SEVERITY, DISTRIBUTION	GROSS FREE-TEXT COMMENTS / HISTOPATHOLOGIC FINDINGS
GENERAL COMMENT (GC)	. . . . .	
	GROSS: -ALL TISSUES/ORGANS NORMAL	

APPENDIX J

INDIVIDUAL ANIMAL PATHOLOGY DATA

ANIMAL NUMBER: 000972 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, FIRST POST-RECOV SAC
DATE OF DEATH: 02/06/86 STUDY DAY OF DEATH: 212 STUDY WEEK OF DEATH: 31 TERMINAL BODY WEIGHT: 0700.0 GRAMS
DATE AND TIME OF NECROPSY: 02/06/86 PROSECTOR: JACK SERFORT RECORDER: RUTH SCHMITZ
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. WILLIAM E. FIELD WEIGHER: RUTH SCHMITZ

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
THYROID(S)/PARA (TYO)	.958	.0110 %	.0145	WEIGHT TAKEN
HEART (HT)	73.045	.8396 %	1.1077	WEIGHT TAKEN
ADRENAL(S) (AD)	1.014	.0117 %	.0154	WEIGHT TAKEN
SPLEEN (SP)	24.899	.2862 %	.3776	WEIGHT TAKEN
THYMUS (TH)	8.068	.0927 %	.1224	WEIGHT TAKEN
SALIVARY GLD(S) (SG)	16.1270	.1854 %	.2446	WEIGHT TAKEN
KIDNEY(S) (KD)	34.406	.3955 %	.5218	WEIGHT TAKEN
LIVER (LI)	219.124	2.5187 %	3.3230	WEIGHT TAKEN
UTERUS (UT)	13.9560	.1604 %	.2116	WEIGHT TAKEN
OVARIES (OV)	1.044	.0120 %	.0158	WEIGHT TAKEN
BRAIN (BR)	65.941	.7579 %	1.0000	WEIGHT TAKEN
PITUITARY (PI)	.040	.0005 %	.0006	WEIGHT TAKEN

*** P A T H O L O G Y O B S E R V A T I O N S ***

ORGAN NAME	KEYWORDS, SEVERITY, DISTRIBUTION	GROSS FREE-TEXT COMMENTS / HISTOPATHOLOGIC FINDINGS
EAR (ER)		
	MICRO: -MODERATE	-ACANTHOSIS
	HISTOPATHOLOGICAL COMMENT: >PINNA AND EAR ARE SYNONYMS	
PINNA (PN)		
	GROSS: -DIFFUSELY RED	-BILATERAL: ONE COLLECTED

APPENDIX J

INDIVIDUAL ANIMAL PATHOLOGY DATA

ANIMAL NUMBER: 000979 SEX: FEMALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, FIRST POST-RECOV SAC
DATE OF DEATH: 02/07/86 STUDY DAY OF DEATH: 213 STUDY WEEK OF DEATH: 31 TERMINAL BODY WEIGHT: 9600.0 GRAMS
DATE AND TIME OF NECROPSY: 02/07/86 PROSECTOR: DENNIS HOFFMAN RECORDER: RUTH SCHMITZ
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. WILLIAM E. FIELD WEIGHER: RUTH SCHMITZ

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
THYROID(S)/PARA (TYO)	.048	.0008 %	.0122	WEIGHT TAKEN
HEART (HT)	64.638	.6733 %	.9275	WEIGHT TAKEN
ADRENAL(S) (AD)	1.109	.0116 %	.0159	WEIGHT TAKEN
SPLEEN (SP)	29.562	.3079 %	.4242	WEIGHT TAKEN
THYMUS (TH)	6.675	.0695 %	.0958	WEIGHT TAKEN
SALIVARY GLD(S) (SG)	13.2500	.1381 %	.1902	WEIGHT TAKEN
KIDNEY(S) (KD)	35.735	.3722 %	.5128	WEIGHT TAKEN
LIVER (LI)	224.494	2.3385 %	3.2214	WEIGHT TAKEN
UTERUS (UT)	14.4950	.1510 %	.2080	WEIGHT TAKEN
OVARIES (OV)	1.175	.0122 %	.0169	WEIGHT TAKEN
BRAIN (BR)	69.688	.7259 %	1.0000	WEIGHT TAKEN
PITUITARY (PI)	.047	.0005 %	.0007	WEIGHT TAKEN

*** P A T H O L O G Y O B S E R V A T I O N S ***

ORGAN NAME	KEYWORDS, SEVERITY, DISTRIBUTION	GROSS FREE-TEXT COMMENTS / HISTOPATHOLOGIC FINDINGS
GENERAL COMMENT (GC)	. . . . .	
	GROSS: -ALL TISSUES/ORGANS NORMAL	

APPENDIX J

INDIVIDUAL ANIMAL PATHOLOGY DATA

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

PRINTED: 22-MAY-86
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STUDY NUMBER: 6127111

ANIMAL NUMBER: 000980 SEX: FEMALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 01/08/86 STUDY DAY OF DEATH: 183 STUDY WEEK OF DEATH: 27 TERMINAL BODY WEIGHT: 9000.0 GRAMS
DATE AND TIME OF NECROPSY: 01/08/86 PROSECTOR: JANELLE RASCHEIN RECORDER: RUTH SCHMITZ
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. WILLIAM E. FIELD WEIGHER: RUTH SCHMITZ

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
THYROID(S)/PARA (TYO)	.700	.0008 %	.0113	WEIGHT TAKEN
HEART (HT)	78.610	.8734 %	1.1291	WEIGHT TAKEN
ADRENAL(S) (AD)	1.206	.0134 %	.0173	WEIGHT TAKEN
SPLEEN (SP)	29.088	.3232 %	.4178	WEIGHT TAKEN
THYMUS (TH)	3.896	.0433 %	.0560	WEIGHT TAKEN
SALIVARY GLD(S) (SG)	12.2000	.1356 %	.1752	WEIGHT TAKEN
KIDNEY(S) (KD)	36.131	.4015 %	.5190	WEIGHT TAKEN
LIVER (LI)	268.115	2.9791 %	3.8511	WEIGHT TAKEN
UTERUS (UT)	2.1300	.0237 %	.0306	WEIGHT TAKEN
OVARIES (OV)	.606	.0067 %	.0087	WEIGHT TAKEN
BRAIN (BR)	69.620	.7736 %	1.0000	WEIGHT TAKEN
PITUITARY (PI)	.047	.0005 %	.0007	WEIGHT TAKEN

*** P A T H O L O G Y O B S E R V A T I O N S ***

ORGAN NAME	KEYWORDS, SEVERITY, DISTRIBUTION	GROSS FREE-TEXT COMMENTS / HISTOPATHOLOGIC FINDINGS
GENERAL COMMENT (GC)		
GROSS:	-ALL TISSUES/ORGANS NORMAL	
KIDNEY, LEFT (KDO)		
MICRO:	-MINIMAL	-MINERALIZATION
PITUITARY (PI)		
MICRO:	-PRESENT	-CYST(S)
TONGUE (TO)		
GROSS:	-MISSING/LOST/NOT IDENTIFIED	-TRIMMING COMMENT: NOT FOUND IN WET TISSUE
MICRO:	-TISSUE MISSING	

APPENDIX J

INDIVIDUAL ANIMAL PATHOLOGY DATA

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

PRINTED: 22-MAY-86
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STUDY NUMBER: 6127111

ANIMAL NUMBER: 000981 SEX: FEMALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, FIRST POST-RECOV SAC
DATE OF DEATH: 02/06/86 STUDY DAY OF DEATH: 212 STUDY WEEK OF DEATH: 31 TERMINAL BODY WEIGHT: 9000.0 GRAMS
DATE AND TIME OF NECROPSY: 02/06/86 PROSECTOR: JACK SERFORT RECORDER: RUTH SCHMITZ
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. WILLIAM E. FIELD WEIGHER: RUTH SCHMITZ

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
THYROID(S)/PARA (TYO)	1.100	.0112 %	.0162	WEIGHT TAKEN
HEART (HT)	79.389	.8101 %	1.1705	WEIGHT TAKEN
ADRENAL(S) (AD)	1.599	.0163 %	.0236	WEIGHT TAKEN
SPLEEN (SP)	35.016	.3573 %	.5163	WEIGHT TAKEN
THYMUS (TH)	8.503	.0868 %	.1254	WEIGHT TAKEN
SALIVARY GLD(S) (SG)	17.5320	.1791 %	.2586	WEIGHT TAKEN
KIDNEY(S) (KD)	42.219	.4308 %	.6225	WEIGHT TAKEN
LIVER (LI)	283.871	2.8966 %	4.1855	WEIGHT TAKEN
UTERUS (UT)	21.5640	.2200 %	.3179	WEIGHT TAKEN
OVARIES (OV)	1.927	.0197 %	.0284	WEIGHT TAKEN
BRAIN (BR)	67.823	.6921 %	1.0000	WEIGHT TAKEN
PITUITARY (PI)	.058	.0006 %	.0009	WEIGHT TAKEN

*** P A T H O L O G Y O B S E R V A T I O N S ***

ORGAN NAME	KEYWORDS, SEVERITY, DISTRIBUTION	GROSS FREE-TEXT COMMENTS / HISTOPATHOLOGIC FINDINGS
GENERAL COMMENT (GC)	. . . . .	
	GROSS: -ALL TISSUES/ORGANS NORMAL	

APPENDIX J

INDIVIDUAL ANIMAL PATHOLOGY DATA

ANIMAL NUMBER: 000982 SEX: FEMALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 01/09/86 STUDY DAY OF DEATH: 184 STUDY WEEK OF DEATH: 27 TERMINAL BODY WEIGHT: 0000.0 GRAMS
DATE AND TIME OF NECROPSY: 01/09/86 PROSECTOR: JACK SERFORT RECORDER: RUTH SCHMITZ
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. WILLIAM E. FIELD WEIGHER: RUTH SCHMITZ

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
THYROID(S)/PARA (TYO)	1.007	.0126 %	.0142	WEIGHT TAKEN
HEART (HT)	66.391	.8324 %	.9381	WEIGHT TAKEN
ADRENAL(S) (AD)	1.439	.0180 %	.0203	WEIGHT TAKEN
SPLEEN (SP)	20.627	.2578 %	.2906	WEIGHT TAKEN
THYMUS (TH)	7.131	.0891 %	.1005	WEIGHT TAKEN
SALIVARY GLD(S) (SG)	12.1160	.1515 %	.1707	WEIGHT TAKEN
KIDNEY(S) (KD)	36.156	.4520 %	.5094	WEIGHT TAKEN
LIVER (LI)	189.352	2.3669 %	2.6676	WEIGHT TAKEN
UTERUS (UT)	5.4210	.0678 %	.0764	WEIGHT TAKEN
OVARIES (OV)	1.326	.0166 %	.0187	WEIGHT TAKEN
BRAIN (BR)	70.983	.8873 %	1.0000	WEIGHT TAKEN
PITUITARY (PI)	.061	.0008 %	.0009	WEIGHT TAKEN

*** P A T H O L O G Y O B S E R V A T I O N S ***

ORGAN NAME	KEYWORDS, SEVERITY, DISTRIBUTION	GROSS FREE-TEXT COMMENTS / HISTOPATHOLOGIC FINDINGS
SKIN (SK)		
	GROSS: -ALOPECIA-BILATERAL	-BILATERAL, LATERAL LUMBAR REGIONS: (CAP 36)
	MICRO: -UNREMARKABLE	
		HISTOPATHOLOGICAL COMMENT: >NO MICROSCOPIC CORRELATION WITH GROSS FINDING

APPENDIX J

INDIVIDUAL ANIMAL PATHOLOGY DATA

ANIMAL NUMBER: 000983 SEX: FEMALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 01/08/86 STUDY DAY OF DEATH: 183 STUDY WEEK OF DEATH: 27 TERMINAL BODY WEIGHT: 9100.0 GRAMS
DATE AND TIME OF NECROPSY: 01/08/86 PROSECTOR: JANELLE RASCHEIN RECORDER: RUTH SCHMITZ
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. WILLIAM E. FIELD WEIGHER: RUTH SCHMITZ

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
THYROID(S)/PARA (TYO)	.929	.0102 %	.0121	WEIGHT TAKEN
HEART (HT)	70.483	.7745 %	.9147	WEIGHT TAKEN
ADRENAL(S) (AD)	.954	.0105 %	.0124	WEIGHT TAKEN
SPLEEN (SP)	36.471	.4008 %	.4733	WEIGHT TAKEN
THYMUS (TH)	6.875	.0755 %	.0892	WEIGHT TAKEN
SALIVARY GLD(S) (SG)	16.6280	.1827 %	.2158	WEIGHT TAKEN
KIDNEY(S) (KD)	39.873	.4382 %	.5175	WEIGHT TAKEN
LIVER (LI)	225.708	2.4803 %	2.9292	WEIGHT TAKEN
UTERUS (UT)	2.5810	.0284 %	.0335	WEIGHT TAKEN
OVARIES (OV)	.719	.0079 %	.0093	WEIGHT TAKEN
BRAIN (BR)	77.055	.8468 %	1.0000	WEIGHT TAKEN
PITUITARY (PI)	.062	.0007 %	.0008	WEIGHT TAKEN

*** P A T H O L O G Y O B S E R V A T I O N S ***

ORGAN NAME	KEYWORDS, SEVERITY, DISTRIBUTION	GROSS FREE-TEXT COMMENTS / HISTOPATHOLOGIC FINDINGS
GENERAL COMMENT (GC)		
	GROSS: -ALL TISSUES/ORGANS NORMAL	
KIDNEY, RIGHT (KD1)		
	MICRO: -MINIMAL	-MINERALIZATION

APPENDIX J

INDIVIDUAL ANIMAL PATHOLOGY DATA

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

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STUDY NUMBER: 6127111

ANIMAL NUMBER: 000904 SEX: FEMALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 01/08/86 STUDY DAY OF DEATH: 183 STUDY WEEK OF DEATH: 27 TERMINAL BODY WEIGHT: 7000.0 GRAMS
DATE AND TIME OF NECROPSY: 01/08/86 PROSECTOR: JACK SERFORT RECORDER: RUTH SCHMITZ
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. WILLIAM E. FIELD WEIGHER: RUTH SCHMITZ

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
THYROID(S)/PARA (TYO)	.744	.0106 %	.0107	WEIGHT TAKEN
HEART (HT)	63.407	.9058 %	.9139	WEIGHT TAKEN
ADRENAL(S) (AD)	1.225	.0175 %	.0177	WEIGHT TAKEN
SPLEEN (SP)	24.846	.3549 %	.3581	WEIGHT TAKEN
THYMUS (TH)	3.023	.0432 %	.0436	WEIGHT TAKEN
SALIVARY GLD(S) (SG)	10.4220	.1489 %	.1502	WEIGHT TAKEN
KIDNEY(S) (KD)	37.373	.5339 %	.5387	WEIGHT TAKEN
LIVER (LI)	182.049	2.6007 %	2.6240	WEIGHT TAKEN
UTERUS (UT)	1.3610	.0194 %	.0196	WEIGHT TAKEN
OVARIES (OV)	.679	.0097 %	.0098	WEIGHT TAKEN
BRAIN (BR)	69.378	.9911 %	1.0000	WEIGHT TAKEN
PITUITARY (PI)	.018	.0003 %	.0003	WEIGHT TAKEN

*** P A T H O L O G Y O B S E R V A T I O N S ***

ORGAN NAME	KEYWORDS, SEVERITY, DISTRIBUTION	GROSS FREE-TEXT COMMENTS / HISTOPATHOLOGIC FINDINGS
GENERAL COMMENT (GC)		
GROSS:	-ALL TISSUES/ORGANS NORMAL	
KIDNEY, RIGHT (KD1)		
MICRO:	-MINIMAL	-MINERALIZATION
PARATHYROID(S) (PT)		
MICRO:	-PRESENT	-ONE EXAMINED

APPENDIX J

INDIVIDUAL ANIMAL PATHOLOGY DATA

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

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STUDY NUMBER: 6127111

ANIMAL NUMBER: 000991 SEX: FEMALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 01/10/86 STUDY DAY OF DEATH: 185 STUDY WEEK OF DEATH: 27 TERMINAL BODY WEIGHT: 9700.0 GRAMS
DATE AND TIME OF NECROPSY: 01/10/86 PROSECTOR: NANCY DIEDRICH RECORDER: JACK SERFORT
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. WILLIAM E. FIELD WEIGHER: JACK SERFORT

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
THYROID(S)/PARA (TYO)	.967	.0100 %	.0144	WEIGHT TAKEN
HEART (HT)	89.395	.9237 %	1.3318	WEIGHT TAKEN
ADRENAL(S) (AD)	1.088	.0112 %	.0162	WEIGHT TAKEN
SPLEEN (SP)	26.392	.2721 %	.3923	WEIGHT TAKEN
THYMUS (TH)	11.293	.1164 %	.1679	WEIGHT TAKEN
SALIVARY GLD(S) (SG)	13.7510	.1418 %	.2044	WEIGHT TAKEN
KIDNEY(S) (KD)	43.025	.4436 %	.6396	WEIGHT TAKEN
LIVER (LI)	246.090	2.5370 %	3.6581	WEIGHT TAKEN
UTERUS (UT)	4.0210	.0415 %	.0598	WEIGHT TAKEN
OVARIES (OV)	.885	.0091 %	.0132	WEIGHT TAKEN
BRAIN (BR)	67.272	.6935 %	1.0000	WEIGHT TAKEN
PITUITARY (PI)	.050	.0005 %	.0007	WEIGHT TAKEN

*** P A T H O L O G Y O B S E R V A T I O N S ***

ORGAN NAME	KEYWORDS, SEVERITY, DISTRIBUTION	GROSS FREE-TEXT COMMENTS / HISTOPATHOLOGIC FINDINGS
GENERAL COMMENT (GC)		
GROSS:	-ALL TISSUES/ORGANS NORMAL	
KIDNEY, LEFT (KDO)		
MICRO:	-MINIMAL	-MINERALIZATION
KIDNEY, RIGHT (KD1)		
MICRO:	-MINIMAL	-MINERALIZATION
MAMMARY GLAND (MG)		
MICRO:	-TISSUE MISSING	
SALIVARY GLD(S) (SG)		
MICRO:	-SLIGHT, FOCAL	-MONONUCLEAR INFILTRATION

APPENDIX J

INDIVIDUAL ANIMAL PATHOLOGY DATA

ANIMAL NUMBER: 000992 SEX: FEMALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 01/10/86 STUDY DAY OF DEATH: 185 STUDY WEEK OF DEATH: 27 TERMINAL BODY WEIGHT: 9900.0 GRAMS
DATE AND TIME OF NECROPSY: 01/10/86 PROSECTOR: JANELLE RASCHEIN RECORDER: JACK SERFORT
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. WILLIAM E. FIELD WEIGHER: JACK SERFORT

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
THYROID(S)/PARA (TYO)	.800	.0081 %	.0112	WEIGHT TAKEN
HEART (HT)	85.292	.8615 %	1.1952	WEIGHT TAKEN
ADRENAL(S) (AD)	1.387	.0140 %	.0194	WEIGHT TAKEN
SPLEEN (SP)	22.977	.2321 %	.3220	WEIGHT TAKEN
THYMUS (TH)	4.830	.0488 %	.0677	WEIGHT TAKEN
SALIVARY GLD(S) (SG)	15.3670	.1552 %	.2153	WEIGHT TAKEN
KIDNEY(S) (KD)	42.430	.4286 %	.5945	WEIGHT TAKEN
LIVER (LI)	234.922	2.3729 %	3.2918	WEIGHT TAKEN
UTERUS (UT)	2.8870	.0292 %	.0405	WEIGHT TAKEN
OVARIES (OV)	1.008	.0102 %	.0141	WEIGHT TAKEN
BRAIN (BR)	71.365	.7209 %	1.0000	WEIGHT TAKEN
PITUITARY (PI)	.048	.0005 %	.0007	WEIGHT TAKEN

*** PATHOLOGY OBSERVATIONS ***

ORGAN NAME	KEYWORDS, SEVERITY, DISTRIBUTION	GROSS FREE-TEXT COMMENTS / HISTOPATHOLOGIC FINDINGS
GENERAL COMMENT (GC)		
GROSS:	-ALL TISSUES/ORGANS NORMAL	
KIDNEY, LEFT (KD0)		
MICRO:	-MINIMAL	-MINERALIZATION
KIDNEY, RIGHT (KD1)		
MICRO:	-MINIMAL	-MINERALIZATION

APPENDIX J

INDIVIDUAL ANIMAL PATHOLOGY DATA

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

STUDY NUMBER: 6127111

ANIMAL NUMBER: 000993 SEX: FEMALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 01/09/86 STUDY DAY OF DEATH: 184 STUDY WEEK OF DEATH: 27 TERMINAL BODY WEIGHT: 9600.0 GRAMS
DATE AND TIME OF NECROPSY: 01/09/86 PROSECTOR: NANCY DIEDRICH RECORDER: RUTH SCHMITZ
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. WILLIAM E. FIELD WEIGHER: RUTH SCHMITZ

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
THYROID(S)/PARA (TYO)	1.072	.0112 %	.0154	WEIGHT TAKEN
HEART (HT)	98.600	.9229 %	1.2738	WEIGHT TAKEN
ADRENAL(S) (AD)	1.055	.0110 %	.0152	WEIGHT TAKEN
SPLEEN (SP)	30.458	.3173 %	.4379	WEIGHT TAKEN
THYMUS (TH)	3.430	.0357 %	.0493	WEIGHT TAKEN
SALIVARY GLD(S) (SG)	14.1660	.1476 %	.2037	WEIGHT TAKEN
KIDNEY(S) (KD)	39.602	.4125 %	.5694	WEIGHT TAKEN
LIVER (LI)	221.164	2.3038 %	3.1797	WEIGHT TAKEN
UTERUS (UT)	3.9920	.0416 %	.0574	WEIGHT TAKEN
OVARIES (OV)	.867	.0090 %	.0125	WEIGHT TAKEN
BRAIN (BR)	69.556	.7245 %	1.0000	WEIGHT TAKEN
PITUITARY (PI)	.063	.0007 %	.0009	WEIGHT TAKEN

*** PATHOLOGY OBSERVATIONS ***

ORGAN NAME	KEYWORDS, SEVERITY, DISTRIBUTION	GROSS FREE-TEXT COMMENTS / HISTOPATHOLOGIC FINDINGS
GENERAL COMMENT (GC)		
	GROSS: -ALL TISSUES/ORGANS NORMAL	
KIDNEY, RIGHT (KD1)		
	MICRO: -MINIMAL	-MINERALIZATION
LUNG (LU)		
	MICRO: -SLIGHT, MULTI-FOCAL	-PNEUMONITIS
PARATHYROID(S) (PT)		
	MICRO: -PRESENT	-CYST(S)

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INDIVIDUAL ANIMAL PATHOLOGY DATA

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
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STUDY NUMBER: 6127111

ANIMAL NUMBER: 000994 SEX: FEMALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 01/08/86 STUDY DAY OF DEATH: 103 STUDY WEEK OF DEATH: 27 TERMINAL BODY WEIGHT: 0900.0 GRAMS
DATE AND TIME OF NECROPSY: 01/08/86 PROSECTOR: JANELLE RASCHEIN RECORDER: RUTH SCHMITZ
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. WILLIAM E. FIELD WEIGHER: RUTH SCHMITZ

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
THYROID(S)/PARA (TYG)	.791	.0089 %	.0107	WEIGHT TAKEN
HEART (HT)	80.201	.9020 %	1.0885	WEIGHT TAKEN
ADRENAL(S) (AD)	.991	.0111 %	.0134	WEIGHT TAKEN
SPLEEN (SP)	28.670	.3222 %	.3888	WEIGHT TAKEN
THYMUS (TH)	5.449	.0612 %	.0739	WEIGHT TAKEN
SALIVARY GLD(S) (SG)	14.3300	.1610 %	.1943	WEIGHT TAKEN
KIDNEY(S) (KD)	41.963	.4715 %	.5690	WEIGHT TAKEN
LIVER (LI)	257.955	2.8984 %	3.4976	WEIGHT TAKEN
UTERUS (UT)	17.6350	.1981 %	.2391	WEIGHT TAKEN
OVARIES (OV)	1.263	.0142 %	.0171	WEIGHT TAKEN
BRAIN (BR)	73.751	.8287 %	1.0000	WEIGHT TAKEN
PITUITARY (PI)	.056	.0006 %	.0008	WEIGHT TAKEN

*** P A T H O L O G Y O B S E R V A T I O N S ***

ORGAN NAME	KEYWORDS, SEVERITY, DISTRIBUTION	GROSS FREE-TEXT COMMENTS / HISTOPATHOLOGIC FINDINGS
KIDNEY, LEFT (KDO)		
	MICRO: -MODERATE	-MINERALIZATION
KIDNEY, RIGHT (KD1)		
	MICRO: -SLIGHT	-MINERALIZATION
SKIN (SK)		
	GROSS: -RED FOCUS(I)/AREA(S)	-MULTIPLE, RED AREAS, CONSISTENT WITH CLIPPED AREAS; SECTION COLLECTED FROM RIGHT LATERAL THORACIC REGION (CAPSULE 36)
	MICRO: -UNREMARKABLE	
	HISTOPATHOLOGICAL COMMENT:	>NO MICROSCOPIC CORRELATION WITH GROSS FINDING
TONGUE (TG)		
	MICRO: -SLIGHT, FOCAL	-INFILTRATE,MONONUCLEAR CELLS

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INDIVIDUAL ANIMAL PATHOLOGY DATA

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
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STUDY NUMBER: 6127111

ANIMAL NUMBER: 000995 SEX: FEMALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, FIRST POST-RECOV SAC
DATE OF DEATH: 02/06/86 STUDY DAY OF DEATH: 212 STUDY WEEK OF DEATH: 31 TERMINAL BODY WEIGHT: 9000.0 GRAMS
DATE AND TIME OF NECROPSY: 02/06/86 PROSECTOR: DENNIS HOFFMAN RECORDER: RUTH SCHMITZ
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. WILLIAM E. FIELD WEIGHER: RUTH SCHMITZ

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
THYROID(S)/PARA (TYG)	.793	.0088 %	.0107	WEIGHT TAKEN
HEART (HT)	64.544	.7172 %	.8676	WEIGHT TAKEN
ADRENAL(S) (AD)	.951	.0106 %	.0128	WEIGHT TAKEN
SPLEEN (SP)	24.940	.2771 %	.3353	WEIGHT TAKEN
THYMUS (TH)	5.759	.0640 %	.0774	WEIGHT TAKEN
SALIVARY GLD(S) (SG)	15.9070	.1767 %	.2138	WEIGHT TAKEN
KIDNEY(S) (KD)	34.259	.3807 %	.4605	WEIGHT TAKEN
LIVER (LI)	191.538	2.1282 %	2.5747	WEIGHT TAKEN
UTERUS (UT)	4.4540	.0495 %	.0599	WEIGHT TAKEN
OVARIES (OV)	.897	.0100 %	.0121	WEIGHT TAKEN
BRAIN (BR)	74.392	.8266 %	1.0000	WEIGHT TAKEN
PITUITARY (PI)	.045	.0005 %	.0006	WEIGHT TAKEN

*** PATHOLOGY OBSERVATIONS ***

ORGAN NAME	KEYWORDS, SEVERITY, DISTRIBUTION	GROSS FREE-TEXT COMMENTS / HISTOPATHOLOGIC FINDINGS
GENERAL COMMENT (GC)		. . . . .
	GROSS: -ALL TISSUES/ORGANS NORMAL	

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INDIVIDUAL ANIMAL PATHOLOGY DATA

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

PRINTED: 22-MAY-86
PAGE: 48

STUDY NUMBER: 6127111

ANIMAL NUMBER: 000996 SEX: FEMALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, FIRST POST-RECOV SAC
DATE OF DEATH: 02/07/86 STUDY DAY OF DEATH: 213 STUDY WEEK OF DEATH: 31 TERMINAL BODY WEIGHT: 0200.0 GRAMS
DATE AND TIME OF NECROPSY: 02/07/86 PROSECTOR: DENNIS HOFFMAN RECORDER: RUTH SCHMITZ
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. WILLIAM E. FIELD WEIGHER: RUTH SCHMITZ

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
THYROID(S)/PARA (TYO)	.735	.0090 %	.0101	WEIGHT TAKEN
HEART (HT)	70.939	.8651 %	.9714	WEIGHT TAKEN
ADRENAL(S) (AD)	1.361	.0166 %	.0186	WEIGHT TAKEN
SPLEEN (SP)	23.157	.2824 %	.3171	WEIGHT TAKEN
THYMUS (TH)	7.103	.0866 %	.0973	WEIGHT TAKEN
SALIVARY GLD(S) (SG)	11.5560	.1409 %	.1582	WEIGHT TAKEN
KIDNEY(S) (KD)	36.040	.4395 %	.4935	WEIGHT TAKEN
LIVER (LI)	236.189	2.8804 %	3.2344	WEIGHT TAKEN
UTERUS (UT)	4.1460	.0506 %	.0568	WEIGHT TAKEN
OVARIES (OV)	1.083	.0132 %	.0148	WEIGHT TAKEN
BRAIN (BR)	73.025	.8905 %	1.0000	WEIGHT TAKEN
PITUITARY (PI)	.050	.0006 %	.0007	WEIGHT TAKEN

*** P A T H O L O G Y O B S E R V A T I O N S ***

ORGAN NAME	KEYWORDS, SEVERITY, DISTRIBUTION	GROSS FREE-TEXT COMMENTS / HISTOPATHOLOGIC FINDINGS
GENERAL COMMENT (GC)	. . . . .	
	GROSS: -ALL TISSUES/ORGANS NORMAL	

APPENDIX J

INDIVIDUAL ANIMAL PATHOLOGY DATA

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

PRINTED: 22-MAY-86
PAGE: 49

STUDY NUMBER: 6127111

ANIMAL NUMBER: 000004 SEX: FEMALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 01/10/86 STUDY DAY OF DEATH: 185 STUDY WEEK OF DEATH: 27 TERMINAL BODY WEIGHT: 9900.0 GRAMS
DATE AND TIME OF NECROPSY: 01/10/86 PROSECTOR: DENNIS HOFFMAN RECORDER: JACK SERFORT
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. WILLIAM E. FIELD WEIGHER: JACK SERFORT

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
THYROID(S)/PARA (TYO)	.754	.0076 %	.0095	WEIGHT TAKEN
HEART (HT)	73.573	.7432 %	.9225	WEIGHT TAKEN
ADRENAL(S) (AD)	.958	.0097 %	.0120	WEIGHT TAKEN
SPLEEN (SP)	23.537	.2377 %	.2951	WEIGHT TAKEN
THYMUS (TH)	3.493	.0353 %	.0438	WEIGHT TAKEN
SALIVARY GLD(S) (SG)	15.4150	.1557 %	.1933	WEIGHT TAKEN
KIDNEY(S) (KD)	39.748	.4015 %	.4984	WEIGHT TAKEN
LIVER (LI)	237.962	2.4037 %	2.9839	WEIGHT TAKEN
UTERUS (UT)	5.3200	.0538 %	.0668	WEIGHT TAKEN
OVARIES (OV)	.936	.0095 %	.0117	WEIGHT TAKEN
BRAIN (BR)	79.750	.8056 %	1.0000	WEIGHT TAKEN
PITUITARY (PI)	.059	.0006 %	.0007	WEIGHT TAKEN

*** PATHOLOGY OBSERVATIONS ***

ORGAN NAME	KEYWORDS, SEVERITY, DISTRIBUTION	GROSS FREE-TEXT COMMENTS / HISTOPATHOLOGIC FINDINGS
GENERAL COMMENT (GC)		
	GROSS: -ALL TISSUES/ORGANS NORMAL	
KIDNEY, LEFT (KDO)		
	MICRO: -MINIMAL	-MINERALIZATION
SPINAL CORD (SC)		
	GROSS:	NECROPSY NOTE: >TRIMMING COMMENT: ONE SPINAL CORD MISSING FROM WET TISSUE

APPENDIX J

INDIVIDUAL ANIMAL PATHOLOGY DATA

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

PRINTED: 22-MAY-86
PAGE: 50

STUDY NUMBER: 6127111

ANIMAL NUMBER: 000005 SEX: FEMALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, FIRST POST-RECOV SAC
DATE OF DEATH: 02/06/86 STUDY DAY OF DEATH: 212 STUDY WEEK OF DEATH: 31 TERMINAL BODY WEIGHT: 9900.0 GRAMS
DATE AND TIME OF NECROPSY: 02/06/86 PROSECTOR: JACK SERFORT RECORDER: RUTH SCHMITZ
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. WILLIAM E. FIELD WEIGHER: RUTH SCHMITZ

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
THYROID(S)/PARA (TYO)	.886	.0089 %	.0125	WEIGHT TAKEN
HEART (HT)	83.313	.8415 %	1.1730	WEIGHT TAKEN
ADRENAL(S) (AD)	1.270	.0128 %	.0179	WEIGHT TAKEN
SPLEEN (SP)	25.512	.2577 %	.3592	WEIGHT TAKEN
THYMUS (TH)	8.725	.0881 %	.1228	WEIGHT TAKEN
SALIVARY GLD(S) (SG)	13.3970	.1353 %	.1886	WEIGHT TAKEN
KIDNEY(S) (KD)	44.138	.4458 %	.6215	WEIGHT TAKEN
LIVER (LI)	287.949	2.9086 %	4.0543	WEIGHT TAKEN
UTERUS (UT)	5.6770	.0573 %	.0799	WEIGHT TAKEN
OVARIES (OV)	1.109	.0112 %	.0156	WEIGHT TAKEN
BRAIN (BR)	71.023	.7174 %	1.0000	WEIGHT TAKEN
PITUITARY (PI)	.047	.0005 %	.0007	WEIGHT TAKEN

*** PATHOLOGY OBSERVATIONS ***

ORGAN NAME	KEYWORDS, SEVERITY, DISTRIBUTION	GROSS FREE-TEXT COMMENTS / HISTOPATHOLOGIC FINDINGS
GENERAL COMMENT (GC)	. . . . .	
GROSS: -ALL TISSUES/ORGANS NORMAL		

APPENDIX J

INDIVIDUAL ANIMAL PATHOLOGY DATA

ANIMAL NUMBER: 000006 SEX: FEMALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, FIRST POST-RECOV SAC
DATE OF DEATH: 02/07/86 STUDY DAY OF DEATH: 213 STUDY WEEK OF DEATH: 31 TERMINAL BODY WEIGHT: 9600.0 GRAMS
DATE AND TIME OF NECROPSY: 02/07/86 PROSECTOR: DENNIS HOFFMAN RECORDER: RUTH SCHMITZ
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. WILLIAM E. FIELD WEIGHER: RUTH SCHMITZ

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
THYROID(S)/PARA (TYO)	.927	.0097 %	.0125	WEIGHT TAKEN
HEART (HT)	73.383	.7644 %	.9872	WEIGHT TAKEN
ADRENAL(S) (AD)	1.115	.0116 %	.0150	WEIGHT TAKEN
SPLEEN (SP)	27.180	.2831 %	.3656	WEIGHT TAKEN
THYMUS (TH)	5.928	.0618 %	.0797	WEIGHT TAKEN
SALIVARY GLD(S) (SG)	15.6310	.1628 %	.2103	WEIGHT TAKEN
KIDNEY(S) (KD)	39.929	.4159 %	.5371	WEIGHT TAKEN
LIVER (LI)	263.290	2.7426 %	3.5418	WEIGHT TAKEN
UTERUS (UT)	5.7850	.0603 %	.0778	WEIGHT TAKEN
OVARIES (OV)	.659	.0069 %	.0089	WEIGHT TAKEN
BRAIN (BR)	74.337	.7743 %	1.0000	WEIGHT TAKEN
PITUITARY (PI)	.060	.0006 %	.0008	WEIGHT TAKEN

*** P A T H O L O G Y O B S E R V A T I O N S ***

ORGAN NAME	KEYWORDS, SEVERITY, DISTRIBUTION	GROSS FREE-TEXT COMMENTS / HISTOPATHOLOGIC FINDINGS
GENERAL COMMENT (GC)	. . . . .	
	GROSS: -ALL TISSUES/ORGANS NORMAL	

APPENDIX J

INDIVIDUAL ANIMAL PATHOLOGY DATA

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

PRINTED: 22-MAY-86
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STUDY NUMBER: 6127111

ANIMAL NUMBER: 000007 SEX: FEMALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 01/09/86 STUDY DAY OF DEATH: 184 STUDY WEEK OF DEATH: 27 TERMINAL BODY WEIGHT: 9300.0 GRAMS
DATE AND TIME OF NECROPSY: 01/09/86 PROSECTOR: JANELLE RASCHEIN RECORDER: RUTH SCHMITZ
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. WILLIAM E. FIELD WEIGHER: RUTH SCHMITZ

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
THYROID(S)/PARA (TYO)	.909	.0098 %	.0117	WEIGHT TAKEN
HEART (HT)	62.554	.6726 %	.8025	WEIGHT TAKEN
ADRENAL(S) (AD)	1.246	.0134 %	.0160	WEIGHT TAKEN
SPLEEN (SP)	21.385	.2299 %	.2743	WEIGHT TAKEN
THYMUS (TH)	6.940	.0746 %	.0890	WEIGHT TAKEN
SALIVARY GLD(S) (SG)	15.0180	.1615 %	.1927	WEIGHT TAKEN
KIDNEY(S) (KD)	43.843	.4714 %	.5624	WEIGHT TAKEN
LIVER (LI)	241.357	2.5952 %	3.0962	WEIGHT TAKEN
UTERUS (UT)	25.1370	.2703 %	.3225	WEIGHT TAKEN
OVARIES (OV)	1.702	.0183 %	.0218	WEIGHT TAKEN
BRAIN (BR)	77.953	.8382 %	1.0000	WEIGHT TAKEN
PITUITARY (PI)	.047	.0005 %	.0006	WEIGHT TAKEN

*** PATHOLOGY OBSERVATIONS ***

ORGAN NAME	KEYWORDS, SEVERITY, DISTRIBUTION	GROSS FREE-TEXT COMMENTS / HISTOPATHOLOGIC FINDINGS
GENERAL COMMENT (GC)		
	GROSS: -ALL TISSUES/ORGANS NORMAL	
KIDNEY, RIGHT (KD1)		
	MICRO: -MINIMAL	-MINERALIZATION

APPENDIX J

INDIVIDUAL ANIMAL PATHOLOGY DATA

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PRINTED: 22-MAY-86
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STUDY NUMBER: 6127111

ANIMAL NUMBER: 000008 SEX: FEMALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 01/10/86 STUDY DAY OF DEATH: 185 STUDY WEEK OF DEATH: 27 TERMINAL BODY WEIGHT: 7000.0 GRAMS
DATE AND TIME OF NECROPSY: 01/10/86 PROSECTOR: DENNIS HOFFMAN RECORDER: JACK SERFORT
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. WILLIAM E. FIELD WEIGHER: JACK SERFORT

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
THYROID(S)/PARA (TYO)	.817	.0105 %	.0123	WEIGHT TAKEN
HEART (HT)	68.333	.8786 %	1.0286	WEIGHT TAKEN
ADRENAL(S) (AD)	.820	.0105 %	.0123	WEIGHT TAKEN
SPLEEN (SP)	24.933	.3197 %	.3742	WEIGHT TAKEN
THYMUS (TH)	4.630	.0594 %	.0695	WEIGHT TAKEN
SALIVARY GLD(S) (SG)	14.5810	.1869 %	.2188	WEIGHT TAKEN
KIDNEY(S) (KD)	32.748	.4198 %	.4915	WEIGHT TAKEN
LIVER (LI)	231.712	2.9707 %	3.4776	WEIGHT TAKEN
UTERUS (UT)	5.1540	.0661 %	.0774	WEIGHT TAKEN
OVARIES (OV)	.883	.0113 %	.0133	WEIGHT TAKEN
BRAIN (BR)	66.629	.8542 %	1.0000	WEIGHT TAKEN
PITUITARY (PI)	.046	.0006 %	.0007	WEIGHT TAKEN

*** PATHOLOGY OBSERVATIONS ***

ORGAN NAME	KEYWORDS, SEVERITY, DISTRIBUTION	GROSS FREE-TEXT COMMENTS / HISTOPATHOLOGIC FINDINGS
GENERAL COMMENT (GC)		
GROSS:	-ALL TISSUES/ORGANS NORMAL	
KIDNEY, LEFT (KDO)		
MICRO:	-MINIMAL	-MINERALIZATION
PARATHYROID(S) (PT)		
MICRO:	-PRESENT	-ONE EXAMINED
THYMUS (TH)		
MICRO:	-SLIGHT	-INVOLUTION
THYROID(S) (TY)		
		NECROPSY NOTE: >TRIMMING COMMENT: ONE THYROID MISSING FROM WET TISSUE
MICRO:	-PRESENT	-ONE EXAMINED

APPENDIX J

INDIVIDUAL ANIMAL PATHOLOGY DATA

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
MADISON, WISCONSIN 53707

*** PATH/TOX SYSTEM OUTPUT ***

PRINTED: 22-MAY-86
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STUDY NUMBER: 6127111

ANIMAL NUMBER: 000009 SEX: FEMALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 01/08/86 STUDY DAY OF DEATH: 183 STUDY WEEK OF DEATH: 27 TERMINAL BODY WEIGHT: 0700.0 GRAMS
DATE AND TIME OF NECROPSY: 01/08/86 PROSECTOR: JACK SERFORT RECORDER: RUTH SCHMITZ
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. WILLIAM E. FIELD WEIGHER: RUTH SCHMITZ

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
THYROID(S)/PARA (TYO)	1.178	.0135 %	.0175	WEIGHT TAKEN
HEART (HT)	65.336	.7510 %	.9698	WEIGHT TAKEN
ADRENAL(S) (AD)	1.103	.0127 %	.0164	WEIGHT TAKEN
SPLEEN (SP)	20.984	.2412 %	.3111	WEIGHT TAKEN
THYMUS (TH)	4.737	.0544 %	.0702	WEIGHT TAKEN
SALIVARY GLD(S) (SG)	11.0310	.1270 %	.1639	WEIGHT TAKEN
KIDNEY(S) (KD)	34.406	.3955 %	.5102	WEIGHT TAKEN
LIVER (LI)	232.447	2.6718 %	3.4466	WEIGHT TAKEN
UTERUS (UT)	4.2900	.0493 %	.0636	WEIGHT TAKEN
OVARIES (OV)	.849	.0098 %	.0126	WEIGHT TAKEN
BRAIN (BR)	67.442	.7752 %	1.0000	WEIGHT TAKEN
PITUITARY (PI)	.048	.0006 %	.0007	WEIGHT TAKEN

*** P A T H O L O G Y O B S E R V A T I O N S ***

ORGAN NAME	KEYWORDS, SEVERITY, DISTRIBUTION	GROSS FREE-TEXT COMMENTS / HISTOPATHOLOGIC FINDINGS
KIDNEY, LEFT (KDO)		
	MICRO: -MINIMAL	-MINERALIZATION
KIDNEY, RIGHT (KD1)		
	MICRO: -SLIGHT	-MINERALIZATION
MAMMARY GLAND (MG)		
	MICRO: -TISSUE MISSING	
SPLEEN (SP)		
	GROSS: -ADHESION(S)	-CAUDAL END: RED FIBROUS MATERIAL ADHERED TO SPLEEN (CAP 36)
	-OPAQUE CAPSULE	-MULTIFOCAL AREAS: LARGEST IS 10 MM IN DIAMETER (CAP 37)
	MICRO: -SLIGHT, FOCAL	-FIBROSIS,CAPSULAR
	HISTOPATHOLOGICAL COMMENT:	>FIBROSIS CONSISTS OF PIECE OF MESENTERY (OMENTUM) ADHERED TO CAPSULE

APPENDIX K

Data Transformations

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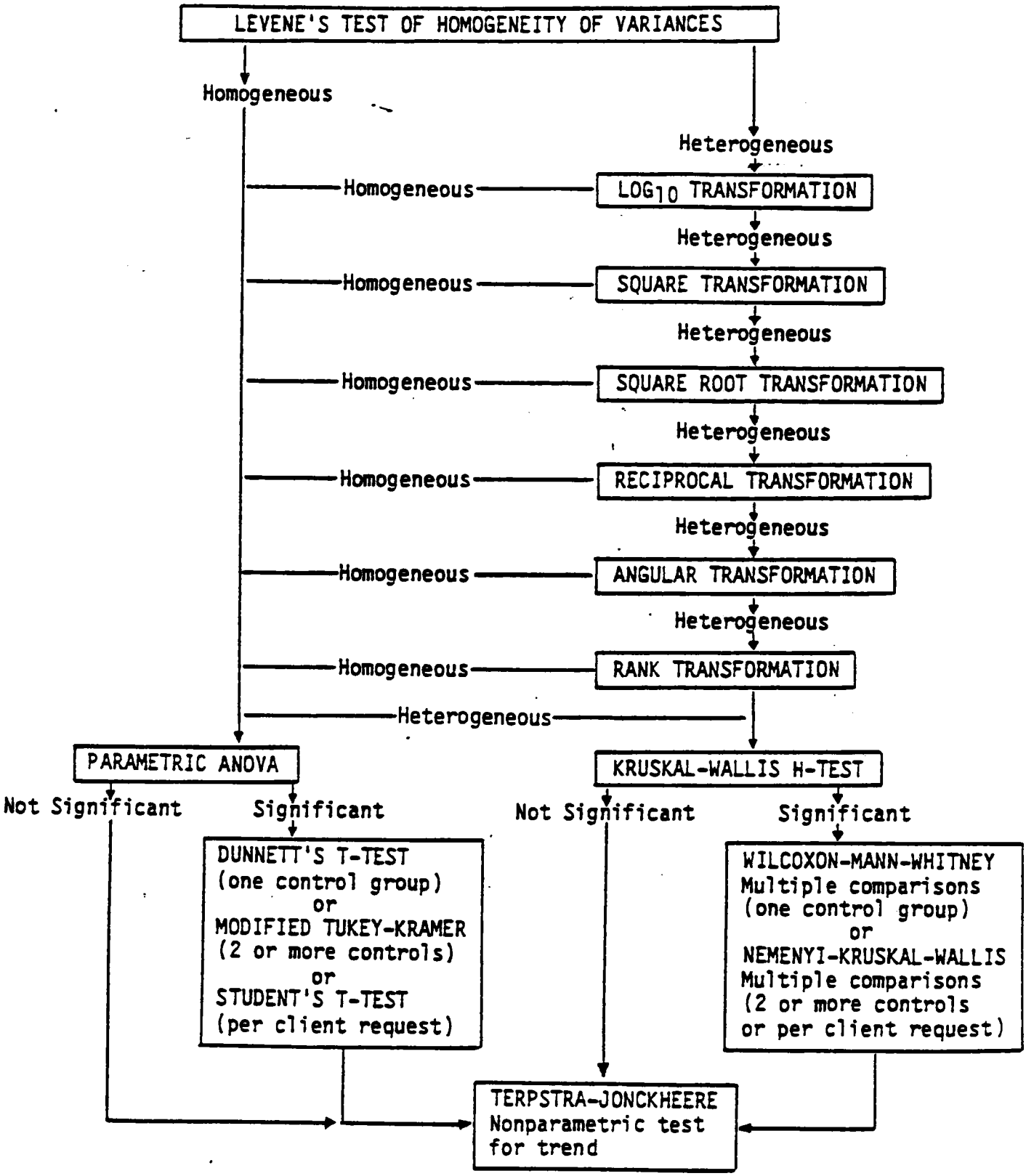
Figure 3


LEVENE'S TEST OF HOMOGENEITY OF VARIANCES
Homogeneous
Heterogeneous
Homogeneous
LOG10 TRANSFORMATION
Heterogeneous
Homogeneous
SQUARE TRANSFORMATION
Heterogeneous
Homogeneous
SQUARE ROOT TRANSFORMATION
Heterogeneous
Homogeneous
RECIPROCAL TRANSFORMATION
Heterogeneous
Homogeneous
ANGULAR TRANSFORMATION
Heterogeneous
Homogeneous
RANK TRANSFORMATION
Heterogeneous
PARAMETRIC ANOVA
KRUSKAL-WALLIS H-TEST
Not Significant
Significant
Not Significant
Significant
DUNNETT'S T-TEST
(one control group)
or
MODIFIED TUKEY-KRAMER
(2 or more controls)
or
STUDENT'S T-TEST
(per client request)
WILCOXON-MANN-WHITNEY
Multiple comparisons
(one control group)
or
NEMENYI-KRUSKAL-WALLIS
Multiple comparisons
(2 or more controls
or per client request)
TERPSTRA-JONCKHEERE
Nonparametric test
for trend

Study No. 6127-111

Transformation Code

Parameter	Interval	Sex	Transformation						Variance Heterogeneity p		Significant ANOVA
			Log X	X^2	$X^{1/2}$	1/X	Arcsine $X^{1/2}$	Rank X	Before Transform.	After Transform.	
Food consumption	Week 24	F						T	0.0106	0.0343	
Respiratory rate	Baseline	M						T	0.0005	0.0054	
Rectal temperature	Week 26	Both						T	0.0094	0.0974	
Respiratory rate	Week 30	Both						T	0.0113	0.0117	
Respiratory rate	Week 8	Both	T						0.0394	0.0950	
P-R Interval	Baseline	M						T	0.0001	0.0001	
S-Amplitude	Baseline	M						T	0.0067	0.0003	
Electricol axis	Week 8	M	T						0.0341	0.0501	
S Amplitude	Week 8	M						T	0.0397	0.0002	
P Wave amplitude	Baseline	F					T		0.0259	0.0645	

Study No. 6127-111

Transformation Code

Parameter	Interval	Sex	Transformation						Variance Heterogeneity p		Significant ANOVA
			Log X	X^2	$X^{1/2}$	1/X	Arcsine $X^{1/2}$	Rank X	Before Transform.	After Transform.	
S Amplitude	Baseline	F						T	0.0074	0.0001	
S Amplitude	Week 8	F						T	0.0150	0.0006	
P-R Interval	Baseline	Both						T	0.0009	0.0211	
S Amplitude	Baseline	Both						T	0.0212	0.0000	
Q-T Interval	Week 8	Both		T					0.0418	0.0555	
S Amplitude	Week 8	Both						T	0.0021	0.0000	
P-Wave interval	Week 17	M						T	0.0011	0.0011	
Q Amplitude	Week 17	M	T						0.0291	0.0657	
Electrical axis	Week 17	Both						T	0.0055	0.6392	
P-Wave interval	Week 17	Both						T	0.0329	0.0329	
Q Amplitude	Week 17	Both						T	0.0054	0.1796	
Heart rate	Week 26	F	T						0.0308	0.0548	

Transformation Code

Parameter	Interval	Sex	Transformation						Variance Heterogeneity p		Significant ANOVA
			Log X	X^2	$X^{1/2}$	1/X	Arcsine $X^{1/2}$	Rank X	Before Transform.	After Transform.	
QRS Interval	Week 26	F						T	0.0178	0.0021	
Electrical axis	Week 26	F						T	0.0340	0.1723	
P-Wave interval	Week 26	F						T	0.0000	0.0000	
P-Wave interval	Week 26	Both						T	0.0044	0.1278	
P-R Interval	Week 26	Both						T	0.0083	0.0332	
P-Wave interval	Week 30	Both						T	0.0346	0.0207	
NRBC	-2	M						T	0.0054	0.0090	
E-Absolute	-2	M						T	0.0095	0.2594	
B-Absolute	-2	M						T	0.0000	0.0000	
E-%	-2	M	T						0.0040	0.0502	
B-%	-2	M						T	0.0000	0.0000	
PH	-2	M						T	0.0134	0.0190	

Transformation Code

Parameter	Interval	Sex	Transformation						Variance Heterogeneity p		Significant ANOVA
			Log X	X^2	$X^{1/2}$	1/X	Arcsine $X^{1/2}$	Rank X	Before Transform.	After Transform.	
PT	-2	M						T	0.0124	0.0101	
PTT	-2	M						T	0.0193	0.0926	
T PRO	-2	M						T	0.0191	0.0058	
T Bili	-2	M						T	0.0036	0.0036	
RBC	-2	F						T	0.0067	0.0090	
MCHC	-2	F						T	0.0308	0.0153	
B-Absolute	-2	F						T	0.0036	0.0036	
B-%	-2	F						T	0.0036	0.0036	
SP GR	-2	F						T	0.0343	0.1261	
PH	-2	F						T	0.0277	0.0277	
PT	-2	F						T	0.0023	0.8951	
CL	-2	F						T	0.0373	0.0916	
NRBC	-2	Both						T	0.0069	0.0219	
M-Absolute	-2	Both						T	0.0343	0.2677	

Study No. 6127-111

Transformation Code

Parameter	Interval	Sex	Transformation						Variance Heterogeneity p		Significant ANOVA
			Log X	X^2	$X^{1/2}$	1/X	Arcsine $X^{1/2}$	Rank X	Before Transform.	After Transform.	
B-Absolute	-2	Both						T	0.0002	0.0005	
M-%	-2	Both						T	0.0005	0.0539	
E-%	-2	Both	T						0.0179	0.2828	
B-%	-2	Both						T	0.0005	0.0006	
PT	-2	Both						T	0.0188	0.3505	
SP GR	-2	Both						T	0.0252	0.0385	
T-Bili	-2	Both						T	0.0060	0.0180	
ALT/SPGT	-2	Both						T	0.0040	0.3324	
NRBC	8	M						T	0.0003	0.0001	
BANDS-N	8	M						T	0.0191	0.0191	
BANDS-N	8	M						T	0.0181	0.0190	
PT	8	M						T	0.0000	0.9539	
PH	8	M						T	0.0000	0.0000	
AST/SGOT	8	M						T	0.0372	0.0234	

Study No. 127-111

Transformation Code

Parameter	Interval	Sex	Transformation						Variance Heterogeneity p		Significant ANOVA
			Log X	X^2	$X^{1/2}$	1/X	Arcsine $X^{1/2}$	Rank X	Before Transform.	After Transform.	
NRBC	8	F						T	0.0134	0.0134	
WBC	8	F	T						0.0209	0.0989	
PTT	8	F						T	0.0190	0.0310	
PH	8	F						T	0.0255	0.1159	
T-Bili	8	F	T						0.0315	0.0704	
HCT	8	Both						T	0.0102	0.0372	
BANDS-N	8	Both						T	0.0314	0.0314	
BANDS-N	8	Both						T	0.0297	0.0314	
BANDS-N	17	M						T	0.0191	0.0191	
BANDS-N	17	M						T	0.0161	0.0190	
PT	17	M						T	0.0020	0.1736	
PH	17	M						T	0.0002	0.0002	
T-PRO	17	M						T	0.0305	0.0062	S
NRBC	17	F						T	0.0036	0.0036	

Transformation Code

Parameter	Interval	Sex	Transformation						Variance Heterogeneity p		Significant ANOVA
			Log X	X^2	$X^{1/2}$	1/X	Arcsine $X^{1/2}$	Rank X	Before Transform.	After Transform.	
WBC	17	F						T	0.0000	0.0079	S
N-Seg-absolute	17	F	T						0.0327	0.1467	
BANDS-N	17	F						T	0.0134	0.0134	
BANDS-N	17	F						T	0.0301	0.0166	
PH	17	F						T	0.0000	0.0000	
T-PRO	17	F						T	0.0212	0.3329	
T-Bili	17	F						T	0.0119	0.1581	
MCH	17	Both						T	0.0309	0.0470	
NRBC	17	Both						T	0.0054	0.0054	
WBC	17	Both	T						0.0483	0.0873	
L-%	17	Both		T					0.0437	0.0505	
BANDS-N	17	Both						T	0.0071	0.0071	
BANDS-N	17	Both						T	0.0031	0.0067	

Study No. 27-111

Transformation Code

Parameter	Interval	Sex	Transformation						Variance Heterogeneity p		Significant ANOVA
			Log X	X^2	$X^{1/2}$	1/X	Arcsine $X^{1/2}$	Rank X	Before Transform.	After Transform.	
PH	17	Both						T	0.0008	0.0074	
U-Volume	17	Both	T						0.0497	0.1249	
NRBC	26	M						T	0.0036	0.0036	
N-Seg-%	26	M						T	0.0161	0.0474	
M-%	26	M	T						0.0150	0.1105	
PT	26	M						T	0.0012	0.0723	
PTT	26	M						T	0.0156	0.0159	S
PH	26	M						T	0.0006	0.0708	
U-Volume	26	M						T	0.0154	0.0268	
NRBC	26	F						T	0.0134	0.0134	
PTT	26	F						T	0.0202	0.1894	
PH	26	F						T	0.0000	0.0001	
U-Volume	26	F						T	0.0132	0.0051	
T-Bili	26	F						T	0.0000	0.2317	

Study No. 6127-111

Transformation Code

Parameter	Interval	Sex	Transformation						Variance Heterogeneity p		Significant ANOVA
			Log X	X^2	$X^{1/2}$	1/X	Arcsine $X^{1/2}$	Rank X	Before Transform.	After Transform.	
K	26	F						T	0.0395	0.1609	
PT	26	Both	T						0.0468	0.0726	
PTT	26	Both						T	0.0224	0.0542	
PH	26	Both						T	0.0000	0.0004	
T-Bili	26	Both				T			0.0078	0.4219	
MCV	31	Both						T	0.0080	0.0201	
N-Seg-%	31	Both						T	0.0143	0.0303	
PT	31	Both	T						0.0435	0.0698	
PH	31	Both						T	0.0015	0.0005	
T-PRO	31	Both						T	0.0066	0.2176	
Glob	31	Both						T	0.0223	0.0519	
T-Bili	31	Both						T	0.0021	0.0021	
Adrenal	Terminal	M						T	0.0184	0.3585	
Prostate	Terminal	M						T	0.0470	0.2888	

Study No. 7-111

Transformation Code

Parameter	Interval	Sex	Transformation						Variance Heterogeneity p		Significant ANOVA
			Log X	X^2	$X^{1/2}$	1/X	Arcsine $X^{1/2}$	Rank X	Before Transform.	After Transform.	
Terminal body weight	Terminal	M		T					0.0400	0.0636	
Adrenal	Terminal	M	T						0.0394	0.0901	
Brain	Terminal	F						T	0.0145	0.0223	
Kidneys	Terminal	F						T	0.0153	0.1473	
Liver	Terminal	F		T					0.0469	0.0643	
Spleen	Terminal	F						T	0.0075	0.2088	
Adrenal	Terminal	F				T			0.0135	0.0628	

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APPENDIX L

Deviations from the Protocol
Study Protocol
Amendment Nos. 1 through 6 to the Protocol

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DEVIATIONS FROM THE PROTOCOL

- From July 8 through 12, 1985, mixed food (dosed) was stored at room temperature instead of refrigerated as stated in the protocol.
- Chi-square contingency analysis was not performed on urinalysis count data as stated in the protocol.
- Urine volume, pH, and specific gravity were statistically analyzed even though not required by protocol.
- Because of a scheduling error, the Week 7 ophthalmological examinations were not performed.
- Because of scheduling difficulties, the Week 30 clinical pathology work-up was performed during Week 31.
- Because of technical error, food consumptions were not determined on the day of the Week 25 pharmacokinetic blood sampling (December 30, 1986). At the Sponsor's request, the pharmacokinetic blood samples were recollected and food consumptions were determined on January 7, 1986 (Week 26). Both sets of blood samples were sent to G. D. Searle & Co. on January 13, 1986.
- During the Week 26 physical examinations, the examinations were performed but the data were not recorded for Animal No. H00977 (Group 2 male) and Animal No. H00980 (Group 2 female).
- During the main study, terminal sacrifice Animal No. H00004, Group 4 female (recovery animal), was inadvertently sacrificed instead of Animal No. H00006, Group 4 female. It was decided to use Animal No. H00006 in place of Animal No. H00004 for the recovery phase of the study. Animal No. H00006 received 2 more days of dosed food than the other reversal animals.
- On several occasions, the temperature and humidity in Room Nos. 225N and 226N were outside of the ranges presented in the protocol.

CONTRACTS 2
CENTRAL
~~M-KGWG~~
TOX file

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3301 KINSMAN BLVD. • P.O. BOX 7545 • MADISON, WI 53707 • (608) 241-4471 • TLX 703956 HAZRAL MDS UD

FINAL

PROTOCOL TP5059

Twenty-six Week Subchronic Toxicity Study in Dogs with SC-19129 Admixed in the Diet

HLA Study No. 6127-111
Searle Study No. S.A. 2530

for

G. D. Searle & Co.
4901 Searle Parkway
Skokie, Illinois

by

Hazleton Laboratories America, Inc.
Life Sciences Division
3301 Kinsman Boulevard
Madison, Wisconsin 53704

June 7, 1985

* 1985, Hazleton Laboratories America, Inc.

PROTOCOL TP5059

Twenty-six Week Subchronic Toxicity Study in Dogs with SC-19129 Admixed in the Diet

Study No.	6127-111
Study Location	Hazleton Laboratories America, Inc. 3301 Kinsman Boulevard Madison, Wisconsin 53704
Test Material	SC-19129
Sponsor's Study Coordinator	James Allen, PhD
Hazleton's Study Director	Bruce Dickie
Proposed Starting Date	July 10, 1985
Proposed Completion Date	
Week-27 sacrifice	January 8 through 10, 1986
Week-31 sacrifice	February 6 through 7, 1986

OBJECTIVES

The objectives of the main study are to determine the toxic effects as evidenced by clinical signs and specific organ damage in dogs fed SC-19129 in the diet for 26 weeks and to assess any reversal of these effects from Weeks 27 through 30. In addition, pharmacokinetic analyses will be performed to determine the absorption of the test article, the relationship of plasma concentration of SC-19129 with dosage, and the relationship of SC-19129 with duration of dosing.

COMPLIANCE

All aspects of this study will conform to the U. S. Food and Drug Administration's (FDA) guidelines for the safety assessment of food additives,[1] and it will be conducted in accordance with the FDA's Good Laboratory Practice Regulations for Nonclinical Laboratory Studies.[2] All procedures will be done according to Hazleton Laboratories America, Inc. (HLA) Standard Operating Procedures (SOPs), and will be monitored by the HLA Quality Assurance Unit.

TEST MATERIAL

Identification

G. D. Searle & Co. will provide the test material (SC-19129) identified by code number, batch number, date of synthesis, and/or other suitable means.

G. D. Searle & Co. will also provide the following information as it becomes available:

- Chemical name: N-L-α-aspartyl-L-phenylalanine, 1-methyl ester
- Purity of the test material
- Physical/chemical properties

- Composition (including impurities)
- Toxicity
- Stability
- Safety (Safety Data Sheet)

Storage

The test compound SC-19129 will be stored in a well-closed, light-resistant container at room temperature.

Test diets will be refrigerated from the time they are mixed until fed, and additional unfed diet will be refrigerated through the end of the feeding period.

Safety Precautions

Personnel working with the test material, the finished diets, and in the animal room will wear disposable gloves, hair covers, shoe covers, face masks, and other appropriate clothing such as laboratory coats and/or uniforms.

TEST SYSTEM

Test Animal

Beagle dogs, 5 to 6 months old, purchased from Hazleton Research Products, Cumberland, Virginia will be used as test animals. Upon receipt, the animals will be taken to Rooms 225 and 226 and acclimated for at least 14 days before being placed on test. During acclimation, the animals will be examined for clinical abnormalities indicative of health problems (e.g., diarrhea, ectoparasites, endoparasites, nasal or ocular discharge, evidence of injury, etc.).Any animal regarded as unacceptable for the study because of improper size, poor physical condition, ocular lesions, or other reasons will be discarded and the reason(s) will be documented.

Beagle dogs have been used for toxicity studies at HLA, and growth and pathology data are available for historical comparisons.

Identification

Prior to being placed on test, each animal in the study will be assigned an identification number and will be permanently identified with a numbered ear tag. All data collected from an animal will be recorded and filed under its identification number, except for certain clinical pathology parameters which use only a portion of the number.

Housing and Maintenance

Two temperature- and humidity-controlled rooms (Nos. 224 and 225) will be assigned solely to this study. The room will have a temperature of 22°C ±3°, a relative humidity of 50% ±25%, and a minimum of 10 changes per hour of filtered 100% outside air. The room will be kept on a 12-hour light/12-hour dark cycle. Variations from prescribed environmental conditions will be documented.

Animal husbandry and housing at HLA comply with the "Guide for the Care and Use of Laboratory Animals." The animals will be housed individually in stainless steel mesh-bottom cages with urine- and feces-collecting pans. The pans will be cleaned daily, and cages will be changed every 2 weeks. Care will be taken to ensure that the animals are not disturbed for reasons other than data collection and routine maintenance.

Feed will be provided for a 3-hour period daily from "J-Feeders" that limit spillage and allow easy inspection of the amount and condition of the feed. Tap water will be provided ad libitum from an automatic water system

(Systems Engineering, Palo Alto, California). Samples of the water are analyzed quarterly for total dissolved solids, conductivity, microbiological content, and selected elements, e.g., heavy metals, organophosphates, and chlorinated hydrocarbons; the data are kept on file at HLA.

Treatment Duration

Treatment will be initiated when the animals are approximately 5 to 6 months old. All animals will receive test diets for a 3-hour period daily for at least 180 days (26 weeks), unless they die or are sacrificed prior to study termination. Those animals not selected for necropsy during Week 27 will be placed on a 4-week recovery study and will be fed the basal diet.

Study Design

Animals will be randomly assigned, using a random block design, to test and control groups from a supply of more than 48 dogs.

Group	Sex	Number of Animals	SC-19129 Treatment (mg/kg BW/Day)
1	M	6	0
1	F	6	0
2	M	6	250
2	F	6	250
3	M	6	500
3	F	6	500
4	M	6	1,000
4	F	6	1,000

The study will be divided into two phases: the main study and a 4-week recovery phase. During the antemortem period of the study, animals will have observations, body weight, feed consumption, ophthalmic examinations, electrocardiograph measurements, and clinical laboratory data collected.

Two randomly selected animals of each sex from each group will be assigned to the 4-week recovery phase after 26 weeks on test and will be placed on the control diet from Weeks 27 through 30. Observations, body weights, and feed consumptions will be recorded for Weeks 27 through 30. After 30 weeks on test (4-week recovery period), all animals in the recovery study will have ophthalmic examinations, electrocardiograph measurements, and clinical laboratory data collected.

PROCEDURES

Test Diet

Since humans will be exposed to the test material by the oral route the test material (SC-19129) will be administered to the test animals in their basal diet. The basal diet for this study will be Purina Certified Canine Diet®. This feed will be analyzed by the manufacturer for nutritional components and environmental contaminants; the minimum or maximum concentrations of these materials will be specified. No components or contaminants known to be in the basal diet are expected to interfere with the study. A record will be maintained of all lot numbers of feed used in this study. Finished diets will be refrigerated in covered polyethylene containers unless stability data dictate otherwise.

Dosage Levels

Four test diets will be fed for a 3-hour period daily throughout the study: a negative control diet (basal) and the following three daily dosage levels based on the milligrams of SC-19129 per kg of body weight.

0 mg/kg	Control
250 mg/kg	Low level
500 mg/kg	Mid-level
1,000 mg/kg	High level

Diet Preparation

Based on estimated body weights and feed consumptions for the subsequent feeding period, the appropriate amount of SC-19129 will be admixed with basal diet to achieve the proper concentration in the feed. Diets will be recalculated weekly through Week 26. Diets will be mixed fresh weekly.

All diet equipment will be thoroughly cleaned before and after each mixing. Prepared diets will be refrigerated in covered containers.

Stability and Characterization of Test Article in the Diet

Except for purity of the test article, HLA will conduct all analyses for this study. Analysis for impurities in the test article will be conducted by the Sponsor.

Prior to study initiation, HLA will conduct a homogeneity and stability study according to Appendix A.

HLA will assay each dose level (finished diet) and the control diet mixed and fed during Weeks 1, 3, and 5 of the study. Subsequently, all dose levels and control diet for Weeks 10, 15, 20, and 25 will be assayed.

Antemortem Observations

At least twice daily (pre- and post-prandial), all animals will be observed for moribundity, death, and obvious indications of a toxic effect. At least once each week, animals will be removed from their cages and carefully examined for behavioral abnormalities and clinical signs of toxic or pharmacological effects. Dead or moribund animals will be removed immediately and the tissues preserved without delay. Autolysis in dead animals will be minimized by placing them in a refrigerator until the necropsy is started.

Qualified personnel will be available 7 days a week so that necropsies may be performed on a timely basis and tissues promptly fixed. A complete physical examination will be done on each animal prior to study initiation and during Weeks 8, 17, 26, and 30.

Body Weights and Feed Consumptions

Individual body weights will be recorded weekly prior to initiation, and initially and weekly thereafter through 26 weeks.

Individual feed consumptions will be recorded to the nearest 0.1 kg weekly from Week -3. Feed consumption will be determined on days of pharmacokinetic blood sampling. Animals in the recovery phase will have body weights and feed consumptions collected during Weeks 27 through 30.

Ophthalmological Examination

Slit lamp and indirect ophthalmoscopic examinations will be conducted on all animals prior to study initiation, and during Weeks 7, 16, 25, and 30 by a veterinary ophthalmologist. Animals with abnormal findings prior to initiation of the study will be eliminated if possible from selection procedures.

Electrocardiography

An electrocardiogram (leads I, II, III, aVR, aVL, aVF, CV_5RL, CV_6LL, CV_6LU, and V_{10}) will be recorded for each animal prior to study initiation and during Weeks 8, 17, 26, and 30.

Clinical Laboratory Studies

Blood and urine will be collected from all animals for hematology, blood chemistry, and urinalysis before study initiation, and during Weeks 8, 17, 26, and 30.

Blood will be collected from the jugular or cephalic vein. Urine will be collected for a 24-hour period in metabolism pans.

The following hematology tests will be done:

- Total erythrocyte count (and indices)
- Hemoglobin content
- Hematocrit
- Platelet count
- Total leukocyte count
- Differential leukocyte count (relative and absolute)
- Prothrombin time
- Activated partial thromboplastin time
- Bone marrow smears prepared at scheduled necropsies and held (examined only if considered necessary)

The following blood chemistry tests will be done (listed in order of priority if sample is limited):

- Alanine aminotransferase (ALT)
- Alkaline phosphatase
- Urea nitrogen
- Aspartate aminotransferase (AST)
- Glucose
- Total bilirubin
- Creatinine
- Total protein
- Albumin
- Globulin and A/G ratio
- Total cholesterol
- Calcium
- Sodium
- Potassium
- Chloride

The following urinalysis determinations will be done:

- Volume (24 hour) and appearance
- pH
- Blood
- Protein
- Bilirubin
- Glucose
- Urobilinogen
- Ketones
- Specific gravity
- Microscopic examination of sediment

Pharmacokinetic Sampling

Venous blood samples (approximately 5 mL) will be collected from all animals at 0, 3, 5, and 7 hours after the start of the feeding period on Day 1 and during Weeks 12 and 25. Blood will be collected in heparinized tubes from the jugular or cephalic veins.

Plasma samples will be transferred to the Sponsor for analysis.

The results of these analyses will appear in a report provided to the HLA Study Director by the Sponsor's Drug Metabolism Department.

Anatomical Pathology

All animals placed on test, regardless of their fate, will be subjected to gross postmortem examination (necropsy) and tissue collection.

The necropsy will include examination of the external surface, all orifices, the cranial cavity, carcass, external and cut surfaces of the brain, spinal cord, the nasal cavity and paranasal sinuses, and the abdominal, thoracic, and pelvic cavities and their viscera.

The following tissues and organs will be examined grossly then preserved in 10% phosphate-buffered formalin.

Gross lesions requiring histologic characterization
Adrenal glands
Aorta
Bone with marrow (femur with articular surfaces and sternum)
Brain (sections to include medulla, pons, cerebral cortex, and cerebellar cortex)
Cecum
Cervix
Colon
Duodenum
Epididymides
Esophagus
Eyes*
Gallbladder
Heart
Ileum
Jejunum
Kidneys
Liver
Lungs
Lymph nodes (submandibular and mesenteric)
Mammary gland (females only)
Muscle (skeletal, posterior to femur to include sciatic nerve)
Ovaries
Pancreas
Parathyroid glands
Pituitary
Prostate
Rectum
Salivary glands
Skin
Spleen
Spinal cord (three sections: cervical, mid-thoracic, lumbar)
Stomach
Testes**
Thymus
Thyroid glands
Tongue
Trachea
Urinary bladder
Uterus
Vagina

*Eyes fixed in Zenker's fixative at scheduled sacrifices.
**Testes fixed in Bouin's fixative at scheduled sacrifices.

Bone marrow smears will be made from all animals sacrificed at 27 and 31 weeks on test.

In addition to terminal body weight, the following organs will be weighed:

Adrenals	Liver	Spleen
Brain	Ovaries	Testes
Epididymides	Pituitary	Thymus
Heart	Prostate	Thyroids*
Kidneys	Salivary gland	Uterus

*Includes parathyroid.

Paired organs will be weighed paired.

Histopathology

The following hematoxylin- and eosin-stained (H&E) tissues will be examined microscopically:

- All tissues from all animals that die or are sacrificed prior to and during Week 27, and gross lesions that require microscopic confirmation. Parathyroids will be examined only when present in the thyroid section.
- Target organs only in the appropriate groups from animals in the recovery study sacrificed during Week 31.

Statistical Analysis

Body weight, feed consumption, organ weight, the ratios of organ weight to body weight and of organ weight to brain weight, physical examination data, electrocardiograph measurements, blood chemistry, and hematology data, where appropriate, will be analyzed separately for each sex. In addition, except for body weights, food consumptions, and organ weights, the data will be analyzed for combined sexes. Statistically significant differences will be reported at $p \leq 0.05$, $p < 0.01$, and $p < 0.001$ levels. The Levene test for homogeneity of variance will also be computed at $p < 0.001$ level. If the group means differ significantly by analysis of variance, then Dunnett's t-test will be used to compare the treatment means with the control mean. Count data will be analyzed using contingency Chi-square analysis.

Reports

Status reports will be submitted monthly indicating the number of survivors in each group, mean body weights and feed consumptions, individual and mean physical examination data, electrocardiograph measurements, and any apparent compound-related effects.

The final report will present a description of the test material, results of analyses of test diets, a description of the test system, all individual data, summaries of all data collected, results of statistical analyses, and discussions relevant to the findings.

Maintenance of Raw Data and Specimens

Original data or copies thereof will be available at HLA to facilitate auditing the study during its progress and prior to acceptance of the final report. When the final report is completed, all original paper data and magnetically encoded records generated by HLA as well as the final report and all specimens (wet tissues, blocks, slides, etc.) will be retained in the archives of Hazleton Laboratories America, Inc. Upon acceptance of the final report, HLA will transfer and the remainder of the test material to G. D. Searle & Co.

PROTOCOL APPROVAL

James L. Allen, PhD
Study Coordinator
Product Safety Assessment

6-17-85
Date

F. N. Kotsonis, PhD
Director, Toxicology
Product Safety Assessment

6/19/85
Date

D. C. Dodd, BVSc., MA
Director, Pathology
Product Safety Assessment

6.26.85
Date

Frederick M. Radzialowski, PhD
Senior Director
Product Safety Assessment

Date

Bruce C. Dickie
Study Director
Toxicology Department
Hazleton Laboratories America, Inc.

6/10/85
Date

Steven R. Sorenson
Inspector, Quality Assurance Unit
Hazleton Laboratories America, Inc.

6-10 85
Date

(1325a/emm)

RECEIVED

JUL 09 1985

HLA Madison

REFERENCES

1. "Guidelines for Subchronic Oral Toxicity Studies," Toxicological Principles for the Safety Assessment of Direct Food Additives and Color Additives Used in Food, Appendix II, pp. 19-29, U. S. Food and Drug Administration (1982).

2. 21 CFR 58.

Study 6127-111

Appendix A

Procedure for Homogeneity and Stability Analyses

Prior to study initiation a homogeneity study will be conducted to determine the mixing characteristics of the test article.

The test article will be mixed into basal diet in the manner to be used during the study. Nine 5-gram samples will be taken from various levels in the mixing bowl. These samples will be forwarded to the analytical laboratory, where they will be analyzed in their entirety for the content of SC-19129.

Homogeneity will be conducted at both the high and low dosage levels.

Following the preparation of the high level diet the mixing bowl will be cleaned in the normal manner. Immediately after this cleanup procedure is completed, the bowl will be washed with 4 liters of methanol. The methanol will be collected and concentrated in the analytical laboratory. The concentrated methanol will be analyzed and the residual SC-19129 determined.

Using the result from this determination and the mass of feed used in the smallest batch to be prepared, a maximum possible contamination level will be calculated.

In-cage stability studies will also be conducted at the high and low dose levels, using surplus animals.

Diets will be mixed in the manner to be used in the study and sampled in the identical manner of the homogeneity study. These are the T = 0 samples.

The diets will then be presented to the animals for consumption. On Day 8, sufficient sample will be collected from the feeder to provide three 5-gram samples for each dosage level.

All samples will be analyzed for SC-19129 using the appropriate methodology.

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06/24/85

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Protocol TP5059
Twenty-Six Week Subchronic Toxicity Study in Dogs
with SC-19129 Admixed in the Diet

HLA Study No. 6127-111
G. D. Searle Study No. SA 2530

Sponsor	Contractor
G. D. Searle & Co. Searle Research and Development 4901 Searle Parkway Skokie IL 60077	Hazleton Laboratories America, Inc. Life Sciences Division 3301 Kinsman Boulevard Madison WI 53704
Study Coordinator	**Study Director**
James L. Allen, PhD	Bruce C. Dickie

Amendment No. 1
Effective July 10, 1985

This amendment modifies the following portions of the protocol.

1) Page 3, Housing and Maintenance, paragraph 1, sentence 1. To correct the room numbers the animals are housed in, substitute the underlined below for "(Nos. 224 and 225)".

> Two temperature- and humidity-controlled rooms (Nos. 225 and 226) will be assigned solely to this study.

2) Page 7, Antemortem Observations, sentence 2. At Sponsor's request, add the underlined.

> A complete physical examination will be done on each animal prior to study initiation and immediately after the 3 hour feeding period during Weeks 8, 17, 26, and 30.

3) Page 7, Electrocardiography, sentence 1. At Sponsor's request, add the underlined.

> An electrocardiogram (leads I, II, III, aVR, aVL, aVF, CV_5RL, CV_6LL, CV_6LU, and V_{10}) will be recorded for each animal prior to study initiation and immediately after the 3 hour feeding period during Weeks 8, 17, 26, and 30.

4) Page 8, Clinical Laboratory Studies, paragraph 1. At Sponsor's request, add the following after sentence 1.

> If animals become moribund, a blood sample will be drawn for clinical pathology determinations.

5) Page 9, Pharmacokinetic Sampling, paragraph 1, sentence 1. To define the times pharmacokinetic samples are actually taken, substitute the following.

> Venous blood samples (approximately 5 mL) will be collected from all animals at 3, 5, 7, and 24 hours after the start of the feeding period on Day 1 and during Weeks 12 and 25.

6) Page 10, paragraph 3, sentence 1. At Sponsor's request, substitute the following.

> In addition to terminal body weight, the following organs will be weighed from all animals regardless of fate:

AMENDMENT APPROVAL

James L. Allen, PhD — 10-8-85
Study Coordinator — Date
Product Safety Assessment
G. D. Searle & Co.

Bruce C. Dickie — 10/4/85
Study Director, Toxicology — Date
Hazleton Laboratories America, Inc.

Susan Glad Anderson — 10/4/85
Manager, Quality Assurance Unit — Date
Hazleton Laboratories America, Inc.

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OCT 11 1985
HLA Madison

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3301 KINSMAN BLVD. • P.O. BOX 7545 • MADISON, WI 53707 • (608) 241-4471 • TLX 703956 HAZRAL MDS UD

Protocol TP5059
Twenty-Six Week Subchronic Toxicity Study in Dogs
with SC-19129 Admixed in the Diet

HLA Study No. 6127-111
G. D. Searle Study No. SA 2530

Sponsor

G. D. Searle & Co.
Searle Research and Development
4901 Searle Parkway
Skokie IL 60077

Study Coordinator

James L. Allen, PhD

Contractor

Hazleton Laboratories America, Inc.
Life Sciences Division
3301 Kinsman Boulevard
Madison WI 53704

Study Director

Bruce C. Dickie

Amendment No. 2
Effective January 7 ,1986

This amendment modifies the following portions of the protocol.

1) Page 9, Pharmacokinetic Sampling, paragraph 1, sentence 1. Due to technical error during the Week 25 collection substitute the following underlined.

> Venous blood samples (approximately 5 ml) will be collected from all animals at 3, 5, 7, and 24 hours after the start of the feeding period on Day 1 and during Weeks 12, 25, and 26.

AMENDMENT APPROVAL

James L. Allen, PhD
Study Coordinator
Product Safety Assessment
G. D. Searle & Co.

1-22-86
Date

Bruce C. Dickie
Study Director, Toxicology
Hazleton Laboratories America, Inc.

1/16/86
Date

L. Lea Gough
Inspector, Quality Assurance Unit
Hazleton Laboratories America, Inc.

1/16/86
Date

(0884t/jrh)

HAZLETON LABORATORIES AMERICA, INC.

3301 KINSMAN BLVD. • P.O. BOX 7545 • MADISON, WI 53707 • (608) 241-4471 • TLX 703956 HAZRAL MDS UD

Protocol TP5059
Twenty-Six Week Subchronic Toxicity Study in Dogs
with SC-19129 Admixed in the Diet

HLA Study No. 6127-111
G. D. Searle Study No. SA 2530

Sponsor	Contractor
G. D. Searle & Co. Searle Research and Development 4901 Searle Parkway Skokie IL 60077	Hazleton Laboratories America, Inc. Life Sciences Division 3301 Kinsman Boulevard Madison WI 53704
Study Coordinator	**Study Director**
James L. Allen, PhD	Bruce C. Dickie

Amendment No. 3
Effective March 4, 1986

This amendment modifies the following portions of the protocol.

1) Page 2, TEST SYSTEM, Test Animal, sentence 1. To define the actual ages of the animals used in the study, substitute the following:

> Beagle dogs, 5 to 7 months old, purchased from Hazleton Research Products, Cumberland, Virginia, will be used as test animals.

2) Page 9, Pharmacokinetic Sampling, paragraph 3. At the Sponsor's request, delete paragraph 3 and substitute the following:

> Results of the the Day 1, Weeks 12 and 26 analyses will appear in a report prepared by the Sponsor's Drug Metabolism Department.

3) Appendix A (to the protocol), paragraph 6. To reflect procedures actually performed insert the following underlined:

> In-cage stability and in-cage homogeneity studies will also be conducted at the high and low dose levels, using surplus animals.

AMENDMENT APPROVAL

James L. Allen, PhD
Study Coordinator
Product Safety Assessment
G. D. Searle & Co.

4-10-86
Date

Bruce C. Dickie
Study Director, Toxicology
Hazleton Laboratories America, Inc.

4/4/86
Date

L. Lea Gough
Inspector, Quality Assurance Unit
Hazleton Laboratories America, Inc.

4/4/86
Date

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PROTOCOL TP5059

Twenty-Six Week Subchronic Toxicity Study in Dogs with SC-19129 Admixed in the Diet

HLA Study No. 6127-111
Searle Study No. S. A. 2530

Sponsor

G. D. Searle & Co.
Searle Research and Development
4901 Searle Parkway
Skokie IL 60077

Contractor

Hazleton Laboratories America, Inc.
3301 Kinsman Boulevard
Madison WI 53704

Study Coordinator

James L. Allen, PhD

Study Director

Bruce C. Dickie

Amendment No. 4
Effective May 27, 1986

This amendment modifies the following portion of the protocol.

1. Page 12, Reports, Paragraph 2. Per Sponsor's request, substitute the following:

> The final report will present a description of the test material, results of analyses of test diets, a description of the test system, all individual data (except antemortem observations--only treatment-related antemortem observations will be reported), results of statistical analyses, and discussions of relevant findings.

AMENDMENT APPROVAL

James Allen, PhD
Study Coordinator
Product Safety Assessment
G. D. Searle & Co.

6-10-86
Date

Bruce C. Dickie
Study Director, Toxicology
Hazleton Laboratories America, Inc.

6/6/86
Date

Quality Assurance Representative
Hazleton Laboratories America, Inc.

6/6/86
Date

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PROTOCOL TP5059

Twenty-Six Week Subchronic Toxicity Study in Dogs with SC-19129 Admixed in the Diet

HLA Study No. 6127-111
Searle Study No. S. A. 2530

Sponsor	Contractor
G. D. Searle & Co. Searle Research and Development 4901 Searle Parkway Skokie IL 60077	Hazleton Laboratories America, Inc. 3301 Kinsman Boulevard Madison WI 53704
Study Coordinator	**Study Director**
Christopher Chengelis, PhD	Bruce C. Dickie

Amendment No. 5
Effective June 13, 1986

This amendment modifies the following portion of the protocol.

1. Page i, Study Coordinator. To reflect a change in the Sponsor's Study Coordinator, substitute the following for "James L. Allen, PhD":

   Christopher Chengelis, PhD

AMENDMENT APPROVAL

Christopher Chengelis, PhD
Study Coordinator
Product Safety Assessment
G. D. Searle & Co.

7/31/86
Date

Bruce C. Dickie
Study Director, Toxicology
Hazleton Laboratories America, Inc.

7/11/86
Date

Quality Assurance Representative
Hazleton Laboratories America, Inc.

7/11/86
Date

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PROTOCOL TP5059

Twenty-Six Week Subchronic Toxicity Study in Dogs
with SC-19129 Admixed in the Diet

HLA Study No. 6127-111
Searle Study No. S. A. 2530

Sponsor	Contractor
G. D. Searle & Co. Searle Research and Development 4901 Searle Parkway Skokie IL 60077	Hazleton Laboratories America, Inc. 3301 Kinsman Boulevard Madison WI 53704
Study Coordinator	**Study Director**
Christopher Chengelis, PhD	Bruce C. Dickie

Amendment No. 6
Effective September 18, 1986

This amendment modifies the following portion of the protocol.

1. Page 11, Statistical Analysis. Per Sponsor's request and to provide a more complete description of the statistics used in the data analysis, substitute the following:

   Statistical Analysis

   Body weight; food consumption; physical examination measurements; electrocardiograph measurements; clinical chemistry; hematology; urine pH, volume, and specific gravity; organ weight data; and organ-to-body weight and organ-to-brain weight ratios will be analyzed separately for each sex using one-way analysis of variance (ANOVA) with transformation when necessary ($\log_{10}$, square, square root, reciprocal, arcsine, rank) to attain variance homogeneity.[3] Physical examination measurements; electrocardiograph measurements; clinical chemistry; hematology; and urine pH, volume and specific gravity; organ weight data will be analyzed after pooling sexes.

When indicated, analysis of covariance (ANCOVA) will be performed on body weight data with Day 0 weight as the covariate.[4] If the ANOVA (or ANCOVA) is significant, Dunnett's t-test will be used to compare each group with the control.[5] When no transformation establishes variance homogeneity at $p < 0.001$, the data will also be examined by nonparametric techniques. These statistics include the Kruskal-Wallis H-test analysis of variance[6] and, if this test is significant, the Nemenyi-Kruskal-Wallis test for multiple comparisons[7] or the Wilcoxon-Mann-Whitney two-sample rank test.[8] All group comparisions found to be statistically significant at $p \leq 0.05$, $p \leq 0.01$, and $p \leq 0.001$ will be documented.

2. Page 14, REFERENCES. To complete the list of references to include those cited above in 1, add the following:

[3]Winer, B. J., Statistical Principles in Experimental Design, McGraw-Hill, New York, Second Ed., Ch. 3, 1971.

[4]Ibid, Ch. 10.

[5]Dunnett, C. W., "New Tables for Multiple Comparisons with a Control," Biometrics, 20:482-491, 1964.

[6]Kruskal, W. H. and W. A. Wallis, "Use of Ranks in One-Criterion Variance Analysis," J. Am. Stat. Assoc., 47:583-621, 1952.

[7]Nemenyi, P. Distribution-free Multiple Comparisons, PhD Thesis, Princeton University, pp. 23.1-23.7, 1963.

[8]Wilcoxon, F., "Individual Comparisons by Ranking Methods," Biometrics, 1:80-83, 1945 and Mann, H. B. and D. R. Whitney, "On a Test Whether One of Two Random Variables is Statistically Larger Than the Other," Ann. Math. Stat., 18:50-60, 1947.

AMENDMENT APPROVAL

Christopher Coengelis, PhD
Study Coordinator
Product Safety Assessment
G. D. Searle & Co.

Date 9/24/86

Bruce C. Dickie
Study Director
Toxicology
Hazleton Laboratories America, Inc.

Date 9/22/86

Representative
Quality Assurance Unit
Hazleton Laboratories America, Inc.

Date 9/22/86

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R&D PRODUCT DEVELOPMENT FUNCTION
REPORT REVIEW AND RELEASE

DEPARTMENT: Product Development Analytical

DOCUMENT NUMBER: F-391-034-16 CROSS REFERENCE: F-392-034-17

TITLE OF REPORT: SC-19129 (β-APM)

TYPE OF REPORT: Analytical Summary in Support of Product Safety Assessment Study Number 2530

AUTHOR(S):	DATE	REVIEWER(S):	DATE
Mark D. Mast	4-11-86	Daniel J. Sweeney	5-7-86
		J. Jagannathan	5/7/86

TECHNICAL WRITER: Michele Newcomb Michele Newcomb Date 5/7/86

APPROVAL: DATE

07-May-86

APPROVAL FOR RELEASE:

R. Baum, Director
Analytical Development — Date 5/13/86

L. Hansen,
Senior Director
Product Development — Date 5/16/86

NORTH AMERICAN PRECLINICAL RESEARCH AND DEVELOPMENT
SEARLE PHARMACEUTICALS AND CONSUMER PRODUCTS
SKOKIE, ILLINOIS

A2

Subject: SC-19129 (β-APM)

Summary Number: F-391-034-16

Applicable to SA Study Number: 2530

I. Test Article Characterization and Stability

Lot 84K-054-101 and 84K-056-101 of SC-19129 were analyzed using the release methods of testing, released against the current specifications (NS-S84-015-A), and given a re-evaluation period of one year. Lot 84K-056-101 was re-analyzed and given an extended re-evaluation of fifteen months. The results of analysis are presented in Tables 1 and 2.

Table 1

SC-19129, Lot 84K-054-101

	Pre-Study
Report of Analysis	84N1146
Completion Date	12/18/84
Identity (HPLC)	Conforms to standard
Assay (HPLC) (on Dried Basis)	100.1% n = 3 s = 0.5
Water	9.7%

Table 2

SC-19129, Lot 84K-056-101

	Pre-Study	Re-Analysis	Post-Study
Report of Analysis	84N1157	85N0917	86N0109
Completion Date	12/18/84	10/31/85	02/13/86
Identity	Conforms to standard	Conforms to standard	Conforms to standard
Assay (HPLC) (on Dried Basis)	99.5% n = 3 s = 0.1	101.1% n = 3 s = 0.9	100.6% n = 2 s = 0.3
Water	8.0%	7.5%	7.2%

These results and all other results, coupled with the use of lots 84K-054-101 and 84K-056-101 within their re-evaluation periods, indicate that these lots of SC-19129 were suitable for use in this study.

Subject: SC-19129 (β-APM)

Summary Number: F-391-034-16

Applicable to SA Study Number: 2530

Stability of Test Article in Carrier

The stability of SC-19129 (Lot 84K-047-101) in canine diet admixture (Ralston Purina 5007) was determined by using a stability-indicating HPLC method (M84-048-A). Diet admixture samples prepared at dosing concentrations of 1 g and 200 g of SC-19129/kg of canine diet admixture were stored at ambient conditions.

The 1 g/kg dosing concentration samples were prepared over a seventeen day period for days 0, 3, 6, 7, 10, 14, and 17. The 200 g/kg dosing concentration samples were prepared over a seventeen day period for days 0, 2, 6, 7, 10, 14, and 17. The statistics are based on the relative percent recovery values. The results of the analyses are presented in Tables 3 and 4.

For the low dosing concentration, 1 g/kg, Table 3, the results of the linear regression analysis (MINITAB, Reference 1) for the relative percent recovery of SC-19129 versus time, gave a t-ratio value less than the table value, t = 1.812 (Reference 2, Table A-4), indicating no significant downward trend. The correlation between the observed recovery values and the predicted recovery values exhibited a normal probability plot (References 1 and 3). The results indicate that SC-19129 in canine diet admixture at 1 g/kg, stored at ambient conditions, does not undergo significant degradation for at least seventeen days.

For the high dosing concentrations, 200 g/kg, Table 4, the results of the linear regression analysis (MINITAB, Reference 1) for the relative percent recovery of SC-19129 versus time, gave a t-ratio value less than the table value, t = 1.812 (Reference 2, Table A-4), indicating no significant downward trend. The correlation between the observed recovery values and the predicted recovery values exhibited a normal probability plot (References 1 and 3). The results indicate that SC-19129 in canine diet admixture at 200 g/kg, stored at ambient conditions, does not undergo significant degradation for at least seventeen days.

Since SC-19129 is stable at low and high dosing concentrations at ambient conditions, all dosing concentrations between 1 g and 200 g of SC-19129/kg of canine diet admixture are considered to be stable for at least seventeen days when stored under equivalent conditions.

Notebook Reference: M. Napier, PDAD-0028, pp. 290-303.

Subject: SC-19129 (β-APM)

Summary Number: F-391-034-16

Applicable to SA Study Number: 2530

Table 3

Stability of Test Article in Carrier

1 g of SC-19129/kg of Canine Diet Admixture

Time (Days)	Sample	% SC-19129 Recovered	% Relative Recovery
0	3	100.8	
	4	99.9	
	5	100.6	
	6	100.9	
Reference		$\bar{X}$=100.6	
3	1	100.8	100.2
	2	101.0	100.4
6	1	100.1	99.5
	2	99.5	98.9
7	1	97.7	97.1
	2	98.7	98.1
10	1	99.4	98.8
	2	101.5	100.9
14	1	99.8	99.2
	2	98.6	98.0
17	1	99.0	98.4
	2	98.9	98.3
Intercept			99.8
Slope			- 0.0865
t-Ratio			- 1.34
t (0.95, df = 10)			1.812
Correlation: Predicted vs Observed			0.979

Subject: SC-19129 (β-APM)

Summary Number: F-391-034-16

Applicable to SA Study Number: 2530

Table 4

Stability of the Test Article in Carrier

200 g of SC-19129/kg of Canine Diet Admixture

Time (Days)	Sample	% SC-19129 Recovered	% Relative Recovery
0	3	97.2	
	4	101.3	
	5	98.7	
	6	99.3	
Reference		$\bar{X}$ = 99.1	
2	1	99.1	100.0
	2	101.4	102.3
6	1	98.5	99.4
	2	101.1	102.0
7	1	99.5	100.4
	2	94.0	94.9
10	1	98.1	99.0
	2	98.3	99.2
14	1	97.3	98.2
	2	94.6	95.5
17	1	99.9	100.8
	2	98.6	99.5
Intercept			100.0
Slope			- 0.128
t-Ratio			- 1.00
t (0.95, df = 10)			1.812
Correlation: Predicted vs Observed			0.943

Subject: SC-19129 (β-APM)

Summary Number: F-391-034-16

Applicable to SA Study Number: 2530

References:

1. Ryan, Jr., T. A., Joiner, B. L., and Ryan, B. F., "MINITAB Student Handbook", 1976, Wadsworth Publishing Co., Inc.

2. Natrella, M. G., "Experimental Statistics, National Bureau of Standards Handbook 91", 1963, US Government Printing Office

3. Filliben, J., Technometrics, 17, (1), 111 (1975)

Subject: SC-19129 (β-APM)

Summary Number: F-391-034-16

Applicable to SA Study Number: 2530

GLP Compliance Statement

To the best of our knowledge, the support activities provided by the Product Development Analytical Department for this study were conducted in compliance with the Good Laboratory Practices Regulations, as set forth in part 58, 21 CFR.

B1

Department of Drug Metabolism

GLP COMPLIANCE STATEMENT

To my knowledge, the study described in the attached report (S.A. 2530) was conducted in compliance with the Good Laboratory Practice Regulations as set forth in part 58, 21 CFR.

9/5/86

James A. Oppermann, Ph.D. Date
Director
Department of Drug Metabolism

62

Evaluation of the Plasma Concentration Data from the Twenty-Six Week Dietary Admix Toxicity Study of SC-19129 in the Dog, S.A. 2530

Document Number: MRC-861-0042

Authored by:

Earl G. Burton 9/5/86

Earl G. Burton, Ph.D. Date
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Grant L. Schoenhard, Ph.D. Date
Section Head, Metabolism
Department of Drug Metabolism

9/5/86.

James A. Oppermann, Ph.D. Date
Director
Department of Drug Metabolism

B2

Evaluation of the Plasma Concentration Data from the Twenty-six Week Dietary Admix Toxicity Study of SC-19129 in the Dog, S.A. 2530

I. Study Design and Collection and Analysis of Samples

The test article-diet mixture was made available to the animals for approximately 3 hours each day during the study. The intended dosages were 250, 500 and 1000 mg/kg. The actual dose received by each dog on the days blood samples were taken for pharmacokinetic analysis was calculated from the measured consumption of the test article-diet mixture on the appropriate day. Venous blood samples were collected at 3, 5, 7 and 24 hours after the start of the feeding period on days 1, 83 and 182. Blood was collected in tubes containing heparin and plasma was prepared by centrifugation. The concentration of SC-19200 (β-AP), the free acid of SC-19129, in each plasma sample was determined by a high performance liquid chromatography (HPLC) procedure (1).

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II. Statistical Analysis

The maximum observed concentration (Cmax) of SC-19200 for each dog on each day was obtained by inspection of the plasma concentration data (Table 1). Areas under the plasma concentration-time curves (AUC) from 0 to 7 hours after the initiation of dosing were calculated using the trapezoidal rule. Values below the validated sensitivity limit of the assay (see Table 1) were treated as zeros for these calculations. The concentraton of SC-19200 at 0 hours on day 1 was taken to be zero, and the concentrations at 0 hours on days 83 and 182 were taken to be the same as the respective concentrations at 24 hours for these days, for these calculations.

The Cmax and AUC values were adjusted for the actual dose received by each dog by multiplying each value by a factor equal to the intended dose divided by the measured dose received by that dog on the respective day. The values for the measured doses received are given in Appendix D of Reference 2. The dose adjusted Cmax and AUC values were then normalized to a 250 mg/kg (low dose) basis by dividing by 1, 2 and 4 for the low (250 mg/kg), medium (500 mg/kg) and high (1000 mg/kg) dose groups respectively. The normalized Cmax and AUC values were tested for dose, sex and day effects using analysis of variance techniques.

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III. Results and Discussion

A. Absorption of the Test Article:

Studies with [^{14}C]-SC-19129 have indicated that SC-19129 is not detectable in the systemic circulation following oral administration (3). An assay was therefore developed for the free acid, SC-19200 (β-AP), in plasma (1).

Individual plasma concentrations of SC-19200 and individual AUC values are given in Tables 1 and 2, respectively. Mean plasma concentrations of SC-19200 are given in Table 1 and shown in Figure 1. Plasma concentrations of SC-19200 were measureable in all treated animals on each day, demonstrating absorption of SC-19129 or its free acid, SC-19200, at all doses.

B. Relationship of Plasma Concentraton to Dosage:

Mean Cmax values (mcg/ml) for the low, medium and high dose males were 5.03 ± 0.48 (± standard error of the mean), 11.1 ± 1.4 and 23.2 ± 1.4 respectively on day 1, 6.48 ± 0.56, 13.9 ± 1.4 and 21.5 ± 1.6 on day 83 and 6.87 ± 0.68, 12.7 ± 1.8 and 27.7 ± 1.7 on day 182 (Table 3, Figure 2). Mean Cmax values for the low, medium and high dose females were 5.47 ± 0.48, 10.4 ± 0.8 and 24.9 ± 1.6 on day 1, 7.45 ± 0.59, 11.8 ± 2.5 and 24.4 ± 1.5 on day 83 and 6.51 ± 0.57, 16.9 ± 0.8 and 29.4 ± 0.9 on day 182 (Table 3, Figure 2). Mean AUC values (Table 4, Figure 3) closely paralleled the

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mean Cmax values with respect to dose dependent and time dependent trends for both sexes. Thus the plasma concentrations of SC-19200 increased as the dose was increased.

Mean plasma Cmax (Table 3, Figure 2) and AUC (Table 4, Figure 3) and mean normalized Cmax (Table 5, Figure 2) and normalized AUC (Table 6, Figure 3) values did not differ markedly nor in a consistent direction in one sex as compared to the other. The analysis of variance of the normalized Cmax (Table 7) and normalized AUC (Table 8) values likewise indicated no significant sex or dose effect. However the presence of a highly significant ($p < 0.001$, Tables 7-8) day*sex*dose interaction (see discussion below) in the overall analyses of variance required that further examination of the effect of sex and dose on plasma concentrations be based on separate comparisons within each day (Tables 9-10).

There were no significant dose or sex effects on normalized Cmax (Table 9) and normalized AUC (Table 10) values on day 1 and day 182, indicating dose proportionality on these days. Male normalized Cmax (Table 5) and normalized AUC (Table 6) values on day 83 were disproportionately high in the medium dose group, and disproportionately low in the high dose group, when compared to the low dose group. Also, on day 83 male normalized Cmax and normalized AUC means were appreciably higher (77% and 67% respectively) in the medium dose group and appreciably lower (33% and 36% respectively) in the high dose group, than the corresponding female means. The analyses of

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variance for day 83 reflected these differences as a significant sex*dose interaction (Tables 9-10) and the significant day*sex*dose interaction in the overall analysis of variance (Tables 7-8) was also probably due largely to these differences. Visual inspection of the Cmax and AUC versus dose curves (Figure 2, top row and Figure 3, top row, respectively) does not suggest any marked departure from dose proportionality on day 83 compared to days 1 and 182. It is concluded that plasma concentrations of SC-19200 were essentially proportional to dose during this study. The same conclusion was reached in an earlier study (3) in which the same doses were administered for 4 weeks.

C. Relationship of Plasma Concentration to Duration of Dosing:

The analyses of variance of the normalized Cmax (Table 7) and normalized AUC (Table 8) values indicated a significant ($p < 0.05$) effect of sampling day on plasma concentrations. However the significant day*sex*dose interaction complicated the interpretation of the significant day effect. Further evaluation of the effect of sampling day on the actual systemic exposure to SC-19200 was based on the Cmax and AUC without normalizaton for dose.

Plasma Cmax (Table 3, Figure 4) and plasma AUC (Table 4, Figure 4) values tended to increase between successive sampling days. However the increase of the day 182 over the day 1 values for 12 comparisons (2 sexes x 2 parameters x 3 dosage groups) was only 23.6 $\pm$ 16.9% (mean $\pm$ standard

deviation). In the high dose group, where dose accumulation would be most likely to occur, day 1 and day 182 mean Cmax and mean AUC values differed by less than 20%. Finally, only 2 out of 108 samples taken at 24 hours after dosing (dog H00990 and dog H00008, both on day 182) contained a measurable amount of SC-19200 (> 1.0 mcg/ml; Table 1) indicating that accumulation leading to sustained plasma concentrations of SC-19200 did not occur. It is concluded that plasma concentration profiles of SC-19200 were essentially constant across sampling days during this study.

IV. Conclusions

The plasma concentration data demonstrate that SC-19129 or its free acid, SC-19200, was absorbed at all dose levels by all dogs. Plasma Cmax and AUC values for SC-19200 increased with dose and, when normalized to the actual doses received by the diet admix route, were proportional to dose. Plasma Cmax and AUC values did not differ markedly between days 1, 83 and 182 and systemic exposure to SC-19200 was essentially constant throughout the study.

B10

V. Reference

1. Schmidt, R.E., J. Hill and G.L. Schoenhard. Method Development and Validation of the High Performance Liquid Chromatographic Assay for N-L-β-Aspartyl-L-Phenylalanine (βAP) in Dog Plasma. G.D. Searle & Co., Research and Development Division, MRC-842-0079, May, 1985.

2. Lester, B.J. and Dickie, B.C. Twenty-six Week Subchronic Toxicity Study in Dogs with SC-19129 admixed in the Diet. Hazleton Laboratories America, Inc., Madison, Wisconsin, Study No.6127-111, June, 1986.

3. Burton, E., I. Dressler, K. Hoglund and J. Hribar. Pharmacokinetics and Metabolism of [^{14}C]-SC-19129 in the Rhesus Monkey. Department of Drug Metabolism, Research and Development Division. G.D. Searle & Co., MRC-842-0056, July, 1985.

4. Burton, E. Evaluation of the Plasma Concentration Data from the Four Week Dietary Admix Toxicity Study of SC-19129 in the Dog, S.A. 2449. Research and Development Division, G.D. Searle & Co., May, 1985.

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Table 1

Individual Animal Plasma Concentrations of SC-19200 During the 26 Week Dietary Admix Toxicity Study of SC-19129 in the Dog, S.A. 2530

LOW DOSE (250 mg/kg)

Males

Treatment Day	Time (hours)	SC-19200 Plasma Concentrations (mcg/ml)[a] H00973	H00974	H00975	H00976	H00977	H00978	MEAN[b]	SEM[b]
1	3	3.52	2.26	2.63	2.86	5.06	1.74	3.01	0.48
	5	6.72[c]	3.94[c]	4.49[c]	5.54[c]	5.77[c]	3.16	4.94	0.54
	7	3.01	3.30	3.21	4.66	4.86	3.74[c]	3.80	0.32
	24	<1.00	<1.00	<1.00	<1.00	<1.00	<1.00	0	0
83	3	4.68	<1.00	2.26	3.83	3.82	2.78	2.90	0.68
	5	7.13[c]	3.34	6.12	6.15	6.79	4.03	5.59	0.63
	7	5.96	5.62[c]	7.12[c]	6.91[c]	7.98[c]	4.12[c]	6.28	0.55
	24	<1.00	<1.00	<1.00	<1.00	<1.00	<1.00	0	0
182	3	6.99	3.77	5.29	4.90	5.77	3.83	5.09	0.50
	5	<10.0	4.32	5.68	4.64	9.07[c]	<2.00	3.95	1.43
	7	7.73[c]	6.26[c]	7.62[c]	6.27[c]	7.67	4.26[c]	6.64	0.55
	24	<1.00	<1.00	<1.00	<1.00	<1.00	<1.00	0	0

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Table 1 (cont'd)

Individual Animal Plasma Concentrations of SC-19200 During the 26 Week Dietary Admix Toxicity Study of SC-19129 in the Dog, S.A. 2530

LOW DOSE (250 mg/kg)

Females

SC-19200 Plasma Concentrations (mcg/ml)[a]

Treatment Day	Time (hours)	H00979	H00980	H00981	H00982	H00983	H00984	MEAN[b]	SEM[b]
1	3	2.84	4.90[c]	3.44	4.18	4.49[c]	2.36	3.70	0.40
	5	5.19[c]	5.13	5.08	6.13	4.00	3.98	4.92	0.33
	7	4.27	4.90	4.72	7.79[c]	1.60	5.16[c]	4.74	0.81
	24	<1.00	<1.00	<1.00	<1.00	<1.00	<1.00	0	0
83	3	4.78	5.83	4.70	5.13	5.23	4.06	4.95	0.24
	5	6.14[c]	6.98	6.47	7.11	7.54[c]	6.42	6.78	0.21
	7	4.58	10.2[c]	6.65[c]	7.48[c]	7.42	6.71[c]	7.17	0.74
	24	<1.00	<1.00	<1.00	<1.00	<1.00	<1.00	0	0
182	3	3.53	3.88	3.07	4.91	5.41	4.00	4.13	0.36
	5	3.54	4.72	<5.00	5.77	<20.0	5.01	3.17	1.05
	7	4.45[c]	7.55[c]	6.75[c]	6.51[c]	8.33[c]	5.50[c]	6.51	0.57
	24	<1.00	<1.00	<1.00	<1.00	<1.43	<1.00	0	0

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Table 1 (cont'd)

Individual Animal Plasma Concentrations of SC-19200 During the 26 Week Dietary Admix Toxicity Study of SC-19129 in the Dog, S.A. 2530

MEDIUM DOSE (500 mg/kg)

Males

Treatment Day	Time (hours)	SC-19200 Plasma Concentrations (mcg/ml)[a] H00985	H00986	H00987	H00988	H00989	H00990	MEAN[b]	SEM[b]
1	3	6.71	11.9	9.98[c]	5.90[c]	9.47	10.0	8.99	0.92
	5	6.52	16.5[c]	9.93	5.56	10.1	12.6[c]	10.2	1.6
	7	10.8[c]	13.4	9.34	5.88	11.0[c]	8.87	9.68	1.03
	24	<1.00	<1.00	<1.00	<1.00	<1.00	<1.00	0	0
83	3	6.43	13.0	10.0	6.86	3.77	10.0	8.34	1.34
	5	10.8[c]	19.7[c]	13.9[c]	10.7[c]	13.0[c]	15.3[c]	13.9	1.4
	7	8.09	12.5	11.7	4.38	11.1	8.15	9.32	1.24
	24	<1.00	<1.00	<1.00	<1.00	<1.00	<1.00	0	0
182	3	9.63	14.7	9.62	6.98[c]	11.6[c]	11.9	10.7	1.1
	5	8.78	16.5	12.7[c]	6.67	11.3	13.2[c]	11.5	1.4
	7	11.0[c]	20.4[c]	10.7	5.41	8.82	9.48	11.0	2.1
	24	<1.00	<1.25	<1.00	<1.00	<1.00	1.20	0.20	0.20

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Table 1 (cont'd)

Individual Animal Plasma Concentrations of SC-19200 During the 26 Week Dietary Admix Toxicity Study of SC-19129 in the Dog, S.A. 2530

MEDIUM DOSE (500 mg/kg)

Females

Treatment Day	Time (hours)	SC-19200 Plasma Concentrations (mcg/ml)[a] H00991	H00992	H00993	H00994	H00995	H00996	MEAN[b]	SEM[b]
1	3	8.97	10.2	8.47	7.08[c]	6.61	7.87	8.20	0.53
	5	9.99[c]	10.3	10.0[c]	4.89	11.2[c]	11.4	9.63	0.96
	7	6.44	12.6[c]	5.55	1.95	11.0	11.7[c]	8.21	1.72
	24	<1.00	<1.00	<1.00	<1.00	<1.00	<1.00	0	0
83	3	8.80	10.3	<1.00	10.5	10.3	7.81	7.95	1.65
	5	12.6[c]	14.7[c]	<1.00	18.3[c]	13.0[c]	12.1[c]	11.8	2.5
	7	9.76	12.1	<1.00	11.3	10.2	5.98	8.22	1.86
	24	<1.00	<1.00	<1.00	<1.00	<1.00	<1.00	0	0
182	3	8.11	9.57	5.95	13.1	8.76	9.08	9.10	0.95
	5	13.3[c]	13.6	15.1	16.3	14.2	16.1	14.8	0.6
	7	12.4	15.9[c]	18.0[c]	17.3[c]	18.1[c]	18.8[c]	16.8	1.0
	24	<1.00	<1.00	<1.00	<1.00	<1.00	<1.00	0	0

B15

Table 1 (cont'd)

Individual Animal Plasma Concentrations of SC-19200 During the 26 Week Dietary Admix Toxicity Study of SC-19129 in the Dog, S.A. 2530

HIGH DOSE (1000 mg/kg)

Males

SC-19200 Plasma Concentrations (mcg/ml)[a]

Treatment Day	Time (hours)	H00001	H00002	H00003	H00997	H00998	H00999	MEAN[b]	SEM[b]
1	3	12.8	18.4	13.1	15.5	13.9	15.8	14.9	0.9
	5	22.1	21.0[c]	21.4	20.6	24.3[c]	18.9[c]	21.4	0.7
	7	23.8[c]	17.6	22.3[c]	28.7[c]	24.1	13.8	21.7	2.2
	24	<1.00	<1.00	<1.00	<1.00	<1.00	<1.00	0	0
83	3	12.7	12.7	15.1	15.8	17.5	10.8	14.1	1.0
	5	21.4[c]	20.0[c]	22.4	22.6	25.8[c]	14.9[c]	21.2	1.5
	7	20.6	13.3	22.9[c]	24.1[c]	23.2	12.6	19.5	2.1
	24	<1.00	<1.00	<1.00	<1.00	<1.00	<1.00	0	0
182	3	18.6	13.7	16.2	17.0	19.6	12.7	16.3	1.1
	5	26.0[c]	23.6	26.4[c]	32.5[c]	27.2[c]	20.9[c]	26.1	1.6
	7	23.7	30.7[c]	23.8	30.7	29.8	d	27.7	1.6
	24	<1.00	<1.00	<1.00	<1.00	<1.00	<1.00	0	0

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Table 1 (cont'd)

Individual Animal Plasma Concentrations of SC-19200 During the 26 Week Dietary Admix Toxicity Study of SC-19129 in the Dog, S.A. 2530

HIGH DOSE (1000 mg/kg)

Females

Treatment Day	Time (hours)	SC-19200 Plasma Concentrations (mcg/ml)[a] H00004	H00005	H00006	H00007	H00008	H00009	MEAN[b]	SEM[b]
1	3	14.4	14.0	14.6	17.2	14.4	16.7	15.2	0.6
	5	19.3[c]	25.0[c]	23.4[c]	24.5	23.1[c]	30.0[c]	24.2	1.4
	7	18.0	19.4	21.2	28.4[c]	22.8	17.2	21.2	1.7
	24	<1.00	<1.00	<1.00	<1.00	<1.00	<1.00	0	0
83	3	16.4	16.2	23.6[c]	22.2	17.8	16.6	18.8	1.3
	5	22.1[c]	23.2[c]	21.6	27.4	23.4[c]	22.2[c]	23.3	0.9
	7	21.3	18.2	20.0	31.7[c]	17.4	19.0	21.3	2.2
	24	<1.00	<1.00	<1.00	<1.00	<1.00	<1.00	0	0
182	3	14.7	14.5	16.3	16.0	13.1	17.6	15.4	0.6
	5	19.9	24.8	25.7[c]	33.1	23.2	27.7[c]	25.7	1.8
	7	27.7[c]	29.7[c]	27.3	33.2[c]	27.9[c]	30.3[c]	29.4	0.9
	24	<1.00	<1.00	<1.00	<1.00	1.18	<1.00	0.20	0.20

a The standard volume of plasma used in the assay is 1.0 ml. The sensitivity limit of the assay using this volume is 1.0 mcg/ml. In some cases less than 1.0 ml of plasma was available and samples were brought to the 1.0 ml volume by adding plasma from untreated animals prior to assay. The sensitivity limit of the assay for these diluted samples is inversely proportional to the fraction of 1.0 ml available for assay. Samples with concentrations below the sensitivity limit of the assay are reported as less than (<) the appropriate value.

b The mean ± standard error of the mean (SEM) was calculated from the individual values for 6 animals. Values below the sensitivity limit of the assay were treated as zeros for these calculations.

c The indicated value is the maximum plasma concentration (Cmax) for the animal.

d Sample not submitted for analysis.

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Table 2

Indvidual Animal AUC Values
During the Twenty-Six Week
Dietary Admix Toxicity Study of
SC-19129 in the Dog, S.A. 2530

Treatment Group	Animal Number	Sex	AUC ([mcg/ml]hour) Day 1	Day 83	Day 182
Low Dose (250 mg/kg)	H00973	Male	25.3	31.9	25.2
	974		16.8	12.3	24.3
	975		18.8	25.0	32.2
	976		22.9	28.8	27.8
	977		29.1	31.1	40.2
	978		14.4	19.1	13.8
	979	Female	21.8	28.8	20.4
	980		27.4	38.7	26.7
	981		23.5	31.3	14.4
	982		30.5	34.5	30.3
	983		20.8	35.6	21.9
	984		19.0	29.7	25.5
Medium Dose (500 mg/kg)	985	Male	40.6	45.8	52.6
	986		76.2	84.4	90.2
	987		54.2	64.5	60.2
	988		31.8	42.9	36.2
	989		54.9	46.5	60.4
	990		59.1	63.8	67.4
	991	Female	48.8	57.0	59.3
	992		58.7	67b3	67.0
	993		46.7	0	63.1
	994		29.4	74.2	82.7
	995		49.9	62.0	68.4
	996		54.2	49.7	73.7

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Table 2 (cont'd)

Treatment Group	Animal Number	Sex	AUC ([mcg/ml]hour) Day 1	Day 83	Day 182
High Dose (1000 mg/kg)	997	Male	109	109	138
	998		107	119	133
	999		91.1	69.4	73.6
	001		100	95.2	122
	002		106	85.1	112
	003		97.9	105	117
	004	Female	92.6	107	104
	005		104	105	116
	006		105	122	119
	007		120	142	139
	008		105	109	109
	009		119	105	130

a Areas under the plasma concentration-time curves from 0 to 7 hours calculated by the trapezoidal rule. The concentrations of SC-19200 at 0 hours were assumed to be zero for these calculations. The above values are rounded to 3 significant digits.

b All concentration values for this dog on this day were below the sensitivity limit of the assay (see Table 1).

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Table 3

Maximum Plasma Concentrations (Cmax) of SC-19200 During the Twenty-Six Week Dietary Admix Toxicity Study of SC-19129 in the Dog, S.A. 2530

Treatment Group	Sex	Cmax (mcg/ml)[a] Day 1	Day 83	Day 182
Low Dose (250 mg/kg)	Male	5.03 ± 0.48	6.48 ± 0.56	6.87 ± 0.68
	Female	5.47 ± 0.48	7.45 ± 0.59	6.51 ± 0.57
Medium Dose (500 mg/kg)	Male	11.1 ± 1.4	13.9 ± 1.4	12.7 ± 1.8
	Female	10.4 ± 0.8	11.8 ± 2.5	16.9 ± 0.8
High Dose (1000 mg/kg)	Male	23.2 ± 1.4	21.5 ± 1.6	27.7 ± 1.7
	Female	24.9 ± 1.6	24.4 ± 1.5	29.4 ± 0.9

[a] Values are the mean ± SEM of 6 animals. Individual animal values are in Table 1.

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Table 4

Areas Under the Plasma Concentration-Time Curves (AUC) for SC-19200 During the Twenty-Six Week Dietary Admix Toxicity Study of SC-19129 in the Dog, S.A. 2530

Treatment Group	Sex	AUC [(mcg/ml)hours][a] Day 1	Day 83	Day 182
Low Dose (250 mg/kg)	Male	21.2 ± 2.3	24.7 ± 3.1	27.3 ± 3.6
	Female	23.8 ± 1.8	33.1 ± 1.6	23.2 ± 2.3
Medium Dose (500 mg/kg)	Male	52.8 ± 6.3	58.0 ± 6.5	61.2 ± 7.3
	Female	48.0 ± 4.1	51.7 ± 10.9	69.0 ± 3.4
High Dose (1000 mg/kg)	Male	102 ± 3	97.1 ± 7.3	116 ± 9
	Female	108 ± 4	115 ± 6	120 ± 5

[a] Values are the mean ± SEM of 6 animals. The means and standard errors were calculated using unrounded AUC values. Individual animal values (rounded) are in Table 2.

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Table 5

Maximum Plasma Concentrations Normalized
for Dose Received During the
Twenty-Six Week Dietary Admix Toxicity Study of
SC-19129 in the Dog, S.A. 2530

Treatment Group	Sex	Normalized Cmax (mcg/ml)[a] Day 1	Day 83	Day 182
Low Dose (250 mg/kg)	Male	8.15 ± 0.80	11.1 ± 1.0	7.69 ± 0.98
	Female	8.17 ± 0.76	10.3 ± 1.0	6.03 ± 0.44
Medium Dose (500 mg/kg)	Male	8.08 ± 0.58	13.9 ± 0.5	6.15 ± 1.36
	Female	10.1 ± 1.0	7.85 ± 1.6	8.44 ± 0.74
High Dose (1000 mg/kg)	Male	7.52 ± 0.65	6.63 ± 0.96	6.59 ± 0.90
	Female	8.37 ± 0.87	9.92 ± 1.20	8.38 ± 0.75

[a] Values are the mean ± SEM of 6 animals. The individual animal Cmax values (Table 1) were multiplied by 250 ÷ dose received (reference 2, Appendix D) to obtain the normalized Cmax values.

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Table 6

Areas Under the Plasma Concentration-Time Curves for SC-19200, Normalized for Dose Received, During the Twenty-Six Week Dietary Admix Toxicity Study of SC-19129 in the Dog, S.A. 2530

Treatment Group	Sex	Normalized AUC [(mcg/ml)hours][a] Day 1	Day 83	Day 182
Low Dose (250 mg/kg)	Male	34.4 ± 3.9	43.5 ± 7.2	29.7 ± 4.0
	Female	35.9 ± 3.7	46.1 ± 3.9	22.2 ± 3.0
Medium Dose (500 mg/kg)	Male	39.3 ± 4.0	57.7 ± 2.2	29.5 ± 5.6
	Female	46.2 ± 4.3	34.5 ± 7.0	34.7 ± 3.3
High Dose (1000 mg/kg)	Male	33.1 ± 2.7	29.8 ± 4.2	27.4 ± 3.9
	Female	36.1 ± 2.9	46.5 ± 5.1	34.1 ± 3.1

[a] Values are the mean ± SEM of 6 animals. The individual animal values (Table 2) were multiplied by 250 ÷ dose received (reference 2, Appendix D) to obtain the normalized AUC values.

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Table 7

Summary of the Analysis of Variance Results
for Dose Proportionality and
Steady State Attainment

Normalized Cmax

Source	DF	Sum of Squares	F-Test [a]	p-Value
Sex	1	1.04	0.14	0.7123
Dose	2	25.77	1.71	0.1977
Sex*Dose	2	43.04	2.86	0.0731
Error (Animal)	30	225.87	--	--
Day	2	136.99	16.46	0.0001*
Day*Sex	2	26.09	3.14	0.0507
Day*Dose	4	37.28	2.24	0.0753
Day*Sex*Dose	4	123.21	7.40	0.0001*
Error (Day)	60	249.64	--	--

a
Sex, Dose and Sex*Dose effects tested against Error (Animal) sum of squares. All other effects tested against Error (Day) sum of squares.

*
Significant at the 0.05 level.

Table 8

Summary of the Analysis of Variance Results
for Dose Proportionality and
Steady State Attainment

Normalized AUC

Source	DF	Sum of Squares	F-Test [a]	p-Value
Sex	1	47.25	0.31	0.5790
Dose	2	710.51	2.37	0.1112
Sex*Dose	2	786.44	2.62	0.0895
Error (Animal)	30	4505.63	--	--
Day	2	3279.53	17.61	0.0001*
Day*Sex	2	116.86	0.63	0.5374
Day*Dose	4	465.22	1.25	0.3000
Day*Sex*Dose	4	2097.65	5.63	0.0006*
Error (Day)	60	5586.18	--	--

a
Sex, Dose and Sex*Dose effects tested against Error (Animal) sum of squares. All other effects tested against Error (Day) sum of squares.

*
Significant at the 0.05 level.

B25

Table 9

Summary of the Analysis of Variance Results
for Effect of Sex and Dose Within Days

Normalized Cmax

Day 1

Source	DF	Sum of Squares	F-Test [a]	p-Value
Sex	1	8.57	2.29	0.1410
Dose	2	9.14	1.22	0.3097
Sex*Dose	2	6.24	0.83	0.4449
Error	30	112.46	--	--

Day 83

Source	DF	Sum of Squares	F-Test [a]	p-Value
Sex	1	12.74	1.77	0.1930
Dose	2	51.45	3.58	0.0404*
Sex*Dose	2	132.23	9.20	0.0008*
Error	30	215.64	--	--

Day 182

Source	DF	Sum of Squares	F-Test [a]	p-Value
Sex	1	5.82	1.18	0.2853
Dose	2	2.46	0.25	0.7799
Sex*Dose	2	27.77	2.83	0.0751
Error	30	147.41	--	--

* Significant at the 0.05 level.

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Table 10

Summary of the Analysis of Variance Results
for Effects of Sex and Dose Within Days

Normalized AUC

Day 1

Source	DF	Sum of Squares	F-Test [a]	p-Value
Sex	1	130.64	1.67	0.2067
Dose	2	489.41	3.12	0.0587
Sex*Dose	2	46.37	0.30	0.7462
Error	30	2352.69	--	--

Day 83

Source	DF	Sum of Squares	F-Test [a]	p-Value
Sex	1	14.79	0.09	0.7668
Dose	2	435.51	1.32	0.2827
Sex*Dose	2	2467.82	7.47	0.0023*
Error	30	4955.87	--	--

Day 182

Source	DF	Sum of Squares	F-Test [a]	p-Value
Sex	1	18.68	0.20	0.6568
Dose	2	250.80	1.35	0.2741
Sex*Dose	2	369.90	1.99	0.1539
Error	30	2738.25	--	--

* Significant at the 0.05 level.

B27

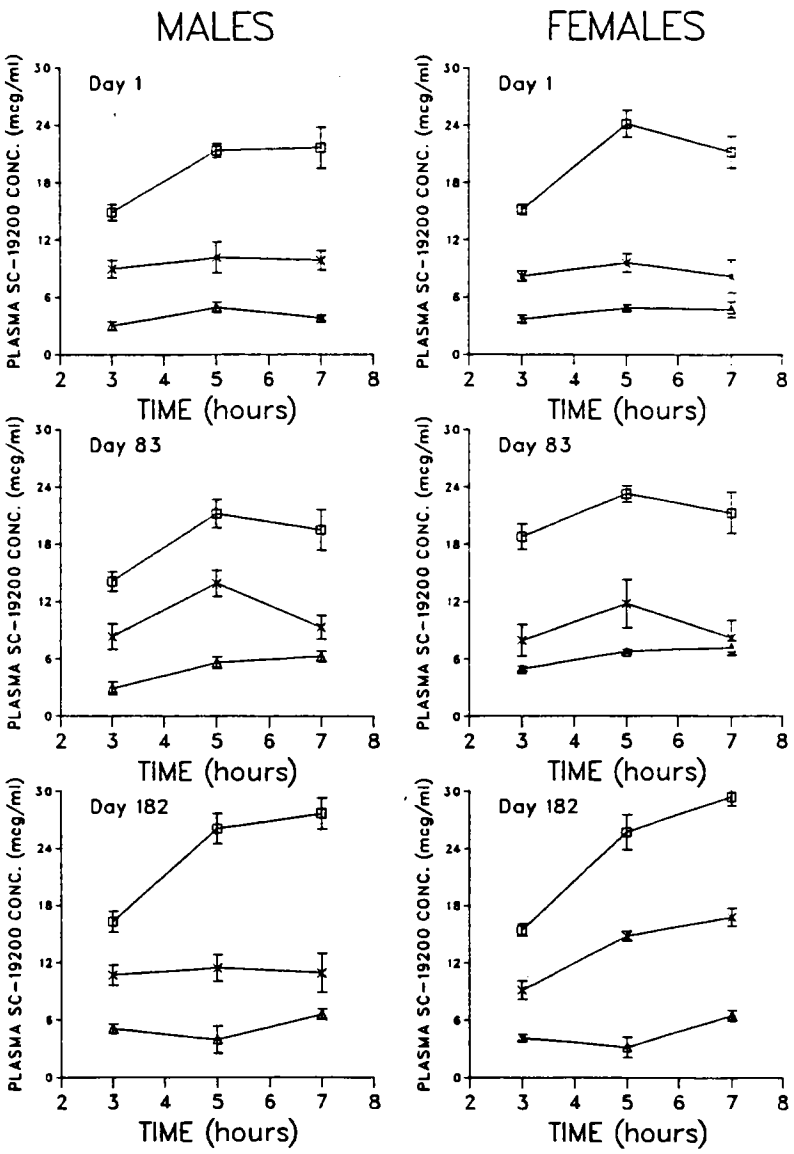

Figure 1. Mean plasma concentrations of SC-19200 for doses of 250 (△), 500 (x) and 1000 (□) mg of SC-19129 per kg body weight during study S.A. 2530. The subplot identities are: top row, day 1; middle row, day 83; bottom row, day 182; left column, males; right column, females. Ordinate: concentration of SC-19200 in plasma (mcg/ml). Abscissas: time after initiation of dose administration (hours). The vertical bars indicate the standard errors of the means.

628

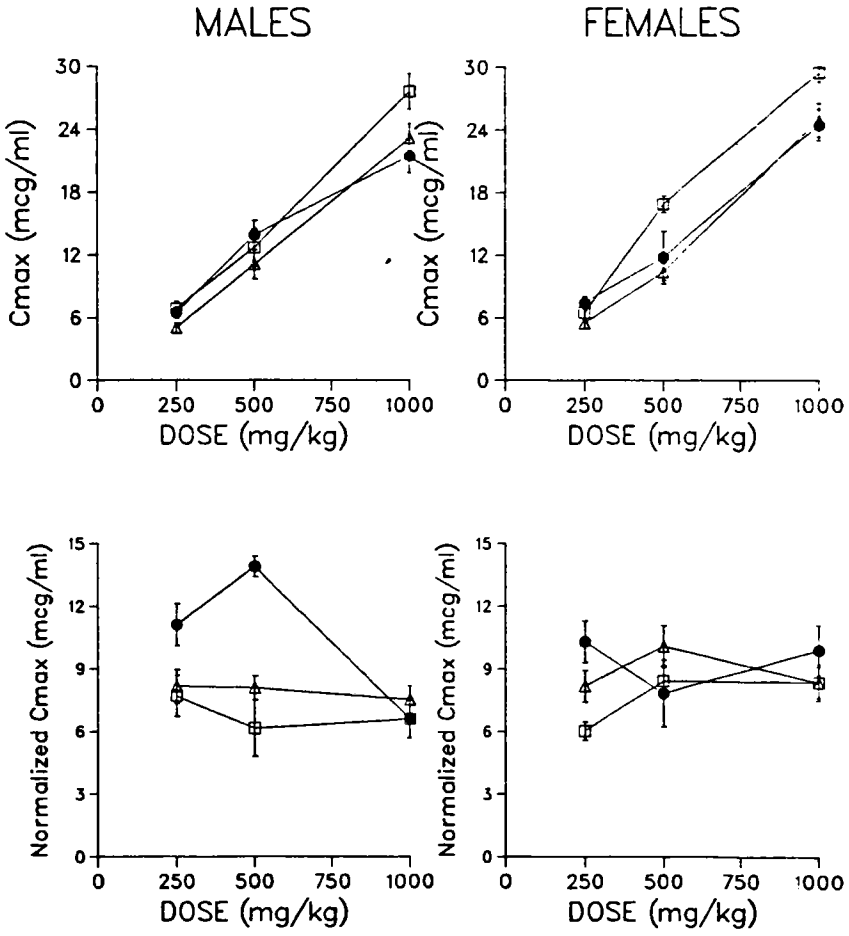

Figure 2. Mean peak plasma concentration (Cmax) and normalized Cmax values for SC-19200 on day 1 (Δ) day 83 (●) and day 182 (□) of study S.A. 2530. The subplot identities are: top row, Cmax (see Table 3); bottom row, normalized Cmax (see Table 4); left column, males; right column, females. Ordinates: mean Cmax (mcg/ml) or normalized Cmax (mcg/ml) of SC-19200. Abscissa: intended dose (mg/kg). The vertical bars indicate the standard errors of the means.

B29

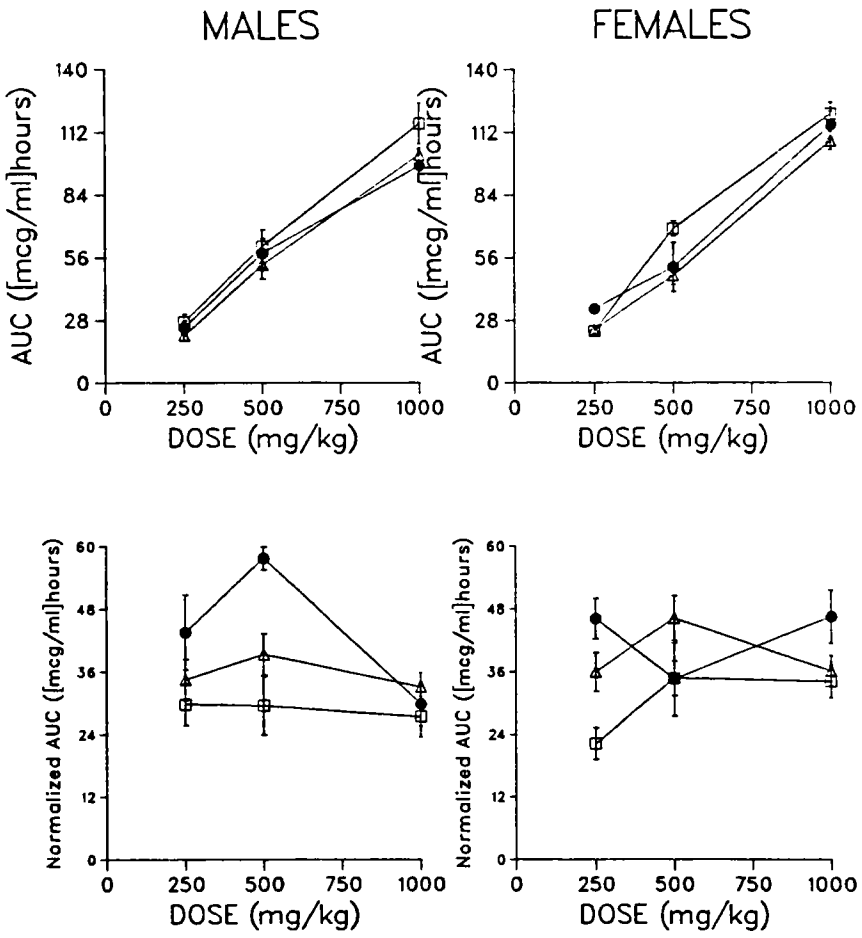

Figure 3. Mean plasma AUC and normalized AUC values for SC-19200 on day 1 (Δ), day 83 (●) and day 182 (□) of study S.A. 2530. The subplot identities are: top row, AUC (see Table 5); bottom row normalized AUC (see Table 6); left column, males; right column, females. Ordinates: mean AUC ([mcg/ml]hours) or normalized AUC ([mcg/ml]hours). Abscissas: intended dose (mg/kg). The vertical bars indicate the standard errors of the mean.

630

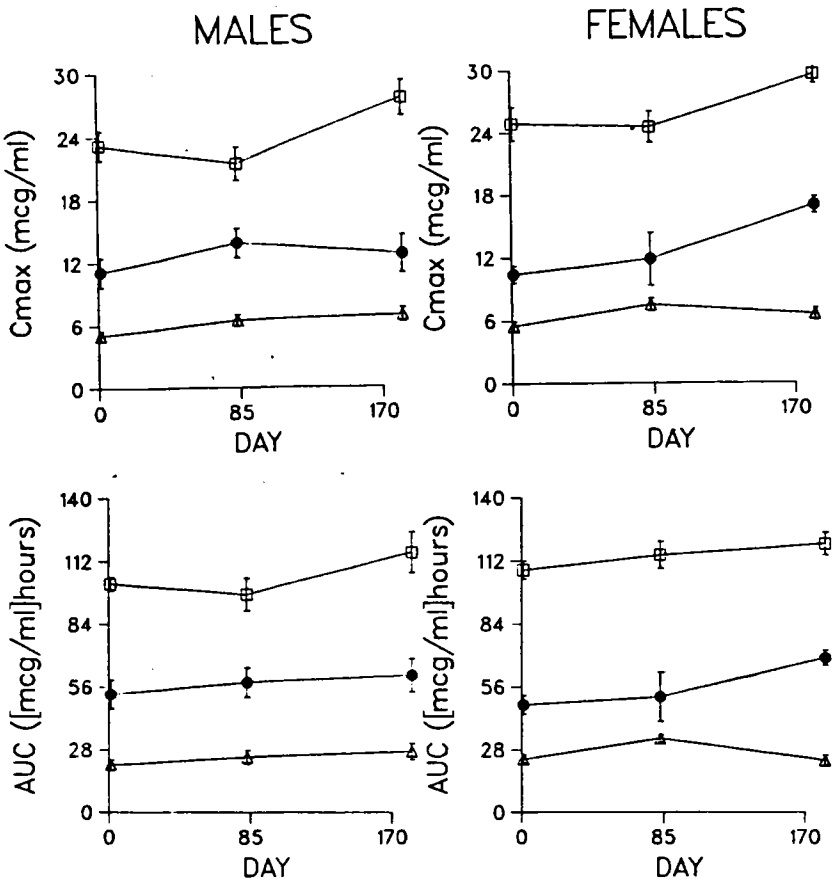

Figure 4. Mean peak plasma concentrations (Cmax) and AUC values for SC-19200 for doses of 250 (△), 500 (●) and 1000 (□) mg of SC-19200 per kg body weight during study S.A. 2530. The subplot identities are: top row, Cmax values; bottom row, AUC values; left column, males; right column, females. Ordinates: mean Cmax (mcg/ml) or mean AUC ([mcg/ml]hours) for plasma SC-19200. Abscissas: study day. The vertical bars indicate the standard errors of the means.