8EHQ-0195-13309

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Regulatory Affairs and Toxic Substances Compliance
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COMPANY SANITIZED

Ciba-Geigy Corporation
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Ardsley, New York 10502-2699
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January 13, 1995

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Document Processing Center (7407)
(Attn.: Section 8(e) Coordinator)
Office of Pollution Prevention and Toxics
U. S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

RE.: **TSCA Section 8(e) Notice; FAT 45'169/A**

Dear Section 8(e) Coordinator:

Ciba-Geigy Corporation (Ciba) requests that the chemical substance identity information bracketed in this letter be treated as Confidential Business Information. We enclose a sanitized copy of this letter for the public file.

In accordance with EPA's March 16, 1978, policy statement on Section 8(e) reporting under the Toxic Substances Control Act and EPA's June 1991 TSCA Section 8(e) Reporting Guide, Ciba wishes to bring to your attention kidney effects seen in a 28-Day Oral Toxicity Study in Rats with FAT 45'169/A. Chemically, FAT 45'169/A is [ ]. The substance may be referred to generically in the public file as "Naphthalenesulfonic acid, azo substituted naphthalene amino triazinyl aminophenyl azo substituted naphthalene amino substituted triazin."

FAT 45'169/A was administered by gavage at daily doses of 0, 10, 50, 200, and 1000 mg/kg to groups of five rats per sex for 28 days. After termination of the treatment period, half of the animals of the control and high dose groups were observed for an additional 14 days (recovery period). Standard necropsy procedures were performed on all animals in the study. No deaths occurred prior to scheduled times of termination and there were no remarkable signs of clinical toxicity observed.

At the 1000 mg/kg dose, histopathological examination revealed evidence of nephrotoxicity. Renal cortical tubular basophilia and degeneration were observed along with an increased severity of tubular hyaline droplets in the high dose group animals. These kidney lesions were still evident after the 14-day recovery period. Concurrent with these histopathological

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findings were increases in kidney weights and alterations in clinical chemistry parameters, including increases in creatinine and uric acid plasma concentrations. Also observed in high dose animals were increases in liver weights and phospholipid concentrations. However, target organ effects on the liver are doubtful in the absence of histopathological findings.

A "no-observed-adverse-effect level" (NOAEL) of 200 mg/kg/day was identified in this study.

A copy of the final report, entitled "Subacute 28-Day Oral Toxicity (Gavage) Study with FAT'169/A in the Rat" is enclosed (366 pages).

The subject chemical substance is a reactive dye intended for dying cellulosic fibers. A PMN for this substance was filed in 1994 (P94-1798) and a Notice of Commencement was submitted on November 3, 1994.

In response to these findings, Ciba will reflect this information in the Material Safety Data Sheet, thereby notifying relevant workers and potential customers in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200).

Please contact the undersigned if you require additional information.

Very truly yours,

A. Di Battista

Anthony Di Battista

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RCC PROJECT 372881

SUBACUTE 28-DAY ORAL TOXICITY (GAVAGE) STUDY WITH

FAT 45'169/A

IN THE RAT

REPORT

Authors: Dr. A. Dotti, H. Luetkemeier, K. Biedermann
Dr. med. vet. M.F. Martland

Date: 01-DEC-1994

RCC
Group

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SCHEDULE

Delivery of Animals	06-JUN-1994
Acclimatization	07-JUN-1994 to 13-JUN-1994
Administration/Treatment	14-JUN-1994 to 11-JUL-1994
Recovery	12-JUL-1994 to 25-JUL-1994
Termination	Allocation A animals: 12-JUL-1994 Allocation B animals: 26-JUL-1994
Report	01-DEC-1994

ARCHIVING

The Research & Consulting Company Ltd. (CH-4452 Itingen) will archive the following data for at least 10 years:

Protocol, report, raw data, specimens of laboratory investigations, specimens and slides of pathology and histopathology and the test article reference sample. No data will be discarded without the sponsor's consent.

PREFACE

GENERAL

Title	Subacute 28-day oral (gavage) toxicity study with FAT 45'169/A in rats.
Sponsor	CIBA-GEIGY AG Dr. B. Bruttel Produktesicherheit TF 5.31 CH - 4002 Basel
Monitoring Scientist	E. Rüdin RCC, Registration & Consulting Company Ltd CH-4452 Itingen/Switzerland
Testing Facilities	RCC, Research and Consulting Company, Ltd, and RCC Umweltchemie AG 4452 Itingen and BRL, Biological Research Laboratories, Ltd. Wölferstrasse 4, 4414 Füllinsdorf / Switzerland Preclinical Safety Consultants Est. 7 Earning Street / Godmanchester Cambridgeshire, PE18 8JD, England
RCC Project Number	372881
Test Article	FAT 45'169/A
Test System	Rat

PROJECT STAFF

Study Director	Dr. A. Dotti
Deputy for the Study Director	C.N. Crouch
Technical Coordinator	P. Althaus
Clinical Laboratory Investigations	H. Luetkemeier
Analytical Chemistry	K. Biedermann
Necropsy/Histotechnique	Dr. J. Wilson / K. Weber
Histopathology/Reporting	Dr. M.F. Martland
EDP and Statistics	TEC, Terrier EDV Consulting AG Schneckelerstr. 9 CH-4414 Füllinsdorf/Switzerland

QUALITY ASSURANCE STATEMENT

RCC, RESEARCH & CONSULTING COMPANY LTD, CH-4452 ITINGEN

PROJECT NUMBER	:	372881
TEST ARTICLE	:	FAT 45'169/A
STUDY DIRECTOR	:	Dr. A. Dotti
TITLE	:	Subacute 28-day oral (gavage) toxicity study with FAT 45'169/A in the rat.

The conduct of this study was subjected to periodic inspections and the report audited by the RCC Quality Assurance Unit. The dates are given below.

Dates of QAU Inspections / Audits	Dates of Reports to the Study Director and to Management
06. 06. 1994	06. 06. 1994
07. 06. 1994	07. 06. 1994
14. 06. 1994	14. 06. 1994
21. 06. 1994	21. 06. 1994
28. 06. 1994	28. 06. 1994
12. 07. 1994	12. 07. 1994
25. 07. 1994	25. 07. 1994
09. 11. 1994	
10. 11. 1994	
16. 11. 1994	
18. 11. 1994	
22. 11. 1994	
23. 11. 1994	23. 11. 1994

Manager, Quality Assurance Unit

Dr. G. Menne

.....

date: December 05, 1994

PROJECT STAFF SIGNATURES

Study Director — Dr. A. Dotti

.....
date: December 01, 1994

Deputy for the Study Director — C.N. Crouch

.....
date: November 23, 1994

Technical Coordinator — P. Althaus

.....
date: 23-NOV-94

Clinical Laboratory Investigations — for H. Luetkemeier

.....
date: November 23, 1994

Analytical Chemistry — K. Biedermann

.....
date: November 23, 1994

Necropsy/Histotechnique — Dr. J. Wilson / K. Weber

.....
date: 23.Nov.94

Histopathology/Reporting — for Dr. M.F. Martland

.....
date: 23.Nov.94

TEST GUIDELINES

The study procedures described in this report conform with the following guidelines:

"Repeated-Dose Oral Toxicity" OECD Guidelines for the Testing of Chemicals, Section 4, Health Effects, Number 407, May 12, 1981.

Directive 92/69/EEC, B.7. "Subacute Toxicity-Oral", July 31, 1992.

Revised Japanese Chemical Substance Law (1987) according to the notification of December 9, 1986 by EA, Environmental Agency (No. 700); MHW, Ministry of Health and Welfare (No. 1039) and MITI, Ministry of International Trade and Industry (No. 1014).

SUMMARY OF PROTOCOL DEVIATIONS

- From the report, only the original version will be archived.
- Body weights during weeks 4 of treatment and 2 of the recovery period were recorded twice.
- Preclinical Safety Consultants Est. was a testing facility of the study.

GOOD LABORATORY PRACTICE

STATEMENT OF COMPLIANCE / GLP GUIDELINES

RCC PROJECT NUMBER	:	372881
TEST ARTICLE	:	FAT 45'169/A
STUDY DIRECTOR	:	Dr. A. Dotti
TITLE	:	Subacute 28-day oral (gavage) toxicity study with FAT 45'169/A in the rat.

The study described in this report was conducted in compliance with the following Good Laboratory Practice Standards:

Environmental Protection Agency; Good Laboratory Practice Standards; Final Rule, U.S.A., Federal Register, Vol. 54, No. 158, August 17, 1989.

OECD Principles of Good Laboratory Practice, Paris, France, adopted May 12, 1981.

Good Laboratory Practice (GLP) in Switzerland, Procedures and Principles, March 1986.

MITI 1984; Chemical Substances Control law. Japanese Directive. Kanpogyo No. 39 Environmental Agency, Kikyoku No. 85, 31 March 1984.

There were no circumstances that may have affected the quality or integrity of the data presented.

Study Director — Dr. A. Dotti

date: December 01, 1994

Managing Director — A. Eichenberger

date: Mon - 21 - 1994

SUMMARY (CONT'D)

ORGAN WEIGHTS, ORGAN TO BODY WEIGHT AND ORGAN TO BRAIN WEIGHT RATIOS

Slight increases in kidneys and liver weights were noted in the males of the highest dose group (1000 mg/kg) at the end of the treatment period. These findings were considered to be a slight effect of treatment with the test article and respected the histopathological findings in the kidneys or the increase in total cholesterol in clinical biochemistry data, respectively.

MACROSCOPIC FINDINGS

There was a general body discoloration (reddish) in all animals treated at 1000 mg/kg. Reddish discoloration of the kidneys and of the mesenteric lymph nodes was also noted in all animals dosed at 200 mg/kg.

MICROSCOPIC FINDINGS

At 1000 mg/kg, there was histopathological evidence of nephrotoxicity in both sexes in the form of increased renal cortical tubular basophilia and degeneration. Increased severity of tubular hyaline droplets was apparent in the males and red tubular hyaline droplets were also present in the females. The kidneys lesions were still apparent after a 14-day treatment free recovery period.
In addition, cluster of foamy macrophages containing red pigment droplets were found in the lungs of two male rats. One male still showed the lesion after the 14-day recovery period. In the absence of any accompanying inflammation these were considered to be due to a systemic accumulation of compound in the pulmonary macrophages rather than an inhalation reaction.

SUMMARY

In this subacute toxicity study, FAT 45'169/A was administered daily by gavage to SPF-bred Wistar rats of both sexes at dose levels of 0, 10, 50, 200 and 1000 mg/kg body weight/day for a period of 28 days.
After termination of the treatment period half of the animals of the control group and of the high dose group were observed for a further 14-day treatment-free recovery period.

RESULTS

MORTALITY AND CLINICAL SIGNS

No test article related deaths or clinical signs of reaction to treatment were noted.

FOOD CONSUMPTION AND BODY WEIGHTS

Up to and including the highest dose level of 1000 mg/kg, there were no test article related effects neither on the food consumption nor on the body weight development of the animals.

OPHTHALMOSCOPIC EXAMINATIONS

No test article related abnormal findings were noted.

HEMATOLOGY

The hematology parameters assessed gave no indications of test article related adverse effects.

CLINICAL BIOCHEMISTRY

The plasma samples of the animals dosed at 1000 mg/kg collected at the end of treatment showed a pink to deep pink discoloration. This finding was considered to be caused by treatment with the test article. Generally, the differences noted from the control values were only of slight nature and were considered to suggest metabolic adaptation without any toxicological significance. However, some differences in group 5 (1000 mg/kg) - increased creatinine, uric acid and phosholipid levels - could be correlated to the results of the histopathological examination of the kidneys which indicated nephrotoxicity at this dose level. In addition, the slight increase in total cholesterol in the male animals was considered to correlated with the slight increase liver weight noted in these animals.

URINALYSIS

None of the findings noted were considered to be of toxicological significance.

Test article related discoloration of the urine was noted in the animals of the highest dose group (1000 mg/kg). This finding was still present at the end of the 14-day recovery period.

OBJECTIVE

PURPOSE AND RATIONALE

The purpose of this oral toxicity (gavage) study was to assess the cumulative toxicity of FAT 45'169/A when administered daily to rats by oral ingestion for a period of 28 days, followed by a 14-day treatment-free recovery period.

This study should provide a rational basis for the toxicologic risk assessment in man. The results of this study should indicate potential target organs.

MATERIALS AND METHODS

Experimental Design and General Conduct

TEST ARTICLE (according to information provided by the sponsor)

Identification	FAT 45'169/A
Synonyma	Reactive Red DER 7650
Description	dark red powder
Batch number	1/2, 94
Purity	approx. 60%
Stability of test article	Expiration date: April, 1998
Stability of test article dilution	At least for two hours
Instructions for test article storage	at room temperature in the dark
Safety precautions	Gloves, goggles and face mask were sufficient to assure health and safety of the personnel.

ASSESSMENT

In this subacute toxicity study, FAT 45'169/A was administered daily by gavage to SPF-bred Wistar rats of both sexes at dose levels of 0, 10, 50, 200 and 1000 mg/kg body weight/day for a period of 28 days.
After termination of the treatment period half of the animals of the control group and of the high dose group were observed for a further 14-day treatment-free recovery period.

Up to and including the highest dose level of 1000 mg/kg, there were no test article related mortalities or clinical signs of reaction to treatment or effects on the food consumption and body weight gain of the animals. Ophthalmoscopic examination as well as the assessment of the hematology and urinalysis parameters gave no indications of test article related effects.

At 1000 mg/kg, general body discoloration (reddish) was noted at terminal macroscopical examination. Histopathological examination gave evidence of nephrotoxicity in both sexes in the form of increased renal cortical tubular basophilia and degeneration. Increased severity of tubular hyaline droplets was apparent in the males and red tubular hyaline droplets were also present in the females. The kidneys lesions were still present after the 14-day treatment free recovery period. The differences noted in the assessment of the clinical biochemistry parameters, in particular the increase of creatinine, uric acid and phospholipid plasma levels, and the increase of the kidneys weight in the male animals were considered to correlated with the data of the histopathological examination and to indicate the kidneys as a target organ at this dose level. In addition, slightly increased total cholesterol and liver weight was noted in the males of this dose group. Cluster of foamy macrophages containing red pigment droplets were found in the lungs of two male rats. One male still showed the lesion after the 14-day recovery period. In the absence of any accompanying inflammation these were considered to be due to a systemic accumulation of compound in the pulmonary macrophages rather than an inhalation reaction.

At 200 mg/kg, reddish discoloration of the kidneys and of the mesenteric lymph nodes was noted at terminal necropsy. No histopathological counterparts were noted.

Based upon the results obtained in this study, the "No-observed-effect level" (NOEL) of FAT 45'169/A for male and female rats was 50 mg/kg body weight/day whereas the "No-observed adverse effect level" (NOAEL) was 200 mg/kg body weight/day in consideration that the reddish discoloration of the kidneys and mesenteric lymph nodes was indicated as a passive coloration by the test article without toxicological significance.

TREATMENT

Method	Oral by gavage
Rationale	Accidental oral ingestion is a possible route of human exposure.
Frequency	Once daily, 7 days per week
Dose levels	Group 1 (control): 0 mg/kg per treatment day Group 2 : 10 mg/kg per treatment day Group 3 : 50 mg/kg per treatment day Group 4 : 200 mg/kg per treatment day Group 5 : 1000 mg/kg per treatment day
Rationale for dose level selection	Based upon data from acute oral toxicity study (RCC Project 372835) and a 5-day dose-range finding study (RCC Project 372892) in which FAT 45'169/A was administered orally by gavage to rats.
Dose volume	10 ml/kg body weight per treatment day.
Duration of treatment	From 14-JUN-1994 to 11-JUL-1994
Duration of recovery	From 12-JUL-1994 to 25-JUL-1994

ALLOCATION

The animals were assigned identification numbers and allocated to the test groups as follows:

		GROUP 1* 0 mg/kg	GROUP 2 10 mg/kg	GROUP 3 50 mg/kg	GROUP 4 200 mg/kg	GROUP 5 1000 mg/kg
MALES	A	1 - 5	11 - 15	16 - 20	21 - 25	26 - 30
	B	6 - 10				31 - 35
FEMALES	A	36 - 40	46 - 50	51 - 55	56 - 60	61 - 65
	B	41 - 45				66 - 70

* Control animals were gavaged with the vehicle only (Bi-distilled water)
A = Toxicity testing (termination after 28 treatment days)
B = Recovery testing (termination after an additional 14-day recovery period)

Test article preparation	The test article was weighed into a glass beaker on a tared Mettler PM 480 balance and the vehicle was added. The mixture (w/v) was prepared using a homogenizer. Homogeneity of the test article in the vehicle was maintained during treatment using a magnetic stirrer.
Vehicle	Bi-distilled water
Frequency of preparation	Daily prior to each application
Chemical analysis of dose preparations	Concentration, homogeneity and stability of the test article/vehicle mixtures were determined during acclimatization. Further samples for analysis were taken during week 3 of the test and subsequently analyzed. The analyses were performed in the Analytical Laboratories of RCC Umweltchemie AG, according to a method which was supplied by the sponsor. At acclimatization - 09-JUN-1994 At 3 weeks - 30-JUN-1994

TEST SYSTEM

Test system	Rat, HanIbm: WIST (SPF)
Rationale	Recognized by the international guidelines as the recommended test system.
Source	BRL, Biological Research Laboratories Ltd. Wölferstrasse 4 4414 Fuellinsdorf/Switzerland
Total number of animals per group	Groups 1 and 5: 10 males and 10 females groups 2, 3 and 4: 5 males and 5 females
Total number of animals	35 males 35 females
Age at delivery	6 weeks
Body Weight and Range at acclimatization/pretest	Males: 140.9 - 156.0 g Females: 116.6 - 133.7 g
Identification	Individual cage number and corresponding ear tattoo.
Randomization	Computer-generated random algorithm.
Acclimatization	From 07-JUN-1994 to 13-JUN-1994 under laboratory conditions, after veterinary examination. Only animals without any visual signs of illness were used for the study.

Clinical Laboratory Investigations

GENERAL

Blood samples for hematology and clinical biochemistry were collected from all animals under light ether anesthesia. The animals were fasted in metabolic cages for approximately 18 hours before blood sampling but allowed access to water ad libitum. Blood samples were collected between the hours of 07.00 and 08.50 to reduce biological variation caused by circadian rhythms. Blood samples were drawn from the retro-orbital plexus using a micro-hematocrit glass capillary tube.

Urine was collected during the 18-hours fasting period into a specimen vial.

Blood and urine sampling:

After 4 weeks 12-JUL-1994
After 6 weeks 26-JUL-1994

The assays of blood and urine parameters were performed, at BRL Biological Research Laboratories Ltd., under internal laboratory quality control conditions to assure reliable test results.

The summary and individual tables were generated by a computer. The program used limits the width of each column to 10 characters. Therefore, the names of some parameters have been abbreviated. Any abbreviation has been defined in this section under "Parameter" in upper-case letters enclosed by parentheses.

Clinical laboratory data are expressed in general accordance with the International System of Units (SI), which in structure comprises base units, derived units and supplementary units. It also includes a series of prefixes by means of which decimal multiples and submultiples of these units can be formed. In some cases non-SI units or conventional units may be used.

Remark code identification:

NV = no value for one or more parameters
NS = no sample

General remarks:
Explanatory notes for data not presented in the tables, see p. 157.
Historical reference values for untreated Wistar Han-Ibm rats, see pp. 232-249.

Key to abbreviations of Units of Measure:

L	: liter	T	: tera (10^{12})
MOL	: mole	G	: giga (10^{9})
SEC	: second	M	: milli (10^{-3})
g	: gram	µ	: micro (10^{-6})
KG	: kilogram	N	: nano (10^{-9})
KAT	: katal	F	: femto (10^{-15})

HEMATOLOGY

The following anticoagulants were used during blood collection:
EDTA-K2 (hematology) / Lithium heparin 30 I.U./ml (methemoglobin)
Sodium citrate, 3.8% (coagulation; 1 part anticoagulant to 9 parts blood)

The following commercial reference controls were used to monitor the performance of the method:

Hematology:
Eightcheck-3WP (normal range)
Eightcheck-L-3WP (low abnormal range)
Ret-check (reticulocyte control)
(TOA Medical Electronics Co., Ltd. Kobe/Japan)

HUSBANDRY

Room No.: 106 (BRL, Füllinsdorf)

Conditions
Standard Laboratory Conditions.
Air-conditioned with 10-15 air changes per hour, and continuously monitored environment with a temperature range of 21-25 degrees centigrade and a relative humidity between 49-67%. 12 hours artificial fluorescent light. 12 hours dark, music during the light period.

Accommodation

Individually in Makrolon type-3 cages with autoclaved standard softwood bedding ('Lignocel', Schill AG, CH-4132 Muttenz).

Water

Community tap-water from Füllinsdorf was available ad libitum. Results of bacteriological, chemical and contaminant analyses are included in this report (see pp. 223 - 225).

Diet

Pelleted standard Kliba no. 343, Batch nos. 74/94 and 75/94, rat maintenance diet ('Kliba', Klingentalmuehle AG, CH-4303 Kaiseraugst) ad libitum. Results of contaminant analyses are included in this report (see pp. 227 - 230).

Observations

MORTALITY / VIABILITY AND CLINICAL SIGNS

Observations for mortality/viability and clinical signs of toxicity were recorded once daily.

FOOD CONSUMPTION

The food consumption was recorded once during the acclimatization period and weekly thereafter using an on-line electronic recording system consisting of a Mettler PM 4800 balance connected to the RCC computer.

BODY WEIGHTS

The body weight of each animal was recorded on the same days as the food consumption using the same recording system. Additionally, terminal body weights were recorded at the end of the application period (all animals) and at the end of the recovery period (allocation B animals).

OPHTHALMOSCOPIC EXAMINATIONS

Dates:	at 4 weeks:	11-JUL-1994	(on all animals)
	at 6 weeks:	25-JUL-1994	(on all recovery animals of groups 1 and 5)

A description of any abnormality was recorded. 10 - 85 minutes after the application of a mydriatic solution (Dispersa AG, CH-8442 Hettlingen) the cornea, lens, anterior chamber, vitreous body and ocular fundus of both eyes were examined under dimmed light using a Heine BETA 200 Ophthalmoscope (Eisenhut Vet. AG, CH-4123 Allschwil).

Parameter	Method / Instrumentation	Unit
Nucleated erythrocytes (normoblasts) (NEN)	Reported as number of nucleated erythrocytes per 100 leukocytes in the differential leukocyte count (see next page)	NEN/100 WBC
Heinz bodies (HEINZ-BOD.)	Supravital staining with neutral red and brilliant green - Manual count of 1000 erythrocytes of stained film using a Leitz Laborlux 12 or Dialux 22 light microscope	o/oo
Methemoglobin (MET-HB)	Spectrophotometric method based on the following equation using an IL 482 CO-Oximeter $\% \text{ MetHb} = \frac{\text{MetHb}}{(\text{RHb})+(\text{O}_2\text{Hb})+(\text{COHb})+(\text{MetHb})}$ $= \frac{\text{MetHb}}{\text{Total Hb}} \times 100$	%
Total leukocyte count (WBC)	Electric resistance detection - Sysmex (TOA) E-4000 Multi-Parameter Automated Hematology Analyzer	G/l
Differential leukocyte count (Diff. WBC Count)	Monocellular layer blood smears produced with an Omron Microx Centrifugal Spinner Blood smear stained with a modified Wright's Eosin Methylene Blue solution (OMRON) using an Omron Microx Auto-Stainer Manual count of 100 leukocytes using a Leitz Laborlux 12 or Dialux 22 light microscope Cell classification: BAND. = Band Neutrophil SEG. = Segmented Neutrophil EO. = Eosinophil BASO. = Basophil LYMPH. = Lymphocyte MONO. = Monocyte PLAS. = Plasma Cell OTHER = Blast Cell (undifferentiated)	 1 (rel.) G/l (abs.)

Methemoglobin:
CalDye Reference Standard
IL Multi-4 CO-Oximeter Control
(Instrumentation Laboratory, Lexington, Ma./U.S.A)

Coagulation:
IL Control Plasma (normal range)
IL Control Plasma (abnormal range)
(Instrumentation Laboratory, SpA, Milano/Italy)

The following methods were used to determine the values of the parameters listed:

Parameter	Method / Instrumentation	Unit
Erythrocyte count (RBC)	Hydrodynamic focusing electric resistance detection - Sysmex (TOA) E-4000 Multi-Parameter Automated Hematology Analyzer	T/l
Hemoglobin (HB)	Cyanmethemoglobin - Sysmex (TOA) E-4000 Multi-Parameter Automated Hematology Analyzer	mmol/l
Hematocrit (HCT)	Cumulative pulse height detection - Sysmex (TOA) E-4000 Multi-Parameter Automated Hematology Analyzer	l/l
Mean corpuscular volume (MCV)	Calculated value: HCT/RBC - Sysmex (TOA) E-4000 Multi-Parameter Automated Hematology Analyzer	fl
Mean corpuscular hemoglobin (MCH)	Calculated value: HB/RBC - Sysmex (TOA) E-4000 Multi-Parameter Automated Hematology Analyzer	fmol
Mean corpuscular hemoglobin concentration (MCHC)	Calculated value: HB/HCT - Sysmex (TOA) E-4000 Multi-Parameter Automated Hematology Analyzer	mmol/l
Platelet count (PLATELETS)	Hydrodynamic focusing electric resistance detection - Sysmex (TOA) E-4000 Multi-Parameter Automated Hematology Analyzer	G/l
Reticulocyte count (RETIC.)	Flow cytometric analysis based on RNA fluorescently labelled cells using Auramine-O and an argon laser - Sysmex (TOA) R-1000 Automated Reticulocyte Analyzer	% (rel.) T/l (abs.)
Reticulocyte fluorescence ratios (HFR = high MFR = middle LFR = low)	Flow cytometric analysis based on RNA fluorescently labelled cells using Auramine-O and an argon laser - Sysmex (TOA) R-1000 Automated Reticulocyte Analyzer	%

The following methods were used to determine the values of the parameters listed:

Parameter	Method / Instrumentation	Unit
Glucose	GLUC-DH - Eris Selective Multi-Test Analyzer 6170 (Eppendorf/Olympus)	mmol/l
Urea	Urease-GLDH - Eris Selective Multi-Test Analyzer 6170 (Eppendorf/Olympus)	mmol/l
Creatinine	Jaffé-reaction without deproteinization, kinetic - Eris Selective Multi-Test Analyzer 6170 (Eppendorf/Olympus)	µmol/l
Uric acid	Uricase-PAP - Eris Selective Multi-Test Analyzer 6170 (Eppendorf/Olympus)	µmol/l
Bilirubin, total (BILI. T.)	DPD - Eris Selective Multi-Test Analyzer 6170 (Eppendorf/Olympus)	µmol/l
Cholesterol, total (CHOLEST. T.)	CHOD-PAP - Eris Selective Multi-Test Analyzer 6170 (Eppendorf/Olympus)	mmol/l
Triglycerides (TRIGL.)	GPO-PAP - Eris Selective Multi-Test Analyzer 6170 (Eppendorf/Olympus)	mmol/l
Phospholipids (PHOS.LIPID)	Phospholipase D/choline oxidase/ PAP - Eris Selective Multi-Test Analyzer 6170 (Eppendorf/Olympus)	mmol/l
Aspartate aminotrans-ferase (ASAT/GOT)	Kinetic measurement of the rate of decrease in NADH (NADH/MDH coupled reaction). Method based on German Soc. of Clin. Chem. (DGKC) recommendations - Eris Selective Multi-Test Analyzer 6170 (Eppendorf/Olympus)	µkat/l (37°C)
Alanine aminotrans-ferase (ALAT/GPT)	Kinetic measurement of the rate of decrease in NADH (NADH/LDH coupled reaction). Method based on German Soc. of Clin. Chem. (DGKC) recommendations - Eris Selective Multi-Test Analyzer 6170 (Eppendorf/Olympus)	µkat/l (37°C)

Parameter	Method / Instrumentation	Unit
Red cell morphology	By microscopic examination of stained blood smear. Erythrocytes that vary from the normal in size, shape and hemoglobin content, or contain greater amounts of nuclear remnants are indicated as abnormal erythrocytes, and are characterized as such. Normal red cell morphology key: score = 0	normal/ abnormal
Coagulation:		
Thromboplastin time (=Prothrombin time) (PT)	Automated laser-nephelometric centrifugal analyzer method, using an IL™ calcium thromboplastin reagent (a lyophilized extract from rabbit brain, certified according to ICSH/ICTH (*) recommendation) - Instrumentation Laboratory (IL) ACL 300 Coagulation System	sec
Activated partial thromboplastin time (APTT)	Automated laser-nephelometric centrifugal analyzer method, using an IL™ bovine brain cephalin, ellagic acid activated reagent - Instrumentation Laboratory (IL) ACL 300 Coagulation System	sec

(*) ICSH = International Committee for Standardization in Hematology
ICTH = International Committee on Thrombosis and Hemostasis

CLINICAL BIOCHEMISTRY

The following anticoagulant was used during blood collection:
Lithium heparin (15 I.U./ml).

The following commercial reference controls were used to monitor the performance of the methods:

Clinical Biochemistry:
Qualitrol HS-N (normal range)
Qualitrol HS-P (high range)
(E. Merck, Darmstadt/Germany)

Lyotrol N (normal range - for the assay control of phospholipids)
(bio Mérieux, Charbonnières-les Bains/France)

Parameter	Method / Instrumentation	Unit
Chloride	ISE (Ion-Selective Electrode/ Indirect potentiometry) - Eris Selective Multi-Test Analyzer 6170 (Eppendorf/Olympus)	mmol/l
Albumin	Bromocresol green (BCG) - Eris Selective Multi-Test Analyzer 6170 (Eppendorf/Olympus)	g/l
Protein, total	Biuret reaction - Eris Selective Multi-Test Analyzer 6170 (Eppendorf/Olympus)	g/l
Globulin	Calculated value obtained by difference (total protein minus albumin = globulin)	g/l
Albumin/Globulin ratio (A/G RATIO)	Calculated ratio based on the albumin concentration / globulin concentration	-

URINALYSIS

The following commercial reference control was used to monitor the performance of the method:

Urinalysis:
Chek-Stix Urinalysis Control Strips
(Ames Division, Miles Laboratories, Inc., Elkhart, Indiana/USA)

Lyphochek Quantitative Urine Control - Normal I and Abnormal II - (for the assay control of Osmolality)
(Bio-Rad, ECS Division, Anaheim, California/USA)

The following methods were used to determine the values of the parameters listed:

Parameter	Method / Instrumentation	Unit
Volume (18-hour)	Metabolism cage (Model K. Ehret & Co., Emmendingen/Germany)	ml
Specific gravity (SPEC. GRAV.)	Atago Uricon Refractometer	1
Osmolality	Freezing-point depression - Fiske 2400 Multi-Sample Osmometer	mmol/kg
Color	Visual observation	-
Appearance	Visual observation	-

Parameter	Method / Instrumentation	Unit
Lactate dehydrogenase (LDH)	Kinetic measurement of the rate of decrease in NADH (direct NADH/LDH coupled reaction using pyruvate as substrate PYR --> LAC reaction). Method based on German Soc. of Clin. Chem. (DGKC) recommendations - Eris Selective Multi-Test Analyzer 6170 (Eppendorf/Olympus)	µkat/l (37°C)
Creatine kinase (CK)	Kinetic measurement of the rate of increase in NADPH (CK-NAC activated). Method based on German Soc. of Clin. Chem. (DGKC) recommendations - Eris Selective Multi-Test Analyzer 6170 (Eppendorf/Olympus)	µkat/l (37°C)
Alkaline phosphatase (ALP)	Kinetic chromogenic method measuring the formation of p-nitrophenylate (hydrolysis of p-nitrophenylphosphate, diethanolamine buffer pH 9.8). Method based on German Soc. of Clin. Chem. (DGKC) recommendations - Eris Selective Multi-Test Analyzer 6170 (Eppendorf/Olympus)	µkat/l (37°C)
Gamma-glutamyl-transferase (G-GT)	Kinetic colorimetric method based on the procedure of Szasz, using L-gamma-glutamyl-3-carboxy-4-nitroanilide as substrate - Eris Selective Multi-Test Analyzer 6170 (Eppendorf/Olympus)	nkat/l (37°C)
Calcium	Reaction with o-cresolphthalein complexone - Eris Selective Multi-Test Analyzer 6170 (Eppendorf/Olympus)	mmol/l
Phosphorus	Direct phosphomolybdate reaction (340/380 nm) - Eris Selective Multi-Test Analyzer 6170 (Eppendorf/Olympus)	mmol/l
Sodium	ISE (Ion-Selective Electrode/ Indirect potentiometry) - Eris Selective Multi-Test Analyzer 6170 (Eppendorf/Olympus)	mmol/l
Potassium	ISE (Ion-Selective Electrode/ Indirect potentiometry) - Eris Selective Multi-Test Analyzer 6170 (Eppendorf/Olympus)	mmol/l

Parameter	Method / Instrumentation	Unit
Urine Sediment (SED.MICRO.)	Specimen centrifugation at 3000 r.p.m. for 10 minutes. Microscopic examination of 10 high power fields (400x) in different parts of cover-slipped area for normal and abnormal constituents using a Leitz Laborlux 12 light microscope. normal - score = 0 Normal urine contains a minute amount of cellular and non-cellular constituents of the urinary tract including white cells, red cells, epithelial cells, hyaline or granular casts, mucous threads, and amorphous or crystalline forms of normal solids. abnormal - score = 1, 2, or 3 1 = small amount 2 = moderate amount 3 = large amount Presence of abnormal amounts of urinary constituents are reported. The evaluation is based on findings relative to the control group, on dose-related changes, the presence of a small amount of red blood cells, the presence of a moderate amount of white blood cells, epithelial cells, casts, mucous threads, amorphous or crystalline forms of solids. A combination of two or more of these findings in a smaller amount is also considered abnormal. Key for indicated amounts of urinary constituents: TRIP.PHOS. = Triple phosphate crystals	

Parameter	Method / Instrumentation	Unit
pH	Reagent-Test-Strip (Ames Multistix 10 SG) - Clini-Tek 200 Semi-Automated Urine Chemistry Analyzer (Ames)	-
Protein	Reagent-Test-Strip (Ames Multistix 10 SG) - Clini-Tek 200 Semi-Automated Urine Chemistry Analyzer (Ames) Questionable results are confirmed with Albustix Reagent-Test-Strip (Ames)	score: 0=negative/trace 1=0.3 g/l 2=1.0 g/l 3=≥3.0 g/l
Glucose	Reagent-Test-Strip (Ames Multistix 10 SG) - Clini-Tek 200 Semi-Automated Urine Chemistry Analyzer (Ames)	0=negative 1=5.5 mmol/l 1=14 mmol/l 2=28 mmol/l 3=≥55 mmol/l
Ketone	Reagent-Test-Strip (Ames Multistix 10 SG) - Clini-Tek 200 Semi-Automated Urine Chemistry Analyzer (Ames)	0=neg mmol/l 0=0.5 mmol/l 1=1.5 mmol/l 2=4.0 mmol/l 3=≥8.0 mmol/l
Bilirubin	Reagent-Test-Strip (Ames Multistix 10 SG) - Clini-Tek 200 Semi-Automated Urine Chemistry Analyzer (Ames) Positive results are confirmed with Ictotest Reagent Tablets (Ames)	0=negative 1=small 2=moderate 3=large
Blood	Reagent-Test-Strip (Ames Multistix 10 SG) - Clini-Tek 200 Semi-Automated Urine Chemistry Analyzer (Ames) Questionable results are confirmed with Hemastix Reagent-Test-Strip (Ames)	0=negative 1=trace/small 2=moderate 3=large
Urobilinogen (UROBILI.)	Reagent-Test-Strip (Ames Multistix 10 SG) - Clini-Tek 200 Semi-Automated Urine Chemistry Analyzer (Ames)	0= 3.2 µmol/l 0=16 µmol/l 1=33 µmol/l 2=66 µmol/l 3=≥131 µmol/l

DATA COMPILATION

GENERAL

The following data were recorded on-line: food consumption, body weights and organ weights.

The following data were compiled into the RCC computer system during recording: clinical signs, mortality, macroscopic findings at necropsy and histopathology.

Clinical Laboratory data were recorded on-line (Sysmex TOA E-4000 Multiparameter Automated Hematology Analyzer, Sysmex TOA R-1000 Automated Reticulocyte Analyzer, Instrumentation Laboratory ACL 300 Coagulation System, Eris Selective Multi-Test Analyzer 6170 and Clini-Tek 200 Semi-Automated Urine Chemistry Analyzer (Ames)) or on data sheet and then transferred into the computer system.

Ophthalmoscopic data were recorded on data sheets and transcribed for compilation and analysis into the computer system.

The computer-generated values which appear in the tables represent the rounded-off results of the raw data values or of calculations which used the exact raw data values.

Group means were calculated according to the definition of any mean value using the individual values per animal and the number of animals.

CALCULATION OF FOOD CONSUMPTION AND RELATIVE FOOD CONSUMPTION

The food consumption was calculated per rat and per food consumption interval. It expresses the average food consumed per animal and per day over the food consumption interval.

Formula (for each rat separately):

$$FC = \frac{C}{AD}$$

where

FC = Food consumption (in g of food per animal and per day).

C = Measured food consumption per animal over the consumption interval (in g of food).

AD = Total of consumption days during the consumption interval. The date of death was considered if applicable.

Pathology

NECROPSY

after 4 weeks - 12-JUL-1994
after 6 weeks - 26-JUL-1994

All animals were necropsied and descriptions of all macroscopic abnormalities were recorded. Prior to necropsy, the animals were fasted for approximately 18 hours, but free access to water was provided. Necropsies were performed by experienced prosectors supervised by an experienced veterinary pathologist. At the end of the treatment or recovery period the animals designated according to the necropsy schedule were anesthetized by intraperitoneal injection of NARCOREN (Rhone Merieux GmbH, D-88471 Laupheim), weighed and sacrificed by exsanguination.

Samples of the following tissues and organs were collected from all animals at necropsy and fixed in phosphate buffered neutral 4 % formaldehyde solution:

Adrenals; aorta; bone (sternum, femur); bone marrow (sternum, femur); brain; cecum; colon; duodenum; epididymides; esophagus; eyes with optic nerve and Harderian gland; femur including joint; heart; ileum; jejunum; kidneys; larynx; lacrimal gland, exorbital; liver; lung infused with formalin; lymph nodes, mandibular, mesenteric; mammary gland area; nasal cavity; ovaries; pancreas; pituitary gland; prostate gland; rectum; salivary gland, (mandibular, sublingual); seminal vesicles; sciatic nerve; skeletal muscle; skin; spinal cord, (cervical, midthoracic, lumbar); spleen; stomach; testes; thymus; thyroid incl. parathyroid gland; tongue; trachea; urinary bladder infused with formalin; uterus; vagina and gross lesions.

ABSOLUTE AND RELATIVE ORGAN WEIGHTS

The following organ weights were recorded on the scheduled dates of necropsy: Adrenals, brain, heart, kidneys, liver, ovaries, pituitary, spleen, testes, thyroid including parathyroid gland.

The organ to terminal body weight ratios as well as the organ to brain weight ratios were determined.

The determination of the terminal body weight was performed immediately prior to necropsy using an on-line electronic recording system consisting of a Mettler PM 4000 balance connected to a computer system.

HISTOTECHNIQUE

All organ and tissue samples, as defined under Histopathology were processed, embedded, cut at an approximate thickness of 4 micrometers, and stained with hematoxylin and eosin.

HISTOPATHOLOGY

Slides of adrenals, heart, kidneys, liver, lungs, spleen, stomach and testes collected at terminal sacrifice from the animals of the control and high-dose groups were examined by a pathologist. The same applied to all gross lesions from all rats. All abnormalities were described and included in the report.

Statistical Analysis

METHODS

The following statistical methods were used to analyze the body weights, food consumption, organ weights and all ratios and clinical laboratory data :

When the variables could be assumed to follow a normal distribution, the Dunnett-test (many to one t-test) based on a pooled variance estimate was applied for the comparison between the treated groups and the control groups for each sex.

The Steel-test (many-one rank test) was applied when the data could not be assumed to follow a normal distribution.

The Fisher's exact test was applied to the ophthalmoscopy data.

References:

C.W. Dunnett: A Multiple Comparison Procedure for Comparing Several Treatments with a Control, J. Amer. Statist. Assoc. 50, 1096-1121 (1955).

R.G. Miller: Simultaneous Statistical Inference, Springer Verlag, New York (1981).

R.A. Fisher: Statistical Methods for Research Workers, Oliver and Boyd, Edinburgh (1950).

The relative food consumption was calculated according to the following formula:

RFC = $\frac{\text{FC (in gram)}}{\text{BW (i)(in gram)}} \times 1000$

Unit = Gram food per kg body weight and day

FC = Food consumption per animal and per day (gram)

BW (i) = Most ideal body weight = body weight (of the corresponding rat) recorded on the day most close to the middle of the food consumption interval. In cases of equal "closeness" of two body weight records the earlier one was chosen.

CLINICAL SIGNS

The clinical signs were evaluated on a daily basis.

Daily evaluation:

- The individual data represent the maximum scores observed per animal and per day.
- The summary data show for each treatment group the median of the individual maximum scores, together with a code representing the percentage of animals affected.

- Markedly increased uric acid by 101% to 248% on average in both sexes of group 5.
- Markedly increased bilirubin by 278% to 543% on average in both sexes of group 5.
- Slightly increased total cholesterol level by 37% in males of group 5.
- Slightly increased phospholipid level by 28% in males of group 5.
- Slightly decreased albumin level by 8% in females of group 5.

In group 5 (1000 mg/kg), the findings were found to be reversed after the 14-day recovery period, with the exception of the increase of creatinine and bilirubin levels.

Generally, the differences were only of slight nature and were considered to suggest metabolic adaptation without any toxicological significance. However, some data, in particular increased creatinine, uric acid and phospholipid, could give indications of nephrotoxicity and correlated to the findings noted at histopathological examination in the kidneys. In addition, it is to note that for bilirubin and uric acid spectral interference by the red test article or metabolites thereof with the assay procedure is not to rule out. The slight increase in total cholesterol in the male animals was considered to correlated with the slight increase liver weight noted in these animals.

All other differences in the results of the clinical biochemistry parameters were considered to be incidental and unrelated to the treatment, and of normal biological variation for rats of this strain and age (see also historical control data for untreated Wistar Han-Ibm rats, pp. 232-249).

URINALYSIS (see pp. 86-87, 190-203)

For urinalysis data the following changes were recorded in group 5 (1000 mg/kg) rats:

- Slight increase by 1% in specific gravity in male animals.
- Slight increase by 43% of the osmolality in male animals.
- Slight increase in urine protein (score) in male animals.
- Slight increase in urine bilirubin (score) in male animals.
- Slight increase in occult blood (score) in male and female animals. This finding was also observed at the end of the recovery period.

The changes noted were not considered to be of any toxicological significance. Again, spectral interference or metabolites may have contributed to the findings for bilirubin and occult blood. This was supported by the fact that the urine of the group 5 (1000 mg/kg) animals collected at the end of treatment showed a light orange to light red discoloration. Light orange to orange discoloration of the urine was also seen in the group 5 (1000 mg/kg) animals at the end of the recovery period.

All other results of the urinalysis parameters ranged within the normal biological variation for rats of this strain and age (see also historical control data for untreated Wistar Han-Ibm rats, pp. 232-249).

RESULTS

MORTALITY (see pp. 101-110)

No test article related deaths were noted in this study. Control male no. 3 died during narcosis for blood sampling on day of schedule necropsy.

CLINICAL SIGNS (see pp. 42-51, 111-120)

No test article related clinical signs of reaction to treatment were noted in all dose groups (10, 50, 200 and 1000 mg/kg).

Alopecia on the chest wall and front paws was noted in control male no. 10. This finding was first noted during week two of treatment and lasted until the end of the recovery period.

FOOD CONSUMPTION (see pp. 52-59, 121-130) / **RELATIVE FOOD CONSUMPTION** (see pp. 52-59, 121-130)

The differences in food consumption between the control animals and the animals in all dose groups (10, 50, 200 and 1000 mg/kg) were not considered to be caused by treatment with the test article. The only difference which attained statistical significance was for relative food consumption in group 4 (200 mg/kg) males between days 8 and 15 of treatment. This single finding was considered to be incidental.

BODY WEIGHTS (see pp. 68-75, 141-150)

Up to and including the highest dose level of 1000 mg/kg, there were no effects on the body weight development in both male and female animals.

OPHTHALMOSCOPIC EXAMINATIONS (see pp. 76-77, 151-156)

No test article related abnormal findings were noted.

HEMATOLOGY (see pp. 78-81, 158-175)

No test article related effects on the hematology parameters were noted. All the differences noted in the data were considered to be incidental and unrelated to the treatment and of normal biological variation for rats of this strain and age (see also historical control data for untreated Wistar Han-Ibm rats, pp. 232-249).

CLINICAL BIOCHEMISTRY (see pp. 82-85, 176-189)

Plasma discoloration

All plasma samples of the animals of group 5 at the end of the treatment showed a pink to deep pink discoloration.

For clinical biochemistry data the following effects were recorded in rats of group 4 (200 mg/kg) and/or 5 (1000 mg/kg) at termination of the treatment:

- Slightly decreased glucose level by 20% and 17% in females of groups 4 and 5, respectively.
- Slightly decreased urea level by 15% in females of group 5.
- Slightly increased creatinine level by 19% in males of group 5.

FIGURES

ORGAN WEIGHTS, ORGAN TO BODY WEIGHT AND ORGAN TO BRAIN WEIGHT RATIOS
(see pp. 88-99, 204-221)

The single findings of note were a slight increase of the kidneys and liver weights in males of groups 5 (1000 mg/kg). In both cases, the difference from the respective control values attained statistical significance for the organ/body weight ratios, only. These findings were considered to be test article related and to correlate to the findings noted at histopathological examination in the kidneys or with the increase in total cholesterol assessed in the recording of clinical biochemistry parameters, respectively.

All other differences in organ weights between the control animals and the treated animals were considered to be incidental without any toxicological significance.

MACROSCOPIC FINDINGS (see Pathology Report, pp. 267-363)

At terminal necropsy, there was general body discoloration (reddish) in all animals of group 5 (1000 mg/kg). Reddish discoloration of the kidneys and of the mesenteric lymph nodes was also noted in all animals of group 4 (200 mg/kg).

There were no other treatment related necropsy findings.

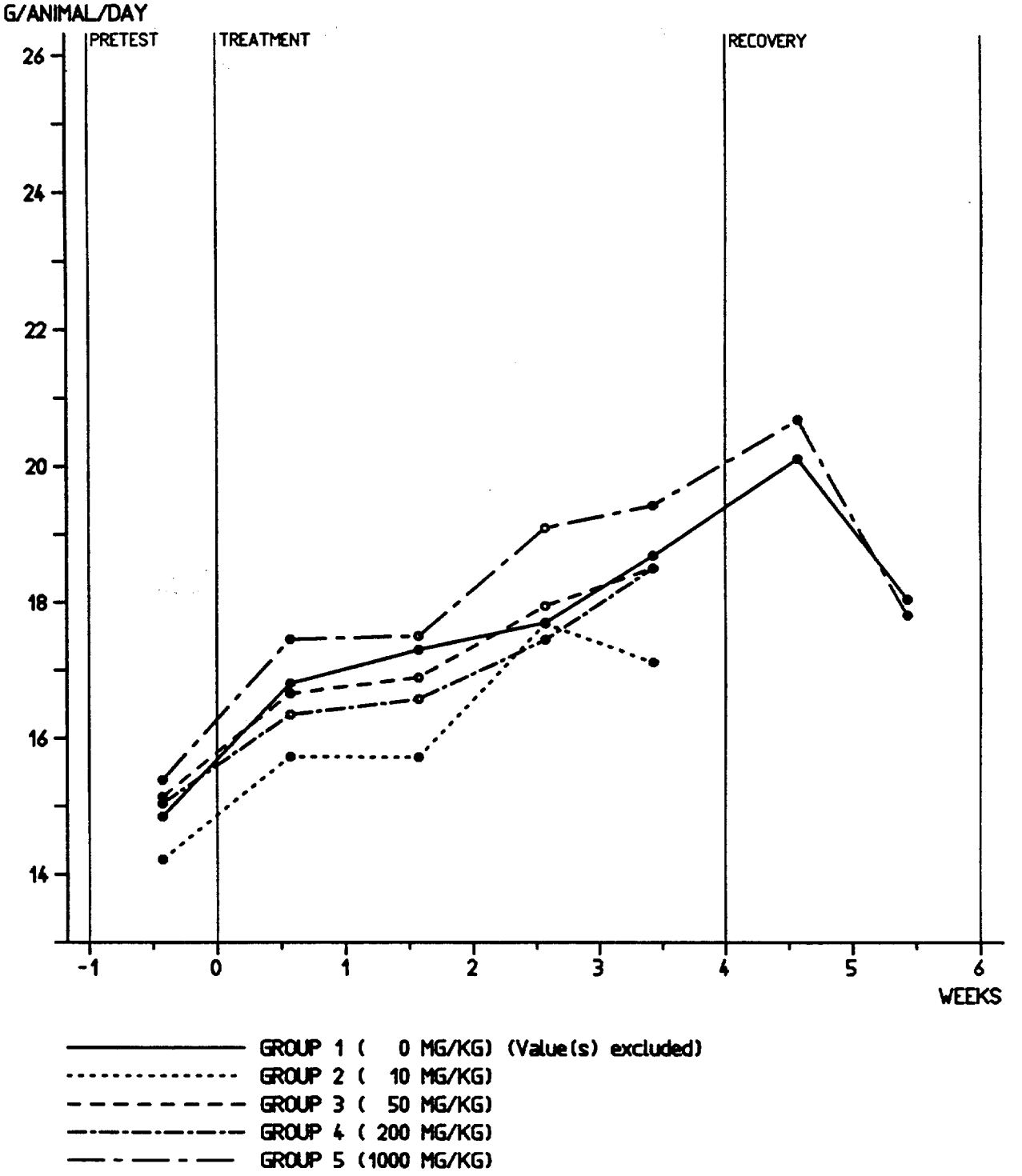
MICROSCOPIC FINDINGS (see Pathology Report, pp. 267-363)

At 1000 mg/kg, there was histopathological evidence of nephrotoxicity in both sexes in the form of increased renal cortical tubular basophilia and degeneration. Increased severity of tubular hyaline droplets was apparent in the males and red tubular hyaline droplets were also present in the females. The kidneys lesions were still apparent after a 14-day treatment free recovery period.

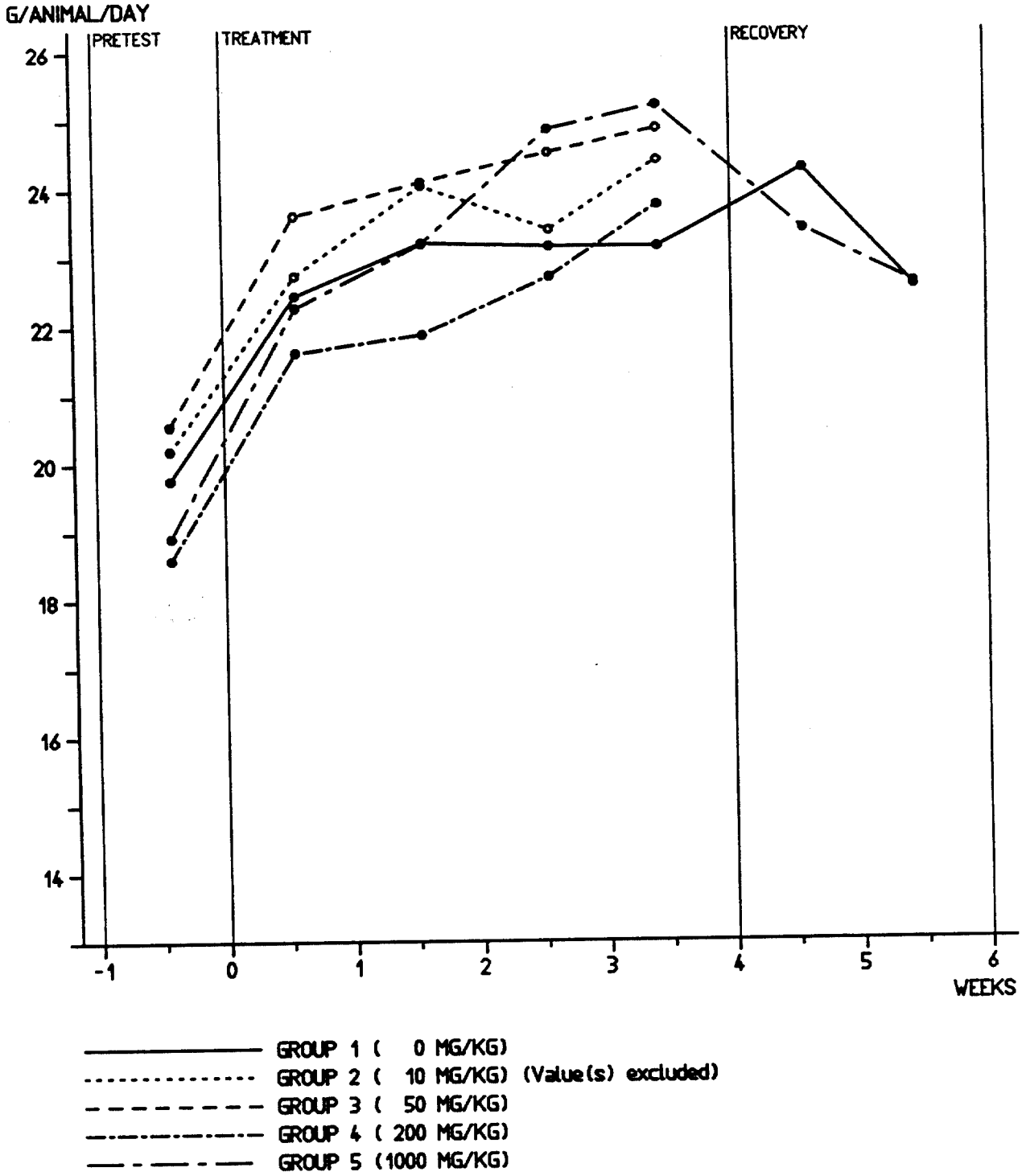
In addition, cluster of foamy macrophages containing red pigment droplets were found in the lungs of two male rats. One male still showed the lesion after the 14-day recovery period. In the absence of any accompanying inflammation these were considered to be due to a systemic accumulation of compound in the pulmonary macrophages rather than an inhalation reaction.

There were no other treatment-related histopathological findings. To the reddish discolorations noted in the animals of groups 5 (1000 mg/kg) and 4 (200 mg/kg), no histopathological counterparts were noted. The cause of death of the control male died on day 28 during anesthesia could not be determined on the basis of this histopathological examination.

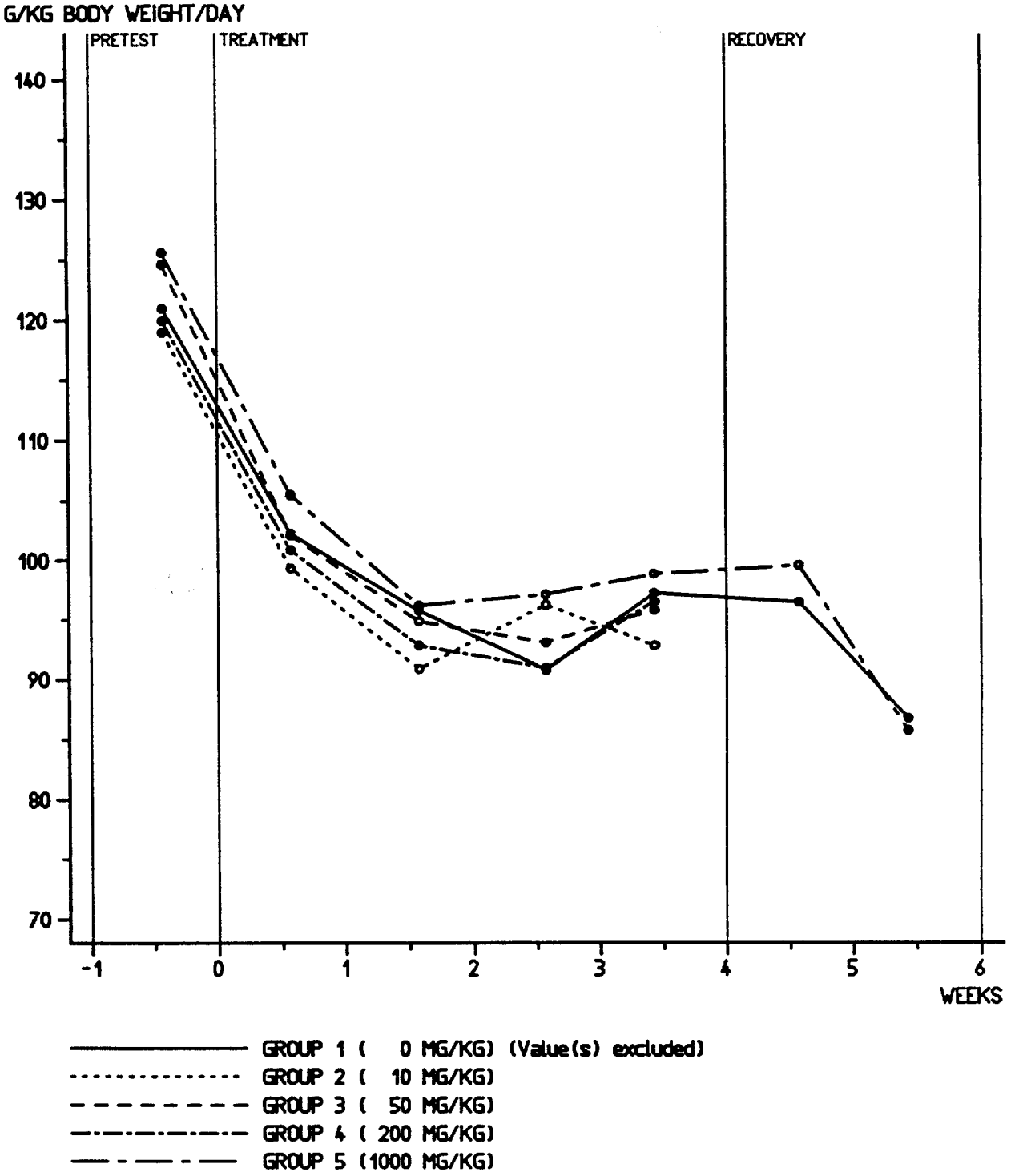
FOOD CONSUMPTION
FEMALES



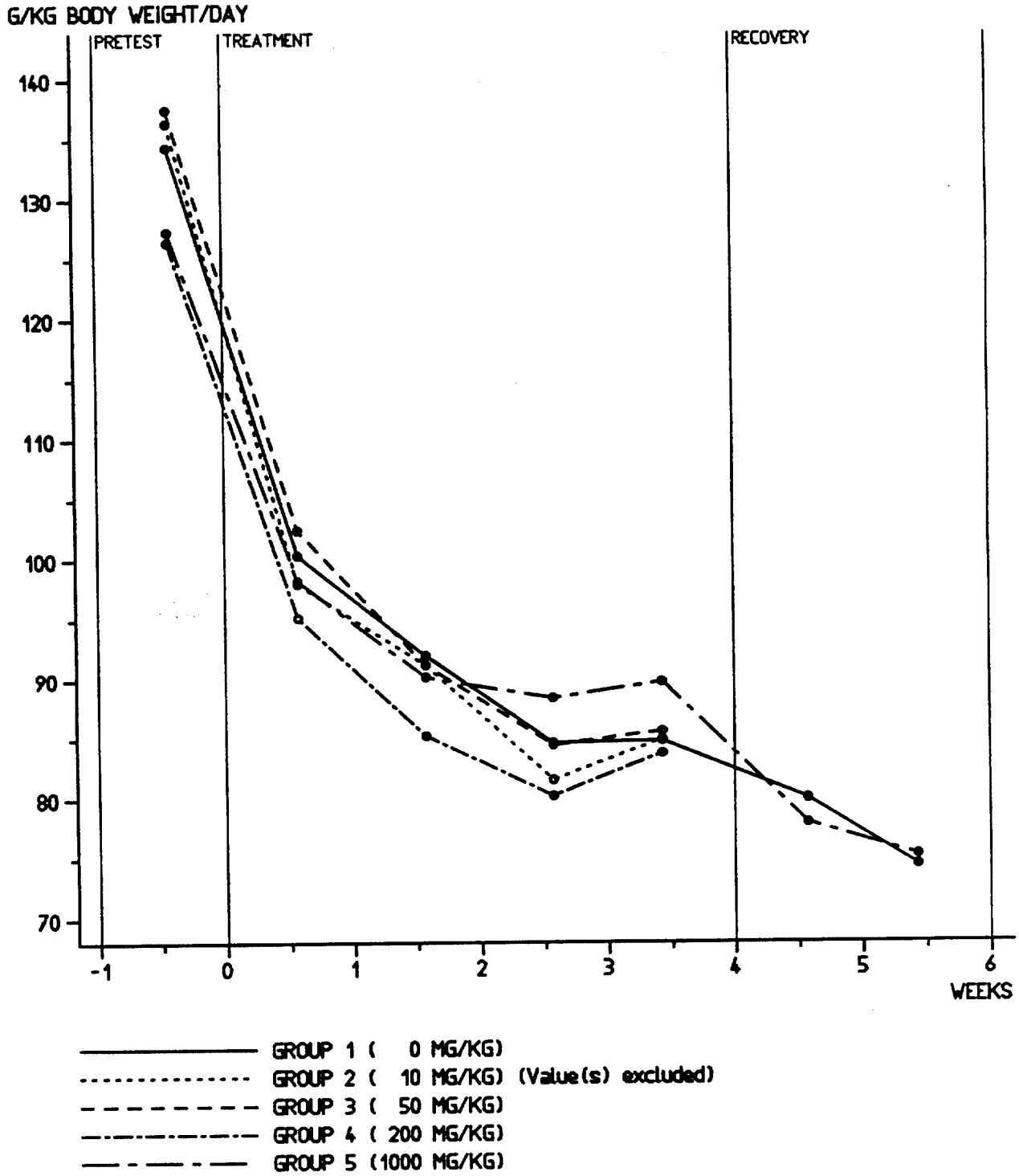
FOOD CONSUMPTION
MALES



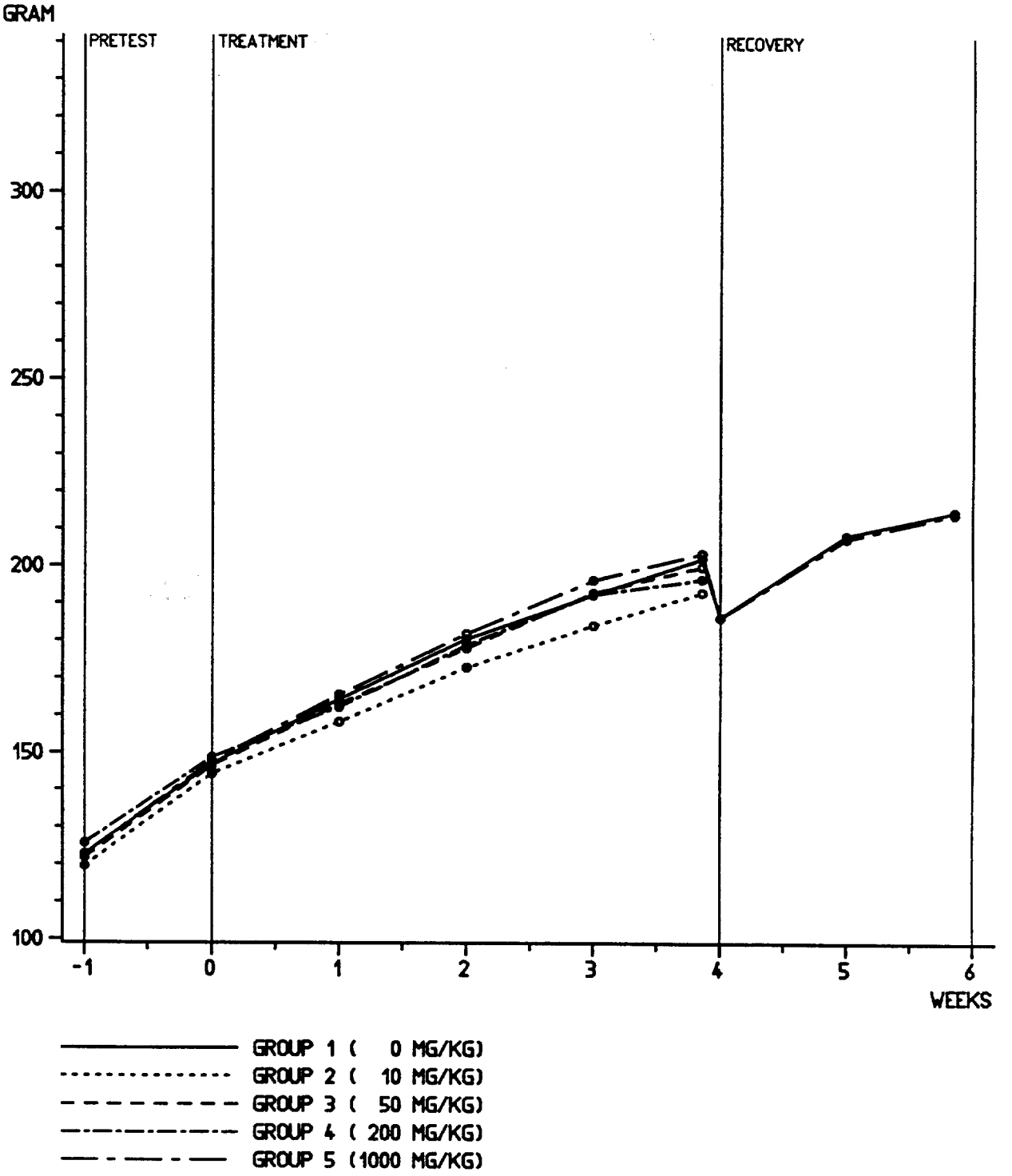
RELATIVE FOOD CONSUMPTION
FEMALES



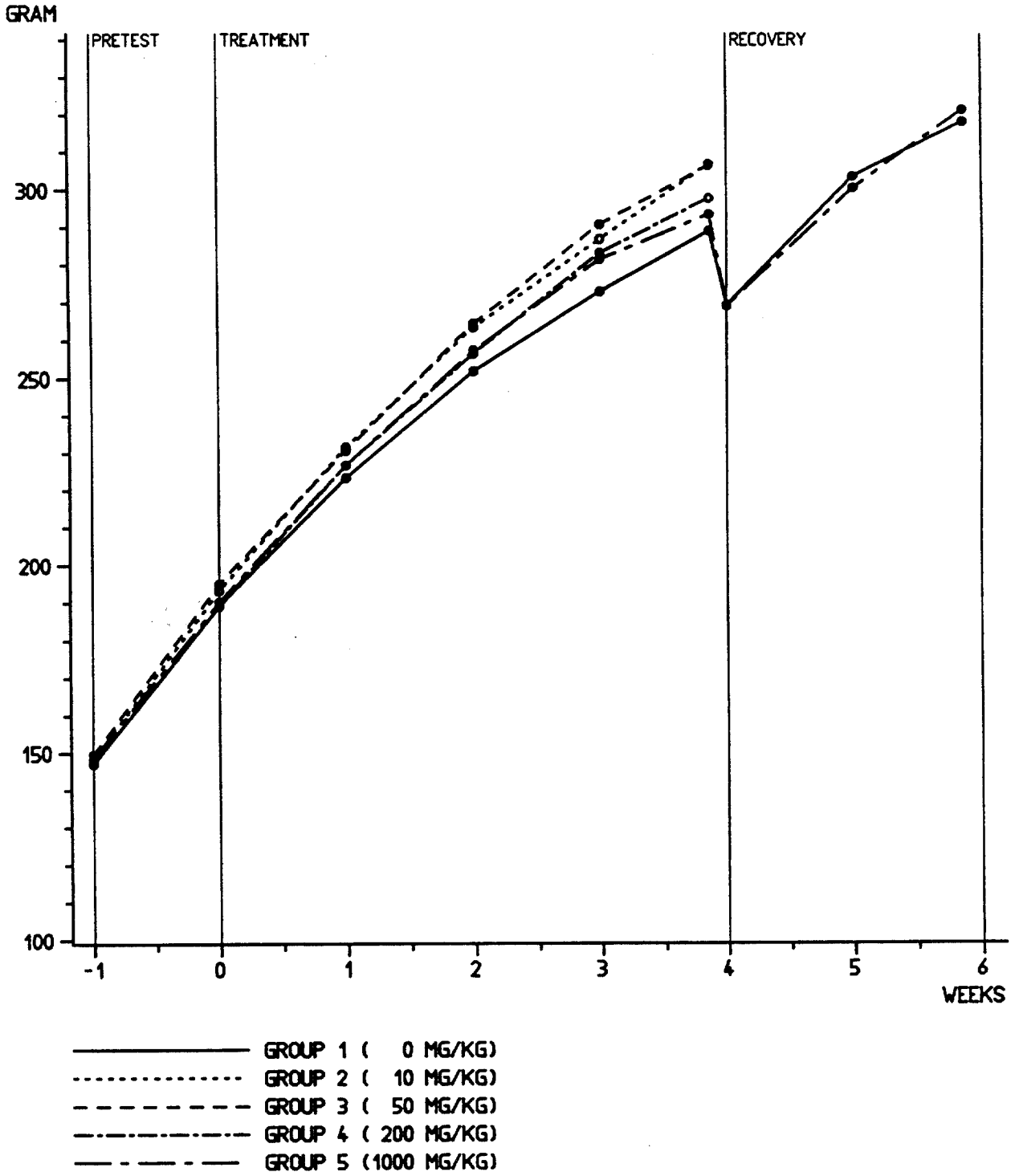
RELATIVE FOOD CONSUMPTION
MALES



BODY WEIGHTS
FEMALES



BODY WEIGHTS
MALES



CLINICAL SIGNS, DAILY (SUMMARY)
MALES
GROUP 1 (0 MG/KG)

SIGN (MAX.GRADE) LOCATION	WEEKS:	PRETEST 1.....	TREATMENT 1.....2.....3.....4.....	RECOVERY 1.....2.....
SKIN / FUR				
ALOPECIA (3) (CHEST WALL)	G:	.....	1111111111111111111	11111111111111
	%:	.....	1111111111111111111	12222222222222
ALOPECIA (3) (PAW FRONT LEFT)	G:	.....	.....	11111111
	%:	.....	.....	22222222
ALOPECIA (3) (PAW FRONT RIGHT)	G:	.....	.....	11111111
	%:	.....	.....	22222222

G: Median value of the highest individual daily grades
%: Percent of affected animals (0 = less than 5%, 1 = between 5% and 15%,..., A = more than 95%)

TABLES - SUMMARY DATA

CLINICAL SIGNS, DAILY (SUMMARY)
MALES
GROUP 3 (50 MG/KG)

SIGN (MAX.GRADE) LOCATION	PRETEST WEEKS: 1.....	TREATMENT 1.....2.....3.....4.....	RECOVERY 1.....2.....

NO CLINICAL SIGNS NOTED

CLINICAL SIGNS, DAILY (SUMMARY)
MALES
GROUP 2 (10 MG/KG)

SIGN (MAX.GRADE) LOCATION	PRETEST WEEKS: 1.....	TREATMENT 1.....2.....3.....4.....	RECOVERY 1.....2.....

NO CLINICAL SIGNS NOTED

CLINICAL SIGNS, DAILY (SUMMARY)
MALES
GROUP 5 (1000 MG/KG)

SIGN (MAX.GRADE)	PRETEST	TREATMENT	RECOVERY
LOCATION	WEEKS: 1.....	1.....2.....3.....4.....	1.....2.....

NO CLINICAL SIGNS NOTED

CLINICAL SIGNS, DAILY (SUMMARY)
MALES
GROUP 4 (200 MG/KG)

SIGN (MAX.GRADE) LOCATION	PRETEST WEEKS: 1.....	TREATMENT 1.....2.....3.....4.....	RECOVERY 1.....2.....

NO CLINICAL SIGNS NOTED

CLINICAL SIGNS, DAILY (SUMMARY)
FEMALES
GROUP 2 (10 MG/KG)

SIGN (MAX.GRADE) LOCATION	PRETEST WEEKS: 1.....	TREATMENT 1.....2.....3.....4.....	RECOVERY 1.....2.....

NO CLINICAL SIGNS NOTED

CLINICAL SIGNS, DAILY (SUMMARY)
FEMALES
GROUP 1 (0 MG/KG)

SIGN (MAX.GRADE) LOCATION	PRETEST WEEKS: 1.....	TREATMENT 1.....2.....3.....4.....	RECOVERY 1.....2.....

NO CLINICAL SIGNS NOTED

CLINICAL SIGNS, DAILY (SUMMARY)
FEMALES
GROUP 4 (200 MG/KG)

SIGN (MAX.GRADE) LOCATION	PRETEST WEEKS: 1.....	TREATMENT 1.....2.....3.....4.....	RECOVERY 1.....2.....

NO CLINICAL SIGNS NOTED

CLINICAL SIGNS, DAILY (SUMMARY)
FEMALES
GROUP 3 (50 MG/KG)

SIGN (MAX.GRADE) LOCATION	PRETEST WEEKS: 1.....	TREATMENT 1.....2.....3.....4.....	RECOVERY 1.....2.....

NO CLINICAL SIGNS NOTED

FOOD CONSUMPTION (G/ANIMAL/DAY) SUMMARY
MALES

PRETEST		GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 50 MG/KG	GROUP 4 200 MG/KG
DAYS 1-8 WEEKS 1/2	MEAN	19.8	20.2	20.6	18.6
	ST.DEV.	1.6	1.8	1.2	0.6
	N	10	5	5	5

		GROUP 5 1000 MG/KG
	MEAN	18.9
	ST.DEV.	1.4
	N	10

* / ** : Dunnett-Test based on pooled variance significant at 5% (*) or 1% (**) level

CLINICAL SIGNS, DAILY (SUMMARY)
FEMALES
GROUP 5 (1000 MG/KG)

SIGN (MAX.GRADE) LOCATION	PRETEST WEEKS: 1.....	TREATMENT 1.....2.....3.....4.....	RECOVERY 1.....2.....

NO CLINICAL SIGNS NOTED

FOOD CONSUMPTION (G/ANIMAL/DAY) SUMMARY
MALES

TREATMENT		GROUP 5 1000 MG/KG
	MEAN	25.2
	ST.DEV.	2.2
	N	10

MEAN OF MEANS OVER TREATMENT		GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 50 MG/KG	GROUP 4 200 MG/KG
	MEAN	23.0	23.7	24.3	22.5

		GROUP 5 1000 MG/KG
	MEAN	23.9

* / ** : Dunnett-Test based on pooled variance significant at 5% (*) or 1% (**) level

FOOD CONSUMPTION (G/ANIMAL/DAY) SUMMARY
MALES

TREATMENT		GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 50 MG/KG	GROUP 4 200 MG/KG
DAYS 1-8 WEEKS 1/2	MEAN	22.5	22.7	23.6	21.6
	ST.DEV.	2.1	2.5	0.8	2.0
	N	10	5	5	5
		GROUP 5 1000 MG/KG			
	MEAN	22.3			
	ST.DEV.	1.2			
	N	10			

		GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 50 MG/KG	GROUP 4 200 MG/KG
DAYS 8-15 WEEKS 2/3	MEAN	23.2	24.0	24.1	21.9
	ST.DEV.	2.8	2.0	1.3	1.8
	N	10	5	5	5
		GROUP 5 1000 MG/KG			
	MEAN	23.2			
	ST.DEV.	1.6			
	N	10			

		GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 50 MG/KG	GROUP 4 200 MG/KG
DAYS 15-22 WEEKS 3/4	MEAN	23.2	23.4	24.5	22.7
	ST.DEV.	3.0	2.3	1.4	2.2
	N	10	4 x	5	5
		GROUP 5 1000 MG/KG			
	MEAN	24.9			
	ST.DEV.	1.8			
	N	10			

		GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 50 MG/KG	GROUP 4 200 MG/KG
DAYS 22-28 WEEK 4	MEAN	23.2	24.4	24.9	23.8
	ST.DEV.	2.5	3.2	1.7	3.1
	N	10	5	5	5

x Explanations for excluded data are listed in the tables of individual values
* / ** : Dunnett-Test based on pooled variance significant at 5% (*) or 1% (**) level

FOOD CONSUMPTION (G/ANIMAL/DAY) SUMMARY
FEMALES

PRETEST		GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 50 MG/KG	GROUP 4 200 MG/KG
DAYS 1-8 WEEKS 1/2	MEAN	14.8	14.2	15.1	15.0
	ST.DEV.	0.9	0.6	1.0	0.9
	N	10	5	5	5

		GROUP 5 1000 MG/KG
	MEAN	15.4
	ST.DEV.	0.9
	N	10

* / ** : Dunnett-Test based on pooled variance significant at 5% (*) or 1% (**) level

FOOD CONSUMPTION (G/ANIMAL/DAY) SUMMARY
MALES

RECOVERY		GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 50 MG/KG	GROUP 4 200 MG/KG
DAYS 1-8 WEEKS 1/2	MEAN	24.3	---	---	---
	ST.DEV.	1.9	---	---	---
	N	5	0	0	0
		GROUP 5 1000 MG/KG			
	MEAN	23.4			
	ST.DEV.	1.5			
	N	5			

		GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 50 MG/KG	GROUP 4 200 MG/KG
DAYS 8-14 WEEK 2	MEAN	22.6	---	---	---
	ST.DEV.	2.2	---	---	---
	N	5	0	0	0
		GROUP 5 1000 MG/KG			
	MEAN	22.6			
	ST.DEV.	2.1			
	N	5			

MEAN OF MEANS OVER RECOVERY		GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 50 MG/KG	GROUP 4 200 MG/KG
	MEAN	23.4	---	---	---
		GROUP 5 1000 MG/KG			
	MEAN	23.0			

* / ** : Dunnett-Test based on pooled variance significant at 5% (*) or 1% (**) level

FOOD CONSUMPTION (G/ANIMAL/DAY) SUMMARY
FEMALES

TREATMENT		GROUP 5 1000 MG/KG
	MEAN	19.4
	ST.DEV.	1.7
	N	10

MEAN OF MEANS OVER TREATMENT		GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 50 MG/KG	GROUP 4 200 MG/KG
	MEAN	17.6	16.6	17.5	17.2

		GROUP 5 1000 MG/KG
	MEAN	18.4

* / ** : Dunnett-Test based on pooled variance significant at 5% (*) or 1% (**) level

FOOD CONSUMPTION (G/ANIMAL/DAY) SUMMARY
FEMALES

TREATMENT		GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 50 MG/KG	GROUP 4 200 MG/KG
DAYS 1-8 WEEKS 1/2	MEAN	16.8	15.7	16.7	16.3
	ST.DEV.	1.2	1.3	1.3	1.1
	N	10	5	5	5
		GROUP 5 1000 MG/KG			
	MEAN	17.5			
	ST.DEV.	0.8			
	N	10			

		GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 50 MG/KG	GROUP 4 200 MG/KG
DAYS 8-15 WEEKS 2/3	MEAN	17.3	15.7	16.9	16.6
	ST.DEV.	1.6	1.1	1.3	1.0
	N	10	5	5	5
		GROUP 5 1000 MG/KG			
	MEAN	17.5			
	ST.DEV.	1.0			
	N	10			

		GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 50 MG/KG	GROUP 4 200 MG/KG
DAYS 15-22 WEEKS 3/4	MEAN	17.7	17.7	17.9	17.4
	ST.DEV.	1.1	2.9	0.8	0.5
	N	8 x	5	5	5
		GROUP 5 1000 MG/KG			
	MEAN	19.1			
	ST.DEV.	1.6			
	N	10			

		GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 50 MG/KG	GROUP 4 200 MG/KG
DAYS 22-28 WEEK 4	MEAN	18.7	17.1	18.5	18.5
	ST.DEV.	1.0	1.7	1.7	0.7
	N	10	5	5	5

x Explanations for excluded data are listed in the tables of individual values
* / ** : Dunnett-Test based on pooled variance significant at 5% (*) or 1% (**) level

RELATIVE FOOD CONSUMPTION SUMMARY
(G/KG BODY WEIGHT/DAY)
MALES

PRETEST		GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 50 MG/KG	GROUP 4 200 MG/KG
DAYS 1-8 WEEKS 1/2	MEAN ST.DEV. N	134.4 9.4 10	136.4 14.5 5	137.5 8.2 5	126.5 5.5 5

		GROUP 5 1000 MG/KG
	MEAN ST.DEV. N	127.3 9.2 10

* / ** : Dunnett-Test based on pooled variance significant at 5% (*) or 1% (**) level

FOOD CONSUMPTION (G/ANIMAL/DAY) SUMMARY
FEMALES

RECOVERY		GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 50 MG/KG	GROUP 4 200 MG/KG
DAYS 1-8 WEEKS 1/2	MEAN	20.1	---	---	---
	ST.DEV.	0.9	---	---	---
	N	5	0	0	0
		GROUP 5 1000 MG/KG			
	MEAN	20.7			
	ST.DEV.	1.5			
	N	5			

		GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 50 MG/KG	GROUP 4 200 MG/KG
DAYS 8-14 WEEK 2	MEAN	18.0	---	---	---
	ST.DEV.	0.5	---	---	---
	N	5	0	0	0
		GROUP 5 1000 MG/KG			
	MEAN	17.8			
	ST.DEV.	1.3			
	N	5			

MEAN OF MEANS OVER RECOVERY		GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 50 MG/KG	GROUP 4 200 MG/KG
	MEAN	19.1	---	---	---
		GROUP 5 1000 MG/KG			
	MEAN	19.2			

* / ** : Dunnett-Test based on pooled variance significant at 5% (*) or 1% (**) level

RELATIVE FOOD CONSUMPTION SUMMARY
(G/KG BODY WEIGHT/DAY)
MALES

TREATMENT		GROUP 5 1000 MG/KG
	MEAN	89.8
	ST.DEV.	8.5
	N	10

MEAN OF MEANS OVER TREATMENT		GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 50 MG/KG	GROUP 4 200 MG/KG
	MEAN	90.5	88.9	90.9	86.1

		GROUP 5 1000 MG/KG
	MEAN	91.7

* / ** : Dunnett-Test based on pooled variance significant at 5% (*) or 1% (**) level

RELATIVE FOOD CONSUMPTION SUMMARY
(G/KG BODY WEIGHT/DAY)
MALES

TREATMENT		GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 50 MG/KG	GROUP 4 200 MG/KG
DAYS 1-8 WEEKS 1/2	MEAN	100.4	98.0	102.5	95.2
	ST.DEV.	4.4	7.6	3.2	3.7
	N	10	5	5	5
		GROUP 5 1000 MG/KG			
	MEAN	98.3			
	ST.DEV.	3.0			
	N	10			

		GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 50 MG/KG	GROUP 4 200 MG/KG
DAYS 8-15 WEEKS 2/3	MEAN	92.0	91.2	91.2	85.3 **
	ST.DEV.	4.9	3.7	3.5	2.6
	N	10	5	5	5
		GROUP 5 1000 MG/KG			
	MEAN	90.2			
	ST.DEV.	2.8			
	N	10			

		GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 50 MG/KG	GROUP 4 200 MG/KG
DAYS 15-22 WEEKS 3/4	MEAN	84.6	81.5	84.5	80.2
	ST.DEV.	4.8	3.9	5.4	2.2
	N	10	4 x	5	5
		GROUP 5 1000 MG/KG			
	MEAN	88.4			
	ST.DEV.	4.8			
	N	10			

		GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 50 MG/KG	GROUP 4 200 MG/KG
DAYS 22-28 WEEK 4	MEAN	84.8	84.9	85.6	83.8
	ST.DEV.	3.6	7.9	5.6	5.7
	N	10	5	5	5

x Explanations for excluded data are listed in the tables of individual values
* / ** : Dunnett-Test based on pooled variance significant at 5% (*) or 1% (**) level

RELATIVE FOOD CONSUMPTION SUMMARY (G/KG BODY WEIGHT/DAY) FEMALES

PRETEST		GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 50 MG/KG	GROUP 4 200 MG/KG
DAYS 1-8 WEEKS 1/2	MEAN	121.0	118.9	124.6	119.9
	ST.DEV.	6.6	4.9	11.2	9.3
	N	10	5	5	5

		GROUP 5 1000 MG/KG
	MEAN	125.6
	ST.DEV.	8.4
	N	10

* / ** : Dunnett-Test based on pooled variance significant at 5% (*) or 1% (**) level

RELATIVE FOOD CONSUMPTION SUMMARY
(G/KG BODY WEIGHT/DAY)
MALES

RECOVERY		GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 50 MG/KG	GROUP 4 200 MG/KG
DAYS 1-8 WEEKS 1/2	MEAN	80.0	---	---	---
	ST.DEV.	1.6	---	---	---
	N	5	0	0	0
		GROUP 5 1000 MG/KG			
	MEAN	77.9			
	ST.DEV.	4.5			
	N	5			

		GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 50 MG/KG	GROUP 4 200 MG/KG
DAYS 8-14 WEEK 2	MEAN	74.4	---	---	---
	ST.DEV.	5.2	---	---	---
	N	5	0	0	0
		GROUP 5 1000 MG/KG			
	MEAN	75.3			
	ST.DEV.	5.9			
	N	5			

MEAN OF MEANS OVER RECOVERY		GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 50 MG/KG	GROUP 4 200 MG/KG
	MEAN	77.2	---	---	---
		GROUP 5 1000 MG/KG			
	MEAN	76.6			

* / ** : Dunnett-Test based on pooled variance significant at 5% (*) or 1% (**) level

RELATIVE FOOD CONSUMPTION SUMMARY
(G/KG BODY WEIGHT/DAY)
FEMALES

TREATMENT		GROUP 5 1000 MG/KG
	MEAN	98.8
	ST.DEV.	5.9
	N	10

MEAN OF MEANS OVER TREATMENT		GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 50 MG/KG	GROUP 4 200 MG/KG
	MEAN	96.5	94.8	96.5	95.3

		GROUP 5 1000 MG/KG
	MEAN	99.4

* / ** : Dunnett-Test based on pooled variance significant at 5% (*) or 1% (**) level

RELATIVE FOOD CONSUMPTION SUMMARY (G/KG BODY WEIGHT/DAY) FEMALES

TREATMENT		GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 50 MG/KG	GROUP 4 200 MG/KG
DAYS 1-8 WEEKS 1/2	MEAN	102.3	99.3	102.1	100.9
	ST.DEV.	5.3	4.7	4.6	4.6
	N	10	5	5	5
		GROUP 5 1000 MG/KG			
	MEAN	105.5			
	ST.DEV.	4.6			
	N	10			

		GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 50 MG/KG	GROUP 4 200 MG/KG
DAYS 8-15 WEEKS 2/3	MEAN	95.8	90.9	94.9	92.8
	ST.DEV.	5.1	3.5	4.6	5.1
	N	10	5	5	5
		GROUP 5 1000 MG/KG			
	MEAN	96.2			
	ST.DEV.	3.4			
	N	10			

		GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 50 MG/KG	GROUP 4 200 MG/KG
DAYS 15-22 WEEKS 3/4	MEAN	90.8	96.3	93.1	90.9
	ST.DEV.	3.0	17.8	4.0	5.6
	N	8 x	5	5	5
		GROUP 5 1000 MG/KG			
	MEAN	97.1			
	ST.DEV.	5.8			
	N	10			

		GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 50 MG/KG	GROUP 4 200 MG/KG
DAYS 22-28 WEEK 4	MEAN	97.2	92.8	95.8	96.5
	ST.DEV.	5.2	7.1	7.4	8.5
	N	10	5	5	5

x Explanations for excluded data are listed in the tables of individual values
* / ** : Dunnett-Test based on pooled variance significant at 5% (*) or 1% (**) level

RELATIVE FOOD CONSUMPTION SUMMARY
(G/KG BODY WEIGHT/DAY)
FEMALES

RECOVERY		GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 50 MG/KG	GROUP 4 200 MG/KG
DAYS 1-8 WEEKS 1/2	MEAN	96.5	---	---	---
	ST.DEV.	2.2	---	---	---
	N	5	0	0	0
		GROUP 5 1000 MG/KG			
	MEAN	99.6			
	ST.DEV.	5.8			
	N	5			

		GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 50 MG/KG	GROUP 4 200 MG/KG
DAYS 8-14 WEEK 2	MEAN	86.8	---	---	---
	ST.DEV.	6.1	---	---	---
	N	5	0	0	0
		GROUP 5 1000 MG/KG			
	MEAN	85.8			
	ST.DEV.	4.5			
	N	5			

MEAN OF MEANS OVER RECOVERY		GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 50 MG/KG	GROUP 4 200 MG/KG
	MEAN	91.6	---	---	---
		GROUP 5 1000 MG/KG			
	MEAN	92.7			

* / ** : Dunnett-Test based on pooled variance significant at 5% (*) or 1% (**) level

BODY WEIGHTS (GRAM) SUMMARY
MALES

TREATMENT		GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 50 MG/KG	GROUP 4 200 MG/KG
DAY 1 WEEK 1	MEAN	189.3	193.3	195.0	189.2
	ST.DEV.	8.9	4.3	9.4	5.8
	N	10	5	5	5

		GROUP 5 1000 MG/KG
	MEAN	190.3
	ST.DEV.	6.7
	N	10

		GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 50 MG/KG	GROUP 4 200 MG/KG
DAY 8 WEEK 2	MEAN	223.4	231.6	230.6	226.8
	ST.DEV.	14.6	8.5	10.2	12.9
	N	10	5	5	5

		GROUP 5 1000 MG/KG
	MEAN	226.7
	ST.DEV.	11.0
	N	10

		GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 50 MG/KG	GROUP 4 200 MG/KG
DAY 15 WEEK 3	MEAN	251.8	263.3	264.4	256.4
	ST.DEV.	21.0	12.0	12.0	16.9
	N	10	5	5	5

		GROUP 5 1000 MG/KG
	MEAN	257.2
	ST.DEV.	16.2
	N	10

		GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 50 MG/KG	GROUP 4 200 MG/KG
DAY 22 WEEK 4	MEAN	272.8	286.8	290.7	283.1
	ST.DEV.	23.3	13.7	11.2	24.4
	N	10	5	5	5

* / ** : Dunnett-Test based on pooled variance significant at 5% (*) or 1% (**) level

BODY WEIGHTS (GRAM) SUMMARY
MALES

PRETEST		GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 50 MG/KG	GROUP 4 200 MG/KG
DAY 1	MEAN	147.0	148.3	149.5	147.1
WEEK 1	ST.DEV.	3.7	4.3	6.0	1.9
	N	10	5	5	5

	GROUP 5 1000 MG/KG
MEAN	148.5
ST.DEV.	3.7
N	10

* / ** : Dunnett-Test based on pooled variance significant at 5% (*) or 1% (**) level

BODY WEIGHTS (GRAM) SUMMARY
MALES

RECOVERY		GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 50 MG/KG	GROUP 4 200 MG/KG
DAY 1 WEEK 1	MEAN	269.3	---	---	---
	ST.DEV.	18.2	---	---	---
	N	5	0	0	0

		GROUP 5 1000 MG/KG
	MEAN	269.0
	ST.DEV.	8.9
	N	5

		GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 50 MG/KG	GROUP 4 200 MG/KG
DAY 8 WEEK 2	MEAN	303.6	---	---	---
	ST.DEV.	21.8	---	---	---
	N	5	0	0	0

		GROUP 5 1000 MG/KG
	MEAN	300.4
	ST.DEV.	8.1
	N	5

		GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 50 MG/KG	GROUP 4 200 MG/KG
DAY 14 WEEK 2	MEAN	318.1	---	---	---
	ST.DEV.	22.5	---	---	---
	N	5	0	0	0

		GROUP 5 1000 MG/KG
	MEAN	321.4
	ST.DEV.	6.9
	N	5

* / ** : Dunnett-Test based on pooled variance significant at 5% (*) or 1% (**) level

BODY WEIGHTS (GRAM) SUMMARY
MALES

TREATMENT		GROUP 5 1000 MG/KG
	MEAN	281.5
	ST.DEV.	17.2
	N	10

			GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 50 MG/KG	GROUP 4 200 MG/KG
DAY	28	MEAN	289.0	306.8	306.4	297.7
WEEK	4	ST.DEV.	22.9	16.8	15.5	29.9
		N	10	5	5	5

	GROUP 5 1000 MG/KG
MEAN	293.4
ST.DEV.	20.8
N	10

* / ** : Dunnett-Test based on pooled variance significant at 5% (*) or 1% (**) level

BODY WEIGHTS (GRAM) SUMMARY
FEMALES

TREATMENT		GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 50 MG/KG	GROUP 4 200 MG/KG
DAY 1 WEEK 1	MEAN	146.9	144.3	146.4	148.7
	ST.DEV.	5.8	3.2	2.2	6.1
	N	10	5	5	5

		GROUP 5 1000 MG/KG
	MEAN	147.7
	ST.DEV.	3.1
	N	10

		GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 50 MG/KG	GROUP 4 200 MG/KG
DAY 8 WEEK 2	MEAN	164.3	158.2	163.0	162.2
	ST.DEV.	7.7	6.3	5.9	10.6
	N	10	5	5	5

		GROUP 5 1000 MG/KG
	MEAN	165.5
	ST.DEV.	3.7
	N	10

		GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 50 MG/KG	GROUP 4 200 MG/KG
DAY 15 WEEK 3	MEAN	180.4	172.8	177.9	178.8
	ST.DEV.	9.7	7.3	8.0	11.1
	N	10	5	5	5

		GROUP 5 1000 MG/KG
	MEAN	181.8
	ST.DEV.	5.7
	N	10

		GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 50 MG/KG	GROUP 4 200 MG/KG
DAY 22 WEEK 4	MEAN	192.4	184.1	192.9	192.4
	ST.DEV.	10.8	6.0	5.5	12.6
	N	10	5	5	5

* / ** : Dunnett-Test based on pooled variance significant at 5% (*) or 1% (**) level

BODY WEIGHTS (GRAM) SUMMARY
FEMALES

TREATMENT		GROUP 5 1000 MG/KG
	MEAN	196.3
	ST.DEV.	6.5
	N	10

			GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 50 MG/KG	GROUP 4 200 MG/KG
DAY	28	MEAN	202.1	192.9	199.9	196.6
WEEK	4	ST.DEV.	10.2	10.9	6.9	11.5
		N	10	5	5	5

	GROUP 5 1000 MG/KG
MEAN	203.5
ST.DEV.	7.4
N	10

* / ** : Dunnett-Test based on pooled variance significant at 5% (*) or 1% (**) level

BODY WEIGHTS (GRAM) SUMMARY
FEMALES

PRETEST		GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 50 MG/KG	GROUP 4 200 MG/KG
DAY 1	MEAN	122.7	119.5	121.7	125.6
WEEK 1	ST.DEV.	2.8	2.0	3.4	4.8
	N	10	5	5	5

		GROUP 5 1000 MG/KG
	MEAN	122.6
	ST.DEV.	2.6
	N	10

* / ** : Dunnett-Test based on pooled variance significant at 5% (*) or 1% (**) level

BODY WEIGHTS (GRAM) SUMMARY
FEMALES

RECOVERY		GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 50 MG/KG	GROUP 4 200 MG/KG
DAY 1 WEEK 1	MEAN	186.3	---	---	---
	ST.DEV.	11.0	---	---	---
	N	5	0	0	0

	GROUP 5 1000 MG/KG
MEAN	186.1
ST.DEV.	3.5
N	5

		GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 50 MG/KG	GROUP 4 200 MG/KG
DAY 8 WEEK 2	MEAN	208.6	---	---	---
	ST.DEV.	12.1	---	---	---
	N	5	0	0	0

	GROUP 5 1000 MG/KG
MEAN	207.6
ST.DEV.	5.6
N	5

		GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 50 MG/KG	GROUP 4 200 MG/KG
DAY 14 WEEK 2	MEAN	215.0	---	---	---
	ST.DEV.	8.2	---	---	---
	N	5	0	0	0

	GROUP 5 1000 MG/KG
MEAN	214.3
ST.DEV.	5.7
N	5

* / ** : Dunnett-Test based on pooled variance significant at 5% (*) or 1% (**) level

OPHTHALMOSCOPIC EXAMINATIONS SUMMARY
MALES

	GROUP 1 0 MG/	GROUP 2 10 MG/	GROUP 3 50 MG/	GROUP 4 200 MG/	GROUP 5 1000 MG/KG
NO ABNORMALITIES DETECTED					
AT 4 WEEKS	9/10	4/5	5/5	4/5	10/10
AT 6 WEEKS	4/5	0/0	0/0	0/0	5/5
PERSISTENT PUPILLARY MEMBRANE					
AT 4 WEEKS	1/10	1/5	0/5	1/5	0/10
AT 6 WEEKS	1/5	0/0	0/0	0/0	0/5
PERSISTENT HYALOID VESSEL IN VITREOUS					
AT 4 WEEKS	0/10	1/5	0/5	0/5	0/10

#/## : Fisher's Exact Test significant at level 5% (#) or 1% (##)

OPHTHALMOSCOPIC EXAMINATIONS SUMMARY
FEMALES

	GROUP 1 0 MG/	GROUP 2 10 MG/	GROUP 3 50 MG/	GROUP 4 200 MG/	GROUP 5 1000 MG/KG
NO ABNORMALITIES DETECTED					
AT 4 WEEKS	10/10	4/5	5/5	5/5	8/10
AT 6 WEEKS	5/5	0/0	0/0	0/0	4/5
HAEMORRHAGIA IN VITREOUS BODY					
AT 4 WEEKS	0/10	1/5	0/5	0/5	1/10
CORNEAL OPACITY					
AT 4 WEEKS	0/10	0/5	0/5	0/5	1/10
AT 6 WEEKS	0/5	0/0	0/0	0/0	1/5

#/## : Fisher's Exact Test significant at level 5% (#) or 1% (##)

HEMATOLOGY SUMMARY
MALES

	RBC T/L	HB MMOL/L	HCT L/L	MCV FL	MCH FMOL	MCHC MMOL/L	PLATELETS G/L
AFTER 4 WEEKS							
1 0 MG/KG	9.36	10.7	0.53	56.3	1.14	20.2	922
2 10 MG/KG	9.36	10.6	0.53	56.7	1.14	20.1	928
3 50 MG/KG	9.23	10.4	0.52	56.3	1.13	20.0	1037
4 200 MG/KG	9.03	10.2	0.52	57.2	1.13	19.7	1005
5 1000 MG/KG	9.20	10.3	0.51	55.9	1.12	20.1	995
AFTER 6 WEEKS							
1 0 MG/KG	9.03	10.7	0.53	58.3	1.18	20.3	912
5 1000 MG/KG	8.66	10.0 **	0.49	56.8	1.15	20.3	1092

	RETICULOCYTE COUNT						
	RETIC. %	RETIC. T/L	HFR %	MFR %	LFR %	NEN /100 WBC	HEINZ BOD. o/oo
AFTER 4 WEEKS							
1 0 MG/KG	2.60	0.2196	6.3	34.6	59.1	0.2	0
2 10 MG/KG	2.74	0.2327	8.4	36.3	55.3	0.0	0
3 50 MG/KG	2.54	0.2118	6.0	35.8	58.2	0.2	0
4 200 MG/KG	2.57	0.2113	7.2	36.9	55.9	0.0	0
5 1000 MG/KG	2.44	0.2059	5.8	33.4	60.8	0.3	0
AFTER 6 WEEKS							
1 0 MG/KG	2.64	0.2278	3.4	33.9	62.6	0.0	0
5 1000 MG/KG	2.90	0.2395	3.2	31.3	65.5	0.0	0

			DIFF.WBC COUNT (REL.)				
	MET-HB %	WBC G/L	BAND 1	SEG. 1	EO. 1	BASO. 1	LYMPH. 1
AFTER 4 WEEKS							
1 0 MG/KG	1.1	7.5	0.00	0.14	0.01	0.00	0.84
2 10 MG/KG	1.2	8.8	0.00	0.10	0.01	0.00	0.89
3 50 MG/KG	1.1	8.6	0.00	0.09	0.01	0.00	0.90
4 200 MG/KG	0.9	7.5	0.00	0.08	0.01	0.00	0.92
5 1000 MG/KG	1.0	9.5 *	0.00	0.10	0.01	0.00	0.89
AFTER 6 WEEKS							
1 0 MG/KG	1.0	7.0	0.00	0.15	0.00	0.00	0.84
5 1000 MG/KG	1.1	9.0 *	0.00	0.07 +	0.00	0.00	0.92 +

	DIFF.WBC COUNT (REL.)			DIFF.WBC COUNT (ABS.)			
	MOND. 1	PLAS. 1	OTHER 1	BAND G/L	SEG. G/L	EO. G/L	BASO. G/L
AFTER 4 WEEKS							
1 0 MG/KG	0.01	0.00	0.00	0.0	1.1	0.1	0.0
2 10 MG/KG	0.00	0.00	0.00	0.0	0.9	0.1	0.0
3 50 MG/KG	0.00	0.00	0.00	0.0	0.7	0.1	0.0
4 200 MG/KG	0.00	0.00	0.00	0.0	0.6	0.0	0.0
5 1000 MG/KG	0.01	0.00	0.00	0.0	0.9	0.0	0.0

*/**: Dunnett-test based on pooled variance sig. at 5% or 1% level. +: Steel-test sig. at 5% level.

HEMATOLOGY SUMMARY
MALES

	DIFF.WBC COUNT (REL.)			DIFF.WBC COUNT (ABS.)			
	MONO. 1	PLAS. 1	OTHER 1	BAND G/L	SEG. G/L	EO. G/L	BASO. G/L
AFTER 6 WEEKS							
1 0 MG/KG	0.00	0.00	0.00	0.0	1.1	0.0	0.0
5 1000 MG/KG	0.00	0.00	0.00	0.0	0.6 **	0.0	0.0

	DIFF.WBC COUNT (ABS.)				COAGULATION	
	LYMPH. G/L	MONO. G/L	PLAS. G/L	OTHER G/L	PT SEC	APTT SEC
AFTER 4 WEEKS						
1 0 MG/KG	6.4	0.1	0.0	0.0	11.4	22.9
2 10 MG/KG	7.9	0.0	0.0	0.0	11.3	23.2
3 50 MG/KG	7.8	0.0	0.0	0.0	11.7	23.4
4 200 MG/KG	6.9	0.0	0.0	0.0	11.6	23.4
5 1000 MG/KG	8.5 *	0.0	0.0	0.0	11.0 *	22.6
AFTER 6 WEEKS						
1 0 MG/KG	6.0	0.0	0.0	0.0	11.0	22.1
5 1000 MG/KG	8.3 *	0.0	0.0	0.0	10.8	19.2 *

*/**: Dunnett-test based on pooled variance sig. at 5% or 1% level. +: Steel-test sig. at 5% level.

HEMATOLOGY SUMMARY
FEMALES

	RBC T/L	HB MMOL/L	HCT L/L	MCV FL	MCH FMOL	MCHC MMOL/L	PLATELETS G/L
AFTER 4 WEEKS							
1 0 MG/KG	8.63	9.9	0.50	57.8	1.15	19.9	996
2 10 MG/KG	8.70	9.9	0.50	57.5	1.14	19.8	956
3 50 MG/KG	8.59	9.9	0.50	57.7	1.15	19.9	1003
4 200 MG/KG	8.76	10.0	0.51 +	58.7	1.14	19.5 +	1011
5 1000 MG/KG	8.77	10.0	0.50	57.4	1.14	19.9	1105
AFTER 6 WEEKS							
1 0 MG/KG	8.33	10.4	0.51	61.3	1.25	20.5	985
5 1000 MG/KG	8.42	10.3	0.50	59.4	1.22	20.5	1006

	RETICULOCYTE COUNT						
	RETIC. %	RETIC. T/L	HFR %	MFR %	LFR %	NEN /100 WBC	HEINZ BOD. o/oo
AFTER 4 WEEKS							
1 0 MG/KG	3.23	0.2557	8.4	36.4	55.2	0.4	0
2 10 MG/KG	2.70	0.2155	12.1	36.6	51.3	0.0	0
3 50 MG/KG	2.97	0.2362	7.5	34.6	57.9	0.2	0
4 200 MG/KG	3.04	0.2458	6.9	32.3	60.9	0.0	0
5 1000 MG/KG	2.96	0.2434	8.3	34.7	57.0	0.0	0
AFTER 6 WEEKS							
1 0 MG/KG	2.69	0.2122	2.6	32.1	65.4	0.0	0
5 1000 MG/KG	2.50	0.2011	1.7	31.7	66.6	0.0	0

			DIFF.WBC COUNT (REL.)				
	MET-HB %	WBC G/L	BAND 1	SEG. 1	EO. 1	BASO. 1	LYMPH. 1
AFTER 4 WEEKS							
1 0 MG/KG	1.1	5.6	0.00	0.11	0.00	0.00	0.89
2 10 MG/KG	1.1	4.5	0.00	0.10	0.00	0.00	0.90
3 50 MG/KG	1.0	4.4	0.00	0.15	0.01	0.00	0.84
4 200 MG/KG	1.1	5.8	0.00	0.09	0.01	0.00	0.87
5 1000 MG/KG	1.1	6.0	0.00	0.13	0.01	0.00	0.86
AFTER 6 WEEKS							
1 0 MG/KG	1.1	5.2	0.00	0.10	0.00	0.00	0.90
5 1000 MG/KG	1.4	5.3	0.00	0.10	0.00	0.00	0.90

	DIFF.WBC COUNT (REL.)			DIFF.WBC COUNT (ABS.)			
	MONO. 1	PLAS. 1	OTHER 1	BAND G/L	SEG. G/L	EO. G/L	BASO. G/L
AFTER 4 WEEKS							
1 0 MG/KG	0.00	0.00	0.00	0.0	0.6	0.0	0.0
2 10 MG/KG	0.00	0.00	0.00	0.0	0.5	0.0	0.0
3 50 MG/KG	0.00	0.00	0.00	0.0	0.6	0.0	0.0
4 200 MG/KG	0.01	0.00	0.00	0.0	0.5	0.1	0.0
5 1000 MG/KG	0.00	0.00	0.00	0.0	0.8	0.0	0.0

*/**: Dunnett-test based on pooled variance sig. at 5% or 1% level. +: Steel-test sig. at 5% level.

HEMATOLOGY SUMMARY
FEMALES

	DIFF.WBC COUNT (REL.)			DIFF.WBC COUNT (ABS.)			
	MONO. 1	PLAS. 1	OTHER 1	BAND G/L	SEG. G/L	EO. G/L	BASO. G/L
AFTER 6 WEEKS							
1 0 MG/KG	0.00	0.00	0.00	0.0	0.5	0.0	0.0
5 1000 MG/KG	0.00	0.00	0.00	0.0	0.5	0.0	0.0

	DIFF.WBC COUNT (ABS.)				COAGULATION	
	LYMPH. G/L	MONO. G/L	PLAS. G/L	OTHER G/L	PT SEC	APTT SEC
AFTER 4 WEEKS						
1 0 MG/KG	5.0	0.0	0.0	0.0	11.3	21.5
2 10 MG/KG	4.1	0.0	0.0	0.0	11.1	20.8
3 50 MG/KG	3.8	0.0	0.0	0.0	11.1	21.6
4 200 MG/KG	5.1	0.1 *	0.0	0.0	11.1	20.2
5 1000 MG/KG	5.1	0.0	0.0	0.0	10.6 **	20.8
AFTER 6 WEEKS						
1 0 MG/KG	4.7	0.0	0.0	0.0	10.9	18.4
5 1000 MG/KG	4.8	0.0	0.0	0.0	11.1	19.9

*/**: Dunnett-test based on pooled variance sig. at 5% or 1% level. +: Steel-test sig. at 5% level.

CLINICAL BIOCHEMISTRY SUMMARY
MALES

	GLUCOSE MMOL/L	UREA MMOL/L	CREATININE µMOL/L	URIC ACID µMOL/L	BILI. T. µMOL/L	CHOLEST.T. MMOL/L	TRIGL. MMOL/L
AFTER 4 WEEKS							
1 0 MG/KG	5.88	5.99	39	21.0	3.1	1.63	0.87
2 10 MG/KG	6.20	6.00	41	24.2	2.9	1.96	0.90
3 50 MG/KG	6.78	5.95	44	30.1	3.1	1.70	0.68
4 200 MG/KG	5.38	5.11	41	25.1	3.9	1.48	0.76
5 1000 MG/KG	5.89	6.16	47 **	73.0 **	19.7 **	2.23 **	1.14
AFTER 6 WEEKS							
1 0 MG/KG	5.81	5.13	40	21.3	3.0	1.75	0.76
5 1000 MG/KG	6.41	6.25	42 *	25.5	3.5 **	1.73	0.69

	PHOS.LIPID MMOL/L	ASAT(GOT) µKAT/L	ALAT(GPT) µKAT/L	LDH µKAT/L	CK µKAT/L	ALP µKAT/L	G-GT NKAT/L
AFTER 4 WEEKS							
1 0 MG/KG	1.51	1.20	0.47	1.53	2.88	4.57	11.01
2 10 MG/KG	1.65	1.08	0.40	1.36	2.19	4.80	9.91
3 50 MG/KG	1.50	1.14	0.42	2.24	3.14	4.62	11.08
4 200 MG/KG	1.43	1.20	0.42	1.53	2.42	5.17	9.25
5 1000 MG/KG	1.94 **	1.21	0.31 **	2.15	2.93	5.21	9.19
AFTER 6 WEEKS							
1 0 MG/KG	1.67	1.16	0.48	1.89	2.72	3.90	6.84
5 1000 MG/KG	1.59	1.10	0.33 **	2.07	2.15	4.16	6.40

	CALCIUM MMOL/L	PHOSPHORUS MMOL/L	SODIUM MMOL/L	POTASSIUM MMOL/L	CHLORIDE MMOL/L	ALBUMIN g/L	PROTEIN T. g/L
AFTER 4 WEEKS							
1 0 MG/KG	2.69	2.22	149.8	3.37	103.6	33.0	67.6
2 10 MG/KG	2.76	2.21	149.5	3.25	103.8	32.4	67.4
3 50 MG/KG	2.76	2.28	151.5	3.29	103.8	33.2	67.5
4 200 MG/KG	2.76	2.22	148.9	3.40	103.9	32.4	66.1
5 1000 MG/KG	2.79 *	2.25	149.1	3.23	101.4	33.1	69.3
AFTER 6 WEEKS							
1 0 MG/KG	2.64	1.93	145.0	3.37	104.3	33.0	69.9
5 1000 MG/KG	2.67	2.18 *	148.2	3.73	101.9	32.2	66.5

	GLOBULIN g/L	A/G RATIO
AFTER 4 WEEKS		
1 0 MG/KG	34.6	0.96
2 10 MG/KG	35.0	0.93
3 50 MG/KG	34.3	0.97
4 200 MG/KG	33.7	0.96
5 1000 MG/KG	36.2	0.92

*/**: Dunnett-test based on pooled variance sig. at 5% or 1% level. +: Steel-test sig. at 5% level.

CLINICAL BIOCHEMISTRY SUMMARY
MALES

	GLOBULIN g/L	A/G RATIO
AFTER 6 WEEKS		
1 0 MG/KG	37.0	0.89
5 1000 MG/KG	34.3	0.94

*/**: Dunnett-test based on pooled variance sig. at 5% or 1% level. +: Steel-test sig. at 5% level.

CLINICAL BIOCHEMISTRY SUMMARY
FEMALES

	GLUCOSE MMOL/L	UREA MMOL/L	CREATININE µMOL/L	URIC ACID µMOL/L	BILI. T. µMOL/L	CHOLEST.T. MMOL/L	TRIGL. MMOL/L
AFTER 4 WEEKS							
1 0 MG/KG	5.89	6.58	45	34.1	3.5	1.77	0.40
2 10 MG/KG	5.27	6.29	48	39.7	3.4	2.07	0.43
3 50 MG/KG	5.57	7.00	45	36.7	3.5	1.66	0.41
4 200 MG/KG	4.72 *	6.09	45	37.2	4.0	1.70	0.31
5 1000 MG/KG	4.88 *	5.62 *	48	68.5 **	13.1 **	1.82	0.44
AFTER 6 WEEKS							
1 0 MG/KG	5.23	6.50	48	32.7	3.9	1.58	0.53
5 1000 MG/KG	5.59	7.24	43	30.2	3.4	1.61	0.48

	PHOS.LIPID MMOL/L	ASAT(GOT) µKAT/L	ALAT(GPT) µKAT/L	LDH µKAT/L	CK µKAT/L	ALP µKAT/L	G-GT NKAT/L
AFTER 4 WEEKS							
1 0 MG/KG	1.88	1.14	0.40	1.63	1.91	2.85	11.34
2 10 MG/KG	2.05	1.04	0.30	1.72	2.02	2.04	10.28
3 50 MG/KG	1.80	1.02	0.34	1.61	1.91	1.93 *	10.60
4 200 MG/KG	1.80	1.28	0.36	1.73	2.63	2.19	12.59
5 1000 MG/KG	1.86	1.26	0.26 **	2.67 **	2.39	2.35	8.99
AFTER 6 WEEKS							
1 0 MG/KG	1.72	1.14	0.40	2.28	2.79	2.55	8.24
5 1000 MG/KG	1.68	1.09	0.31	1.86	2.03	1.80	9.52

	CALCIUM MMOL/L	PHOSPHORUS MMOL/L	SODIUM MMOL/L	POTASSIUM MMOL/L	CHLORIDE MMOL/L	ALBUMIN g/L	PROTEIN T. g/L
AFTER 4 WEEKS							
1 0 MG/KG	2.62	1.79	146.6	2.97	106.7	35.1	70.5
2 10 MG/KG	2.66	1.79	148.1	3.04	106.3	34.8	70.1
3 50 MG/KG	2.62	1.67	149.0	3.07	105.9	36.1	70.9
4 200 MG/KG	2.65	1.88	147.6	3.08	107.4	34.6	71.1
5 1000 MG/KG	2.41 **	1.77	148.0	2.92	105.2	32.2 **	67.4
AFTER 6 WEEKS							
1 0 MG/KG	2.65	1.67	146.3	3.52	105.1	34.9	69.0
5 1000 MG/KG	2.60	1.82	145.6	3.46	103.7	33.9	67.6

	GLOBULIN g/L	A/G RATIO
AFTER 4 WEEKS		
1 0 MG/KG	35.5	0.99
2 10 MG/KG	35.3	0.99
3 50 MG/KG	34.8	1.04
4 200 MG/KG	36.5	0.95
5 1000 MG/KG	35.2	0.91

*/**: Dunnett-test based on pooled variance sig. at 5% or 1% level. +: Steel-test sig. at 5% level.

CLINICAL BIOCHEMISTRY SUMMARY
FEMALES

		GLOBULIN g/L	A/G RATIO
AFTER 6 WEEKS			
1	0 MG/KG	34.1	1.02
5	1000 MG/KG	33.7	1.01

*/**: Dunnett-test based on pooled variance sig. at 5% or 1% level. +: Steel-test sig. at 5% level.

URINALYSIS SUMMARY
MALES

	VOLUME/18h ML	SPEC.GRAV. 1	OSMOLALITY MMOL/KG	pH	PROTEIN SCORE 0/3	GLUCOSE SCORE 0/3	KETONE SCORE 0/3
AFTER 4 WEEKS							
1 0 MG/KG	7.8	1.030	984	9	1	0	0
2 10 MG/KG	8.4	1.028	931	9	1	0	0
3 50 MG/KG	8.6	1.027	897	9	1	0	0
4 200 MG/KG	6.8	1.031	1140	8	1	0	0
5 1000 MG/KG	6.4	1.041 **	1410 **	8	3 +	0	0
AFTER 6 WEEKS							
1 0 MG/KG	7.3	1.031	1012	7	1	0	0
5 1000 MG/KG	7.3	1.031	1003	7	1	0	0

	BILIRUBIN SCORE 0/3	BLOOD SCORE 0/3	UROBILI. SCORE 0/3	CRYSTALS TRIP.PHOS. SCORE 0/3
AFTER 4 WEEKS				
1 0 MG/KG	0	0	0	0
2 10 MG/KG	0	0	0	0
3 50 MG/KG	0	0	0	0
4 200 MG/KG	0	0	0	0
5 1000 MG/KG	1 +	1 +	0	0
AFTER 6 WEEKS				
1 0 MG/KG	0	0	0	0
5 1000 MG/KG	0	1 +	0	0

*/**: Dunnett-test based on pooled variance sig. at 5% or 1% level. +: Steel-test sig. at 5% level.

URINALYSIS SUMMARY
FEMALES

	VOLUME/18h ML	SPEC.GRAV. 1	OSMOLALITY MMOL/KG	pH	PROTEIN SCORE 0/3	GLUCOSE SCORE 0/3	KETONE SCORE 0/3
AFTER 4 WEEKS							
1 0 MG/KG	6.7	1.030	1085	7	1	0	0
2 10 MG/KG	4.7	1.035	1311	7	1	0	0
3 50 MG/KG	6.9	1.030	1062	7	0	0	0
4 200 MG/KG	5.7	1.030	1124	7	0	0	0
5 1000 MG/KG	6.9	1.027	1000	7	1	0	0
AFTER 6 WEEKS							
1 0 MG/KG	6.5	1.028	976	6	0	0	0
5 1000 MG/KG	7.1	1.029	1063	6	0	0	0

	BILIRUBIN SCORE 0/3	BLOOD SCORE 0/3	UROBILI. SCORE 0/3	CRYSTALS TRIP.PHOS. SCORE 0/3
AFTER 4 WEEKS				
1 0 MG/KG	0	0	0	0
2 10 MG/KG	0	0	0	0
3 50 MG/KG	0	0	0	0
4 200 MG/KG	0	0	0	0
5 1000 MG/KG	0	1 +	0	0
AFTER 6 WEEKS				
1 0 MG/KG	0	0	0	0
5 1000 MG/KG	0	1	0	0

*/**: Dunnett-test based on pooled variance sig. at 5% or 1% level. +: Steel-test sig. at 5% level.

ORGAN WEIGHTS (GRAM) SUMMARY
AFTER 4 WEEKS
MALES

		GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 50 MG/KG	GROUP 4 200 MG/KG	GROUP 5 1000 MG/KG
BODY W.	MEAN	265.0	273.4	276.7	271.4	264.6
	ST.DEV.	25.3	14.7	13.9	26.5	27.4
	N	4	5	5	5	5
BRAIN	MEAN	1.96	1.98	1.92	1.90	1.94
	ST.DEV.	0.06	0.11	0.04	0.08	0.05
	N	4	5	5	5	5
PITUITARY	MEAN	0.008	0.010	0.009	0.009	0.008
	ST.DEV.	0.002	0.001	0.001	0.002	0.001
	N	4	5	5	5	5
HEART	MEAN	0.999	0.946	0.965	0.884	0.957
	ST.DEV.	0.172	0.083	0.048	0.131	0.075
	N	4	5	5	5	5
THYROIDS	MEAN	0.021	0.020	0.021	0.020	0.018
	ST.DEV.	0.003	0.003	0.005	0.002	0.002
	N	4	5	5	5	5
LIVER	MEAN	8.14	8.56	8.54	7.86	8.85
	ST.DEV.	1.15	0.71	0.75	0.89	1.18
	N	4	5	5	5	5
KIDNEYS	MEAN	1.91	2.04	1.92	1.91	2.17
	ST.DEV.	0.27	0.20	0.10	0.30	0.21
	N	4	5	5	5	5
ADRENALS	MEAN	0.060	0.063	0.057	0.063	0.059
	ST.DEV.	0.012	0.009	0.005	0.008	0.011
	N	4	5	5	5	5
SPLEEN	MEAN	0.557	0.678	0.637	0.649	0.661
	ST.DEV.	0.086	0.054	0.085	0.078	0.182
	N	4	5	5	5	5
TESTES	MEAN	3.21	3.38	3.33	3.06	3.22
	ST.DEV.	0.30	0.16	0.08	0.16	0.32
	N	4	5	5	5	5

*/**: Dunnett-test based on pooled variance sig. at 5% or 1% level.

ORGAN/BODY WEIGHT RATIOS SUMMARY
AFTER 4 WEEKS
MALES

		GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 50 MG/KG	GROUP 4 200 MG/KG	GROUP 5 1000 MG/KG
BODY W.	MEAN	265.0	273.4	276.7	271.4	264.6
(GRAM)	ST.DEV.	25.3	14.7	13.9	26.5	27.4
	N	4	5	5	5	5
BRAIN	MEAN	0.74	0.73	0.69	0.71	0.74
(%)	ST.DEV.	0.06	0.05	0.04	0.06	0.08
	N	4	5	5	5	5
PITUITARY	MEAN	0.003	0.004	0.003	0.003	0.003
(%)	ST.DEV.	0.000	0.000	0.001	0.000	0.000
	N	4	5	5	5	5
HEART	MEAN	0.375	0.346	0.349	0.325 *	0.363
(%)	ST.DEV.	0.036	0.025	0.020	0.022	0.030
	N	4	5	5	5	5
THYROIDS	MEAN	0.008	0.007	0.008	0.007	0.007
(%)	ST.DEV.	0.001	0.001	0.001	0.001	0.001
	N	4	5	5	5	5
LIVER	MEAN	3.06	3.13	3.08	2.89	3.34 *
(%)	ST.DEV.	0.14	0.13	0.14	0.06	0.19
	N	4	5	5	5	5
KIDNEYS	MEAN	0.72	0.74	0.69	0.70	0.82 *
(%)	ST.DEV.	0.04	0.06	0.02	0.05	0.07
	N	4	5	5	5	5
ADRENALS	MEAN	0.022	0.023	0.021	0.023	0.022
(%)	ST.DEV.	0.003	0.004	0.001	0.002	0.003
	N	4	5	5	5	5
SPLEEN	MEAN	0.210	0.249	0.231	0.241	0.249
(%)	ST.DEV.	0.025	0.027	0.034	0.043	0.060
	N	4	5	5	5	5
TESTES	MEAN	1.21	1.24	1.21	1.13	1.22
(%)	ST.DEV.	0.11	0.12	0.06	0.06	0.04
	N	4	5	5	5	5

*/**: Dunnett-test based on pooled variance sig. at 5% or 1% level.

ORGAN/BRAIN WEIGHT RATIOS SUMMARY
AFTER 4 WEEKS
MALES

		GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 50 MG/KG	GROUP 4 200 MG/KG	GROUP 5 1000 MG/KG
BRAIN (GRAM)	MEAN	1.96	1.98	1.92	1.90	1.94
	ST.DEV.	0.06	0.11	0.04	0.08	0.05
	N	4	5	5	5	5
PITUITARY (%)	MEAN	0.429	0.492	0.457	0.490	0.439
	ST.DEV.	0.086	0.049	0.067	0.076	0.065
	N	4	5	5	5	5
HEART (%)	MEAN	50.849	47.750	50.369	46.466	49.474
	ST.DEV.	8.057	3.160	3.294	6.996	4.326
	N	4	5	5	5	5
THYROIDS (%)	MEAN	1.069	1.022	1.115	1.042	0.928
	ST.DEV.	0.139	0.149	0.264	0.064	0.104
	N	4	5	5	5	5
LIVER (%)	MEAN	414.77	432.78	446.17	412.95	457.27
	ST.DEV.	55.99	35.15	47.71	41.89	64.78
	N	4	5	5	5	5
KIDNEYS (%)	MEAN	97.19	102.81	100.10	100.36	112.15
	ST.DEV.	13.73	7.53	7.21	14.72	11.97
	N	4	5	5	5	5
ADRENALS (%)	MEAN	3.030	3.162	2.983	3.308	3.041
	ST.DEV.	0.549	0.438	0.307	0.431	0.630
	N	4	5	5	5	5
SPLEEN (%)	MEAN	28.328	34.287	33.158	34.194	34.140
	ST.DEV.	3.828	2.479	3.911	4.980	9.424
	N	4	5	5	5	5
TESTES (%)	MEAN	163.70	171.32	173.94	160.69	166.45
	ST.DEV.	17.10	14.90	5.88	9.37	18.39
	N	4	5	5	5	5

*/**: Dunnett-test based on pooled variance sig. at 5% or 1% level.

ORGAN WEIGHTS (GRAM) SUMMARY
AFTER 4 WEEKS
FEMALES

		GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 50 MG/KG	GROUP 4 200 MG/KG	GROUP 5 1000 MG/KG
BODY W.	MEAN	178.5	173.9	176.3	175.1	181.5
	ST.DEV.	10.8	7.7	4.8	9.0	9.0
	N	5	5	5	5	5
BRAIN	MEAN	1.80	1.79	1.82	1.82	1.80
	ST.DEV.	0.06	0.02	0.10	0.06	0.09
	N	5	5	5	5	5
PITUITARY	MEAN	0.013	0.014	0.013	0.013	0.013
	ST.DEV.	0.001	0.002	0.002	0.002	0.001
	N	5	5	5	5	5
HEART	MEAN	0.753	0.709	0.719	0.662 *	0.696
	ST.DEV.	0.064	0.032	0.056	0.044	0.063
	N	5	5	5	5	5
THYROIDS	MEAN	0.020	0.019	0.017	0.018	0.018
	ST.DEV.	0.003	0.004	0.004	0.003	0.002
	N	5	5	5	5	5
LIVER	MEAN	6.38	5.67	5.79	5.52 *	6.10
	ST.DEV.	0.50	0.58	0.46	0.29	0.58
	N	5	4	5	5	5
KIDNEYS	MEAN	1.40	1.32	1.40	1.34	1.52
	ST.DEV.	0.10	0.06	0.12	0.04	0.11
	N	5	5	5	5	5
ADRENALS	MEAN	0.085	0.076	0.081	0.081	0.085
	ST.DEV.	0.004	0.003	0.012	0.004	0.006
	N	5	5	5	5	5
SPLEEN	MEAN	0.499	0.508	0.471	0.429	0.510
	ST.DEV.	0.047	0.112	0.037	0.042	0.077
	N	5	5	5	5	5
OVARIES	MEAN	0.118	0.092	0.104	0.111	0.103
	ST.DEV.	0.032	0.020	0.016	0.015	0.024
	N	5	5	5	5	5

*/**: Dunnett-test based on pooled variance sig. at 5% or 1% level.

ORGAN/BODY WEIGHT RATIOS SUMMARY
AFTER 4 WEEKS
FEMALES

		GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 50 MG/KG	GROUP 4 200 MG/KG	GROUP 5 1000 MG/KG
BODY W. (GRAM)	MEAN	178.5	173.9	176.3	175.1	181.5
	ST.DEV.	10.8	7.7	4.8	9.0	9.0
	N	5	5	5	5	5
BRAIN (%)	MEAN	1.01	1.03	1.03	1.04	0.99
	ST.DEV.	0.06	0.05	0.04	0.04	0.06
	N	5	5	5	5	5
PITUITARY (%)	MEAN	0.007	0.008	0.007	0.007	0.007
	ST.DEV.	0.001	0.002	0.001	0.001	0.000
	N	5	5	5	5	5
HEART (%)	MEAN	0.422	0.408	0.407	0.378 *	0.383
	ST.DEV.	0.017	0.018	0.029	0.026	0.024
	N	5	5	5	5	5
THYROIDS (%)	MEAN	0.011	0.011	0.010	0.010	0.010
	ST.DEV.	0.002	0.003	0.002	0.002	0.001
	N	5	5	5	5	5
LIVER (%)	MEAN	3.57	3.28	3.29	3.16 *	3.36
	ST.DEV.	0.16	0.28	0.31	0.11	0.26
	N	5	4	5	5	5
KIDNEYS (%)	MEAN	0.79	0.76	0.79	0.76	0.83
	ST.DEV.	0.02	0.04	0.08	0.03	0.04
	N	5	5	5	5	5
ADRENALS (%)	MEAN	0.048	0.044	0.046	0.046	0.047
	ST.DEV.	0.005	0.003	0.007	0.003	0.005
	N	5	5	5	5	5
SPLEEN (%)	MEAN	0.279	0.291	0.267	0.246	0.280
	ST.DEV.	0.012	0.055	0.021	0.033	0.032
	N	5	5	5	5	5
OVARIES (%)	MEAN	0.067	0.053	0.059	0.063	0.056
	ST.DEV.	0.022	0.010	0.010	0.006	0.012
	N	5	5	5	5	5

*/**: Dunnett-test based on pooled variance sig. at 5% or 1% level.

ORGAN/BRAIN WEIGHT RATIOS SUMMARY
AFTER 4 WEEKS
FEMALES

		GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 50 MG/KG	GROUP 4 200 MG/KG	GROUP 5 1000 MG/KG
BRAIN (GRAM)	MEAN	1.80	1.79	1.82	1.82	1.80
	ST.DEV.	0.06	0.02	0.10	0.06	0.09
	N	5	5	5	5	5
PITUITARY (%)	MEAN	0.701	0.769	0.714	0.704	0.746
	ST.DEV.	0.090	0.120	0.113	0.089	0.049
	N	5	5	5	5	5
HEART (%)	MEAN	41.882	39.657	39.470	36.338 *	38.681
	ST.DEV.	3.127	2.053	2.274	2.937	2.358
	N	5	5	5	5	5
THYROIDS (%)	MEAN	1.126	1.050	0.953	0.961	1.010
	ST.DEV.	0.204	0.217	0.204	0.176	0.105
	N	5	5	5	5	5
LIVER (%)	MEAN	354.86	317.08	319.05	302.96 *	338.82
	ST.DEV.	30.63	35.35	33.65	12.02	21.08
	N	5	4	5	5	5
KIDNEYS (%)	MEAN	78.10	73.83	76.99	73.39	84.26
	ST.DEV.	5.10	3.68	6.63	2.66	3.45
	N	5	5	5	5	5
ADRENALS (%)	MEAN	4.752	4.237	4.450	4.435	4.728
	ST.DEV.	0.357	0.186	0.594	0.202	0.206
	N	5	5	5	5	5
SPLEEN (%)	MEAN	27.748	28.422	25.887	23.612	28.439
	ST.DEV.	2.796	6.448	1.798	2.912	4.842
	N	5	5	5	5	5
OVARIES (%)	MEAN	6.572	5.152	5.750	6.099	5.709
	ST.DEV.	1.884	1.137	1.118	0.640	1.267
	N	5	5	5	5	5

*/**: Dunnett-test based on pooled variance sig. at 5% or 1% level.

ORGAN WEIGHTS (GRAM) SUMMARY
AFTER 6 WEEKS
MALES

		GROUP 1 0 MG/KG	GROUP 5 1000 MG/KG
BODY W.	MEAN	287.9	291.0
	ST.DEV.	18.8	9.8
	N	5	5
BRAIN	MEAN	1.99	1.92
	ST.DEV.	0.14	0.12
	N	5	5
PITUITARY	MEAN	0.009	0.009
	ST.DEV.	0.001	0.001
	N	5	5
HEART	MEAN	0.988	1.018
	ST.DEV.	0.071	0.064
	N	5	5
THYROIDS	MEAN	0.024	0.023
	ST.DEV.	0.009	0.003
	N	5	5
LIVER	MEAN	7.89	8.75
	ST.DEV.	0.57	0.67
	N	5	5
KIDNEYS	MEAN	1.89	2.07
	ST.DEV.	0.15	0.16
	N	5	5
ADRENALS	MEAN	0.074	0.071
	ST.DEV.	0.012	0.006
	N	5	5
SPLEEN	MEAN	0.709	0.699
	ST.DEV.	0.112	0.019
	N	5	5
TESTES	MEAN	3.45	3.25
	ST.DEV.	0.28	0.20
	N	5	5

*/**: Dunnett-test based on pooled variance sig. at 5% or 1% level.

ORGAN/BODY WEIGHT RATIOS SUMMARY
AFTER 6 WEEKS
MALES

		GROUP 1 0 MG/KG	GROUP 5 1000 MG/KG
BODY W.	MEAN	287.9	291.0
(GRAM)	ST.DEV.	18.8	9.8
	N	5	5
BRAIN	MEAN	0.69	0.66
(%)	ST.DEV.	0.04	0.05
	N	5	5
PITUITARY	MEAN	0.003	0.003
(%)	ST.DEV.	0.000	0.000
	N	5	5
HEART	MEAN	0.343	0.350
(%)	ST.DEV.	0.010	0.024
	N	5	5
THYROIDS	MEAN	0.008	0.008
(%)	ST.DEV.	0.003	0.001
	N	5	5
LIVER	MEAN	2.74	3.01
(%)	ST.DEV.	0.17	0.29
	N	5	5
KIDNEYS	MEAN	0.66	0.71
(%)	ST.DEV.	0.05	0.04
	N	5	5
ADRENALS	MEAN	0.026	0.024
(%)	ST.DEV.	0.004	0.002
	N	5	5
SPLEEN	MEAN	0.247	0.240
(%)	ST.DEV.	0.039	0.009
	N	5	5
TESTES	MEAN	1.20	1.12
(%)	ST.DEV.	0.03	0.09
	N	5	5

*/**: Dunnett-test based on pooled variance sig. at 5% or 1% level.

ORGAN/BRAIN WEIGHT RATIOS SUMMARY
AFTER 6 WEEKS
MALES

		GROUP 1 0 MG/KG	GROUP 5 1000 MG/KG
BRAIN (GRAM)	MEAN ST.DEV. N	1.99 0.14 5	1.92 0.12 5
PITUITARY (%)	MEAN ST.DEV. N	0.438 0.031 5	0.495 0.104 5
HEART (%)	MEAN ST.DEV. N	49.695 2.275 5	53.387 6.437 5
THYROIDS (%)	MEAN ST.DEV. N	1.211 0.448 5	1.222 0.225 5
LIVER (%)	MEAN ST.DEV. N	397.75 32.05 5	457.56 48.50 5
KIDNEYS (%)	MEAN ST.DEV. N	94.88 4.89 5	108.55 12.77 5
ADRENALS (%)	MEAN ST.DEV. N	3.727 0.713 5	3.744 0.550 5
SPLEEN (%)	MEAN ST.DEV. N	35.847 6.529 5	36.552 2.661 5
TESTES (%)	MEAN ST.DEV. N	173.69 12.21 5	169.57 12.81 5

*/**: Dunnett-test based on pooled variance sig. at 5% or 1% level.

ORGAN WEIGHTS (GRAM) SUMMARY
AFTER 6 WEEKS
FEMALES

		GROUP 1 0 MG/KG	GROUP 5 1000 MG/KG
BODY W.	MEAN	191.6	190.9
	ST.DEV.	8.4	4.3
	N	5	5
BRAIN	MEAN	1.85	1.85
	ST.DEV.	0.08	0.08
	N	5	5
PITUITARY	MEAN	0.011	0.013
	ST.DEV.	0.002	0.001
	N	5	5
HEART	MEAN	0.746	0.755
	ST.DEV.	0.038	0.026
	N	5	5
THYROIDS	MEAN	0.022	0.021
	ST.DEV.	0.006	0.011
	N	5	5
LIVER	MEAN	5.57	5.98 *
	ST.DEV.	0.29	0.24
	N	5	5
KIDNEYS	MEAN	1.31	1.53 **
	ST.DEV.	0.07	0.11
	N	5	5
ADRENALS	MEAN	0.078	0.081
	ST.DEV.	0.012	0.003
	N	5	5
SPLEEN	MEAN	0.506	0.584
	ST.DEV.	0.065	0.068
	N	5	5
OVARIES	MEAN	0.099	0.111
	ST.DEV.	0.009	0.008
	N	5	5

*/**: Dunnett-test based on pooled variance sig. at 5% or 1% level.

ORGAN/BODY WEIGHT RATIOS SUMMARY
AFTER 6 WEEKS
FEMALES

		GROUP 1 0 MG/KG	GROUP 5 1000 MG/KG
BODY W. (GRAM)	MEAN ST.DEV. N	191.6 8.4 5	190.9 4.3 5
BRAIN (%)	MEAN ST.DEV. N	0.97 0.03 5	0.97 0.05 5
PITUITARY (%)	MEAN ST.DEV. N	0.006 0.001 5	0.007 0.000 5
HEART (%)	MEAN ST.DEV. N	0.389 0.017 5	0.395 0.015 5
THYROIDS (%)	MEAN ST.DEV. N	0.011 0.003 5	0.011 0.006 5
LIVER (%)	MEAN ST.DEV. N	2.91 0.10 5	3.14 * 0.13 5
KIDNEYS (%)	MEAN ST.DEV. N	0.68 0.04 5	0.80 * 0.07 5
ADRENALS (%)	MEAN ST.DEV. N	0.041 0.005 5	0.042 0.002 5
SPLEEN (%)	MEAN ST.DEV. N	0.264 0.027 5	0.305 0.032 5
OVARIES (%)	MEAN ST.DEV. N	0.051 0.004 5	0.058 0.005 5

*/**: Dunnett-test based on pooled variance sig. at 5% or 1% level.

ORGAN/BRAIN WEIGHT RATIOS SUMMARY
AFTER 6 WEEKS
FEMALES

		GROUP 1 0 MG/KG	GROUP 5 1000 MG/KG
BRAIN (GRAM)	MEAN	1.85	1.85
	ST.DEV.	0.08	0.08
	N	5	5
PITUITARY (%)	MEAN	0.613	0.687
	ST.DEV.	0.105	0.043
	N	5	5
HEART (%)	MEAN	40.245	40.921
	ST.DEV.	2.547	1.345
	N	5	5
THYROIDS (%)	MEAN	1.175	1.141
	ST.DEV.	0.327	0.540
	N	5	5
LIVER (%)	MEAN	300.25	324.90
	ST.DEV.	11.83	21.59
	N	5	5
KIDNEYS (%)	MEAN	70.73	82.89 **
	ST.DEV.	3.41	6.13
	N	5	5
ADRENALS (%)	MEAN	4.189	4.389
	ST.DEV.	0.516	0.220
	N	5	5
SPLEEN (%)	MEAN	27.295	31.662
	ST.DEV.	3.500	3.883
	N	5	5
OVARIES (%)	MEAN	5.320	6.046
	ST.DEV.	0.591	0.512
	N	5	5

*/**: Dunnett-test based on pooled variance sig. at 5% or 1% level.

TABLES - INDIVIDUAL DATA

MORTALITY DATA
MALES
GROUP 1 (0 MG/KG)

ANIMAL	SCHEDULED NECROPSY	OTHER	COMMENT	TREATMENT FROM	TO
1	12-JUL-94		---	14-JUN-94	11-JUL-94
2	12-JUL-94		---	14-JUN-94	11-JUL-94
3		12-JUL-94	DIED DURING ANESTHESIA	14-JUN-94	11-JUL-94
4	12-JUL-94		---	14-JUN-94	11-JUL-94
5	12-JUL-94		---	14-JUN-94	11-JUL-94
6	26-JUL-94		---	14-JUN-94	11-JUL-94
7	26-JUL-94		---	14-JUN-94	11-JUL-94
8	26-JUL-94		---	14-JUN-94	11-JUL-94
9	26-JUL-94		---	14-JUN-94	11-JUL-94
10	26-JUL-94		---	14-JUN-94	11-JUL-94

MORTALITY DATA
MALES
GROUP 2 (10 MG/KG)

ANIMAL	SCHEDULED NECROPSY	OTHER	COMMENT	TREATMENT FROM	TO
11	12-JUL-94		---	14-JUN-94	11-JUL-94
12	12-JUL-94		---	14-JUN-94	11-JUL-94
13	12-JUL-94		---	14-JUN-94	11-JUL-94
14	12-JUL-94		---	14-JUN-94	11-JUL-94
15	12-JUL-94		---	14-JUN-94	11-JUL-94

MORTALITY DATA
MALES
GROUP 3 (50 MG/KG)

ANIMAL	SCHEDULED NECROPSY	OTHER	COMMENT	TREATMENT FROM	TO
16	12-JUL-94		---	14-JUN-94	11-JUL-94
17	12-JUL-94		---	14-JUN-94	11-JUL-94
18	12-JUL-94		---	14-JUN-94	11-JUL-94
19	12-JUL-94		---	14-JUN-94	11-JUL-94
20	12-JUL-94		---	14-JUN-94	11-JUL-94

MORTALITY DATA
MALES
GROUP 4 (200 MG/KG)

ANIMAL	SCHEDULED NECROPSY	OTHER	COMMENT	TREATMENT FROM	TO
21	12-JUL-94		---	14-JUN-94	11-JUL-94
22	12-JUL-94		---	14-JUN-94	11-JUL-94
23	12-JUL-94		---	14-JUN-94	11-JUL-94
24	12-JUL-94		---	14-JUN-94	11-JUL-94
25	12-JUL-94		---	14-JUN-94	11-JUL-94

MORTALITY DATA
MALES
GROUP 5 (1000 MG/KG)

ANIMAL	SCHEDULED NECROPSY	OTHER	COMMENT	TREATMENT FROM	TO
26	12-JUL-94		---	14-JUN-94	11-JUL-94
27	12-JUL-94		---	14-JUN-94	11-JUL-94
28	12-JUL-94		---	14-JUN-94	11-JUL-94
29	12-JUL-94		---	14-JUN-94	11-JUL-94
30	12-JUL-94		---	14-JUN-94	11-JUL-94
31	26-JUL-94		---	14-JUN-94	11-JUL-94
32	26-JUL-94		---	14-JUN-94	11-JUL-94
33	26-JUL-94		---	14-JUN-94	11-JUL-94
34	26-JUL-94		---	14-JUN-94	11-JUL-94
35	26-JUL-94		---	14-JUN-94	11-JUL-94

MORTALITY DATA
FEMALES
GROUP 1 (0 MG/KG)

ANIMAL	SCHEDULED NECROPSY	OTHER	COMMENT	TREATMENT FROM	TO
36	12-JUL-94		---	14-JUN-94	11-JUL-94
37	12-JUL-94		---	14-JUN-94	11-JUL-94
38	12-JUL-94		---	14-JUN-94	11-JUL-94
39	12-JUL-94		---	14-JUN-94	11-JUL-94
40	12-JUL-94		---	14-JUN-94	11-JUL-94
41	26-JUL-94		---	14-JUN-94	11-JUL-94
42	26-JUL-94		---	14-JUN-94	11-JUL-94
43	26-JUL-94		---	14-JUN-94	11-JUL-94
44	26-JUL-94		---	14-JUN-94	11-JUL-94
45	26-JUL-94		---	14-JUN-94	11-JUL-94

MORTALITY DATA
FEMALES
GROUP 2 (10 MG/KG)

ANIMAL	SCHEDULED NECROPSY	OTHER	COMMENT	TREATMENT FROM	TO
46	12-JUL-94		---	14-JUN-94	11-JUL-94
47	12-JUL-94		---	14-JUN-94	11-JUL-94
48	12-JUL-94		---	14-JUN-94	11-JUL-94
49	12-JUL-94		---	14-JUN-94	11-JUL-94
50	12-JUL-94		---	14-JUN-94	11-JUL-94

MORTALITY DATA
FEMALES
GROUP 3 (50 MG/KG)

ANIMAL	SCHEDULED NECROPSY	OTHER	COMMENT	TREATMENT FROM	TO
51	12-JUL-94		---	14-JUN-94	11-JUL-94
52	12-JUL-94		---	14-JUN-94	11-JUL-94
53	12-JUL-94		---	14-JUN-94	11-JUL-94
54	12-JUL-94		---	14-JUN-94	11-JUL-94
55	12-JUL-94		---	14-JUN-94	11-JUL-94

MORTALITY DATA
FEMALES
GROUP 4 (200 MG/KG)

ANIMAL	SCHEDULED NECROPSY	OTHER	COMMENT	TREATMENT FROM	TO
56	12-JUL-94		---	14-JUN-94	11-JUL-94
57	12-JUL-94		---	14-JUN-94	11-JUL-94
58	12-JUL-94		---	14-JUN-94	11-JUL-94
59	12-JUL-94		---	14-JUN-94	11-JUL-94
60	12-JUL-94		---	14-JUN-94	11-JUL-94

MORTALITY DATA
FEMALES
GROUP 5 (1000 MG/KG)

ANIMAL	SCHEDULED NECROPSY	OTHER	COMMENT	TREATMENT FROM	TO
61	12-JUL-94		---	14-JUN-94	11-JUL-94
62	12-JUL-94		---	14-JUN-94	11-JUL-94
63	12-JUL-94		---	14-JUN-94	11-JUL-94
64	12-JUL-94		---	14-JUN-94	11-JUL-94
65	12-JUL-94		---	14-JUN-94	11-JUL-94
66	26-JUL-94		---	14-JUN-94	11-JUL-94
67	26-JUL-94		---	14-JUN-94	11-JUL-94
68	26-JUL-94		---	14-JUN-94	11-JUL-94
69	26-JUL-94		---	14-JUN-94	11-JUL-94
70	26-JUL-94		---	14-JUN-94	11-JUL-94

CLINICAL SIGNS, DAILY
MALES
GROUP 1 (0 MG/KG)

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SIGN (MAX.GRADE)                    PRETEST      TREATMENT                          RECOVERY
(LOCATION)                   WEEKS: 1......      1......2......3......4......        1......2......
-------------------------------------------------------------------------------------------------
ANIMAL 1
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NO CLINICAL SIGNS NOTED

ANIMAL 2
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NO CLINICAL SIGNS NOTED

ANIMAL 3
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NO CLINICAL SIGNS NOTED

ANIMAL 4
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NO CLINICAL SIGNS NOTED

ANIMAL 5
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NO CLINICAL SIGNS NOTED

ANIMAL 6
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NO CLINICAL SIGNS NOTED

ANIMAL 7
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NO CLINICAL SIGNS NOTED

ANIMAL 8
--------------------------------
NO CLINICAL SIGNS NOTED

ANIMAL 9
--------------------------------
NO CLINICAL SIGNS NOTED

ANIMAL 10
--------------------------------
SKIN / FUR
  ALOPECIA (3)               G: .......      ..........1111111111111111111       1111111111111
  (CHEST WALL)
  ALOPECIA (3)               G: .......      ............................       ......11111111
  (PAW FRONT LEFT)
  ALOPECIA (3)               G: .......      ............................       ......11111111
  (PAW FRONT RIGHT)
```

G: Highest daily grades

CLINICAL SIGNS, DAILY
MALES
GROUP 2 (10 MG/KG)

SIGN (MAX.GRADE) (LOCATION)	PRETEST WEEKS: 1.....	TREATMENT 1.....2.....3.....4.....	RECOVERY 1.....2.....
ANIMAL 11			
NO CLINICAL SIGNS NOTED			
ANIMAL 12			
NO CLINICAL SIGNS NOTED			
ANIMAL 13			
NO CLINICAL SIGNS NOTED			
ANIMAL 14			
NO CLINICAL SIGNS NOTED			
ANIMAL 15			
NO CLINICAL SIGNS NOTED			

CLINICAL SIGNS, DAILY
MALES
GROUP 3 (50 MG/KG)

SIGN (MAX.GRADE) (LOCATION)	PRETEST WEEKS: 1.....	TREATMENT 1.....2.....3.....4.....	RECOVERY 1.....2.....

ANIMAL 16

NO CLINICAL SIGNS NOTED

ANIMAL 17

NO CLINICAL SIGNS NOTED

ANIMAL 18

NO CLINICAL SIGNS NOTED

ANIMAL 19

NO CLINICAL SIGNS NOTED

ANIMAL 20

NO CLINICAL SIGNS NOTED

CLINICAL SIGNS, DAILY
MALES
GROUP 4 (200 MG/KG)

SIGN (MAX.GRADE) (LOCATION)	PRETEST WEEKS: 1.....	TREATMENT 1.....2.....3.....4.....	RECOVERY 1.....2.....
ANIMAL 21			
NO CLINICAL SIGNS NOTED			
ANIMAL 22			
NO CLINICAL SIGNS NOTED			
ANIMAL 23			
NO CLINICAL SIGNS NOTED			
ANIMAL 24			
NO CLINICAL SIGNS NOTED			
ANIMAL 25			
NO CLINICAL SIGNS NOTED			

CLINICAL SIGNS, DAILY
MALES
GROUP 5 (1000 MG/KG)

SIGN (MAX.GRADE) (LOCATION)	WEEKS:	PRETEST 1.....	TREATMENT 1.....2.....3.....4.....	RECOVERY 1.....2.....
ANIMAL 26				
NO CLINICAL SIGNS NOTED				
ANIMAL 27				
NO CLINICAL SIGNS NOTED				
ANIMAL 28				
NO CLINICAL SIGNS NOTED				
ANIMAL 29				
NO CLINICAL SIGNS NOTED				
ANIMAL 30				
NO CLINICAL SIGNS NOTED				
ANIMAL 31				
NO CLINICAL SIGNS NOTED				
ANIMAL 32				
NO CLINICAL SIGNS NOTED				
ANIMAL 33				
NO CLINICAL SIGNS NOTED				
ANIMAL 34				
NO CLINICAL SIGNS NOTED				
ANIMAL 35				
NO CLINICAL SIGNS NOTED				

CLINICAL SIGNS, DAILY
FEMALES
GROUP 1 (0 MG/KG)

SIGN (MAX.GRADE) (LOCATION)	PRETEST WEEKS: 1.....	TREATMENT 1.....2.....3.....4.....	RECOVERY 1.....2.....

ANIMAL 36
NO CLINICAL SIGNS NOTED

ANIMAL 37
NO CLINICAL SIGNS NOTED

ANIMAL 38
NO CLINICAL SIGNS NOTED

ANIMAL 39
NO CLINICAL SIGNS NOTED

ANIMAL 40
NO CLINICAL SIGNS NOTED

ANIMAL 41
NO CLINICAL SIGNS NOTED

ANIMAL 42
NO CLINICAL SIGNS NOTED

ANIMAL 43
NO CLINICAL SIGNS NOTED

ANIMAL 44
NO CLINICAL SIGNS NOTED

ANIMAL 45
NO CLINICAL SIGNS NOTED

CLINICAL SIGNS, DAILY
FEMALES
GROUP 2 (10 MG/KG)

SIGN (MAX.GRADE) (LOCATION)	PRETEST WEEKS: 1.....	TREATMENT 1.....2.....3.....4.....	RECOVERY 1.....2.....

ANIMAL 46

NO CLINICAL SIGNS NOTED

ANIMAL 47

NO CLINICAL SIGNS NOTED

ANIMAL 48

NO CLINICAL SIGNS NOTED

ANIMAL 49

NO CLINICAL SIGNS NOTED

ANIMAL 50

NO CLINICAL SIGNS NOTED

CLINICAL SIGNS, DAILY
FEMALES
GROUP 3 (50 MG/KG)

SIGN (MAX.GRADE) (LOCATION)	WEEKS:	PRETEST 1.....	TREATMENT 1.....2.....3.....4.....	RECOVERY 1.....2.....
ANIMAL 51				
NO CLINICAL SIGNS NOTED				
ANIMAL 52				
NO CLINICAL SIGNS NOTED				
ANIMAL 53				
NO CLINICAL SIGNS NOTED				
ANIMAL 54				
NO CLINICAL SIGNS NOTED				
ANIMAL 55				
NO CLINICAL SIGNS NOTED				

CLINICAL SIGNS, DAILY
FEMALES
GROUP 4 (200 MG/KG)

SIGN (MAX.GRADE) (LOCATION)	WEEKS:	PRETEST 1.....	TREATMENT 1.....2.....3.....4.....	RECOVERY 1.....2.....
ANIMAL 56				
NO CLINICAL SIGNS NOTED				
ANIMAL 57				
NO CLINICAL SIGNS NOTED				
ANIMAL 58				
NO CLINICAL SIGNS NOTED				
ANIMAL 59				
NO CLINICAL SIGNS NOTED				
ANIMAL 60				
NO CLINICAL SIGNS NOTED				

CLINICAL SIGNS, DAILY
FEMALES
GROUP 5 (1000 MG/KG)

SIGN (MAX.GRADE) (LOCATION)	PRETEST WEEKS: 1.....	TREATMENT 1.....2.....3.....4.....	RECOVERY 1.....2.....
ANIMAL 61			
NO CLINICAL SIGNS NOTED			
ANIMAL 62			
NO CLINICAL SIGNS NOTED			
ANIMAL 63			
NO CLINICAL SIGNS NOTED			
ANIMAL 64			
NO CLINICAL SIGNS NOTED			
ANIMAL 65			
NO CLINICAL SIGNS NOTED			
ANIMAL 66			
NO CLINICAL SIGNS NOTED			
ANIMAL 67			
NO CLINICAL SIGNS NOTED			
ANIMAL 68			
NO CLINICAL SIGNS NOTED			
ANIMAL 69			
NO CLINICAL SIGNS NOTED			
ANIMAL 70			
NO CLINICAL SIGNS NOTED			

FOOD CONSUMPTION (G/ANIMAL/DAY)
MALES

GROUP 1 (0 MG/KG)

	PRETEST	TREATMENT				RECOVERY
DAYS	1-8	1-8	8-15	15-22	22-28	1-8
WEEKS	1/2	1/2	2/3	3/4	4	1/2
ANIMAL						
1	21.8	25.0	27.1	27.8	27.3	---
2	19.7	22.7	20.6	19.9	19.0	---
3	18.1	18.8	19.4	19.1	21.1	---
4	19.7	22.6	23.7	24.4	23.3	---
5	20.0	23.9	25.0	25.4	23.7	---
6	17.1	19.5	20.2	20.2	21.1	22.3
7	19.3	23.6	24.7	23.7	24.5	24.0
8	21.3	23.5	23.8	24.4	24.2	25.9
9	21.8	24.5	26.8	26.2	25.9	26.6
10	18.8	20.4	20.7	20.6	21.4	22.6

	RECOVERY
DAYS	8-14
WEEKS	2
ANIMAL	
1	---
2	---
3	---
4	---
5	---
6	21.4
7	20.0
8	24.5
9	25.2
10	21.7

FOOD CONSUMPTION (G/ANIMAL/DAY)
MALES

GROUP 2 (10 MG/KG)

	PRETEST	TREATMENT				RECOVERY
DAYS	1-8	1-8	8-15	15-22	22-28	1-8
WEEKS	1/2	1/2	2/3	3/4	4	1/2
ANIMAL						
11	18.3	19.8	22.2	21.5	20.7	---
12	21.3	23.9	24.9	9.8 (A)	27.0	---
13	18.6	21.1	22.2	21.9	22.0	---
14	22.6	26.3	27.0	26.6	28.2	---
15	20.1	22.6	23.9	23.6	24.2	---

	RECOVERY
DAYS	8-14
WEEKS	2
ANIMAL	
11	---
12	---
13	---
14	---
15	---

(A) Error undetermined

FOOD CONSUMPTION (G/ANIMAL/DAY)
MALES

GROUP 3 (50 MG/KG)

	PRETEST	TREATMENT				RECOVERY
DAYS	1-8	1-8	8-15	15-22	22-28	1-8
WEEKS	1/2	1/2	2/3	3/4	4	1/2
ANIMAL						
16	22.3	23.9	24.9	24.8	25.7	---
17	20.9	24.0	23.6	25.5	25.1	---
18	20.5	24.5	25.8	25.6	26.9	---
19	20.3	23.3	22.7	22.2	22.3	---
20	18.8	22.4	23.4	24.5	24.5	---

	RECOVERY
DAYS	8-14
WEEKS	2
ANIMAL	
16	---
17	---
18	---
19	---
20	---

FOOD CONSUMPTION (G/ANIMAL/DAY)
MALES

GROUP 4 (200 MG/KG)

	PRETEST	TREATMENT				RECOVERY
DAYS	1-8	1-8	8-15	15-22	22-28	1-8
WEEKS	1/2	1/2	2/3	3/4	4	1/2
ANIMAL						
21	18.2	19.7	19.5	20.6	20.9	---
22	17.7	19.6	20.4	20.2	20.5	---
23	19.1	22.0	22.9	23.1	23.9	---
24	19.1	24.3	23.1	24.9	26.0	---
25	19.0	22.5	23.5	24.7	27.7	---

	RECOVERY
DAYS	8-14
WEEKS	2
ANIMAL	
21	---
22	---
23	---
24	---
25	---

FOOD CONSUMPTION (G/ANIMAL/DAY)
MALES

GROUP 5 (1000 MG/KG)

	PRETEST	TREATMENT				RECOVERY
DAYS	1-8	1-8	8-15	15-22	22-28	1-8
WEEKS	1/2	1/2	2/3	3/4	4	1/2
ANIMAL						
26	20.4	22.6	24.3	27.4	25.2	---
27	19.3	21.4	21.5	24.6	28.9	---
28	18.2	21.5	22.5	23.0	23.2	---
29	16.2	20.5	21.3	22.7	23.3	---
30	19.4	24.3	26.4	27.5	28.0	---
31	20.2	22.4	22.2	25.2	26.7	24.2
32	18.7	22.5	24.4	26.1	25.6	22.6
33	17.9	22.4	22.0	25.4	25.4	25.2
34	20.7	24.1	24.6	23.6	22.6	23.8
35	18.1	21.2	22.9	23.1	23.3	21.2

	RECOVERY
DAYS	8-14
WEEKS	2
ANIMAL	
26	---
27	---
28	---
29	---
30	---
31	21.3
32	22.1
33	25.9
34	23.1
35	20.6

FOOD CONSUMPTION (G/ANIMAL/DAY)
FEMALES

GROUP 1 (0 MG/KG)

	PRETEST	TREATMENT				RECOVERY
DAYS	1-8	1-8	8-15	15-22	22-28	1-8
WEEKS	1/2	1/2	2/3	3/4	4	1/2
ANIMAL						
36	13.9	14.2	14.7	15.5	16.7	---
37	13.9	17.3	18.1	51.4 (A)	20.0	---
38	14.9	16.7	16.9	17.5	18.9	---
39	16.1	17.3	17.9	18.7	19.6	---
40	14.6	18.0	19.1	18.0	17.7	---
41	15.7	17.3	17.4	18.0	18.5	20.6
42	13.7	16.2	15.2	54.2 (A)	18.1	19.4
43	14.4	15.3	16.1	17.2	18.5	19.0
44	15.8	17.9	19.6	19.1	19.6	20.7
45	15.5	17.7	18.0	17.4	19.1	20.9

	RECOVERY
DAYS	8-14
WEEKS	2
ANIMAL	
36	---
37	---
38	---
39	---
40	---
41	18.3
42	18.7
43	17.3
44	18.1
45	17.7

(A) Food spillage

FOOD CONSUMPTION (G/ANIMAL/DAY)
FEMALES

GROUP 2 (10 MG/KG)

	PRETEST	TREATMENT				RECOVERY
DAYS	1-8	1-8	8-15	15-22	22-28	1-8
WEEKS	1/2	1/2	2/3	3/4	4	1/2
ANIMAL						
46	14.9	17.5	17.1	18.3	20.1	---
47	13.4	14.3	14.2	22.4	16.0	---
48	14.5	15.9	16.2	15.9	16.6	---
49	14.5	16.2	16.1	16.9	17.2	---
50	13.8	14.7	15.0	14.8	15.8	---

	RECOVERY
DAYS	8-14
WEEKS	2
ANIMAL	
46	---
47	---
48	---
49	---
50	---

FOOD CONSUMPTION (G/ANIMAL/DAY)
FEMALES

GROUP 3 (50 MG/KG)

	PRETEST	TREATMENT				RECOVERY
DAYS	1-8	1-8	8-15	15-22	22-28	1-8
WEEKS	1/2	1/2	2/3	3/4	4	1/2
ANIMAL						
51	16.1	18.1	18.8	18.9	21.3	---
52	15.0	16.0	15.9	17.1	16.8	---
53	16.1	17.9	17.6	18.5	18.7	---
54	14.5	16.2	16.4	17.2	17.9	---
55	13.9	15.2	15.6	18.0	17.7	---

	RECOVERY
DAYS	8-14
WEEKS	2
ANIMAL	
51	---
52	---
53	---
54	---
55	---

FOOD CONSUMPTION (G/ANIMAL/DAY)
FEMALES

GROUP 4 (200 MG/KG)

	PRETEST	TREATMENT				RECOVERY
DAYS	1-8	1-8	8-15	15-22	22-28	1-8
WEEKS	1/2	1/2	2/3	3/4	4	1/2
ANIMAL						
56	14.5	16.4	17.0	17.5	17.9	---
57	14.3	16.3	16.1	16.9	17.6	---
58	14.6	14.9	15.0	17.0	19.1	---
59	16.3	17.9	17.2	17.9	18.7	---
60	15.4	16.2	17.6	17.9	19.1	---

	RECOVERY
DAYS	8-14
WEEKS	2
ANIMAL	
56	---
57	---
58	---
59	---
60	---

FOOD CONSUMPTION (G/ANIMAL/DAY)
FEMALES

GROUP 5 (1000 MG/KG)

	PRETEST	TREATMENT				RECOVERY
DAYS	1-8	1-8	8-15	15-22	22-28	1-8
WEEKS	1/2	1/2	2/3	3/4	4	1/2
ANIMAL						
61	15.1	17.8	18.4	19.5	20.2	---
62	16.0	17.9	19.0	20.8	21.0	---
63	16.1	18.3	18.0	19.3	20.6	---
64	15.1	17.1	16.3	15.7	16.6	---
65	17.0	18.0	17.5	21.4	21.0	---
66	14.4	16.9	16.7	18.0	18.5	18.9
67	14.1	15.6	16.2	19.0	18.4	19.4
68	15.9	18.0	17.9	19.9	21.5	22.7
69	15.7	17.7	18.3	19.5	18.9	21.5
70	14.6	17.5	16.8	17.8	17.6	20.9

	RECOVERY
DAYS	8-14
WEEKS	2
ANIMAL	
61	---
62	---
63	---
64	---
65	---
66	16.1
67	17.6
68	19.2
69	18.9
70	17.3

RELATIVE FOOD CONSUMPTION (G/KG BODY WEIGHT/DAY) MALES

GROUP 1 (0 MG/KG)

	PRETEST	TREATMENT				RECOVERY
DAYS	1-8	1-8	8-15	15-22	22-28	1-8
WEEKS	1/2	1/2	2/3	3/4	4	1/2
ANIMAL						
1	146.4	103.6	96.2	89.8	88.4	---
2	129.9	99.7	84.9	79.0	75.7	---
3	120.5	91.9	87.6	79.4	88.0	---
4	135.1	106.5	98.5	90.6	86.3	---
5	133.2	104.8	97.5	91.2	85.3	---
6	121.2	95.5	87.7	80.7	84.3	78.8
7	133.4	100.0	92.4	83.5	86.4	78.3
8	145.7	101.6	89.2	83.4	82.9	79.7
9	145.5	102.2	96.7	87.7	86.7	82.2
10	132.6	97.8	89.2	81.1	84.1	80.9

	RECOVERY
DAYS	8-14
WEEKS	2
ANIMAL	
1	---
2	---
3	---
4	---
5	---
6	75.9
7	65.4
8	75.4
9	78.0
10	77.4

RELATIVE FOOD CONSUMPTION (G/KG BODY WEIGHT/DAY) MALES

GROUP 2 (10 MG/KG)

	PRETEST	TREATMENT				RECOVERY
DAYS	1-8	1-8	8-15	15-22	22-28	1-8
WEEKS	1/2	1/2	2/3	3/4	4	1/2
ANIMAL						
11	118.1	88.7	87.7	78.1	75.1	---
12	141.4	100.4	93.0	34.1 (A)	93.9	---
13	127.1	94.8	88.9	80.7	81.0	---
14	155.9	109.2	96.8	87.1	92.2	---
15	139.4	97.0	89.6	80.3	82.5	---

	RECOVERY
DAYS	8-14
WEEKS	2
ANIMAL	
11	---
12	---
13	---
14	---
15	---

(A) Value(s) excluded

RELATIVE FOOD CONSUMPTION (G/KG BODY WEIGHT/DAY) MALES

GROUP 3 (50 MG/KG)

	PRETEST	TREATMENT				RECOVERY
DAYS	1-8	1-8	8-15	15-22	22-28	1-8
WEEKS	1/2	1/2	2/3	3/4	4	1/2
ANIMAL						
16	146.8	105.1	95.6	88.3	91.4	---
17	146.1	106.6	92.5	90.3	88.7	---
18	133.2	99.4	90.6	83.0	86.9	---
19	130.1	99.8	86.1	76.4	76.7	---
20	131.4	101.5	91.1	84.4	84.3	---

	RECOVERY
DAYS	8-14
WEEKS	2
ANIMAL	
16	---
17	---
18	---
19	---
20	---

RELATIVE FOOD CONSUMPTION
(G/KG BODY WEIGHT/DAY)
MALES

GROUP 4 (200 MG/KG)

	PRETEST	TREATMENT				RECOVERY
DAYS	1-8	1-8	8-15	15-22	22-28	1-8
WEEKS	1/2	1/2	2/3	3/4	4	1/2
ANIMAL						
21	123.2	93.6	83.1	80.8	81.7	---
22	118.6	89.9	83.6	77.4	78.3	---
23	132.3	95.4	86.9	79.8	82.6	---
24	130.1	99.6	83.7	79.5	82.9	---
25	128.1	97.4	89.0	83.5	93.3	---

	RECOVERY
DAYS	8-14
WEEKS	2
ANIMAL	
21	---
22	---
23	---
24	---
25	---

RELATIVE FOOD CONSUMPTION (G/KG BODY WEIGHT/DAY) MALES

GROUP 5 (1000 MG/KG)

	PRETEST	TREATMENT				RECOVERY
DAYS	1-8	1-8	8-15	15-22	22-28	1-8
WEEKS	1/2	1/2	2/3	3/4	4	1/2
ANIMAL						
26	133.2	99.4	93.1	96.1	88.4	---
27	135.8	101.1	91.4	94.2	110.6	---
28	124.2	100.1	93.0	87.6	88.1	---
29	108.8	91.9	85.4	82.1	84.3	---
30	124.6	97.6	89.6	85.2	86.8	---
31	137.6	99.8	88.2	91.4	96.8	80.7
32	125.6	95.5	91.1	89.1	87.5	73.3
33	120.3	99.5	86.5	90.9	90.7	81.6
34	138.9	101.8	93.8	84.5	81.0	81.4
35	124.5	95.9	89.9	82.9	83.7	72.6

	RECOVERY
DAYS	8-14
WEEKS	2
ANIMAL	
26	---
27	---
28	---
29	---
30	---
31	71.0
32	71.7
33	83.9
34	79.0
35	70.7

RELATIVE FOOD CONSUMPTION (G/KG BODY WEIGHT/DAY) FEMALES

GROUP 1 (0 MG/KG)

	PRETEST	TREATMENT				RECOVERY
DAYS	1-8	1-8	8-15	15-22	22-28	1-8
WEEKS	1/2	1/2	2/3	3/4	4	1/2
ANIMAL						
36	114.4	91.9	87.6	87.7	94.1	---
37	115.8	107.3	104.0	272.5 (A)	106.2	---
38	116.6	97.5	92.5	89.4	96.5	---
39	127.2	103.8	96.9	93.8	98.1	---
40	118.1	105.4	100.2	89.0	87.5	---
41	130.0	103.3	96.7	94.8	97.5	97.6
42	115.1	106.8	92.0	309.0 (A)	103.5	99.5
43	115.9	97.1	91.4	92.7	99.2	96.1
44	130.3	108.3	101.9	92.4	94.6	95.4
45	126.4	101.2	94.5	86.4	95.1	93.9

	RECOVERY
DAYS	8-14
WEEKS	2
ANIMAL	
36	---
37	---
38	---
39	---
40	---
41	86.8
42	96.1
43	87.8
44	83.5
45	79.7

(A) Value(s) excluded

RELATIVE FOOD CONSUMPTION (G/KG BODY WEIGHT/DAY) FEMALES

GROUP 2 (10 MG/KG)

	PRETEST	TREATMENT				RECOVERY
DAYS	1-8	1-8	8-15	15-22	22-28	1-8
WEEKS	1/2	1/2	2/3	3/4	4	1/2
ANIMAL						
46	123.1	105.8	94.0	96.0	105.2	---
47	113.2	92.6	86.9	126.8	90.4	---
48	124.5	99.5	94.9	87.7	91.1	---
49	119.1	100.0	90.5	89.1	90.4	---
50	114.9	98.8	88.0	81.8	87.1	---

	RECOVERY
DAYS	8-14
WEEKS	2
ANIMAL	
46	---
47	---
48	---
49	---
50	---

RELATIVE FOOD CONSUMPTION (G/KG BODY WEIGHT/DAY) FEMALES

GROUP 3 (50 MG/KG)

	PRETEST	TREATMENT				RECOVERY
DAYS	1-8	1-8	8-15	15-22	22-28	1-8
WEEKS	1/2	1/2	2/3	3/4	4	1/2
ANIMAL						
51	136.0	107.7	101.5	95.4	108.0	---
52	120.5	100.5	89.9	91.0	89.6	---
53	136.8	106.3	96.7	95.2	96.4	---
54	118.0	98.2	91.3	87.1	90.1	---
55	111.8	97.9	94.9	96.8	95.1	---

	RECOVERY
DAYS	8-14
WEEKS	2
ANIMAL	
51	---
52	---
53	---
54	---
55	---

RELATIVE FOOD CONSUMPTION (G/KG BODY WEIGHT/DAY) FEMALES

GROUP 4 (200 MG/KG)

	PRETEST	TREATMENT				RECOVERY
DAYS	1-8	1-8	8-15	15-22	22-28	1-8
WEEKS	1/2	1/2	2/3	3/4	4	1/2
ANIMAL						
56	118.8	108.0	98.7	94.9	97.5	---
57	106.9	95.9	85.9	83.2	86.4	---
58	118.8	97.9	92.1	97.4	109.3	---
59	132.9	101.6	90.4	87.8	91.8	---
60	122.2	101.0	96.9	91.3	97.6	---

	RECOVERY
DAYS	8-14
WEEKS	2
ANIMAL	
56	---
57	---
58	---
59	---
60	---

RELATIVE FOOD CONSUMPTION (G/KG BODY WEIGHT/DAY) FEMALES

GROUP 5 (1000 MG/KG)

	PRETEST	TREATMENT				RECOVERY
DAYS	1-8	1-8	8-15	15-22	22-28	1-8
WEEKS	1/2	1/2	2/3	3/4	4	1/2
ANIMAL						
61	120.0	111.7	99.8	97.9	101.4	---
62	136.8	110.4	101.0	100.9	101.4	---
63	129.2	106.1	95.7	95.8	102.2	---
64	122.1	103.2	94.7	86.1	91.0	---
65	140.4	108.1	97.6	106.7	104.9	---
66	114.7	101.0	91.0	92.1	94.8	92.7
67	116.9	96.0	93.5	97.8	95.0	94.0
68	128.9	106.3	97.2	101.2	109.1	104.8
69	127.4	106.5	99.5	100.4	97.1	102.6
70	119.7	105.8	92.1	92.3	91.5	103.7

	RECOVERY
DAYS	8-14
WEEKS	2
ANIMAL	
61	---
62	---
63	---
64	---
65	---
66	78.6
67	85.3
68	88.8
69	90.1
70	86.0

BODY WEIGHTS (GRAM)
MALES

GROUP 1 (0 MG/KG)

	PRETEST	TREATMENT					RECOVERY
DAYS	1	1	8	15	22	28	1
WEEKS	1	1	2	3	4	4	1
ANIMAL							
1	148.8	198.3	240.8	281.6	309.4	328.1	---
2	151.5	197.5	227.3	243.2	251.4	263.4	---
3	150.5	186.4	204.9	221.9	240.3	258.8	---
4	145.9	180.4	212.0	240.3	269.6	287.3	---
5	150.1	191.6	228.4	257.0	278.5	291.8	---
6	140.9	173.5	204.1	230.6	250.3	269.3	248.8
7	144.8	193.3	235.6	267.5	283.7	299.8	277.9
8	146.4	195.2	231.8	267.2	292.0	308.0	286.6
9	149.8	197.6	240.1	276.7	298.7	311.0	282.6
10	141.9	179.2	208.5	231.8	254.4	272.4	250.4

	RECOVERY	
DAYS	8	14
WEEKS	2	2
ANIMAL		
1	---	---
2	---	---
3	---	---
4	---	---
5	---	---
6	282.4	295.9
7	306.5	312.3
8	325.3	345.0
9	323.8	338.4
10	279.9	299.1

BODY WEIGHTS (GRAM)
MALES

GROUP 2 (10 MG/KG)

	PRETEST	TREATMENT					RECOVERY
DAYS	1	1	8	15	22	28	1
WEEKS	1	1	2	3	4	4	1
ANIMAL							
11	154.6	192.7	223.0	252.8	275.5	289.9	---
12	151.0	196.0	238.0	267.7	287.3	314.1	---
13	146.2	187.2	222.6	250.1	271.7	289.2	---
14	145.2	198.4	241.2	279.5	305.4	327.8	---
15	144.5	192.0	233.0	266.7	293.9	313.1	---

	RECOVERY	
DAYS	8	14
WEEKS	2	2
ANIMAL		
11	---	---
12	---	---
13	---	---
14	---	---
15	---	---

BODY WEIGHTS (GRAM)
MALES

GROUP 3 (50 MG/KG)

	PRETEST	TREATMENT					RECOVERY
DAYS	1	1	8	15	22	28	1
WEEKS	1	1	2	3	4	4	1
ANIMAL							
16	151.8	198.2	227.0	260.6	280.9	294.7	---
17	143.1	188.2	225.1	255.4	282.8	295.7	---
18	153.5	205.6	246.7	285.0	309.2	332.3	---
19	156.0	200.7	234.0	264.0	290.5	301.1	---
20	143.3	182.6	220.4	256.8	290.2	308.2	---

	RECOVERY	
DAYS	8	14
WEEKS	2	2
ANIMAL		
16	---	---
17	---	---
18	---	---
19	---	---
20	---	---

BODY WEIGHTS (GRAM)
MALES

GROUP 4 (200 MG/KG)

	PRETEST	TREATMENT					RECOVERY
DAYS	1	1	8	15	22	28	1
WEEKS	1	1	2	3	4	4	1
ANIMAL							
21	147.7	183.4	210.7	234.3	255.4	263.7	---
22	149.1	183.6	217.6	244.1	261.3	270.5	---
23	144.0	190.8	230.8	263.1	289.2	305.0	---
24	146.5	197.3	243.6	276.2	313.5	333.8	---
25	148.1	190.8	231.3	264.5	296.3	315.4	---

	RECOVERY	
DAYS	8	14
WEEKS	2	2
ANIMAL		
21	---	---
22	---	---
23	---	---
24	---	---
25	---	---

BODY WEIGHTS (GRAM)
MALES

GROUP 5 (1000 MG/KG)

	PRETEST	TREATMENT					RECOVERY
DAYS	1	1	8	15	22	28	1
WEEKS	1	1	2	3	4	4	1
ANIMAL							
26	153.0	193.4	227.1	261.2	285.1	289.4	---
27	142.3	181.7	211.4	235.6	261.4	281.6	---
28	146.5	186.8	214.7	241.9	263.0	267.7	---
29	148.6	184.9	223.0	248.8	276.8	288.3	---
30	155.4	203.7	248.7	294.5	322.8	345.4	---
31	147.1	192.7	224.1	251.5	275.6	290.6	265.9
32	148.8	191.6	235.2	267.4	292.8	305.3	283.1
33	149.1	187.9	225.3	254.1	279.9	297.3	271.9
34	149.0	196.7	236.7	262.3	279.0	280.8	260.1
35	145.6	184.0	221.1	254.9	278.2	287.3	264.1

	RECOVERY	
DAYS	8	14
WEEKS	2	2
ANIMAL		
26	---	---
27	---	---
28	---	---
29	---	---
30	---	---
31	300.3	320.2
32	308.1	327.0
33	309.1	329.7
34	292.7	317.2
35	292.0	313.1

BODY WEIGHTS (GRAM)
FEMALES

GROUP 1 (0 MG/KG)

	PRETEST	TREATMENT					RECOVERY
DAYS	1	1	8	15	22	28	1
WEEKS	1	1	2	3	4	4	1
ANIMAL							
36	121.5	142.0	154.8	167.3	177.3	186.8	---
37	120.1	139.2	161.6	174.0	188.8	199.9	---
38	127.6	149.1	171.6	183.0	196.1	206.2	---
39	126.5	150.7	166.8	185.1	199.7	207.5	---
40	123.9	147.2	171.0	191.1	202.7	209.4	---
41	120.5	154.0	167.9	180.3	190.0	206.1	190.3
42	118.8	138.3	151.3	165.1	175.4	185.2	169.9
43	124.1	145.1	157.7	175.8	186.0	194.7	180.6
44	121.5	147.9	165.5	192.1	207.3	211.4	193.3
45	122.8	155.6	174.5	190.5	200.8	214.3	197.3

	RECOVERY	
DAYS	8	14
WEEKS	2	2
ANIMAL		
36	---	---
37	---	---
38	---	---
39	---	---
40	---	---
41	211.1	214.6
42	194.9	204.0
43	197.3	210.4
44	216.9	222.6
45	222.6	223.3

BODY WEIGHTS (GRAM)
FEMALES

GROUP 2 (10 MG/KG)

	PRETEST	TREATMENT					RECOVERY
DAYS	1	1	8	15	22	28	1
WEEKS	1	1	2	3	4	4	1
ANIMAL							
46	121.2	149.4	165.0	182.1	190.6	206.4	---
47	118.4	142.3	154.5	163.5	177.0	183.4	---
48	116.6	144.3	160.0	170.4	181.8	190.4	---
49	121.4	144.5	162.3	178.0	190.1	202.3	---
50	120.2	140.9	149.2	170.0	181.1	182.2	---

	RECOVERY	
DAYS	8	14
WEEKS	2	2
ANIMAL		
46	---	---
47	---	---
48	---	---
49	---	---
50	---	---

BODY WEIGHTS (GRAM)
FEMALES

GROUP 3 (50 MG/KG)

	PRETEST	TREATMENT					RECOVERY
DAYS	1	1	8	15	22	28	1
WEEKS	1	1	2	3	4	4	1
ANIMAL							
51	118.3	144.0	168.0	185.4	197.7	203.6	---
52	124.8	148.6	158.9	177.2	187.9	191.2	---
53	117.8	148.7	168.2	182.5	194.5	205.6	---
54	122.8	146.3	165.0	179.9	198.1	205.3	---
55	124.7	144.6	154.9	164.7	186.3	193.7	---

	RECOVERY	
DAYS	8	14
WEEKS	2	2
ANIMAL		
51	---	---
52	---	---
53	---	---
54	---	---
55	---	---

BODY WEIGHTS (GRAM)
FEMALES

GROUP 4 (200 MG/KG)

	PRETEST	TREATMENT					RECOVERY
DAYS	1	1	8	15	22	28	1
WEEKS	1	1	2	3	4	4	1
ANIMAL							
56	121.8	141.2	152.3	171.7	184.0	187.4	---
57	133.7	155.2	169.6	187.7	203.2	202.4	---
58	123.3	144.7	152.2	163.3	175.0	184.0	---
59	123.0	154.2	176.2	189.7	204.0	212.3	---
60	126.4	148.1	160.8	181.4	195.9	196.8	---

	RECOVERY	
DAYS	8	14
WEEKS	2	2
ANIMAL		
56	---	---
57	---	---
58	---	---
59	---	---
60	---	---

BODY WEIGHTS (GRAM)
FEMALES

GROUP 5 (1000 MG/KG)

	PRETEST	TREATMENT					RECOVERY
DAYS	1	1	8	15	22	28	1
WEEKS	1	1	2	3	4	4	1
ANIMAL							
61	125.8	150.6	159.3	184.2	198.9	199.4	---
62	117.0	144.4	162.2	188.6	206.7	211.6	---
63	124.6	146.1	172.2	187.8	201.6	206.9	---
64	123.8	145.8	165.6	171.5	182.2	187.8	---
65	121.0	150.3	166.1	179.6	200.5	212.8	---
66	125.3	146.5	166.8	183.9	195.0	205.0	181.7
67	120.4	142.7	162.2	173.0	193.9	199.1	185.7
68	123.2	151.9	169.5	184.2	197.0	209.8	191.4
69	123.2	151.2	165.8	183.5	194.6	201.4	186.8
70	121.7	147.1	165.0	182.0	192.5	201.2	185.2

	RECOVERY	
DAYS	8	14
WEEKS	2	2
ANIMAL		
61	---	---
62	---	---
63	---	---
64	---	---
65	---	---
66	204.3	208.8
67	206.4	212.1
68	216.1	223.8
69	209.5	214.9
70	201.5	212.1

OPHTHALMOSCOPIC EXAMINATIONS
MALES
AT 4 WEEKS

GROUP 1 (0 MG/KG)

ANIMAL	EYE(S)	OBSERVATION
1	BOTH	NO ABNORMALITIES DETECTED
2	BOTH	NO ABNORMALITIES DETECTED
3	BOTH	NO ABNORMALITIES DETECTED
4	BOTH	NO ABNORMALITIES DETECTED
5	BOTH	NO ABNORMALITIES DETECTED
6	BOTH	NO ABNORMALITIES DETECTED
7	BOTH	NO ABNORMALITIES DETECTED
8	BOTH	NO ABNORMALITIES DETECTED
9	BOTH	NO ABNORMALITIES DETECTED
10	BOTH	PERSISTENT PUPILLARY MEMBRANE

GROUP 2 (10 MG/KG)

ANIMAL	EYE(S)	OBSERVATION
11	BOTH	NO ABNORMALITIES DETECTED
12	LEFT	PERSISTENT HYALOID VESSEL IN VITREOUS
	RIGHT	PERSISTENT PUPILLARY MEMBRANE
13	BOTH	NO ABNORMALITIES DETECTED
14	BOTH	NO ABNORMALITIES DETECTED
15	BOTH	NO ABNORMALITIES DETECTED

GROUP 3 (50 MG/KG)

ANIMAL	EYE(S)	OBSERVATION
16	BOTH	NO ABNORMALITIES DETECTED
17	BOTH	NO ABNORMALITIES DETECTED
18	BOTH	NO ABNORMALITIES DETECTED
19	BOTH	NO ABNORMALITIES DETECTED
20	BOTH	NO ABNORMALITIES DETECTED

GROUP 4 (200 MG/KG)

ANIMAL	EYE(S)	OBSERVATION
21	BOTH	PERSISTENT PUPILLARY MEMBRANE
22	BOTH	NO ABNORMALITIES DETECTED
23	BOTH	NO ABNORMALITIES DETECTED
24	BOTH	NO ABNORMALITIES DETECTED
25	BOTH	NO ABNORMALITIES DETECTED

OPHTHALMOSCOPIC EXAMINATIONS
MALES
AT 4 WEEKS

GROUP 5 (1000 MG/KG)

ANIMAL	EYE(S)	OBSERVATION
26	BOTH	NO ABNORMALITIES DETECTED
27	BOTH	NO ABNORMALITIES DETECTED
28	BOTH	NO ABNORMALITIES DETECTED
29	BOTH	NO ABNORMALITIES DETECTED
30	BOTH	NO ABNORMALITIES DETECTED
31	BOTH	NO ABNORMALITIES DETECTED
32	BOTH	NO ABNORMALITIES DETECTED
33	BOTH	NO ABNORMALITIES DETECTED
34	BOTH	NO ABNORMALITIES DETECTED
35	BOTH	NO ABNORMALITIES DETECTED

OPHTHALMOSCOPIC EXAMINATIONS
FEMALES
AT 4 WEEKS

GROUP 1 (0 MG/KG)

ANIMAL	EYE(S)	OBSERVATION
36	BOTH	NO ABNORMALITIES DETECTED
37	BOTH	NO ABNORMALITIES DETECTED
38	BOTH	NO ABNORMALITIES DETECTED
39	BOTH	NO ABNORMALITIES DETECTED
40	BOTH	NO ABNORMALITIES DETECTED
41	BOTH	NO ABNORMALITIES DETECTED
42	BOTH	NO ABNORMALITIES DETECTED
43	BOTH	NO ABNORMALITIES DETECTED
44	BOTH	NO ABNORMALITIES DETECTED
45	BOTH	NO ABNORMALITIES DETECTED

GROUP 2 (10 MG/KG)

ANIMAL	EYE(S)	OBSERVATION
46	BOTH	NO ABNORMALITIES DETECTED
47	BOTH	NO ABNORMALITIES DETECTED
48	LEFT	HAEMORRHAGIA IN VITREOUS BODY
49	BOTH	NO ABNORMALITIES DETECTED
50	BOTH	NO ABNORMALITIES DETECTED

GROUP 3 (50 MG/KG)

ANIMAL	EYE(S)	OBSERVATION
51	BOTH	NO ABNORMALITIES DETECTED
52	BOTH	NO ABNORMALITIES DETECTED
53	BOTH	NO ABNORMALITIES DETECTED
54	BOTH	NO ABNORMALITIES DETECTED
55	BOTH	NO ABNORMALITIES DETECTED

GROUP 4 (200 MG/KG)

ANIMAL	EYE(S)	OBSERVATION
56	BOTH	NO ABNORMALITIES DETECTED
57	BOTH	NO ABNORMALITIES DETECTED
58	BOTH	NO ABNORMALITIES DETECTED
59	BOTH	NO ABNORMALITIES DETECTED
60	BOTH	NO ABNORMALITIES DETECTED

OPHTHALMOSCOPIC EXAMINATIONS
FEMALES
AT 4 WEEKS

GROUP 5 (1000 MG/KG)

ANIMAL	EYE(S)	OBSERVATION
61	LEFT	HAEMORRHAGIA IN VITREOUS BODY
62	BOTH	NO ABNORMALITIES DETECTED
63	BOTH	NO ABNORMALITIES DETECTED
64	BOTH	NO ABNORMALITIES DETECTED
65	BOTH	NO ABNORMALITIES DETECTED
66	BOTH	NO ABNORMALITIES DETECTED
67	BOTH	NO ABNORMALITIES DETECTED
68	BOTH	NO ABNORMALITIES DETECTED
69	BOTH	NO ABNORMALITIES DETECTED
70	LEFT	CORNEAL OPACITY

OPHTHALMOSCOPIC EXAMINATIONS
MALES
AT 6 WEEKS

GROUP 1 (0 MG/KG)

ANIMAL	EYE(S)	OBSERVATION
6	BOTH	NO ABNORMALITIES DETECTED
7	BOTH	NO ABNORMALITIES DETECTED
8	BOTH	NO ABNORMALITIES DETECTED
9	BOTH	NO ABNORMALITIES DETECTED
10	BOTH	PERSISTENT PUPILLARY MEMBRANE

GROUP 5 (1000 MG/KG)

ANIMAL	EYE(S)	OBSERVATION
31	BOTH	NO ABNORMALITIES DETECTED
32	BOTH	NO ABNORMALITIES DETECTED
33	BOTH	NO ABNORMALITIES DETECTED
34	BOTH	NO ABNORMALITIES DETECTED
35	BOTH	NO ABNORMALITIES DETECTED

OPHTHALMOSCOPIC EXAMINATIONS
FEMALES
AT 6 WEEKS

GROUP 1 (0 MG/KG)

ANIMAL	EYE(S)	OBSERVATION
41	BOTH	NO ABNORMALITIES DETECTED
42	BOTH	NO ABNORMALITIES DETECTED
43	BOTH	NO ABNORMALITIES DETECTED
44	BOTH	NO ABNORMALITIES DETECTED
45	BOTH	NO ABNORMALITIES DETECTED

GROUP 5 (1000 MG/KG)

ANIMAL	EYE(S)	OBSERVATION
66	BOTH	NO ABNORMALITIES DETECTED
67	BOTH	NO ABNORMALITIES DETECTED
68	BOTH	NO ABNORMALITIES DETECTED
69	BOTH	NO ABNORMALITIES DETECTED
70	LEFT	CORNEAL OPACITY

EXPLANATORY NOTES FOR DATA NOT PRESENTED IN THE TABLES

HEMATOLOGY

Animal No. Sex, Group	Parameter	Remarks
After 4 weeks:		
9-M Gr.1	PT, APTT	Coagulated blood sample
19-M Gr.3	MET-HB, HEINZ BOD.	Coagulated blood sample
29-M Gr.5	PT, APTT	Coagulated blood sample
33-M Gr.5	PT, APTT, MET-HB, HEINZ BOD.	Coagulated blood sample
36-F Gr.1	PT, APTT	Coagulated blood sample
44-F Gr.1	PT, APTT	Coagulated blood sample

HEMATOLOGY
AFTER 4 WEEKS
MALES
GROUP 1 (0 MG/KG)

ANIMAL NUMBER	REMARK	RBC T/L	HB MMOL/L	HCT L/L	MCV FL	MCH FMOL	MCHC MMOL/L	PLATELETS G/L
1	---	9.38	10.8	0.54	57.0	1.15	20.2	1011
2	---	9.62	10.8	0.54	56.0	1.12	20.0	721
3	---	---	---	---	---	---	---	---
4	---	9.54	10.6	0.54	56.1	1.11	19.9	916
5	---	9.14	10.4	0.50	54.6	1.14	20.9	892
6	---	9.07	10.4	0.51	56.6	1.14	20.2	998
7	---	9.25	10.4	0.52	56.6	1.13	19.9	915
8	---	9.19	10.6	0.53	57.7	1.15	20.0	1183
9	NV	9.32	11.0	0.54	57.9	1.19	20.5	852
10	---	9.69	10.8	0.53	54.4	1.12	20.5	812

	RETICULOCYTE COUNT							
ANIMAL NUMBER	RETIC. %	RETIC. T/L	HFR %	MFR %	LFR %	NEN /100 WBC	HEINZ BOD. o/oo	MET-HB %
1	2.40	0.2023	5.2	33.6	61.2	0.0	0	0.8
2	2.12	0.1859	8.6	34.2	57.2	0.0	0	1.1
3	---	---	---	---	---	---	---	---
4	2.85	0.2445	6.0	36.3	57.7	0.0	0	1.0
5	2.59	0.2183	4.2	38.2	57.6	0.0	0	1.6
6	2.88	0.2347	7.5	34.2	58.3	1.0	0	1.0
7	2.46	0.2020	4.9	37.9	57.2	1.0	0	1.2
8	3.10	0.2576	7.1	30.7	62.2	0.0	0	1.1
9	2.47	0.2102	8.3	34.9	56.8	0.0	0	1.0
10	2.52	0.2205	5.3	31.1	63.6	0.0	0	1.3

		DIFF.WBC COUNT (REL.)						
ANIMAL NUMBER	WBC G/L	BAND 1	SEG. 1	EO. 1	BASO. 1	LYMPH. 1	MONO. 1	PLAS. 1
1	7.1	0.00	0.10	0.01	0.00	0.89	0.00	0.00
2	7.6	0.00	0.25	0.01	0.00	0.73	0.01	0.00
3	---	---	---	---	---	---	---	---
4	7.2	0.00	0.18	0.00	0.00	0.81	0.01	0.00
5	7.4	0.00	0.06	0.00	0.00	0.94	0.00	0.00
6	7.6	0.00	0.22	0.01	0.00	0.76	0.01	0.00
7	6.3	0.00	0.16	0.00	0.00	0.83	0.01	0.00
8	8.1	0.00	0.12	0.03	0.00	0.85	0.00	0.00
9	8.7	0.00	0.04	0.01	0.00	0.94	0.01	0.00
10	7.8	0.00	0.15	0.01	0.00	0.83	0.01	0.00

	DIFF.WBC COUNT (REL.)	DIFF.WBC COUNT (ABS.)					
ANIMAL NUMBER	OTHER 1	BAND G/L	SEG. G/L	EO. G/L	BASO. G/L	LYMPH. G/L	MONO. G/L
1	0.00	0.0	0.7	0.1	0.0	6.3	0.0
2	0.00	0.0	1.9	0.1	0.0	5.5	0.1
3	---	---	---	---	---	---	---

HEMATOLOGY
AFTER 4 WEEKS
MALES
GROUP 1 (0 MG/KG)

ANIMAL NUMBER	DIFF.WBC COUNT (REL.) OTHER 1	DIFF.WBC COUNT (ABS.) BAND G/L	SEG. G/L	EO. G/L	BASO. G/L	LYMPH. G/L	MONO. G/L
4	0.00	0.0	1.3	0.0	0.0	5.8	0.1
5	0.00	0.0	0.4	0.0	0.0	7.0	0.0
6	0.00	0.0	1.7	0.1	0.0	5.8	0.1
7	0.00	0.0	1.0	0.0	0.0	5.2	0.1
8	0.00	0.0	1.0	0.2	0.0	6.9	0.0
9	0.00	0.0	0.3	0.1	0.0	8.2	0.1
10	0.00	0.0	1.2	0.1	0.0	6.5	0.1

ANIMAL NUMBER	DIFF.WBC COUNT (ABS.) PLAS. G/L	OTHER G/L	RED CELL MORPHOLOGY TYPE CELL	COAGULATION PT SEC	APTT SEC
1	0.0	0.0	NORMAL	10.9	22.1
2	0.0	0.0	NORMAL	11.7	21.0
3	---	---	---	---	---
4	0.0	0.0	NORMAL	11.9	22.9
5	0.0	0.0	NORMAL	11.1	23.0
6	0.0	0.0	NORMAL	11.3	25.1
7	0.0	0.0	NORMAL	11.2	22.7
8	0.0	0.0	NORMAL	11.3	22.5
9	0.0	0.0	NORMAL	---	---
10	0.0	0.0	NORMAL	11.6	23.6

HEMATOLOGY
AFTER 4 WEEKS
MALES
GROUP 2 (10 MG/KG)

ANIMAL NUMBER	REMARK	RBC T/L	HB MMOL/L	HCT L/L	MCV FL	MCH FMOL	MCHC MMOL/L	PLATELETS G/L
11	---	9.28	10.8	0.53	57.1	1.17	20.4	845
12	---	8.86	10.8	0.53	59.8	1.22	20.4	965
13	---	10.01	10.7	0.53	53.2	1.07	20.0	973
14	---	8.95	10.4	0.52	57.7	1.16	20.1	1042
15	---	9.70	10.6	0.54	55.6	1.09	19.7	813

ANIMAL NUMBER	RETICULOCYTE COUNT RETIC. %	RETIC. T/L	HFR %	MFR %	LFR %	NEN /100 WBC	HEINZ BOD. o/oo	MET-HB %
11	2.60	0.2179	7.3	33.6	59.1	0.0	0	0.9
12	3.03	0.2445	10.8	38.9	50.3	0.0	0	1.1
13	2.45	0.2220	4.6	32.0	63.4	0.0	0	1.5
14	2.79	0.2291	11.9	41.2	46.9	0.0	0	1.3
15	2.85	0.2499	7.3	36.0	56.7	0.0	0	1.1

ANIMAL NUMBER	WBC G/L	DIFF.WBC COUNT (REL.) BAND 1	SEG. 1	EO. 1	BASO. 1	LYMPH. 1	MONO. 1	PLAS. 1
11	8.4	0.00	0.11	0.01	0.00	0.88	0.00	0.00
12	6.5	0.00	0.07	0.00	0.00	0.93	0.00	0.00
13	7.0	0.00	0.17	0.00	0.00	0.83	0.00	0.00
14	9.7	0.00	0.03	0.00	0.00	0.97	0.00	0.00
15	12.5	0.00	0.12	0.02	0.00	0.85	0.01	0.00

ANIMAL NUMBER	DIFF.WBC COUNT (REL.) OTHER 1	DIFF.WBC COUNT (ABS.) BAND G/L	SEG. G/L	EO. G/L	BASO. G/L	LYMPH. G/L	MONO. G/L
11	0.00	0.0	0.9	0.1	0.0	7.4	0.0
12	0.00	0.0	0.5	0.0	0.0	6.0	0.0
13	0.00	0.0	1.2	0.0	0.0	5.8	0.0
14	0.00	0.0	0.3	0.0	0.0	9.4	0.0
15	0.00	0.0	1.5	0.3	0.0	10.6	0.1

ANIMAL NUMBER	DIFF.WBC COUNT (ABS.) PLAS. G/L	OTHER G/L	RED CELL MORPHOLOGY TYPE CELL	COAGULATION PT SEC	APTT SEC
11	0.0	0.0	NORMAL	11.1	21.6
12	0.0	0.0	NORMAL	11.2	22.3
13	0.0	0.0	NORMAL	11.1	23.3
14	0.0	0.0	NORMAL	11.6	23.4
15	0.0	0.0	NORMAL	11.3	25.3

HEMATOLOGY
AFTER 4 WEEKS
MALES
GROUP 3 (50 MG/KG)

ANIMAL NUMBER	REMARK	RBC T/L	HB MMOL/L	HCT L/L	MCV FL	MCH FMOL	MCHC MMOL/L	PLATELETS G/L
16	---	9.21	10.4	0.52	56.0	1.12	20.1	937
17	---	9.42	10.2	0.51	54.1	1.09	20.1	1135
18	---	8.90	10.6	0.52	58.3	1.19	20.4	1175
19	NV	9.42	10.7	0.53	56.7	1.14	20.0	1025
20	---	9.19	10.1	0.52	56.4	1.10	19.5	913

	RETICULOCYTE COUNT							
ANIMAL NUMBER	RETIC. %	RETIC. T/L	HFR %	MFR %	LFR %	NEN /100 WBC	HEINZ BOD. o/oo	MET-HB %
16	2.99	0.2470	4.5	37.0	58.5	0.0	0	1.4
17	2.38	0.2040	4.3	30.9	64.8	0.0	0	1.0
18	2.31	0.1871	7.5	36.3	56.2	1.0	0	1.1
19	2.33	0.1997	4.9	34.3	60.8	0.0	---	---
20	2.67	0.2211	9.0	40 4	50.6	0.0	0	1.0

		DIFF.WBC COUNT (REL.)						
ANIMAL NUMBER	WBC G/L	BAND 1	SEG. 1	EO. 1	BASO. 1	LYMPH. 1	MONO. 1	PLAS. 1
16	7.2	0.00	0.08	0.01	0.00	0.91	0.00	0.00
17	5.3	0.00	0.11	0.01	0.00	0.88	0.00	0.00
18	9.9	0.00	0.06	0.02	0.00	0.92	0.00	0.00
19	10.7	0.00	0.13	0.00	0.00	0.86	0.01	0.00
20	9.8	0.00	0.05	0.00	0.00	0.95	0.00	0.00

	DIFF.WBC COUNT (REL.)	DIFF.WBC COUNT (ABS.)					
ANIMAL NUMBER	OTHER 1	BAND G/L	SEG. G/L	EO. G/L	BASO. G/L	LYMPH. G/L	MONO. G/L
16	0.00	0.0	0.6	0.1	0.0	6.6	0.0
17	0.00	0.0	0.6	0.1	0.0	4.7	0.0
18	0.00	0.0	0.6	0.2	0.0	9.1	0.0
19	0.00	0.0	1.4	0.0	0.0	9.2	0.1
20	0.00	0.0	0.5	0.0	0.0	9.3	0.0

	DIFF.WBC COUNT (ABS.)		RED CELL MORPHOLOGY	COAGULATION	
ANIMAL NUMBER	PLAS. G/L	OTHER G/L	TYPE CELL	PT SEC	APTT SEC
16	0.0	0.0	NORMAL	11.6	23.3
17	0.0	0.0	NORMAL	11.5	23.1
18	0.0	0.0	NORMAL	11.8	23.1
19	0.0	0.0	NORMAL	11.5	24.0
20	0.0	0.0	NORMAL	12.0	23.7

HEMATOLOGY
AFTER 4 WEEKS
MALES
GROUP 4 (200 MG/KG)

ANIMAL NUMBER	REMARK	RBC T/L	HB MMOL/L	HCT L/L	MCV FL	MCH FMOL	MCHC MMOL/L	PLATELETS G/L
21	---	9.10	10.5	0.52	56.8	1.15	20.3	726
22	---	9.38	10.2	0.52	55.5	1.09	19.5	949
23	---	9.48	10.6	0.54	57.1	1.12	19.6	944
24	---	8.39	9.8	0.50	59.8	1.17	19.5	1206
25	---	8.80	9.8	0.50	56.7	1.12	19.7	1198

	RETICULOCYTE COUNT							
ANIMAL NUMBER	RETIC. %	RETIC. T/L	HFR %	MFR %	LFR %	NEN /100 WBC	HEINZ BOD. o/oo	MET-HB %
21	2.69	0.2262	7.5	40.5	52.0	0.0	0	0.8
22	2.47	0.2085	6.9	35.8	57.3	0.0	0	0.8
23	2.63	0.2267	8.6	37.4	54.0	0.0	0	1.1
24	2.54	0.1933	6.0	33.5	60.5	0.0	0	0.9
25	2.54	0.2017	7.2	37.2	55.6	0.0	0	1.0

		DIFF.WBC COUNT (REL.)						
ANIMAL NUMBER	WBC G/L	BAND 1	SEG. 1	EO. 1	BASO. 1	LYMPH. 1	MONO. 1	PLAS. 1
21	6.4	0.00	0.07	0.02	0.00	0.91	0.00	0.00
22	8.0	0.00	0.10	0.00	0.00	0.90	0.00	0.00
23	8.3	0.00	0.07	0.00	0.00	0.93	0.00	0.00
24	7.2	0.00	0.06	0.01	0.00	0.92	0.01	0.00
25	7.5	0.00	0.08	0.00	0.00	0.92	0.00	0.00

	DIFF.WBC COUNT (REL.)	DIFF.WBC COUNT (ABS.)					
ANIMAL NUMBER	OTHER 1	BAND G/L	SEG. G/L	EO. G/L	BASO. G/L	LYMPH. G/L	MONO. G/L
21	0.00	0.0	0.4	0.1	0.0	5.8	0.0
22	0.00	0.0	0.8	0.0	0.0	7.2	0.0
23	0.00	0.0	0.6	0.0	0.0	7.7	0.0
24	0.00	0.0	0.4	0.1	0.0	6.6	0.1
25	0.00	0.0	0.6	0.0	0.0	6.9	0.0

	DIFF.WBC COUNT (ABS.)		RED CELL MORPHOLOGY	COAGULATION	
ANIMAL NUMBER	PLAS. G/L	OTHER G/L	TYPE CELL	PT SEC	APTT SEC
21	0.0	0.0	NORMAL	11.4	25.6
22	0.0	0.0	NORMAL	11.6	21.5
23	0.0	0.0	NORMAL	11.6	24.1
24	0.0	0.0	NORMAL	11.5	23.4
25	0.0	0.0	NORMAL	11.9	22.6

HEMATOLOGY
AFTER 4 WEEKS
MALES
GROUP 5 (1000 MG/KG)

ANIMAL NUMBER	REMARK	RBC T/L	HB MMOL/L	HCT L/L	MCV FL	MCH FMOL	MCHC MMOL/L	PLATELETS G/L
26	---	9.44	11.3	0.55	58.6	1.20	20.4	1010
27	---	9.74	10.1	0.50	51.5	1.03	20.0	913
28	---	10.26	10.9	0.55	53.1	1.07	20.0	981
29	NV	8.72	10.2	0.50	57.7	1.17	20.2	841
30	---	8.96	10.4	0.53	59.3	1.17	19.6	1060
31	---	9.08	10.6	0.52	57.2	1.17	20.4	881
32	---	8.40	9.4	0.47	55.8	1.12	20.1	1061
33	NV	9.44	9.9	0.50	53.1	1.05	19.8	984
34	---	8.89	10.4	0.52	58.4	1.17	20.0	1091
35	---	9.10	10.0	0.50	54.7	1.10	20.0	1127

	RETICULOCYTE COUNT							
ANIMAL NUMBER	RETIC. %	RETIC. T/L	HFR %	MFR %	LFR %	NEN /100 WBC	HEINZ BOD. o/oo	MET-HB %
26	2.75	0.2338	7.9	41.8	50.3	0.0	0	0.8
27	2.79	0.2483	4.4	34.0	61.6	0.0	0	1.1
28	2.70	0.2508	5.4	30.5	64.1	0.0	0	1.6
29	2.97	0.2400	2.0	38.1	59.9	1.0	0	0.9
30	2.89	0.2341	14.1	33.8	52.1	1.0	0	1.0
31	2.44	0.2057	8.5	37.7	53.8	1.0	0	1.1
32	2.19	0.1710	3.7	31.8	64.5	0.0	0	1.0
33	2.19	0.1859	3.3	28.4	68.3	0.0	---	---
34	1.98	0.1618	6.7	34.0	59.3	0.0	0	0.8
35	1.53	0.1274	1.8	24.0	74.2	0.0	0	1.0

		DIFF.WBC COUNT (REL.)						
ANIMAL NUMBER	WBC G/L	BAND 1	SEG. 1	EO. 1	BASO. 1	LYMPH. 1	MONO. 1	PLAS. 1
26	7.1	0.00	0.27	0.00	0.00	0.72	0.01	0.00
27	8.7	0.00	0.07	0.00	0.00	0.92	0.01	0.00
28	9.8	0.00	0.12	0.00	0.00	0.87	0.01	0.00
29	8.1	0.00	0.11	0.02	0.00	0.85	0.02	0.00
30	10.3	0.00	0.06	0.00	0.00	0.94	0.00	0.00
31	9.7	0.00	0.06	0.00	0.00	0.94	0.00	0.00
32	10.3	0.00	0.09	0.00	0.00	0.91	0.00	0.00
33	13.2	0.00	0.10	0.00	0.00	0.90	0.00	0.00
34	7.9	0.00	0.04	0.01	0.00	0.95	0.00	0.00
35	9.5	0.00	0.07	0.02	0.00	0.91	0.00	0.00

	DIFF.WBC COUNT (REL.)	DIFF.WBC COUNT (ABS.)					
ANIMAL NUMBER	OTHER 1	BAND G/L	SEG. G/L	EO. G/L	BASO. G/L	LYMPH. G/L	MONO. G/L
26	0.00	0.0	1.9	0.0	0.0	5.1	0.1
27	0.00	0.0	0.6	0.0	0.0	8.0	0.1
28	0.00	0.0	1.2	0.0	0.0	8.5	0.1

HEMATOLOGY
AFTER 4 WEEKS
MALES
GROUP 5 (1000 MG/KG)

ANIMAL NUMBER	DIFF.WBC COUNT (REL.) OTHER 1	DIFF.WBC COUNT (ABS.) BAND G/L	SEG. G/L	EO. G/L	BASO. G/L	LYMPH. G/L	MONO. G/L
29	0.00	0.0	0.9	0.2	0.0	6.9	0.2
30	0.00	0.0	0.6	0.0	0.0	9.7	0.0
31	0.00	0.0	0.6	0.0	0.0	9.1	0.0
32	0.00	0.0	0.9	0.0	0.0	9.4	0.0
33	0.00	0.0	1.3	0.0	0.0	11.9	0.0
34	0.00	0.0	0.3	0.1	0.0	7.5	0.0
35	0.00	0.0	0.7	0.2	0.0	8.6	0.0

ANIMAL NUMBER	DIFF.WBC COUNT (ABS.) PLAS. G/L	OTHER G/L	RED CELL MORPHOLOGY TYPE CELL	COAGULATION PT SEC	APTT SEC
26	0.0	0.0	NORMAL	10.5	19.6
27	0.0	0.0	NORMAL	11.1	25.0
28	0.0	0.0	NORMAL	11.0	20.7
29	0.0	0.0	NORMAL	---	---
30	0.0	0.0	NORMAL	11.0	23.6
31	0.0	0.0	NORMAL	10.9	22.9
32	0.0	0.0	NORMAL	11.2	22.6
33	0.0	0.0	NORMAL	---	---
34	0.0	0.0	NORMAL	11.2	23.6
35	0.0	0.0	NORMAL	11.2	22.8

HEMATOLOGY
AFTER 4 WEEKS
FEMALES
GROUP 1 (0 MG/KG)

ANIMAL NUMBER	REMARK	RBC T/L	HB MMOL/L	HCT L/L	MCV FL	MCH FMOL	MCHC MMOL/L	PLATELETS G/L
36	NV	9.14	9.9	0.50	54.7	1.09	19.9	1100
37	---	8.23	9.9	0.49	59.5	1.20	20.1	846
38	---	8.71	10.1	0.51	58.2	1.15	19.9	1212
39	---	8.27	9.9	0.49	59.3	1.20	20.3	1029
40	---	8.27	9.8	0.49	59.1	1.19	20.0	851
41	---	8.81	9.9	0.50	56.5	1.13	19.9	1052
42	---	8.40	9.8	0.49	58.2	1.17	20.0	902
43	---	9.32	10.1	0.51	54.8	1.09	19.8	971
44	NV	8.63	9.9	0.50	58.3	1.15	19.7	1122
45	---	8.53	9.9	0.50	59.0	1.17	19.7	872

	RETICULOCYTE COUNT							
ANIMAL NUMBER	RETIC. %	RETIC. T/L	HFR %	MFR %	LFR %	NEN /100 WBC	HEINZ BOD. o/oo	MET-HB %
36	3.46	0.2889	7.9	40.3	51.8	1.0	0	1.1
37	4.24	0.3286	16.5	33.1	50.4	0.0	0	1.0
38	3.72	0.2943	16.2	37.2	46.6	0.0	0	1.1
39	2.75	0.2129	5.0	35.9	59.1	0.0	0	1.0
40	2.73	0.2143	6.2	35.9	57.9	0.0	0	1.0
41	2.53	0.2044	7.5	39.6	52.9	0.0	0	1.0
42	4.81	0.3646	11.1	41.3	47.6	2.0	0	1.1
43	2.82	0.2417	2.4	28.9	68.7	0.0	0	1.1
44	2.77	0.2161	5.4	31.3	63.3	0.0	0	1.0
45	2.49	0.1910	6.1	40.0	53.9	1.0	0	1.1

		DIFF.WBC COUNT (REL.)						
ANIMAL NUMBER	WBC G/L	BAND 1	SEG. 1	EO. 1	BASO. 1	LYMPH. 1	MONO. 1	PLAS. 1
36	9.2	0.00	0.09	0.01	0.00	0.90	0.00	0.00
37	4.0	0.00	0.08	0.00	0.00	0.92	0.00	0.00
38	5.4	0.00	0.11	0.00	0.00	0.89	0.00	0.00
39	5.8	0.00	0.09	0.00	0.00	0.91	0.00	0.00
40	5.2	0.00	0.20	0.00	0.00	0.80	0.00	0.00
41	4.9	0.00	0.05	0.01	0.00	0.94	0.00	0.00
42	6.4	0.00	0.24	0.01	0.00	0.75	0.00	0.00
43	5.1	0.00	0.06	0.00	0.00	0.94	0.00	0.00
44	3.9	0.00	0.14	0.00	0.00	0.86	0.00	0.00
45	6.5	0.00	0.02	0.00	0.00	0.98	0.00	0.00

	DIFF.WBC COUNT (REL.)	DIFF.WBC COUNT (ABS.)					
ANIMAL NUMBER	OTHER 1	BAND G/L	SEG. G/L	EO. G/L	BASO. G/L	LYMPH. G/L	MONO. G/L
36	0.00	0.0	0.8	0.1	0.0	8.3	0.0
37	0.00	0.0	0.3	0.0	0.0	3.7	0.0
38	0.00	0.0	0.6	0.0	0.0	4.8	0.0

HEMATOLOGY
AFTER 4 WEEKS
FEMALES
GROUP 1 (0 MG/KG)

ANIMAL NUMBER	DIFF.WBC COUNT (REL.) OTHER 1	DIFF.WBC COUNT (ABS.) BAND G/L	SEG. G/L	EO. G/L	BASO. G/L	LYMPH. G/L	MONO. G/L
39	0.00	0.0	0.5	0.0	0.0	5.3	0.0
40	0.00	0.0	1.0	0.0	0.0	4.2	0.0
41	0.00	0.0	0.2	0.0	0.0	4.6	0.0
42	0.00	0.0	1.5	0.1	0.0	4.8	0.0
43	0.00	0.0	0.3	0.0	0.0	4.8	0.0
44	0.00	0.0	0.5	0.0	0.0	3.4	0.0
45	0.00	0.0	0.1	0.0	0.0	6.4	0.0

ANIMAL NUMBER	DIFF.WBC COUNT (ABS.) PLAS. G/L	OTHER G/L	RED CELL MORPHOLOGY TYPE CELL	COAGULATION PT SEC	APTT SEC
36	0.0	0.0	NORMAL	---	---
37	0.0	0.0	NORMAL	11.6	22.6
38	0.0	0.0	NORMAL	11.7	21.8
39	0.0	0.0	NORMAL	11.4	23.4
40	0.0	0.0	NORMAL	11.8	18.1
41	0.0	0.0	NORMAL	11.7	18.1
42	0.0	0.0	NORMAL	10.5	25.2
43	0.0	0.0	NORMAL	11.1	22.4
44	0.0	0.0	NORMAL	---	---
45	0.0	0.0	NORMAL	10.9	20.0

HEMATOLOGY
AFTER 4 WEEKS
FEMALES
GROUP 2 (10 MG/KG)

ANIMAL NUMBER	REMARK	RBC T/L	HB MMOL/L	HCT L/L	MCV FL	MCH FMOL	MCHC MMOL/L	PLATELETS G/L
46	---	8.21	10.1	0.51	62.2	1.22	19.7	838
47	---	8.36	9.9	0.48	57.9	1.18	20.4	1113
48	---	8.72	9.7	0.48	55.4	1.11	20.0	1048
49	---	9.27	10.1	0.52	56.0	1.09	19.4	955
50	---	8.96	9.9	0.50	56.1	1.11	19.7	826

	RETICULOCYTE COUNT							
ANIMAL NUMBER	RETIC. %	RETIC. T/L	HFR %	MFR %	LFR %	NEN /100 WBC	HEINZ BOD. o/oo	MET-HB %
46	3.23	0.2432	14.6	37.0	48.4	0.0	0	0.9
47	2.78	0.2191	15.8	38.4	45.8	0.0	0	1.0
48	2.89	0.2321	17.0	41.2	41.8	0.0	0	1.6
49	2.43	0.2046	10.7	38.7	50.6	0.0	0	1.1
50	2.19	0.1785	2.3	27.9	69.8	0.0	0	1.1

		DIFF.WBC COUNT (REL.)						
ANIMAL NUMBER	WBC G/L	BAND 1	SEG. 1	EO. 1	BASO. 1	LYMPH. 1	MONO. 1	PLAS. 1
46	3.8	0.00	0.06	0.00	0.00	0.94	0.00	0.00
47	4.1	0.00	0.12	0.01	0.00	0.87	0.00	0.00
48	4.1	0.00	0.10	0.00	0.00	0.90	0.00	0.00
49	6.5	0.00	0.09	0.00	0.00	0.91	0.00	0.00
50	4.2	0.00	0.14	0.00	0.00	0.86	0.00	0.00

	DIFF.WBC COUNT (REL.)	DIFF.WBC COUNT (ABS.)					
ANIMAL NUMBER	OTHER 1	BAND G/L	SEG. G/L	EO. G/L	BASO. G/L	LYMPH. G/L	MONO. G/L
46	0.00	0.0	0.2	0.0	0.0	3.6	0.0
47	0.00	0.0	0.5	0.0	0.0	3.6	0.0
48	0.00	0.0	0.4	0.0	0.0	3.7	0.0
49	0.00	0.0	0.6	0.0	0.0	5.9	0.0
50	0.00	0.0	0.6	0.0	0.0	3.6	0.0

	DIFF.WBC COUNT (ABS.)		RED CELL MORPHOLOGY	COAGULATION	
ANIMAL NUMBER	PLAS. G/L	OTHER G/L	TYPE CELL	PT SEC	APTT SEC
46	0.0	0.0	NORMAL	10.8	20.8
47	0.0	0.0	NORMAL	11.1	21.0
48	0.0	0.0	NORMAL	11.2	24.3
49	0.0	0.0	NORMAL	11.1	18.7
50	0.0	0.0	NORMAL	11.3	19.1

HEMATOLOGY
AFTER 4 WEEKS
FEMALES
GROUP 3 (50 MG/KG)

ANIMAL NUMBER	REMARK	RBC T/L	HB MMOL/L	HCT L/L	MCV FL	MCH FMOL	MCHC MMOL/L	PLATELETS G/L
51	---	8.74	9.9	0.50	57.2	1.14	19.9	1004
52	---	8.59	9.9	0.49	57.0	1.15	20.1	1058
53	---	8.73	9.8	0.50	57.6	1.12	19.5	985
54	---	8.27	9.7	0.49	58.6	1.18	20.1	1025
55	---	8.60	10.1	0.50	58.3	1.18	20.2	945

	RETICULOCYTE COUNT							
ANIMAL NUMBER	RETIC. %	RETIC. T/L	HFR %	MFR %	LFR %	NEN /100 WBC	HEINZ BOD. o/oo	MET-HB %
51	3.40	0.2751	7.3	36.4	56.3	0.0	0	0.9
52	3.00	0.2379	7.7	32.8	59.5	0.0	0	0.8
53	2.80	0.2223	7.6	39.7	52.7	1.0	0	1.1
54	3.25	0.2522	10.9	35.2	53.9	0.0	0	0.9
55	2.39	0.1936	4.0	29.0	67.0	0.0	0	1.1

		DIFF.WBC COUNT (REL.)						
ANIMAL NUMBER	WBC G/L	BAND 1	SEG. 1	EO. 1	BASO. 1	LYMPH. 1	MONO. 1	PLAS. 1
51	3.3	0.00	0.19	0.01	0.00	0.80	0.00	0.00
52	5.5	0.00	0.09	0.01	0.00	0.89	0.01	0.00
53	4.6	0.00	0.10	0.00	0.00	0.90	0.00	0.00
54	3.9	0.00	0.14	0.01	0.00	0.85	0.00	0.00
55	4.9	0.00	0.22	0.00	0.00	0.77	0.01	0.00

	DIFF.WBC COUNT (REL.)	DIFF.WBC COUNT (ABS.)					
ANIMAL NUMBER	OTHER 1	BAND G/L	SEG. G/L	EO. G/L	BASO. G/L	LYMPH. G/L	MONO. G/L
51	0.00	0.0	0.6	0.0	0.0	2.6	0.0
52	0.00	0.0	0.5	0.1	0.0	4.9	0.1
53	0.00	0.0	0.5	0.0	0.0	4.1	0.0
54	0.00	0.0	0.5	0.0	0.0	3.3	0.0
55	0.00	0.0	1.1	0.0	0.0	3.8	0.0

	DIFF.WBC COUNT (ABS.)		RED CELL MORPHOLOGY	COAGULATION	
ANIMAL NUMBER	PLAS. G/L	OTHER G/L	TYPE CELL	PT SEC	APTT SEC
51	0.0	0.0	NORMAL	11.2	24.7
52	0.0	0.0	NORMAL	10.8	19.4
53	0.0	0.0	NORMAL	10.8	20.1
54	0.0	0.0	NORMAL	10.9	21.5
55	0.0	0.0	NORMAL	11.8	22.2

HEMATOLOGY
AFTER 4 WEEKS
FEMALES
GROUP 4 (200 MG/KG)

ANIMAL NUMBER	REMARK	RBC T/L	HB MMOL/L	HCT L/L	MCV FL	MCH FMOL	MCHC MMOL/L	PLATELETS G/L
56	---	8.53	9.7	0.50	59.0	1.14	19.4	857
57	---	9.16	10.3	0.53	57.5	1.12	19.5	1125
58	---	8.89	10.1	0.52	58.6	1.13	19.3	972
59	---	8.56	10.1	0.51	59.8	1.17	19.6	991
60	---	8.67	9.9	0.51	58.7	1.15	19.5	1109

	RETICULOCYTE COUNT							
ANIMAL NUMBER	RETIC. %	RETIC. T/L	HFR %	MFR %	LFR %	NEN /100 WBC	HEINZ BOD. o/oo	MET-HB %
56	2.58	0.2007	4.2	27.4	68.4	0.0	0	1.4
57	2.43	0.2041	3.7	30.4	65.9	0.0	0	1.1
58	3.71	0.3053	12.3	36.7	51.0	0.0	0	1.1
59	2.72	0.2176	6.4	32.0	61.6	0.0	0	1.0
60	3.77	0.3012	7.7	34.9	57.4	0.0	0	1.1

		DIFF.WBC COUNT (REL.)						
ANIMAL NUMBER	WBC G/L	BAND 1	SEG. 1	EO. 1	BASO. 1	LYMPH. 1	MONO. 1	PLAS. 1
56	4.8	0.00	0.01	0.02	0.00	0.87	0.00	0.00
57	5.0	0.00	0.15	0.02	0.00	0.83	0.00	0.00
58	6.6	0.00	0.07	0.01	0.00	0.89	0.03	0.00
59	6.8	0.00	0.12	0.00	0.00	0.87	0.01	0.00
60	5.9	0.00	0.08	0.00	0.00	0.91	0.01	0.00

	DIFF.WBC COUNT (REL.)	DIFF.WBC COUNT (ABS.)					
ANIMAL NUMBER	OTHER 1	BAND G/L	SEG. G/L	EO. G/L	BASO. G/L	LYMPH. G/L	MONO. G/L
56	0.00	0.0	0.0	0.1	0.0	4.2	0.0
57	0.00	0.0	0.8	0.1	0.0	4.2	0.0
58	0.00	0.0	0.5	0.1	0.0	5.9	0.2
59	0.00	0.0	0.8	0.0	0.0	5.9	0.1
60	0.00	0.0	0.5	0.0	0.0	5.4	0.1

	DIFF.WBC COUNT (ABS.)		RED CELL MORPHOLOGY	COAGULATION	
ANIMAL NUMBER	PLAS. G/L	OTHER G/L	TYPE CELL	PT SEC	APTT SEC
56	0.0	0.0	NORMAL	11.1	20.8
57	0.0	0.0	NORMAL	11.4	22.3
58	0.0	0.0	NORMAL	10.9	16.3
59	0.0	0.0	NORMAL	10.8	20.2
60	0.0	0.0	NORMAL	11.4	21.3

HEMATOLOGY
AFTER 4 WEEKS
FEMALES
GROUP 5 (1000 MG/KG)

ANIMAL NUMBER	REMARK	RBC T/L	HB MMOL/L	HCT L/L	MCV FL	MCH FMOL	MCHC MMOL/L	PLATELETS G/L
61	---	8.41	9.9	0.50	59.2	1.17	19.8	1047
62	---	8.35	9.3	0.49	58.2	1.12	19.2	1116
63	---	8.65	9.9	0.51	59.4	1.15	19.3	1330
64	---	8.90	10.2	0.52	58.5	1.15	19.7	1074
65	---	8.73	9.9	0.52	59.1	1.14	19.2	1097
66	---	8.69	9.8	0.49	56.2	1.13	20.1	966
67	---	8.53	10.2	0.49	57.7	1.19	20.7	1257
68	---	9.21	10.1	0.50	54.2	1.09	20.2	1080
69	---	9.21	10.6	0.52	56.6	1.15	20.4	1095
70	---	8.98	9.9	0.49	55.0	1.10	20.1	991

	RETICULOCYTE COUNT							
ANIMAL NUMBER	RETIC. %	RETIC. T/L	HFR %	MFR %	LFR %	NEN /100 WBC	HEINZ BOD. o/oo	MET-HB %
61	2.77	0.2166	4.6	28.5	66.9	0.0	0	1.2
62	2.71	0.2108	9.7	28.9	61.4	0.0	0	1.0
63	3.11	0.2494	8.8	36.2	55.0	0.0	0	1.1
64	2.19	0.1851	7.3	29.9	62.8	0.0	0	1.1
65	2.77	0.2258	11.3	35.8	52.9	0.0	0	1.1
66	3.53	0.2870	4.8	33.8	61.4	0.0	0	1.0
67	3.26	0.2621	8.2	37.3	54.5	0.0	0	1.7
68	3.48	0.3035	11.8	37.2	51.0	0.0	0	0.9
69	2.44	0.2106	7.5	36.2	56.3	0.0	0	0.8
70	3.36	0.2829	8.6	43.4	48.0	0.0	0	1.1

		DIFF.WBC COUNT (REL.)						
ANIMAL NUMBER	WBC G/L	BAND 1	SEG. 1	EO. 1	BASO. 1	LYMPH. 1	MONO. 1	PLAS. 1
61	5.7	0.00	0.07	0.01	0.00	0.92	0.00	0.00
62	7.5	0.00	0.16	0.02	0.00	0.80	0.02	0.00
63	5.5	0.00	0.11	0.00	0.00	0.89	0.00	0.00
64	5.3	0.00	0.13	0.00	0.00	0.86	0.01	0.00
65	5.9	0.00	0.09	0.01	0.00	0.90	0.00	0.00
66	4.0	0.00	0.17	0.01	0.00	0.82	0.00	0.00
67	8.9	0.00	0.17	0.01	0.00	0.82	0.00	0.00
68	6.5	0.00	0.14	0.00	0.00	0.86	0.00	0.00
69	6.2	0.00	0.18	0.01	0.00	0.80	0.01	0.00
70	4.5	0.00	0.06	0.00	0.00	0.94	0.00	0.00

	DIFF.WBC COUNT (REL.)	DIFF.WBC COUNT (ABS.)					
ANIMAL NUMBER	OTHER 1	BAND G/L	SEG. G/L	EO. G/L	BASO. G/L	LYMPH. G/L	MONO. G/L
61	0.00	0.0	0.4	0.1	0.0	5.2	0.0
62	0.00	0.0	1.2	0.2	0.0	6.0	0.2
63	0.00	0.0	0.6	0.0	0.0	4.9	0.0

HEMATOLOGY
AFTER 4 WEEKS
FEMALES
GROUP 5 (1000 MG/KG)

ANIMAL NUMBER	DIFF.WBC COUNT (REL.) OTHER 1	DIFF.WBC COUNT (ABS.) BAND G/L	SEG. G/L	EO. G/L	BASO. G/L	LYMPH. G/L	MONO. G/L
64	0.00	0.0	0.7	0.0	0.0	4.6	0.1
65	0.00	0.0	0.5	0.1	0.0	5.3	0.0
66	0.00	0.0	0.7	0.0	0.0	3.3	0.0
67	0.00	0.0	1.5	0.1	0.0	7.3	0.0
68	0.00	0.0	0.9	0.0	0.0	5.6	0.0
69	0.00	0.0	1.1	0.1	0.0	5.0	0.1
70	0.00	0.0	0.3	0.0	0.0	4.2	0.0

ANIMAL NUMBER	DIFF.WBC COUNT (ABS.) PLAS. G/L	OTHER G/L	RED CELL MORPHOLOGY TYPE CELL	COAGULATION PT SEC	APTT SEC
61	0.0	0.0	NORMAL	10.5	20.2
62	0.0	0.0	NORMAL	10.4	20.6
63	0.0	0.0	NORMAL	10.7	22.8
64	0.0	0.0	NORMAL	10.7	23.1
65	0.0	0.0	NORMAL	10.7	19.0
66	0.0	0.0	NORMAL	11.2	20.9
67	0.0	0.0	NORMAL	10.5	21.2
68	0.0	0.0	NORMAL	10.4	22.8
69	0.0	0.0	NORMAL	10.5	20.1
70	0.0	0.0	NORMAL	10.4	17.7

HEMATOLOGY
AFTER 6 WEEKS
MALES
GROUP 1 (0 MG/KG)

ANIMAL NUMBER	REMARK	RBC T/L	HB MMOL/L	HCT L/L	MCV FL	MCH FMOL	MCHC MMOL/L	PLATELETS G/L
6	---	8.71	10.6	0.51	58.9	1.21	20.5	1043
7	---	8.99	10.4	0.51	56.8	1.16	20.4	890
8	---	9.36	10.7	0.55	58.3	1.14	19.5	957
9	---	8.90	10.9	0.53	59.7	1.22	20.5	811
10	---	9.19	10.9	0.53	57.6	1.18	20.5	859

	RETICULOCYTE COUNT							
ANIMAL NUMBER	RETIC. %	RETIC. T/L	HFR %	MFR %	LFR %	NEN /100 WBC	HEINZ BOD. o/oo	MET-HB %
6	2.81	0.2360	3.2	36.3	60.5	0.0	0	0.9
7	2.69	0.2305	3.2	32.7	64.1	0.0	0	0.8
8	2.48	0.2220	3.2	29.5	67.3	0.0	0	1.1
9	2.60	0.2218	5.0	35.0	60.0	0.0	0	1.1
10	2.62	0.2287	2.6	36.1	61.3	0.0	0	1.0

		DIFF.WBC COUNT (REL.)						
ANIMAL NUMBER	WBC G/L	BAND 1	SEG. 1	EO. 1	BASO. 1	LYMPH. 1	MONO. 1	PLAS. 1
6	7.3	0.00	0.16	0.00	0.00	0.84	0.00	0.00
7	5.5	0.00	0.18	0.00	0.00	0.82	0.00	0.00
8	7.0	0.00	0.17	0.00	0.00	0.82	0.01	0.00
9	8.1	0.00	0.14	0.00	0.00	0.86	0.00	0.00
10	7.3	0.00	0.12	0.00	0.00	0.88	0.00	0.00

	DIFF.WBC COUNT (REL.)	DIFF.WBC COUNT (ABS.)					
ANIMAL NUMBER	OTHER 1	BAND G/L	SEG. G/L	EO. G/L	BASO. G/L	LYMPH. G/L	MONO. G/L
6	0.00	0.0	1.2	0.0	0.0	6.1	0.0
7	0.00	0.0	1.0	0.0	0.0	4.5	0.0
8	0.00	0.0	1.2	0.0	0.0	5.7	0.1
9	0.00	0.0	1.1	0.0	0.0	7.0	0.0
10	0.00	0.0	0.9	0.0	0.0	6.4	0.0

	DIFF.WBC COUNT (ABS.)		RED CELL MORPHOLOGY	COAGULATION	
ANIMAL NUMBER	PLAS. G/L	OTHER G/L	TYPE CELL	PT SEC	APTT SEC
6	0.0	0.0	NORMAL	10.8	24.3
7	0.0	0.0	NORMAL	11.0	23.1
8	0.0	0.0	NORMAL	10.8	21.4
9	0.0	0.0	NORMAL	11.3	20.7
10	0.0	0.0	NORMAL	11.2	20.8

HEMATOLOGY
AFTER 6 WEEKS
MALES
GROUP 5 (1000 MG/KG)

ANIMAL NUMBER	REMARK	RBC T/L	HB MMOL/L	HCT L/L	MCV FL	MCH FMOL	MCHC MMOL/L	PLATELETS G/L
31	---	8.83	10.6	0.53	59.5	1.20	20.1	949
32	---	8.33	9.5	0.47	55.8	1.14	20.4	1104
33	---	8.93	9.7	0.49	54.3	1.09	20.1	934
34	---	8.25	10.1	0.49	59.6	1.22	20.4	1140
35	---	8.98	10.1	0.49	54.7	1.12	20.5	1333

	RETICULOCYTE COUNT							
ANIMAL NUMBER	RETIC. %	RETIC. T/L	HFR %	MFR %	LFR %	NEN /100 WBC	HEINZ BOD. o/oo	MET-HB %
31	3.07	0.2610	7.2	35.4	57.4	0.0	0	1.2
32	2.78	0.2180	0.9	26.5	72.6	0.0	0	1.3
33	2.29	0.1960	2.1	27.6	70.3	0.0	0	0.8
34	3.43	0.2727	4.2	37.6	58.2	0.0	0	1.2
35	2.91	0.2500	1.6	29.4	69.0	0.0	0	1.2

		DIFF.WBC COUNT (REL.)						
ANIMAL NUMBER	WBC G/L	BAND 1	SEG. 1	EO. 1	BASO. 1	LYMPH. 1	MONO. 1	PLAS. 1
31	8.5	0.00	0.10	0.00	0.00	0.90	0.00	0.00
32	9.4	0.00	0.07	0.01	0.00	0.92	0.00	0.00
33	10.8	0.00	0.02	0.00	0.00	0.97	0.01	0.00
34	6.9	0.00	0.10	0.00	0.00	0.90	0.00	0.00
35	9.6	0.00	0.08	0.01	0.00	0.91	0.00	0.00

	DIFF.WBC COUNT (REL.)	DIFF.WBC COUNT (ABS.)					
ANIMAL NUMBER	OTHER 1	BAND G/L	SEG. G/L	EO. G/L	BASO. G/L	LYMPH. G/L	MONO. G/L
31	0.00	0.0	0.9	0.0	0.0	7.7	0.0
32	0.00	0.0	0.7	0.1	0.0	8.6	0.0
33	0.00	0.0	0.2	0.0	0.0	10.5	0.1
34	0.00	0.0	0.7	0.0	0.0	6.2	0.0
35	0.00	0.0	0.8	0.1	0.0	8.7	0.0

	DIFF.WBC COUNT (ABS.)		RED CELL MORPHOLOGY	COAGULATION	
ANIMAL NUMBER	PLAS. G/L	OTHER G/L	TYPE CELL	PT SEC	APTT SEC
31	0.0	0.0	NORMAL	10.6	17.2
32	0.0	0.0	NORMAL	10.9	18.2
33	0.0	0.0	NORMAL	11.2	21.2
34	0.0	0.0	NORMAL	10.7	21.2
35	0.0	0.0	NORMAL	10.4	18.0

HEMATOLOGY
AFTER 6 WEEKS
FEMALES
GROUP 1 (0 MG/KG)

ANIMAL NUMBER	REMARK	RBC T/L	HB MMOL/L	HCT L/L	MCV FL	MCH FMOL	MCHC MMOL/L	PLATELETS G/L
41	---	8.46	10.7	0.51	60.5	1.26	20.9	1082
42	---	7.72	10.1	0.49	64.0	1.31	20.5	794
43	---	9.03	10.5	0.52	57.8	1.16	20.1	1117
44	---	8.13	10.2	0.51	62.2	1.26	20.2	1173
45	---	8.30	10.7	0.52	62.2	1.28	20.7	758

	RETICULOCYTE COUNT							
ANIMAL NUMBER	RETIC. %	RETIC. T/L	HFR %	MFR %	LFR %	NEN /100 WBC	HEINZ BOD. o/oo	MET-HB %
41	3.12	0.2546	1.9	32.0	66.1	0.0	0	0.9
42	2.76	0.2056	2.6	34.5	62.9	0.0	0	1.1
43	2.28	0.1922	2.8	33.4	63.8	0.0	0	1.4
44	3.07	0.2324	4.8	34.5	60.7	0.0	0	1.3
45	2.21	0.1761	0.7	26.0	73.3	0.0	0	1.0

		DIFF.WBC COUNT (REL.)						
ANIMAL NUMBER	WBC G/L	BAND 1	SEG. 1	EO. 1	BASO. 1	LYMPH. 1	MONO. 1	PLAS. 1
41	5.2	0.00	0.05	0.00	0.00	0.95	0.00	0.00
42	5.6	0.00	0.09	0.00	0.00	0.91	0.00	0.00
43	5.2	0.00	0.11	0.00	0.00	0.89	0.00	0.00
44	4.5	0.00	0.16	0.00	0.00	0.84	0.00	0.00
45	5.7	0.00	0.07	0.00	0.00	0.93	0.00	0.00

	DIFF.WBC COUNT (REL.)	DIFF.WBC COUNT (ABS.)					
ANIMAL NUMBER	OTHER 1	BAND G/L	SEG. G/L	EO. G/L	BASO. G/L	LYMPH. G/L	MONO. G/L
41	0.00	0.0	0.3	0.0	0.0	4.9	0.0
42	0.00	0.0	0.5	0.0	0.0	5.1	0.0
43	0.00	0.0	0.6	0.0	0.0	4.6	0.0
44	0.00	0.0	0.7	0.0	0.0	3.8	0.0
45	0.00	0.0	0.4	0.0	0.0	5.3	0.0

	DIFF.WBC COUNT (ABS.)		RED CELL MORPHOLOGY	COAGULATION	
ANIMAL NUMBER	PLAS. G/L	OTHER G/L	TYPE CELL	PT SEC	APTT SEC
41	0.0	0.0	NORMAL	11.2	20.2
42	0.0	0.0	NORMAL	11.3	21.0
43	0.0	0.0	NORMAL	10.5	15.8
44	0.0	0.0	NORMAL	10.9	19.2
45	0.0	0.0	NORMAL	10.8	16.0

HEMATOLOGY
AFTER 6 WEEKS
FEMALES
GROUP 5 (1000 MG/KG)

ANIMAL NUMBER	REMARK	RBC T/L	HB MMOL/L	HCT L/L	MCV FL	MCH FMOL	MCHC MMOL/L	PLATELETS G/L
66	---	8.40	10.5	0.50	59.5	1.25	21.0	978
67	---	8.00	10.1	0.49	61.1	1.27	20.7	1169
68	---	8.87	10.3	0.51	57.7	1.16	20.1	984
69	---	8.34	10.4	0.50	60.2	1.25	20.8	1019
70	---	8.49	9.9	0.50	58.4	1.17	20.0	881

	RETICULOCYTE COUNT							
ANIMAL NUMBER	RETIC. %	RETIC. T/L	HFR %	MFR %	LFR %	NEN /100 WBC	HEINZ BOD. o/oo	MET-HB %
66	2.31	0.1878	1.0	30.4	68.6	0.0	0	1.3
67	2.27	0.1743	2.4	34.1	63.5	0.0	0	1.3
68	2.68	0.2230	2.8	30.5	66.7	0.0	0	1.3
69	2.22	0.1789	0.4	29.4	70.2	0.0	0	1.1
70	3.00	0.2415	2.0	33.9	64.1	0.0	0	1.8

		DIFF.WBC COUNT (REL.)						
ANIMAL NUMBER	WBC G/L	BAND 1	SEG. 1	EO. 1	BASO. 1	LYMPH. 1	MONO. 1	PLAS. 1
66	4.8	0.00	0.06	0.01	0.00	0.92	0.01	0.00
67	6.2	0.00	0.05	0.00	0.00	0.95	0.00	0.00
68	6.6	0.00	0.10	0.01	0.00	0.89	0.00	0.00
69	4.9	0.00	0.15	0.00	0.00	0.85	0.00	0.00
70	4.1	0.00	0.12	0.00	0.00	0.88	0.00	0.00

	DIFF.WBC COUNT (REL.)	DIFF.WBC COUNT (ABS.)					
ANIMAL NUMBER	OTHER 1	BAND G/L	SEG. G/L	EO. G/L	BASO. G/L	LYMPH. G/L	MONO. G/L
66	0.00	0.0	0.3	0.0	0.0	4.4	0.0
67	0.00	0.0	0.3	0.0	0.0	5.9	0.0
68	0.00	0.0	0.7	0.1	0.0	5.9	0.0
69	0.00	0.0	0.7	0.0	0.0	4.2	0.0
70	0.00	0.0	0.5	0.0	0.0	3.6	0.0

	DIFF.WBC COUNT (ABS.)		RED CELL MORPHOLOGY	COAGULATION	
ANIMAL NUMBER	PLAS. G/L	OTHER G/L	TYPE CELL	PT SEC	APTT SEC
66	0.0	0.0	NORMAL	11.5	21.8
67	0.0	0.0	NORMAL	11.0	19.9
68	0.0	0.0	NORMAL	11.0	19.7
69	0.0	0.0	NORMAL	10.9	19.7
70	0.0	0.0	NORMAL	10.9	18.4

CLINICAL BIOCHEMISTRY
AFTER 4 WEEKS
MALES
GROUP 1 (0 MG/KG)

ANIMAL NUMBER	REMARK	GLUCOSE MMOL/L	UREA MMOL/L	CREATININE µMOL/L	URIC ACID µMOL/L	BILI. T. µMOL/L	CHOLEST.T. MMOL/L	TRIGL. MMOL/L
1	---	5.89	5.49	35	30.3	3.0	1.65	0.79
2	---	6.51	6.71	41	23.4	3.4	1.62	0.60
3	---	---	---	---	---	---	---	---
4	---	5.68	5.28	37	17.5	3.3	1.26	0.71
5	---	5.15	5.04	37	19.3	2.8	1.25	0.80
6	---	6.42	5.82	42	17.0	2.7	1.59	0.89
7	---	5.58	6.29	47	22.5	3.3	1.87	1.67
8	---	5.24	7.19	40	20.2	3.3	2.11	0.89
9	---	5.61	6.07	38	23.0	2.6	1.63	0.36
10	---	6.85	5.99	38	15.6	3.2	1.70	1.09

ANIMAL NUMBER	PHOS.LIPID MMOL/L	ASAT(GOT) µKAT/L	ALAT(GPT) µKAT/L	LDH µKAT/L	CK µKAT/L	ALP µKAT/L	G-GT NKAT/L	CALCIUM MMOL/L
1	1.49	1.16	0.52	1.74	2.35	3.59	14.50	2.66
2	1.41	1.35	0.50	2.12	1.97	3.08	6.91	2.71
3	---	---	---	---	---	---	---	---
4	1.18	1.06	0.39	1.23	1.98	4.70	12.52	2.75
5	1.31	1.05	0.35	1.11	1.82	4.47	8.96	2.59
6	1.51	1.10	0.46	1.04	2.18	6.92	10.81	2.62
7	1.84	1.34	0.54	1.62	2.33	4.23	9.38	2.68
8	1.72	1.19	0.44	1.47	2.65	5.88	13.41	2.80
9	1.42	1.29	0.53	2.31	7.89	3.46	11.08	2.68
10	1.70	1.27	0.53	1.14	2.75	4.80	11.54	2.70

ANIMAL NUMBER	PHOSPHORUS MMOL/L	SODIUM MMOL/L	POTASSIUM MMOL/L	CHLORIDE MMOL/L	ALBUMIN g/L	PROTEIN T. g/L	GLOBULIN g/L	A/G RATIO
1	2.22	149.4	3.00	104.8	32.1	66.5	34.4	0.93
2	2.16	149.7	3.08	105.1	33.0	68.8	35.8	0.92
3	---	---	---	---	---	---	---	---
4	2.20	148.6	3.18	104.4	33.0	67.1	34.1	0.97
5	1.97	154.8	3.65	99.6	33.5	66.1	32.6	1.03
6	2.06	140.7	2.98	109.6	33.3	68.5	35.2	0.95
7	2.38	154.1	3.67	99.9	32.0	64.1	32.1	1.00
8	2.38	149.3	3.34	102.9	33.5	70.4	36.9	0.91
9	2.60	147.8	3.79	105.6	32.5	66.4	33.9	0.96
10	2.02	153.6	3.65	100.6	34.5	70.8	36.3	0.95

CLINICAL BIOCHEMISTRY
AFTER 4 WEEKS
MALES
GROUP 2 (10 MG/KG)

ANIMAL NUMBER	REMARK	GLUCOSE MMOL/L	UREA MMOL/L	CREATININE µMOL/L	URIC ACID µMOL/L	BILI. T. µMOL/L	CHOLEST.T. MMOL/L	TRIGL. MMOL/L
11	---	5.71	4.83	44	20.2	3.0	2.03	1.72
12	---	5.62	6.92	41	22.0	3.3	2.56	0.54
13	---	6.33	6.78	41	24.3	2.9	1.36	0.63
14	---	7.18	5.76	40	29.9	2.4	2.21	0.70
15	---	6.16	5.73	40	24.8	3.0	1.63	0.92

ANIMAL NUMBER	PHOS.LIPID MMOL/L	ASAT(GOT) µKAT/L	ALAT(GPT) µKAT/L	LDH µKAT/L	CK µKAT/L	ALP µKAT/L	G-GT NKAT/L	CALCIUM MMOL/L
11	1.79	1.14	0.37	1.30	1.92	4.24	12.37	2.86
12	1.90	0.96	0.41	1.75	2.31	4.08	7.64	2.88
13	1.30	1.19	0.50	1.44	2.19	4.75	9.69	2.64
14	1.78	1.05	0.39	1.03	2.49	5.90	9.61	2.62
15	1.48	1.05	0.34	1.27	2.02	5.05	10.24	2.80

ANIMAL NUMBER	PHOSPHORUS MMOL/L	SODIUM MMOL/L	POTASSIUM MMOL/L	CHLORIDE MMOL/L	ALBUMIN g/L	PROTEIN T. g/L	GLOBULIN g/L	A/G RATIO
11	2.30	155.5	3.11	100.6	31.5	66.9	35.4	0.89
12	2.27	155.4	3.53	101.3	32.7	69.5	36.8	0.89
13	2.17	146.6	3.36	106.2	33.4	67.4	34.0	0.98
14	2.20	143.6	3.20	109.8	31.5	64.5	33.0	0.95
15	2.13	146.6	3.06	101.3	33.1	68.9	35.8	0.92

CLINICAL BIOCHEMISTRY
AFTER 4 WEEKS
MALES
GROUP 3 (50 MG/KG)

ANIMAL NUMBER	REMARK	GLUCOSE MMOL/L	UREA MMOL/L	CREATININE µMOL/L	URIC ACID µMOL/L	BILI. T. µMOL/L	CHOLEST.T. MMOL/L	TRIGL. MMOL/L
16	---	7.26	5.87	37	20.2	2.8	1.63	0.81
17	---	5.15	5.46	42	19.3	2.7	1.29	0.45
18	---	8.30	5.91	42	19.3	2.9	1.68	1.13
19	---	5.70	6.41	47	48.2	3.9	1.74	0.50
20	---	7.47	6.09	52	43.6	3.1	2.16	0.49

ANIMAL NUMBER	PHOS.LIPID MMOL/L	ASAT(GOT) µKAT/L	ALAT(GPT) µKAT/L	LDH µKAT/L	CK µKAT/L	ALP µKAT/L	G-GT NKAT/L	CALCIUM MMOL/L
16	1.52	1.00	0.40	1.64	2.06	6.24	9.78	2.75
17	1.27	1.19	0.44	1.68	2.29	4.79	7.76	2.68
18	1.53	0.96	0.36	1.35	2.14	4.37	13.81	2.84
19	1.51	1.32	0.50	3.98	5.71	4.66	13.07	2.80
20	1.67	1.22	0.41	2.57	3.48	3.06	11.00	2.72

ANIMAL NUMBER	PHOSPHORUS MMOL/L	SODIUM MMOL/L	POTASSIUM MMOL/L	CHLORIDE MMOL/L	ALBUMIN g/L	PROTEIN T. g/L	GLOBULIN g/L	A/G RATIO
16	2.33	147.7	3.37	105.0	33.0	64.4	31.4	1.05
17	2.30	149.1	3.21	106.8	31.8	63.8	32.0	0.99
18	2.25	155.3	3.46	100.2	33.9	71.5	37.6	0.90
19	2.26	150.8	3.47	105.9	34.4	69.7	35.3	0.97
20	2.24	154.6	2.96	101.2	32.7	68.0	35.3	0.93

CLINICAL BIOCHEMISTRY
AFTER 4 WEEKS
MALES
GROUP 4 (200 MG/KG)

ANIMAL NUMBER	REMARK	GLUCOSE MMOL/L	UREA MMOL/L	CREATININE µMOL/L	URIC ACID µMOL/L	BILI. T. µMOL/L	CHOLEST.T. MMOL/L	TRIGL. MMOL/L
21	---	4.83	5.46	44	24.8	3.3	1.45	0.78
22	---	5.04	4.27	42	25.3	4.0	1.37	1.00
23	---	5.11	5.98	37	23.9	4.4	1.77	0.87
24	---	4.61	4.63	39	27.6	4.2	1.55	0.33
25	---	7.32	5.22	42	23.9	3.7	1.25	0.80

ANIMAL NUMBER	PHOS.LIPID MMOL/L	ASAT(GOT) µKAT/L	ALAT(GPT) µKAT/L	LDH µKAT/L	CK µKAT/L	ALP µKAT/L	G-GT NKAT/L	CALCIUM MMOL/L
21	1.31	1.29	0.44	1.26	2.32	3.08	12.37	2.71
22	1.48	1.28	0.43	1.35	2.36	4.06	9.12	2.78
23	1.75	1.12	0.42	1.07	2.19	6.75	8.67	2.85
24	1.27	1.13	0.40	1.90	2.53	5.58	5.78	2.72
25	1.35	1.16	0.39	2.08	2.70	6.40	10.30	2.72

ANIMAL NUMBER	PHOSPHORUS MMOL/L	SODIUM MMOL/L	POTASSIUM MMOL/L	CHLORIDE MMOL/L	ALBUMIN g/L	PROTEIN T. g/L	GLOBULIN g/L	A/G RATIO
21	2.24	142.0	3.05	108.9	32.3	66.7	34.4	0.94
22	2.21	149.0	3.45	105.3	33.5	66.7	33.2	1.01
23	2.36	148.6	3.50	102.6	32.5	65.7	33.2	0.98
24	2.28	155.7	3.52	99.3	31.5	66.4	34.9	0.90
25	1.99	149.1	3.50	103.6	32.3	65.0	32.7	0.99

CLINICAL BIOCHEMISTRY
AFTER 4 WEEKS
MALES
GROUP 5 (1000 MG/KG)

ANIMAL NUMBER	REMARK	GLUCOSE MMOL/L	UREA MMOL/L	CREATININE µMOL/L	URIC ACID µMOL/L	BILI. T. µMOL/L	CHOLEST.T. MMOL/L	TRIGL. MMOL/L
26	---	7.31	8.28	54	131.8	40.1	2.66	0.63
27	---	6.21	5.50	41	66.6	13.4	2.35	1.55
28	---	4.04	5.05	45	113.0	25.9	2.25	1.20
29	---	4.68	7.36	51	65.7	15.6	2.80	1.48
30	---	5.86	4.65	39	40.9	10.1	1.93	1.26
31	---	4.87	6.03	43	51.4	14.0	2.18	0.83
32	---	6.95	6.19	51	72.1	19.1	2.09	1.27
33	---	6.17	5.78	42	69.4	21.8	2.24	0.79
34	---	5.91	6.05	47	40.9	12.0	1.85	1.08
35	---	6.94	6.69	57	78.5	25.3	1.98	1.34

ANIMAL NUMBER	PHOS.LIPID MMOL/L	ASAT(GOT) µKAT/L	ALAT(GPT) µKAT/L	LDH µKAT/L	CK µKAT/L	ALP µKAT/L	G-GT NKAT/L	CALCIUM MMOL/L
26	2.01	0.99	0.36	2.04	1.54	5.93	8.00	2.67
27	2.09	1.31	0.35	1.60	2.36	4.84	10.88	2.87
28	1.96	1.27	0.31	2.19	2.36	8.83	11.15	2.86
29	2.23	1.44	0.35	5.20	8.69	4.09	10.31	2.84
30	1.73	1.01	0.30	1.26	2.12	4.10	7.72	2.90
31	1.84	1.13	0.34	2.24	2.27	3.39	6.48	2.77
32	1.92	1.18	0.27	2.19	2.11	5.72	8.30	2.79
33	2.12	1.17	0.28	1.79	3.11	3.68	8.43	2.71
34	1.58	1.40	0.32	1.74	2.74	5.22	11.26	2.75
35	1.89	1.23	0.20	1.20	1.95	6.32	9.36	2.74

ANIMAL NUMBER	PHOSPHORUS MMOL/L	SODIUM MMOL/L	POTASSIUM MMOL/L	CHLORIDE MMOL/L	ALBUMIN g/L	PROTEIN T. g/L	GLOBULIN g/L	A/G RATIO
26	1.99	148.4	2.46	101.3	35.6	79.8	44.2	0.81
27	2.16	147.5	3.23	99.5	33.7	69.2	35.5	0.95
28	2.15	145.5	2.78	105.3	35.1	72.9	37.8	0.93
29	2.31	157.7	3.17	96.3	33.6	70.9	37.3	0.90
30	2.39	145.1	2.97	101.6	33.1	70.2	37.1	0.89
31	2.36	153.5	4.06	98.0	32.4	67.8	35.4	0.92
32	2.34	155.0	3.70	99.0	31.2	65.0	33.8	0.92
33	2.26	147.2	3.42	102.0	31.7	66.2	34.5	0.92
34	2.18	148.1	3.16	103.7	32.9	64.0	31.1	1.06
35	2.31	143.3	3.32	106.9	31.5	66.8	35.3	0.89

CLINICAL BIOCHEMISTRY
AFTER 4 WEEKS
FEMALES
GROUP 1 (0 MG/KG)

ANIMAL NUMBER	REMARK	GLUCOSE MMOL/L	UREA MMOL/L	CREATININE µMOL/L	URIC ACID µMOL/L	BILI. T. µMOL/L	CHOLEST.T. MMOL/L	TRIGL. MMOL/L
36	---	7.40	6.35	55	76.3	3.7	1.73	0.38
37	---	5.94	8.02	44	30.8	3.3	1.96	0.24
38	---	5.87	7.18	46	37.2	3.4	1.82	0.60
39	---	4.93	6.79	38	23.4	3.0	1.41	0.46
40	---	5.13	6.52	44	31.2	3.2	2.35	0.44
41	---	5.65	5.23	47	27.6	3.3	1.54	0.30
42	---	6.96	6.64	48	32.6	3.9	1.34	0.33
43	---	5.36	5.70	41	25.3	3.2	2.07	0.47
44	---	5.57	7.06	50	27.1	3.8	1.52	0.38
45	---	6.08	6.27	41	29.4	3.7	1.92	0.35

ANIMAL NUMBER	PHOS.LIPID MMOL/L	ASAT(GOT) µKAT/L	ALAT(GPT) µKAT/L	LDH µKAT/L	CK µKAT/L	ALP µKAT/L	G-GT NKAT/L	CALCIUM MMOL/L
36	1.91	1.26	0.38	2.82	2.54	2.46	12.65	2.77
37	1.98	0.98	0.26	1.08	1.39	2.52	19.00	2.50
38	2.02	1.07	0.38	1.26	1.71	2.52	10.63	2.66
39	1.50	1.00	0.45	1.50	1.91	2.11	10.61	2.78
40	2.31	1.07	0.36	1.84	1.76	3.13	8.45	2.46
41	1.84	1.26	0.32	1.44	1.92	4.84	6.66	2.40
42	1.65	1.47	0.70	1.66	1.50	2.25	11.23	2.54
43	2.14	1.16	0.36	1.02	1.90	3.80	14.09	2.74
44	1.65	1.04	0.38	1.15	1.77	1.83	10.30	2.70
45	1.81	1.11	0.37	2.49	2.69	3.04	9.75	2.62

ANIMAL NUMBER	PHOSPHORUS MMOL/L	SODIUM MMOL/L	POTASSIUM MMOL/L	CHLORIDE MMOL/L	ALBUMIN g/L	PROTEIN T. g/L	GLOBULIN g/L	A/G RATIO
36	1.28	148.9	2.53	103.0	38.8	76.4	37.6	1.03
37	1.79	143.6	2.47	110.1	34.8	70.9	36.1	0.96
38	1.75	150.3	2.45	108.0	34.4	70.6	36.2	0.95
39	1.91	146.7	3.02	104.6	35.9	75.6	39.7	0.90
40	1.90	146.8	3.27	107.6	32.8	68.4	35.6	0.92
41	1.58	141.3	2.93	110.9	32.4	66.3	33.9	0.96
42	1.64	146.7	2.74	104.7	38.1	73.6	35.5	1.07
43	1.92	152.7	3.36	101.3	33.7	66.0	32.3	1.04
44	2.02	142.8	3.37	110.0	35.6	70.7	35.1	1.01
45	2.07	146.3	3.51	107.0	34.0	66.6	32.6	1.04

CLINICAL BIOCHEMISTRY
AFTER 4 WEEKS
FEMALES
GROUP 2 (10 MG/KG)

ANIMAL NUMBER	REMARK	GLUCOSE MMOL/L	UREA MMOL/L	CREATININE µMOL/L	URIC ACID µMOL/L	BILI. T. µMOL/L	CHOLEST.T. MMOL/L	TRIGL. MMOL/L
46	---	4.93	6.81	52	31.2	3.7	2.04	0.45
47	---	6.17	5.43	42	29.4	3.2	2.71	0.41
48	---	5.07	6.62	50	66.6	3.4	1.83	0.41
49	---	4.64	5.99	45	27.1	3.6	1.62	0.49
50	---	5.53	6.60	52	44.1	3.3	2.13	0.40

ANIMAL NUMBER	PHOS.LIPID MMOL/L	ASAT(GOT) µKAT/L	ALAT(GPT) µKAT/L	LDH µKAT/L	CK µKAT/L	ALP µKAT/L	G-GT NKAT/L	CALCIUM MMOL/L
46	2.00	0.94	0.24	1.50	2.01	2.22	11.39	2.61
47	2.47	1.06	0.35	1.43	1.66	2.27	9.58	2.89
48	1.92	0.99	0.32	2.11	1.90	1.71	7.89	2.41
49	1.83	1.16	0.32	1.62	2.07	2.08	10.23	2.76
50	2.03	1.04	0.28	1.95	2.45	1.90	12.29	2.62

ANIMAL NUMBER	PHOSPHORUS MMOL/L	SODIUM MMOL/L	POTASSIUM MMOL/L	CHLORIDE MMOL/L	ALBUMIN g/L	PROTEIN T. g/L	GLOBULIN g/L	A/G RATIO
46	1.87	154.4	2.96	102.7	32.3	64.7	32.4	1.00
47	1.68	147.1	3.06	102.8	35.0	72.6	37.6	0.93
48	1.89	144.1	2.91	108.0	36.6	69.8	33.2	1.10
49	2.00	151.4	2.84	106.1	34.5	72.2	37.7	0.92
50	1.51	143.6	3.45	111.7	35.5	71.2	35.7	0.99

CLINICAL BIOCHEMISTRY
AFTER 4 WEEKS
FEMALES
GROUP 3 (50 MG/KG)

ANIMAL NUMBER	REMARK	GLUCOSE MMOL/L	UREA MMOL/L	CREATININE µMOL/L	URIC ACID µMOL/L	BILI. T. µMOL/L	CHOLEST.T. MMOL/L	TRIGL. MMOL/L
51	---	6.90	6.91	43	45.0	2.8	1.70	0.31
52	---	5.45	6.09	42	36.3	3.1	1.52	0.40
53	---	5.11	7.30	47	34.5	3.7	1.73	0.43
54	---	5.59	7.37	50	39.0	2.8	1.62	0.28
55	---	4.78	7.34	46	28.9	4.9	1.72	0.64

ANIMAL NUMBER	PHOS.LIPID MMOL/L	ASAT(GOT) µKAT/L	ALAT(GPT) µKAT/L	LDH µKAT/L	CK µKAT/L	ALP µKAT/L	G-GT NKAT/L	CALCIUM MMOL/L
51	1.79	0.93	0.31	1.04	1.27	2.13	8.76	2.68
52	1.72	0.81	0.27	2.39	2.02	1.24	10.00	2.62
53	1.71	1.12	0.34	1.52	1.93	1.90	9.66	2.62
54	1.75	1.24	0.41	1.88	1.87	2.06	15.08	2.56
55	2.03	0.98	0.35	1.22	2.44	2.34	9.50	2.63

ANIMAL NUMBER	PHOSPHORUS MMOL/L	SODIUM MMOL/L	POTASSIUM MMOL/L	CHLORIDE MMOL/L	ALBUMIN g/L	PROTEIN T. g/L	GLOBULIN g/L	A/G RATIO
51	1.40	148.0	2.92	107.6	35.9	71.0	35.1	1.02
52	1.82	150.7	3.35	101.4	35.8	71.5	35.7	1.00
53	1.59	153.6	3.43	102.7	36.7	69.7	33.0	1.11
54	1.80	149.0	2.72	106.7	34.3	67.3	33.0	1.04
55	1.72	143.8	2.93	111.3	37.6	74.8	37.2	1.01

CLINICAL BIOCHEMISTRY
AFTER 4 WEEKS
FEMALES
GROUP 4 (200 MG/KG)

ANIMAL NUMBER	REMARK	GLUCOSE MMOL/L	UREA MMOL/L	CREATININE µMOL/L	URIC ACID µMOL/L	BILI. T. µMOL/L	CHOLEST.T. MMOL/L	TRIGL. MMOL/L
56	---	4.93	5.69	50	36.7	3.9	1.99	0.29
57	---	4.13	6.35	45	28.0	3.8	2.11	0.28
58	---	3.77	5.61	40	48.7	4.0	1.43	0.36
59	---	5.84	7.05	44	40.4	3.7	1.88	0.37
60	---	4.93	5.73	46	32.2	4.5	1.10	0.23

ANIMAL NUMBER	PHOS.LIPID MMOL/L	ASAT(GOT) µKAT/L	ALAT(GPT) µKAT/L	LDH µKAT/L	CK µKAT/L	ALP µKAT/L	G-GT NKAT/L	CALCIUM MMOL/L
56	2.11	1.21	0.47	1.18	1.99	2.17	9.89	2.67
57	2.01	1.41	0.40	1.71	2.39	1.95	13.43	2.80
58	1.58	1.50	0.36	2.59	5.09	3.14	17.15	2.63
59	2.03	0.97	0.24	1.32	1.55	1.37	11.63	2.60
60	1.28	1.29	0.33	1.86	2.11	2.32	10.86	2.55

ANIMAL NUMBER	PHOSPHORUS MMOL/L	SODIUM MMOL/L	POTASSIUM MMOL/L	CHLORIDE MMOL/L	ALBUMIN g/L	PROTEIN T. g/L	GLOBULIN g/L	A/G RATIO
56	2.02	148.1	2.88	106.6	36.4	75.8	39.4	0.92
57	1.89	147.4	2.82	107.8	34.1	69.5	35.4	0.96
58	1.91	156.6	3.29	106.0	30.5	63.7	33.2	0.92
59	1.64	140.7	3.33	107.5	37.8	76.3	38.5	0.98
60	1.92	145.2	3.08	108.9	34.1	70.2	36.1	0.94

CLINICAL BIOCHEMISTRY
AFTER 4 WEEKS
FEMALES
GROUP 5 (1000 MG/KG)

ANIMAL NUMBER	REMARK	GLUCOSE MMOL/L	UREA MMOL/L	CREATININE µMOL/L	URIC ACID µMOL/L	BILI. T. µMOL/L	CHOLEST.T. MMOL/L	TRIGL. MMOL/L
61	---	4.09	5.09	55	112.5	18.6	1.51	0.52
62	---	4.97	5.27	42	45.0	8.7	2.12	0.48
63	---	5.43	5.88	46	75.3	10.6	1.80	0.26
64	---	4.04	5.00	46	88.2	23.3	2.39	0.58
65	---	4.76	5.12	51	44.6	10.1	1.50	0.25
66	---	4.80	5.71	48	66.6	16.9	1.96	0.44
67	---	4.45	7.19	49	56.0	10.1	1.50	0.33
68	---	5.09	5.11	47	59.7	11.7	1.68	0.58
69	---	4.82	6.18	47	90.5	12.1	1.76	0.53
70	---	6.32	5.61	53	46.4	8.5	1.97	0.39

ANIMAL NUMBER	PHOS.LIPID MMOL/L	ASAT(GOT) µKAT/L	ALAT(GPT) µKAT/L	LDH µKAT/L	CK µKAT/L	ALP µKAT/L	G-GT NKAT/L	CALCIUM MMOL/L
61	1.61	1.24	0.25	3.51	2.24	2.15	7.71	2.60
62	2.10	1.09	0.26	1.94	1.88	2.23	7.80	2.41
63	1.69	1.24	0.28	1.86	1.59	3.06	11.79	2.50
64	2.18	1.24	0.21	2.47	2.19	2.45	6.41	2.27
65	1.60	1.26	0.22	2.06	1.97	3.19	10.93	2.48
66	2.00	1.20	0.22	1.66	1.47	1.98	8.43	2.42
67	1.59	1.44	0.33	3.55	3.81	2.03	8.22	2.18
68	2.02	1.38	0.26	3.59	2.65	2.30	10.34	2.30
69	1.88	1.34	0.23	4.29	3.91	2.18	8.67	2.55
70	1.93	1.21	0.32	1.80	2.18	1.94	9.62	2.39

ANIMAL NUMBER	PHOSPHORUS MMOL/L	SODIUM MMOL/L	POTASSIUM MMOL/L	CHLORIDE MMOL/L	ALBUMIN g/L	PROTEIN T. g/L	GLOBULIN g/L	A/G RATIO
61	1.71	144.2	3.06	107.2	34.6	70.1	35.5	0.97
62	1.83	144.9	2.83	105.1	33.1	68.6	35.5	0.93
63	1.65	147.8	2.93	105.9	31.3	64.8	33.5	0.93
64	1.91	156.1	2.92	101.3	30.8	66.3	35.5	0.87
65	1.80	148.6	2.87	106.4	33.3	68.6	35.3	0.94
66	1.77	143.2	2.96	110.8	31.1	67.7	36.6	0.85
67	1.84	148.2	2.73	103.6	30.2	65.6	35.4	0.85
68	1.80	148.2	2.78	101.8	34.1	68.5	34.4	0.99
69	1.76	150.4	3.34	105.5	31.1	64.7	33.6	0.93
70	1.58	148.4	2.73	104.7	32.1	68.7	36.6	0.88

CLINICAL BIOCHEMISTRY
AFTER 6 WEEKS
MALES
GROUP 1 (0 MG/KG)

ANIMAL NUMBER	REMARK	GLUCOSE MMOL/L	UREA MMOL/L	CREATININE µMOL/L	URIC ACID µMOL/L	BILI. T. µMOL/L	CHOLEST.T. MMOL/L	TRIGL. MMOL/L
6	---	5.82	4.18	40	17.0	3.0	1.88	0.74
7	---	4.17	4.52	41	25.0	3.0	1.61	0.87
8	---	5.67	5.80	41	16.5	3.0	1.95	0.91
9	---	6.29	5.78	39	31.7	2.8	1.61	0.46
10	---	7.12	5.37	37	16.5	3.0	1.71	0.82

ANIMAL NUMBER	PHOS.LIPID MMOL/L	ASAT(GOT) µKAT/L	ALAT(GPT) µKAT/L	LDH µKAT/L	CK µKAT/L	ALP µKAT/L	G-GT NKAT/L	CALCIUM MMOL/L
6	1.64	1.04	0.44	2.47	3.15	5.44	6.87	2.64
7	1.70	1.36	0.58	2.87	4.15	2.77	7.07	2.46
8	1.78	1.16	0.36	1.27	2.13	4.35	6.05	2.75
9	1.49	1.17	0.54	1.54	2.14	2.98	2.82	2.67
10	1.72	1.08	0.47	1.30	2.04	3.95	11.37	2.67

ANIMAL NUMBER	PHOSPHORUS MMOL/L	SODIUM MMOL/L	POTASSIUM MMOL/L	CHLORIDE MMOL/L	ALBUMIN g/L	PROTEIN T. g/L	GLOBULIN g/L	A/G RATIO
6	1.90	144.2	3.23	103.7	31.8	68.9	37.1	0.86
7	1.80	146.2	3.38	106.7	30.9	63.7	32.8	0.94
8	1.88	138.3	3.10	107.7	36.3	73.9	37.6	0.97
9	2.26	153.7	3.65	99.4	31.4	69.8	38.4	0.82
10	1.79	142.4	3.48	103.9	34.5	73.4	38.9	0.89

CLINICAL BIOCHEMISTRY
AFTER 6 WEEKS
MALES
GROUP 5 (1000 MG/KG)

ANIMAL NUMBER	REMARK	GLUCOSE MMOL/L	UREA MMOL/L	CREATININE µMOL/L	URIC ACID µMOL/L	BILI. T. µMOL/L	CHOLEST.T. MMOL/L	TRIGL. MMOL/L
31	---	5.87	5.08	44	23.7	3.4	1.90	0.44
32	---	6.99	5.54	41	24.1	3.5	1.66	0.78
33	---	7.02	7.64	41	39.3	3.8	1.86	0.68
34	---	5.49	6.14	42	18.3	3.0	1.66	0.58
35	---	6.70	6.84	44	22.3	3.6	1.57	0.98

ANIMAL NUMBER	PHOS.LIPID MMOL/L	ASAT(GOT) µKAT/L	ALAT(GPT) µKAT/L	LDH µKAT/L	CK µKAT/L	ALP µKAT/L	G-GT NKAT/L	CALCIUM MMOL/L
31	1.56	0.99	0.36	2.30	2.31	2.90	7.65	2.73
32	1.54	1.05	0.30	1.56	2.28	4.61	2.42	2.68
33	1.71	1.19	0.34	2.58	2.40	4.44	6.58	2.67
34	1.47	1.16	0.38	2.39	1.81	4.50	8.50	2.62
35	1.66	1.11	0.25	1.52	1.95	4.33	6.83	2.67

ANIMAL NUMBER	PHOSPHORUS MMOL/L	SODIUM MMOL/L	POTASSIUM MMOL/L	CHLORIDE MMOL/L	ALBUMIN g/L	PROTEIN T. g/L	GLOBULIN g/L	A/G RATIO
31	2.22	144.2	3.58	102.8	33.6	68.0	34.4	0.98
32	2.29	142.2	3.80	102.5	30.9	65.2	34.3	0.90
33	2.22	152.8	4.09	98.5	32.0	65.9	33.9	0.94
34	2.17	154.9	3.86	100.7	31.5	65.9	34.4	0.92
35	2.02	146.7	3.33	104.8	33.0	67.4	34.4	0.96

CLINICAL BIOCHEMISTRY
AFTER 6 WEEKS
FEMALES
GROUP 1 (0 MG/KG)

ANIMAL NUMBER	REMARK	GLUCOSE MMOL/L	UREA MMOL/L	CREATININE µMOL/L	URIC ACID µMOL/L	BILI. T. µMOL/L	CHOLEST.T. MMOL/L	TRIGL. MMOL/L
41	---	6.22	6.91	56	31.7	3.8	1.55	0.39
42	---	5.30	7.63	50	26.3	4.8	1.03	0.60
43	---	5.29	5.28	40	33.0	3.2	1.93	0.46
44	---	4.67	6.22	50	32.1	3.8	1.31	0.79
45	---	4.69	6.45	44	40.2	3.7	2.06	0.39

ANIMAL NUMBER	PHOS.LIPID MMOL/L	ASAT(GOT) µKAT/L	ALAT(GPT) µKAT/L	LDH µKAT/L	CK µKAT/L	ALP µKAT/L	G-GT NKAT/L	CALCIUM MMOL/L
41	1.75	1.30	0.64	2.16	1.95	3.01	2.74	2.62
42	1.28	1.12	0.39	2.54	2.80	1.80	7.72	2.58
43	2.01	1.22	0.31	2.42	4.54	3.92	13.22	2.61
44	1.63	1.12	0.35	1.84	2.32	1.41	7.63	2.73
45	1.95	0.95	0.32	2.45	2.35	2.63	9.89	2.71

ANIMAL NUMBER	PHOSPHORUS MMOL/L	SODIUM MMOL/L	POTASSIUM MMOL/L	CHLORIDE MMOL/L	ALBUMIN g/L	PROTEIN T. g/L	GLOBULIN g/L	A/G RATIO
41	1.51	154.7	3.47	101.8	36.0	71.8	35.8	1.01
42	1.64	142.5	3.20	103.4	35.5	68.5	33.0	1.08
43	1.56	144.0	3.26	105.5	34.7	69.8	35.1	0.99
44	1.67	145.6	3.38	106.7	35.3	67.7	32.4	1.09
45	1.96	144.5	4.27	108.1	32.9	67.0	34.1	0.96

CLINICAL BIOCHEMISTRY
AFTER 6 WEEKS
FEMALES
GROUP 5 (1000 MG/KG)

ANIMAL NUMBER	REMARK	GLUCOSE MMOL/L	UREA MMOL/L	CREATININE µMOL/L	URIC ACID µMOL/L	BILI. T. µMOL/L	CHOLEST.T. MMOL/L	TRIGL. MMOL/L
66	---	4.34	5.34	39	23.2	2.8	1.74	0.56
67	---	5.36	7.89	45	33.0	2.9	1.16	0.57
68	---	5.71	7.57	37	33.9	4.4	1.61	0.51
69	---	6.05	7.01	47	25.0	3.6	1.56	0.42
70	---	6.48	8.40	50	35.7	3.5	1.96	0.36

ANIMAL NUMBER	PHOS.LIPID MMOL/L	ASAT(GOT) µKAT/L	ALAT(GPT) µKAT/L	LDH µKAT/L	CK µKAT/L	ALP µKAT/L	G-GT NKAT/L	CALCIUM MMOL/L
66	1.72	1.00	0.22	1.47	1.76	1.58	11.14	2.55
67	1.31	1.16	0.35	2.31	3.21	1.98	8.31	2.57
68	1.79	1.08	0.31	1.52	1.66	1.88	8.59	2.65
69	1.64	1.12	0.27	2.14	1.93	1.93	10.03	2.55
70	1.93	1.09	0.38	1.84	1.59	1.63	9.52	2.66

ANIMAL NUMBER	PHOSPHORUS MMOL/L	SODIUM MMOL/L	POTASSIUM MMOL/L	CHLORIDE MMOL/L	ALBUMIN g/L	PROTEIN T. g/L	GLOBULIN g/L	A/G RATIO
66	1.77	144.8	3.32	106.5	31.9	66.3	34.4	0.93
67	1.81	151.6	3.62	99.5	33.6	67.9	34.3	0.98
68	2.19	135.4	3.39	107.9	32.5	68.9	36.4	0.89
69	1.68	144.5	3.37	103.9	35.3	65.6	30.3	1.17
70	1.63	151.6	3.61	100.6	36.1	69.2	33.1	1.09

URINALYSIS
AFTER 4 WEEKS
MALES
GROUP 1 (0 MG/KG)

ANIMAL NUMBER	REMARK	VOLUME/18h ML	SPEC.GRAV. 1	OSMOLALITY MMOL/KG	COLOR	APPEARANCE	pH	PROTEIN SCORE 0/3
1	---	12.0	1.026	880	LT.YELLOW	CLEAR	9	1
2	---	6.5	1.029	955	YELLOW	CLEAR	9	1
3	---	8.0	1.027	906	YELLOW	CLEAR	9	1
4	---	8.5	1.027	946	LT.YELLOW	CLEAR	9	1
5	---	5.5	1.035	1132	YELLOW	CLEAR	9	2
6	---	7.5	1.027	901	LT.YELLOW	CLEAR	8	1
7	---	6.5	1.030	983	YELLOW	CLEAR	9	1
8	---	7.5	1.029	928	LT.YELLOW	CLEAR	9	1
9	---	6.5	1.040	1432	YELLOW	CLEAR	8	1
10	---	9.0	1.025	773	LT.YELLOW	CLEAR	9	1

ANIMAL NUMBER	GLUCOSE SCORE 0/3	KETONE SCORE 0/3	BILIRUBIN SCORE 0/3	ICTOTEST	BLOOD SCORE 0/3	UROBILI. SCORE 0/3	SED.MICRO.	CRYSTALS TRIP.PHOS. SCORE 0/3
1	0	0	0	---	0	0	NORMAL	1
2	0	0	0	---	0	0	NORMAL	0
3	0	0	0	---	0	0	NORMAL	0
4	0	0	0	---	0	0	NORMAL	0
5	0	0	0	---	0	0	NORMAL	0
6	0	0	0	---	0	0	NORMAL	1
7	0	0	0	---	0	0	NORMAL	0
8	0	0	0	---	0	0	NORMAL	0
9	0	0	0	---	0	0	NORMAL	0
10	0	0	0	---	0	0	NORMAL	0

URINALYSIS
AFTER 4 WEEKS
MALES
GROUP 2 (10 MG/KG)

ANIMAL NUMBER	REMARK	VOLUME/18h ML	SPEC.GRAV. 1	OSMOLALITY MMOL/KG	COLOR	APPEARANCE	pH	PROTEIN SCORE 0/3
11	---	6.0	1.032	1056	YELLOW	CLEAR	8	1
12	---	8.0	1.030	1062	YELLOW	CLEAR	8	1
13	---	10.5	1.020	668	LT.YELLOW	CLEAR	9	1
14	---	9.0	1.028	958	LT.YELLOW	CLEAR	9	1
15	---	8.5	1.028	909	LT.YELLOW	CLEAR	9	1

ANIMAL NUMBER	GLUCOSE SCORE 0/3	KETONE SCORE 0/3	BILIRUBIN SCORE 0/3	ICTOTEST	BLOOD SCORE 0/3	UROBILI. SCORE 0/3	SED.MICRO.	CRYSTALS TRIP.PHOS. SCORE 0/3
11	0	0	0	---	0	0	NORMAL	0
12	0	0	0	---	0	0	NORMAL	0
13	0	0	0	---	0	0	NORMAL	0
14	0	0	0	---	0	0	NORMAL	1
15	0	0	0	---	0	0	NORMAL	0

URINALYSIS
AFTER 4 WEEKS
MALES
GROUP 3 (50 MG/KG)

ANIMAL NUMBER	REMARK	VOLUME/18h ML	SPEC.GRAV. 1	OSMOLALITY MMOL/KG	COLOR	APPEARANCE	pH	PROTEIN SCORE 0/3
16	---	8.5	1.029	989	YELLOW	CLEAR	9	1
17	---	7.5	1.029	972	YELLOW	CLEAR	9	2
18	---	10.0	1.024	740	LT.YELLOW	CLEAR	9	1
19	---	7.5	1.025	852	YELLOW	CLEAR	9	1
20	---	9.5	1.027	933	LT.YELLOW	CLEAR	9	1

ANIMAL NUMBER	GLUCOSE SCORE 0/3	KETONE SCORE 0/3	BILIRUBIN SCORE 0/3	ICTOTEST	BLOOD SCORE 0/3	UROBILI. SCORE 0/3	SED.MICRO.	CRYSTALS TRIP.PHOS. SCORE 0/3
16	0	0	0	---	0	0	NORMAL	0
17	0	0	0	---	0	0	NORMAL	0
18	0	0	0	---	0	0	NORMAL	0
19	0	0	0	---	0	0	NORMAL	0
20	0	0	0	---	0	0	NORMAL	0

URINALYSIS
AFTER 4 WEEKS
MALES
GROUP 4 (200 MG/KG)

ANIMAL NUMBER	REMARK	VOLUME/18h ML	SPEC.GRAV. 1	OSMOLALITY MMOL/KG	COLOR	APPEARANCE	pH	PROTEIN SCORE 0/3
21	---	7.0	1.030	1023	LT.YELLOW	CLEAR	9	2
22	---	3.5	1.032	1578	YELLOW	CLEAR	8	2
23	---	8.0	1.030	970	YELLOW	CLEAR	8	1
24	---	7.0	1.034	1191	YELLOW	CLEAR	8	1
25	---	8.5	1.027	937	LT.YELLOW	CLEAR	8	1

ANIMAL NUMBER	GLUCOSE SCORE 0/3	KETONE SCORE 0/3	BILIRUBIN SCORE 0/3	ICTOTEST	BLOOD SCORE 0/3	UROBILI. SCORE 0/3	SED.MICRO.	CRYSTALS TRIP.PHOS. SCORE 0/3
21	0	0	0	---	0	0	NORMAL	0
22	0	0	1	NEGATIVE	0	0	NORMAL	0
23	0	0	0	---	0	0	NORMAL	0
24	0	0	0	---	0	0	NORMAL	0
25	0	0	0	---	0	0	NORMAL	0

URINALYSIS
AFTER 4 WEEKS
MALES
GROUP 5 (1000 MG/KG)

ANIMAL NUMBER	REMARK	VOLUME/18h ML	SPEC.GRAV. 1	OSMOLALITY MMOL/KG	COLOR	APPEARANCE	pH	PROTEIN SCORE 0/3
26	---	11.5	1.025	885	LT.YELLOW	CLEAR	9	2
27	---	5.5	1.040	1460	LT.RED	CLEAR	8	3
28	---	7.0	1.035	1186	LT.ORANGE	CLEAR	9	3
29	---	6.5	1.037	1264	ORANGE	CLEAR	8	2
30	---	8.0	1.035	1119	ORANGE	CLEAR	8	2
31	---	6.5	1.040	1447	LT.ORANGE	CLEAR	7	2
32	---	5.5	1.040	1469	LT.ORANGE	CLEAR	9	3
33	---	5.5	1.041	1455	ORANGE	CLEAR	7	2
34	---	3.0	1.068	2300	ORANGE	CLEAR	6	3
35	---	4.5	1.045	1518	LT.RED	CLEAR	7	3

ANIMAL NUMBER	GLUCOSE SCORE 0/3	KETONE SCORE 0/3	BILIRUBIN SCORE 0/3	ICTOTEST	BLOOD SCORE 0/3	UROBILI. SCORE 0/3	SED.MICRO.	CRYSTALS TRIP.PHOS. SCORE 0/3
26	0	0	0	---	0	0	NORMAL	0
27	0	0	1	NEGATIVE	1	0	NORMAL	0
28	0	0	1	NEGATIVE	0	0	NORMAL	0
29	0	0	1	NEGATIVE	1	0	NORMAL	0
30	0	0	1	NEGATIVE	1	0	NORMAL	0
31	0	0	1	NEGATIVE	1	0	NORMAL	0
32	0	0	1	NEGATIVE	0	0	NORMAL	0
33	0	0	1	NEGATIVE	1	0	NORMAL	0
34	0	0	1	NEGATIVE	2	1	NORMAL	0
35	0	1	1	NEGATIVE	2	1	NORMAL	0

URINALYSIS
AFTER 4 WEEKS
FEMALES
GROUP 1 (0 MG/KG)

ANIMAL NUMBER	REMARK	VOLUME/18h ML	SPEC.GRAV. 1	OSMOLALITY MMOL/KG	COLOR	APPEARANCE	pH	PROTEIN SCORE 0/3
36	---	7.5	1.027	953	YELLOW	CLEAR	7	0
37	---	7.0	1.030	1053	YELLOW	CLEAR	7	0
38	---	9.0	1.027	1008	LT.YELLOW	CLEAR	7	1
39	---	5.5	1.034	1291	LT.YELLOW	CLEAR	7	1
40	---	5.5	1.030	1049	LT.YELLOW	CLEAR	8	1
41	---	8.0	1.027	975	LT.YELLOW	CLEAR	7	0
42	---	6.5	1.026	931	LT.YELLOW	CLEAR	7	1
43	---	5.5	1.032	1178	YELLOW	CLEAR	7	1
44	---	6.0	1.032	1240	YELLOW	CLEAR	9	1
45	---	6.5	1.032	1172	LT.YELLOW	CLEAR	9	1

ANIMAL NUMBER	GLUCOSE SCORE 0/3	KETONE SCORE 0/3	BILIRUBIN SCORE 0/3	ICTOTEST	BLOOD SCORE 0/3	UROBILI. SCORE 0/3	SED.MICRO.	CRYSTALS TRIP.PHOS. SCORE 0/3
36	0	0	0	---	0	0	NORMAL	1
37	0	0	0	---	0	0	NORMAL	0
38	0	0	0	---	0	0	NORMAL	0
39	0	0	0	---	0	0	NORMAL	1
40	0	0	0	---	0	0	NORMAL	0
41	0	0	0	---	0	0	NORMAL	0
42	0	0	0	---	0	0	NORMAL	0
43	0	0	0	---	0	0	NORMAL	0
44	0	0	0	---	0	0	NORMAL	0
45	0	0	0	---	0	0	NORMAL	0

URINALYSIS
AFTER 4 WEEKS
FEMALES
GROUP 2 (10 MG/KG)

ANIMAL NUMBER	REMARK	VOLUME/18h ML	SPEC.GRAV. 1	OSMOLALITY MMOL/KG	COLOR	APPEARANCE	pH	PROTEIN SCORE 0/3
46	---	4.5	1.040	1422	YELLOW	CLEAR	6	0
47	---	5.5	1.030	1420	YELLOW	CLEAR	7	1
48	---	5.0	1.032	1004	LT.YELLOW	CLEAR	9	1
49	---	6.0	1.025	865	LT.YELLOW	CLEAR	9	1
50	---	2.5	1.047	1843	YELLOW	CLEAR	7	1

ANIMAL NUMBER	GLUCOSE SCORE 0/3	KETONE SCORE 0/3	BILIRUBIN SCORE 0/3	ICTOTEST	BLOOD SCORE 0/3	UROBILI. SCORE 0/3	SED.MICRO.	CRYSTALS TRIP.PHOS. SCORE 0/3
46	0	0	1	NEGATIVE	0	0	NORMAL	0
47	0	0	0	---	0	0	NORMAL	0
48	0	0	0	---	0	0	NORMAL	0
49	0	0	0	---	0	0	NORMAL	0
50	0	0	0	---	0	0	NORMAL	0

URINALYSIS
AFTER 4 WEEKS
FEMALES
GROUP 3 (50 MG/KG)

ANIMAL NUMBER	REMARK	VOLUME/18h ML	SPEC.GRAV. 1	OSMOLALITY MMOL/KG	COLOR	APPEARANCE	pH	PROTEIN SCORE 0/3
51	---	11.0	1.025	832	LT.YELLOW	CLEAR	8	0
52	---	5.0	1.033	1220	YELLOW	CLEAR	7	0
53	---	7.0	1.028	992	YELLOW	CLEAR	8	0
54	---	8.0	1.025	841	LT.YELLOW	CLEAR	7	0
55	---	3.5	1.037	1424	YELLOW	CLEAR	6	1

ANIMAL NUMBER	GLUCOSE SCORE 0/3	KETONE SCORE 0/3	BILIRUBIN SCORE 0/3	ICTOTEST	BLOOD SCORE 0/3	UROBILI. SCORE 0/3	SED.MICRO.	CRYSTALS TRIP.PHOS. SCORE 0/3
51	0	0	0	---	0	0	NORMAL	0
52	0	0	0	---	0	0	NORMAL	0
53	0	0	0	---	0	0	NORMAL	0
54	0	0	0	---	0	0	NORMAL	0
55	0	0	0	---	0	0	NORMAL	0

URINALYSIS
AFTER 4 WEEKS
FEMALES
GROUP 4 (200 MG/KG)

ANIMAL NUMBER	REMARK	VOLUME/18h ML	SPEC.GRAV. 1	OSMOLALITY MMOL/KG	COLOR	APPEARANCE	pH	PROTEIN SCORE 0/3
56	---	4.0	1.037	1411	YELLOW	CLEAR	7	1
57	---	3.0	1.037	1437	YELLOW	CLEAR	7	0
58	---	6.0	1.030	1042	YELLOW	CLEAR	7	0
59	---	9.0	1.020	691	LT.YELLOW	CLEAR	8	0
60	---	6.5	1.028	1039	YELLOW	CLEAR	6	0

ANIMAL NUMBER	GLUCOSE SCORE 0/3	KETONE SCORE 0/3	BILIRUBIN SCORE 0/3	ICTOTEST	BLOOD SCORE 0/3	UROBILI. SCORE 0/3	SED.MICRO.	CRYSTALS TRIP.PHOS. SCORE 0/3
56	0	0	0	---	0	0	NORMAL	0
57	0	0	0	---	0	0	NORMAL	0
58	0	0	0	---	0	0	NORMAL	0
59	0	0	0	---	0	0	NORMAL	0
60	0	0	0	---	0	0	NORMAL	0

URINALYSIS
AFTER 4 WEEKS
FEMALES
GROUP 5 (1000 MG/KG)

ANIMAL NUMBER	REMARK	VOLUME/18h ML	SPEC.GRAV. 1	OSMOLALITY MMOL/KG	COLOR	APPEARANCE	pH	PROTEIN SCORE 0/3
61	---	5.0	1.032	1239	ORANGE	CLEAR	7	2
62	---	4.5	1.040	1517	ORANGE	CLEAR	7	2
63	---	9.0	1.025	941	LT.ORANGE	CLEAR	7	0
64	---	9.5	1.021	779	LT.ORANGE	CLEAR	8	1
65	---	8.0	1.025	917	LT.ORANGE	CLEAR	8	1
66	---	4.5	1.035	1196	LT.RED	CLEAR	7	1
67	---	11.0	1.025	826	LT.ORANGE	CLEAR	8	1
68	---	1.0	1.022	808	LT.ORANGE	CLEAR	9	1
69	---	7.5	1.025	942	LT.ORANGE	CLEAR	9	1
70	---	8.5	1.024	832	LT.ORANGE	CLEAR	6	1

ANIMAL NUMBER	GLUCOSE SCORE 0/3	KETONE SCORE 0/3	BILIRUBIN SCORE 0/3	ICTOTEST	BLOOD SCORE 0/3	UROBILI. SCORE 0/3	SED.MICRO.	CRYSTALS TRIP.PHOS. SCORE 0/3
61	0	0	1	NEGATIVE	1	0	NORMAL	0
62	0	0	1	NEGATIVE	2	0	NORMAL	0
63	0	0	0	---	1	0	NORMAL	0
64	0	0	0	---	1	0	NORMAL	0
65	0	0	0	---	1	0	NORMAL	0
66	0	0	1	NEGATIVE	2	1	NORMAL	0
67	0	0	0	---	1	0	NORMAL	0
68	0	0	0	---	1	0	NORMAL	0
69	0	0	0	---	0	0	NORMAL	0
70	0	0	0	---	2	0	NORMAL	0

URINALYSIS
AFTER 6 WEEKS
MALES
GROUP 1 (0 MG/KG)

ANIMAL NUMBER	REMARK	VOLUME/18h ML	SPEC.GRAV. 1	OSMOLALITY MMOL/KG	COLOR	APPEARANCE	pH	PROTEIN SCORE 0/3
6	---	6.0	1.030	985	YELLOW	CLEAR	7	1
7	---	5.0	1.035	1181	YELLOW	CLEAR	7	1
8	---	8.5	1.028	846	YELLOW	CLEAR	7	1
9	---	7.5	1.036	1294	YELLOW	CLEAR	7	1
10	---	9.5	1.025	752	YELLOW	CLEAR	7	1

ANIMAL NUMBER	GLUCOSE SCORE 0/3	KETONE SCORE 0/3	BILIRUBIN SCORE 0/3	ICTOTEST	BLOOD SCORE 0/3	UROBILI. SCORE 0/3	SED.MICRO.	CRYSTALS TRIP.PHOS. SCORE 0/3
6	0	0	0	---	0	0	NORMAL	0
7	0	0	0	---	0	0	NORMAL	0
8	0	0	0	---	0	0	NORMAL	1
9	0	0	0	---	0	0	NORMAL	0
10	0	0	0	---	0	0	NORMAL	0

URINALYSIS
AFTER 6 WEEKS
MALES
GROUP 5 (1000 MG/KG)

ANIMAL NUMBER	REMARK	VOLUME/18h ML	SPEC.GRAV. 1	OSMOLALITY MMOL/KG	COLOR	APPEARANCE	pH	PROTEIN SCORE 0/3
31	---	7.0	1.030	960	ORANGE	CLEAR	7	1
32	---	7.0	1.030	1027	ORANGE	CLEAR	7	1
33	---	8.5	1.028	877	ORANGE	CLEAR	7	1
34	---	6.0	1.036	1228	ORANGE	CLEAR	7	1
35	---	8.0	1.029	921	ORANGE	CLEAR	7	1

ANIMAL NUMBER	GLUCOSE SCORE 0/3	KETONE SCORE 0/3	BILIRUBIN SCORE 0/3	ICTOTEST	BLOOD SCORE 0/3	UROBILI. SCORE 0/3	SED.MICRO.	CRYSTALS TRIP.PHOS. SCORE 0/3
31	0	0	0	---	1	0	NORMAL	1
32	0	0	0	---	1	0	NORMAL	0
33	0	0	0	---	1	0	NORMAL	0
34	0	0	0	---	2	0	NORMAL	0
35	0	0	0	---	1	0	NORMAL	0

URINALYSIS
AFTER 6 WEEKS
FEMALES
GROUP 1 (0 MG/KG)

ANIMAL NUMBER	REMARK	VOLUME/18h ML	SPEC.GRAV. 1	OSMOLALITY MMOL/KG	COLOR	APPEARANCE	pH	PROTEIN SCORE 0/3
41	---	7.5	1.025	913	YELLOW	CLEAR	8	0
42	---	6.0	1.027	905	YELLOW	CLEAR	6	0
43	---	8.0	1.025	885	YELLOW	CLEAR	7	1
44	---	4.5	1.034	1190	YELLOW	CLEAR	5	1
45	---	6.5	1.029	986	YELLOW	CLEAR	6	0

ANIMAL NUMBER	GLUCOSE SCORE 0/3	KETONE SCORE 0/3	BILIRUBIN SCORE 0/3	ICTOTEST	BLOOD SCORE 0/3	UROBILI. SCORE 0/3	SED.MICRO.	CRYSTALS TRIP.PHOS. SCORE 0/3
41	0	0	0	---	0	0	NORMAL	1
42	0	0	0	---	0	0	NORMAL	0
43	0	0	0	---	0	0	NORMAL	1
44	0	0	0	---	0	0	NORMAL	0
45	0	0	0	---	0	0	NORMAL	0

URINALYSIS
AFTER 6 WEEKS
FEMALES
GROUP 5 (1000 MG/KG)

ANIMAL NUMBER	REMARK	VOLUME/18h ML	SPEC.GRAV. 1	OSMOLALITY MMOL/KG	COLOR	APPEARANCE	pH	PROTEIN SCORE 0/3
66	---	3.5	1.041	1608	ORANGE	CLEAR	6	1
67	---	11.0	1.022	746	LT.ORANGE	CLEAR	7	0
68	---	8.5	1.025	854	LT.ORANGE	CLEAR	6	0
69	---	7.5	1.026	973	LT.ORANGE	CLEAR	6	0
70	---	5.0	1.031	1133	LT.ORANGE	CLEAR	6	0

ANIMAL NUMBER	GLUCOSE SCORE 0/3	KETONE SCORE 0/3	BILIRUBIN SCORE 0/3	ICTOTEST	BLOOD SCORE 0/3	UROBILI. SCORE 0/3	SED.MICRO.	CRYSTALS TRIP.PHOS. SCORE 0/3
66	0	0	1	NEGATIVE	1	0	NORMAL	0
67	0	0	0	---	0	0	NORMAL	0
68	0	0	0	---	0	0	NORMAL	0
69	0	0	0	---	1	0	NORMAL	0
70	0	0	0	---	1	0	NORMAL	0

ORGAN WEIGHTS (GRAM)
AFTER 4 WEEKS
MALES

GROUP 1 (0 MG/KG)

ANIMAL NUMBER	BODY W.	BRAIN	PITUITARY	HEART	THYROIDS	LIVER	KIDNEYS	ADRENALS
1	296.5	1.96	0.011	1.202	0.021	9.58	2.30	0.071
2	235.3	1.89	0.008	0.800	0.018	6.83	1.66	0.046
3	---	---	---	---	---	---	---	---
4	259.4	2.03	0.008	1.059	0.026	7.81	1.80	0.068
5	268.7	1.96	0.008	0.936	0.019	8.34	1.87	0.053

ANIMAL NUMBER	SPLEEN	TESTES
1	0.631	3.42
2	0.470	3.11
3	---	---
4	0.631	2.83
5	0.496	3.46

GROUP 2 (10 MG/KG)

ANIMAL NUMBER	BODY W.	BRAIN	PITUITARY	HEART	THYROIDS	LIVER	KIDNEYS	ADRENALS
11	262.7	1.91	0.010	0.851	0.021	7.86	1.76	0.074
12	275.3	2.05	0.009	1.059	0.022	9.09	2.18	0.062
13	257.2	1.91	0.010	0.880	0.016	7.75	1.90	0.052
14	295.1	1.89	0.009	0.957	0.023	9.26	2.12	0.057
15	276.9	2.14	0.011	0.981	0.020	8.84	2.23	0.067

ANIMAL NUMBER	SPLEEN	TESTES
11	0.670	3.48
12	0.624	3.17
13	0.707	3.59
14	0.634	3.30
15	0.756	3.36

GROUP 3 (50 MG/KG)

ANIMAL NUMBER	BODY W.	BRAIN	PITUITARY	HEART	THYROIDS	LIVER	KIDNEYS	ADRENALS
16	268.0	1.89	0.008	0.994	0.021	8.38	1.91	0.055
17	267.6	1.95	0.011	0.891	0.019	7.62	1.80	0.052
18	300.5	1.86	0.009	0.999	0.029	9.72	2.07	0.063
19	270.1	1.94	0.007	1.000	0.018	8.42	1.94	0.054
20	277.6	1.95	0.009	0.939	0.019	8.56	1.86	0.062

ORGAN WEIGHTS (GRAM)
AFTER 4 WEEKS
MALES

GROUP 3 (50 MG/KG)

ANIMAL NUMBER	SPLEEN	TESTES
16	0.549	3.27
17	0.632	3.26
18	0.566	3.37
19	0.679	3.45
20	0.757	3.31

GROUP 4 (200 MG/KG)

ANIMAL NUMBER	BODY W.	BRAIN	PITUITARY	HEART	THYROIDS	LIVER	KIDNEYS	ADRENALS
21	241.8	1.83	0.007	0.806	0.018	6.84	1.55	0.060
22	248.0	1.89	0.009	0.756	0.021	7.04	1.78	0.052
23	274.4	1.89	0.009	0.846	0.019	8.09	1.84	0.065
24	304.6	1.87	0.011	1.092	0.019	8.84	2.32	0.073
25	288.1	2.04	0.011	0.920	0.023	8.51	2.07	0.064

ANIMAL NUMBER	SPLEEN	TESTES
21	0.769	2.87
22	0.555	2.94
23	0.629	3.10
24	0.664	3.28
25	0.629	3.09

GROUP 5 (1000 MG/KG)

ANIMAL NUMBER	BODY W.	BRAIN	PITUITARY	HEART	THYROIDS	LIVER	KIDNEYS	ADRENALS
26	256.9	1.92	0.008	0.985	0.020	8.05	1.93	0.061
27	254.7	2.01	0.008	0.984	0.018	9.17	2.24	0.054
28	238.4	1.91	0.009	0.919	0.020	7.85	2.16	0.054
29	262.2	1.95	0.008	0.851	0.016	8.41	2.04	0.048
30	310.9	1.89	0.010	1.047	0.017	10.75	2.49	0.077

ANIMAL NUMBER	SPLEEN	TESTES
26	0.405	3.25
27	0.792	3.18
28	0.655	2.86
29	0.585	3.09
30	0.869	3.72

ORGAN/BODY WEIGHT RATIOS (%)
AFTER 4 WEEKS
MALES

GROUP 1 (0 MG/KG)

ANIMAL NUMBER	BODY W. (GRAM)	BRAIN	PITUITARY	HEART	THYROIDS	LIVER	KIDNEYS	ADRENALS
1	296.5	0.66	0.004	0.405	0.007	3.23	0.77	0.024
2	235.3	0.80	0.003	0.340	0.008	2.90	0.71	0.020
3	---	---	---	---	---	---	---	---
4	259.4	0.78	0.003	0.408	0.010	3.01	0.70	0.026
5	268.7	0.73	0.003	0.348	0.007	3.10	0.69	0.020

ANIMAL NUMBER	SPLEEN	TESTES
1	0.213	1.15
2	0.200	1.32
3	---	---
4	0.243	1.09
5	0.184	1.29

GROUP 2 (10 MG/KG)

ANIMAL NUMBER	BODY W. (GRAM)	BRAIN	PITUITARY	HEART	THYROIDS	LIVER	KIDNEYS	ADRENALS
11	262.7	0.73	0.004	0.324	0.008	2.99	0.67	0.028
12	275.3	0.74	0.003	0.385	0.008	3.30	0.79	0.022
13	257.2	0.74	0.004	0.342	0.006	3.01	0.74	0.020
14	295.1	0.64	0.003	0.324	0.008	3.14	0.72	0.019
15	276.9	0.77	0.004	0.354	0.007	3.19	0.81	0.024

ANIMAL NUMBER	SPLEEN	TESTES
11	0.255	1.33
12	0.227	1.15
13	0.275	1.40
14	0.215	1.12
15	0.273	1.21

GROUP 3 (50 MG/KG)

ANIMAL NUMBER	BODY W. (GRAM)	BRAIN	PITUITARY	HEART	THYROIDS	LIVER	KIDNEYS	ADRENALS
16	268.0	0.71	0.003	0.371	0.008	3.13	0.71	0.020
17	267.6	0.73	0.004	0.333	0.007	2.85	0.67	0.019
18	300.5	0.62	0.003	0.332	0.010	3.23	0.69	0.021
19	270.1	0.72	0.003	0.370	0.007	3.12	0.72	0.020
20	277.6	0.70	0.003	0.338	0.007	3.08	0.67	0.022

ORGAN/BODY WEIGHT RATIOS (%)
AFTER 4 WEEKS
MALES

GROUP 3 (50 MG/KG)

ANIMAL NUMBER	SPLEEN	TESTES
16	0.205	1.22
17	0.236	1.22
18	0.188	1.12
19	0.251	1.28
20	0.273	1.19

GROUP 4 (200 MG/KG)

ANIMAL NUMBER	BODY W. (GRAM)	BRAIN	PITUITARY	HEART	THYROIDS	LIVER	KIDNEYS	ADRENALS
21	241.8	0.76	0.003	0.333	0.008	2.83	0.64	0.025
22	248.0	0.76	0.004	0.305	0.008	2.84	0.72	0.021
23	274.4	0.69	0.003	0.308	0.007	2.95	0.67	0.024
24	304.6	0.61	0.004	0.358	0.006	2.90	0.76	0.024
25	288.1	0.71	0.004	0.319	0.008	2.95	0.72	0.022

ANIMAL NUMBER	SPLEEN	TESTES
21	0.318	1.19
22	0.224	1.18
23	0.229	1.13
24	0.218	1.08
25	0.218	1.07

GROUP 5 (1000 MG/KG)

ANIMAL NUMBER	BODY W. (GRAM)	BRAIN	PITUITARY	HEART	THYROIDS	LIVER	KIDNEYS	ADRENALS
26	256.9	0.75	0.003	0.384	0.008	3.13	0.75	0.024
27	254.7	0.79	0.003	0.386	0.007	3.60	0.88	0.021
28	238.4	0.80	0.004	0.385	0.008	3.29	0.91	0.023
29	262.2	0.74	0.003	0.325	0.006	3.21	0.78	0.018
30	310.9	0.61	0.003	0.337	0.005	3.46	0.80	0.025

ANIMAL NUMBER	SPLEEN	TESTES
26	0.158	1.26
27	0.311	1.25
28	0.275	1.20
29	0.223	1.18
30	0.279	1.20

ORGAN/BRAIN WEIGHT RATIOS (%)
AFTER 4 WEEKS
MALES

GROUP 1 (0 MG/KG)

ANIMAL NUMBER	BRAIN (GRAM)	PITUITARY	HEART	THYROIDS	LIVER	KIDNEYS	ADRENALS	SPLEEN
1	1.96	0.556	61.354	1.087	489.06	117.21	3.609	32.193
2	1.89	0.397	42.333	0.974	361.51	87.85	2.434	24.844
3	---	---	---	---	---	---	---	---
4	2.03	0.369	52.081	1.259	383.93	88.66	3.364	31.038
5	1.96	0.392	47.630	0.957	424.58	95.05	2.714	25.238

ANIMAL NUMBER	TESTES
1	174.68
2	164.44
3	---
4	139.30
5	176.38

GROUP 2 (10 MG/KG)

ANIMAL NUMBER	BRAIN (GRAM)	PITUITARY	HEART	THYROIDS	LIVER	KIDNEYS	ADRENALS	SPLEEN
11	1.91	0.523	44.516	1.073	411.39	91.91	3.893	35.065
12	2.05	0.414	51.624	1.063	443.17	106.06	3.004	30.442
13	1.91	0.524	46.095	0.828	405.72	99.70	2.724	37.024
14	1.89	0.471	50.627	1.217	490.01	112.06	3.036	33.547
15	2.14	0.529	45.889	0.931	413.58	104.33	3.152	35.355

ANIMAL NUMBER	TESTES
11	182.21
12	154.74
13	188.08
14	174.50
15	157.05

GROUP 3 (50 MG/KG)

ANIMAL NUMBER	BRAIN (GRAM)	PITUITARY	HEART	THYROIDS	LIVER	KIDNEYS	ADRENALS	SPLEEN
16	1.89	0.422	52.470	1.114	442.41	100.81	2.898	28.975
17	1.95	0.555	45.762	0.961	391.56	92.63	2.666	32.446
18	1.86	0.484	53.771	1.572	523.13	111.57	3.407	30.468
19	1.94	0.377	51.621	0.950	434.39	99.92	2.761	35.054
20	1.95	0.447	48.219	0.980	439.39	95.59	3.182	38.846

ORGAN/BRAIN WEIGHT RATIOS (%)
AFTER 4 WEEKS
MALES

GROUP 3 (50 MG/KG)

ANIMAL NUMBER	TESTES
16	172.61
17	167.56
18	181.65
19	178.19
20	169.66

GROUP 4 (200 MG/KG)

ANIMAL NUMBER	BRAIN (GRAM)	PITUITARY	HEART	THYROIDS	LIVER	KIDNEYS	ADRENALS	SPLEEN
21	1.83	0.394	44.046	1.001	374.23	84.66	3.297	42.023
22	1.89	0.471	39.984	1.106	372.14	93.91	2.751	29.336
23	1.89	0.461	44.825	0.980	428.65	97.66	3.459	33.293
24	1.87	0.594	58.431	1.006	472.91	124.25	3.917	35.543
25	2.04	0.529	45.043	1.116	416.83	101.31	3.114	30.776

ANIMAL NUMBER	TESTES
21	156.96
22	155.45
23	164.24
24	175.28
25	151.50

GROUP 5 (1000 MG/KG)

ANIMAL NUMBER	BRAIN (GRAM)	PITUITARY	HEART	THYROIDS	LIVER	KIDNEYS	ADRENALS	SPLEEN
26	1.92	0.417	51.336	1.032	419.15	100.33	3.188	21.089
27	2.01	0.393	48.990	0.871	456.63	111.54	2.683	39.438
28	1.91	0.455	48.017	1.045	410.33	113.02	2.822	34.250
29	1.95	0.385	43.639	0.815	431.37	104.43	2.451	29.973
30	1.89	0.545	55.387	0.878	568.89	131.45	4.062	45.951

ANIMAL NUMBER	TESTES
26	169.24
27	158.05
28	149.72
29	158.32
30	196.92

ORGAN WEIGHTS (GRAM)
AFTER 4 WEEKS
FEMALES

GROUP 1 (0 MG/KG)

ANIMAL NUMBER	BODY W.	BRAIN	PITUITARY	HEART	THYROIDS	LIVER	KIDNEYS	ADRENALS
36	162.4	1.76	0.011	0.648	0.016	5.81	1.26	0.089
37	174.1	1.78	0.013	0.742	0.025	6.32	1.36	0.089
38	181.4	1.87	0.013	0.810	0.018	5.99	1.43	0.078
39	184.3	1.84	0.012	0.781	0.020	6.90	1.50	0.086
40	190.5	1.74	0.014	0.787	0.022	6.86	1.48	0.084

ANIMAL NUMBER	SPLEEN	OVARIES
36	0.449	0.146
37	0.459	0.159
38	0.500	0.090
39	0.521	0.098
40	0.564	0.097

GROUP 2 (10 MG/KG)

ANIMAL NUMBER	BODY W.	BRAIN	PITUITARY	HEART	THYROIDS	LIVER	KIDNEYS	ADRENALS
46	185.2	1.78	0.012	0.734	0.013	6.24	1.39	0.076
47	172.2	1.81	0.017	0.697	0.018	5.32	1.33	0.071
48	167.6	1.77	0.013	0.736	0.022	6.09	1.37	0.079
49	177.8	1.78	0.012	0.718	0.019	---	1.27	0.076
50	166.6	1.80	0.016	0.660	0.022	5.04	1.25	0.077

ANIMAL NUMBER	SPLEEN	OVARIES
46	0.670	0.124
47	0.423	0.096
48	0.551	0.068
49	0.508	0.085
50	0.386	0.089

GROUP 3 (50 MG/KG)

ANIMAL NUMBER	BODY W.	BRAIN	PITUITARY	HEART	THYROIDS	LIVER	KIDNEYS	ADRENALS
51	177.3	1.91	0.017	0.806	0.024	6.28	1.61	0.099
52	171.1	1.70	0.013	0.692	0.016	6.25	1.39	0.085
53	182.5	1.93	0.013	0.710	0.014	5.30	1.33	0.084
54	178.9	1.81	0.013	0.730	0.015	5.75	1.29	0.070
55	171.9	1.75	0.010	0.656	0.018	5.39	1.38	0.068

ORGAN WEIGHTS (GRAM)
AFTER 4 WEEKS
FEMALES

GROUP 3 (50 MG/KG)

ANIMAL NUMBER	SPLEEN	OVARIES
51	0.499	0.098
52	0.446	0.127
53	0.500	0.095
54	0.419	0.114
55	0.492	0.086

GROUP 4 (200 MG/KG)

ANIMAL NUMBER	BODY W.	BRAIN	PITUITARY	HEART	THYROIDS	LIVER	KIDNEYS	ADRENALS
56	170.9	1.75	0.013	0.713	0.014	5.57	1.36	0.082
57	181.4	1.82	0.012	0.674	0.019	5.39	1.32	0.075
58	161.7	1.77	0.010	0.601	0.019	5.11	1.28	0.080
59	184.0	1.90	0.016	0.635	0.022	5.89	1.40	0.085
60	177.4	1.88	0.014	0.685	0.014	5.66	1.33	0.082

ANIMAL NUMBER	SPLEEN	OVARIES
56	0.461	0.095
57	0.434	0.126
58	0.449	0.096
59	0.356	0.123
60	0.446	0.118

GROUP 5 (1000 MG/KG)

ANIMAL NUMBER	BODY W.	BRAIN	PITUITARY	HEART	THYROIDS	LIVER	KIDNEYS	ADRENALS
61	182.4	1.72	0.014	0.650	0.020	5.36	1.46	0.083
62	190.9	1.90	0.014	0.802	0.018	6.79	1.67	0.090
63	181.8	1.88	0.014	0.695	0.020	6.52	1.58	0.090
64	166.8	1.77	0.013	0.648	0.016	5.71	1.40	0.088
65	185.5	1.71	0.013	0.684	0.017	6.11	1.46	0.075

ANIMAL NUMBER	SPLEEN	OVARIES
61	0.535	0.124
62	0.554	0.129
63	0.470	0.104
64	0.397	0.075
65	0.593	0.082

ORGAN/BODY WEIGHT RATIOS (%)
AFTER 4 WEEKS
FEMALES

GROUP 1 (0 MG/KG)

ANIMAL NUMBER	BODY W. (GRAM)	BRAIN	PITUITARY	HEART	THYROIDS	LIVER	KIDNEYS	ADRENALS
36	162.4	1.08	0.007	0.399	0.010	3.58	0.77	0.055
37	174.1	1.02	0.008	0.426	0.014	3.63	0.78	0.051
38	181.4	1.03	0.007	0.446	0.010	3.30	0.79	0.043
39	184.3	1.00	0.006	0.424	0.011	3.74	0.81	0.047
40	190.5	0.91	0.008	0.413	0.012	3.60	0.77	0.044

ANIMAL NUMBER	SPLEEN	OVARIES
36	0.277	0.090
37	0.264	0.091
38	0.275	0.049
39	0.283	0.053
40	0.296	0.051

GROUP 2 (10 MG/KG)

ANIMAL NUMBER	BODY W. (GRAM)	BRAIN	PITUITARY	HEART	THYROIDS	LIVER	KIDNEYS	ADRENALS
46	185.2	0.96	0.006	0.397	0.007	3.37	0.75	0.041
47	172.2	1.05	0.010	0.405	0.010	3.09	0.77	0.041
48	167.6	1.06	0.008	0.439	0.013	3.63	0.82	0.047
49	177.8	1.00	0.006	0.404	0.011	---	0.71	0.043
50	166.6	1.08	0.009	0.396	0.013	3.02	0.75	0.046

ANIMAL NUMBER	SPLEEN	OVARIES
46	0.362	0.067
47	0.246	0.056
48	0.329	0.040
49	0.286	0.048
50	0.232	0.053

GROUP 3 (50 MG/KG)

ANIMAL NUMBER	BODY W. (GRAM)	BRAIN	PITUITARY	HEART	THYROIDS	LIVER	KIDNEYS	ADRENALS
51	177.3	1.08	0.009	0.455	0.013	3.54	0.91	0.056
52	171.1	1.00	0.008	0.404	0.010	3.65	0.81	0.049
53	182.5	1.06	0.007	0.389	0.008	2.90	0.73	0.046
54	178.9	1.01	0.007	0.408	0.008	3.21	0.72	0.039
55	171.9	1.02	0.006	0.381	0.010	3.13	0.80	0.040

ORGAN/BODY WEIGHT RATIOS (%)
AFTER 4 WEEKS
FEMALES

GROUP 3 (50 MG/KG)

ANIMAL NUMBER	SPLEEN	OVARIES
51	0.281	0.055
52	0.261	0.074
53	0.274	0.052
54	0.234	0.064
55	0.286	0.050

GROUP 4 (200 MG/KG)

ANIMAL NUMBER	BODY W. (GRAM)	BRAIN	PITUITARY	HEART	THYROIDS	LIVER	KIDNEYS	ADRENALS
56	170.9	1.02	0.007	0.417	0.008	3.26	0.79	0.048
57	181.4	1.00	0.007	0.372	0.010	2.97	0.73	0.042
58	161.7	1.10	0.006	0.372	0.012	3.16	0.79	0.050
59	184.0	1.03	0.008	0.345	0.012	3.20	0.76	0.046
60	177.4	1.06	0.008	0.386	0.008	3.19	0.75	0.046

ANIMAL NUMBER	SPLEEN	OVARIES
56	0.270	0.056
57	0.239	0.069
58	0.277	0.060
59	0.194	0.067
60	0.252	0.066

GROUP 5 (1000 MG/KG)

ANIMAL NUMBER	BODY W. (GRAM)	BRAIN	PITUITARY	HEART	THYROIDS	LIVER	KIDNEYS	ADRENALS
61	182.4	0.94	0.008	0.356	0.011	2.94	0.80	0.045
62	190.9	0.99	0.007	0.420	0.009	3.56	0.88	0.047
63	181.8	1.03	0.008	0.382	0.011	3.59	0.87	0.049
64	166.8	1.06	0.007	0.389	0.010	3.42	0.84	0.053
65	185.5	0.92	0.007	0.369	0.009	3.29	0.79	0.041

ANIMAL NUMBER	SPLEEN	OVARIES
61	0.293	0.068
62	0.290	0.068
63	0.258	0.057
64	0.238	0.045
65	0.320	0.044

ORGAN/BRAIN WEIGHT RATIOS (%)
AFTER 4 WEEKS
FEMALES

GROUP 1 (0 MG/KG)

ANIMAL NUMBER	BRAIN (GRAM)	PITUITARY	HEART	THYROIDS	LIVER	KIDNEYS	ADRENALS	SPLEEN
36	1.76	0.602	36.789	0.925	329.81	71.36	5.070	25.491
37	1.78	0.755	41.770	1.391	356.07	76.72	5.006	25.869
38	1.87	0.674	43.280	0.946	319.98	76.42	4.180	26.713
39	1.84	0.646	42.378	1.091	374.62	81.31	4.658	28.306
40	1.74	0.827	45.191	1.275	393.80	84.70	4.846	32.359

ANIMAL NUMBER	OVARIES
36	8.260
37	8.931
38	4.785
39	5.309
40	5.575

GROUP 2 (10 MG/KG)

ANIMAL NUMBER	BRAIN (GRAM)	PITUITARY	HEART	THYROIDS	LIVER	KIDNEYS	ADRENALS	SPLEEN
46	1.78	0.663	41.251	0.725	350.47	77.82	4.291	37.634
47	1.81	0.916	38.457	0.966	293.53	73.43	3.928	23.350
48	1.77	0.757	41.592	1.260	344.02	77.29	4.436	31.156
49	1.78	0.645	40.283	1.077	---	71.11	4.267	28.491
50	1.80	0.862	36.702	1.224	280.30	69.51	4.262	21.478

ANIMAL NUMBER	OVARIES
46	6.937
47	5.308
48	3.825
49	4.766
50	4.924

GROUP 3 (50 MG/KG)

ANIMAL NUMBER	BRAIN (GRAM)	PITUITARY	HEART	THYROIDS	LIVER	KIDNEYS	ADRENALS	SPLEEN
51	1.91	0.868	42.128	1.249	328.04	83.97	5.169	26.061
52	1.70	0.781	40.634	0.963	366.92	81.85	4.963	26.179
53	1.93	0.646	36.688	0.724	273.85	68.81	4.322	25.858
54	1.81	0.697	40.360	0.808	318.00	71.32	3.877	23.147
55	1.75	0.578	37.539	1.019	308.46	79.01	3.916	28.190

ORGAN/BRAIN WEIGHT RATIOS (%)
AFTER 4 WEEKS
FEMALES

GROUP 3 (50 MG/KG)

ANIMAL NUMBER	OVARIES
51	5.138
52	7.460
53	4.890
54	6.316
55	4.946

GROUP 4 (200 MG/KG)

ANIMAL NUMBER	BRAIN (GRAM)	PITUITARY	HEART	THYROIDS	LIVER	KIDNEYS	ADRENALS	SPLEEN
56	1.75	0.721	40.815	0.790	318.88	77.74	4.665	26.378
57	1.82	0.664	37.002	1.021	295.80	72.24	4.137	23.818
58	1.77	0.581	33.945	1.078	288.34	72.44	4.533	25.319
59	1.90	0.823	33.462	1.155	310.46	73.81	4.492	18.787
60	1.88	0.729	36.464	0.761	301.29	70.74	4.345	23.759

ANIMAL NUMBER	OVARIES
56	5.450
57	6.886
58	5.436
59	6.465
60	6.257

GROUP 5 (1000 MG/KG)

ANIMAL NUMBER	BRAIN (GRAM)	PITUITARY	HEART	THYROIDS	LIVER	KIDNEYS	ADRENALS	SPLEEN
61	1.72	0.830	37.744	1.150	311.33	84.79	4.790	31.044
62	1.90	0.722	42.211	0.943	357.60	88.12	4.719	29.150
63	1.88	0.740	36.992	1.085	346.91	84.22	4.788	24.989
64	1.77	0.705	36.550	0.897	321.77	78.69	4.952	22.400
65	1.71	0.735	39.910	0.974	356.50	85.46	4.393	34.613

ANIMAL NUMBER	OVARIES
61	7.193
62	6.799
63	5.517
64	4.241
65	4.796

ORGAN WEIGHTS (GRAM)
AFTER 6 WEEKS
MALES

GROUP 1 (0 MG/KG)

ANIMAL NUMBER	BODY W.	BRAIN	PITUITARY	HEART	THYROIDS	LIVER	KIDNEYS	ADRENALS
6	270.8	1.86	0.009	0.917	0.035	7.20	1.90	0.069
7	283.8	1.96	0.008	0.938	0.017	7.44	1.72	0.068
8	310.9	1.97	0.008	1.055	0.022	8.64	1.86	0.091
9	304.2	2.22	0.009	1.073	0.031	8.00	2.12	0.060
10	270.1	1.94	0.009	0.956	0.015	8.17	1.83	0.080

ANIMAL NUMBER	SPLEEN	TESTES
6	0.664	3.13
7	0.594	3.42
8	0.853	3.82
9	0.633	3.64
10	0.800	3.24

GROUP 5 (1000 MG/KG)

ANIMAL NUMBER	BODY W.	BRAIN	PITUITARY	HEART	THYROIDS	LIVER	KIDNEYS	ADRENALS
31	290.6	1.91	0.009	0.994	0.024	8.42	1.93	0.073
32	296.3	2.07	0.010	0.942	0.024	8.27	2.22	0.067
33	304.3	1.74	0.012	1.071	0.026	8.98	2.27	0.080
34	284.5	1.90	0.009	1.098	0.026	8.23	1.92	0.072
35	279.2	1.97	0.008	0.986	0.017	9.82	2.02	0.065

ANIMAL NUMBER	SPLEEN	TESTES
31	0.729	3.57
32	0.696	3.17
33	0.694	3.05
34	0.699	3.23
35	0.676	3.20

ORGAN/BODY WEIGHT RATIOS (%)
AFTER 6 WEEKS
MALES

GROUP 1 (0 MG/KG)

ANIMAL NUMBER	BODY W. (GRAM)	BRAIN	PITUITARY	HEART	THYROIDS	LIVER	KIDNEYS	ADRENALS
6	270.8	0.69	0.003	0.339	0.013	2.66	0.70	0.025
7	283.8	0.69	0.003	0.330	0.006	2.62	0.61	0.024
8	310.9	0.63	0.003	0.339	0.007	2.78	0.60	0.029
9	304.2	0.73	0.003	0.353	0.010	2.63	0.70	0.020
10	270.1	0.72	0.003	0.354	0.006	3.02	0.68	0.029

ANIMAL NUMBER	SPLEEN	TESTES
6	0.245	1.16
7	0.209	1.20
8	0.274	1.23
9	0.208	1.20
10	0.296	1.20

GROUP 5 (1000 MG/KG)

ANIMAL NUMBER	BODY W. (GRAM)	BRAIN	PITUITARY	HEART	THYROIDS	LIVER	KIDNEYS	ADRENALS
31	290.6	0.66	0.003	0.342	0.008	2.90	0.66	0.025
32	296.3	0.70	0.003	0.318	0.008	2.79	0.75	0.022
33	304.3	0.57	0.004	0.352	0.008	2.95	0.75	0.026
34	284.5	0.67	0.003	0.386	0.009	2.89	0.68	0.025
35	279.2	0.71	0.003	0.353	0.006	3.52	0.72	0.023

ANIMAL NUMBER	SPLEEN	TESTES
31	0.251	1.23
32	0.235	1.07
33	0.228	1.00
34	0.246	1.13
35	0.242	1.15

ORGAN/BRAIN WEIGHT RATIOS (%)
AFTER 6 WEEKS
MALES

GROUP 1 (0 MG/KG)

ANIMAL NUMBER	BRAIN (GRAM)	PITUITARY	HEART	THYROIDS	LIVER	KIDNEYS	ADRENALS	SPLEEN
6	1.86	0.461	49.171	1.899	386.51	101.72	3.702	35.637
7	1.96	0.409	47.930	0.889	380.38	87.92	3.486	30.349
8	1.97	0.417	53.622	1.093	439.19	94.72	4.621	43.379
9	2.22	0.424	48.355	1.388	360.67	95.55	2.712	28.539
10	1.94	0.480	49.396	0.785	422.01	94.50	4.112	41.332

ANIMAL NUMBER	TESTES
6	168.11
7	174.59
8	194.42
9	164.00
10	167.35

GROUP 5 (1000 MG/KG)

ANIMAL NUMBER	BRAIN (GRAM)	PITUITARY	HEART	THYROIDS	LIVER	KIDNEYS	ADRENALS	SPLEEN
31	1.91	0.444	51.927	1.238	439.98	100.73	3.797	38.072
32	2.07	0.487	45.463	1.168	399.14	107.30	3.210	33.589
33	1.74	0.674	61.689	1.469	517.09	130.92	4.596	39.982
34	1.90	0.459	57.886	1.360	434.12	101.35	3.807	36.878
35	1.97	0.410	49.972	0.876	497.49	102.45	3.308	34.237

ANIMAL NUMBER	TESTES
31	186.68
32	153.06
33	175.75
34	170.07
35	162.30

ORGAN WEIGHTS (GRAM)
AFTER 6 WEEKS
FEMALES

GROUP 1 (0 MG/KG)

ANIMAL NUMBER	BODY W.	BRAIN	PITUITARY	HEART	THYROIDS	LIVER	KIDNEYS	ADRENALS
41	194.1	1.93	0.009	0.743	0.030	5.44	1.29	0.090
42	181.4	1.74	0.011	0.731	0.020	5.14	1.28	0.066
43	184.3	1.85	0.011	0.709	0.015	5.62	1.31	0.065
44	197.4	1.85	0.011	0.809	0.027	5.80	1.25	0.087
45	200.8	1.92	0.014	0.736	0.017	5.84	1.43	0.082

ANIMAL NUMBER	SPLEEN	OVARIES
41	0.438	0.094
42	0.489	0.099
43	0.454	0.089
44	0.567	0.114
45	0.581	0.097

GROUP 5 (1000 MG/KG)

ANIMAL NUMBER	BODY W.	BRAIN	PITUITARY	HEART	THYROIDS	LIVER	KIDNEYS	ADRENALS
66	186.0	1.90	0.012	0.781	0.038	5.75	1.71	0.082
67	190.9	1.85	0.014	0.741	0.016	5.73	1.42	0.077
68	197.5	1.82	0.012	0.778	0.013	6.00	1.48	0.079
69	191.3	1.92	0.013	0.754	0.025	6.27	1.50	0.086
70	188.6	1.73	0.012	0.720	0.015	6.17	1.53	0.081

ANIMAL NUMBER	SPLEEN	OVARIES
66	0.609	0.123
67	0.513	0.103
68	0.688	0.105
69	0.556	0.110
70	0.552	0.116

ORGAN/BODY WEIGHT RATIOS (%)
AFTER 6 WEEKS
FEMALES

GROUP 1 (0 MG/KG)

ANIMAL NUMBER	BODY W. (GRAM)	BRAIN	PITUITARY	HEART	THYROIDS	LIVER	KIDNEYS	ADRENALS
41	194.1	0.99	0.005	0.383	0.015	2.80	0.66	0.046
42	181.4	0.96	0.006	0.403	0.011	2.84	0.70	0.036
43	184.3	1.00	0.006	0.385	0.008	3.05	0.71	0.035
44	197.4	0.94	0.006	0.410	0.014	2.94	0.63	0.044
45	200.8	0.96	0.007	0.366	0.008	2.91	0.71	0.041

ANIMAL NUMBER	SPLEEN	OVARIES
41	0.226	0.048
42	0.270	0.054
43	0.246	0.048
44	0.287	0.058
45	0.289	0.048

GROUP 5 (1000 MG/KG)

ANIMAL NUMBER	BODY W. (GRAM)	BRAIN	PITUITARY	HEART	THYROIDS	LIVER	KIDNEYS	ADRENALS
66	186.0	1.02	0.006	0.420	0.021	3.09	0.92	0.044
67	190.9	0.97	0.007	0.388	0.008	3.00	0.74	0.040
68	197.5	0.92	0.006	0.394	0.007	3.04	0.75	0.040
69	191.3	1.00	0.007	0.394	0.013	3.28	0.78	0.045
70	188.6	0.92	0.006	0.382	0.008	3.27	0.81	0.043

ANIMAL NUMBER	SPLEEN	OVARIES
66	0.327	0.066
67	0.269	0.054
68	0.349	0.053
69	0.290	0.058
70	0.292	0.062

ORGAN/BRAIN WEIGHT RATIOS (%)
AFTER 6 WEEKS
FEMALES

GROUP 1 (0 MG/KG)

ANIMAL NUMBER	BRAIN (GRAM)	PITUITARY	HEART	THYROIDS	LIVER	KIDNEYS	ADRENALS	SPLEEN
41	1.93	0.457	38.549	1.552	282.32	66.82	4.647	22.745
42	1.74	0.640	42.148	1.176	296.31	73.59	3.786	28.203
43	1.85	0.618	38.416	0.818	304.26	71.20	3.532	24.598
44	1.85	0.601	43.776	1.445	314.04	67.64	4.692	30.691
45	1.92	0.750	38.336	0.886	304.33	74.38	4.287	30.241

ANIMAL NUMBER	OVARIES
41	4.865
42	5.682
43	4.826
44	6.180
45	5.048

GROUP 5 (1000 MG/KG)

ANIMAL NUMBER	BRAIN (GRAM)	PITUITARY	HEART	THYROIDS	LIVER	KIDNEYS	ADRENALS	SPLEEN
66	1.90	0.625	41.021	2.017	301.75	89.76	4.291	31.997
67	1.85	0.745	39.951	0.836	309.32	76.58	4.127	27.661
68	1.82	0.680	42.656	0.707	329.08	81.21	4.341	37.729
69	1.92	0.688	39.285	1.303	326.80	77.96	4.467	28.963
70	1.73	0.695	41.694	0.840	357.52	88.92	4.716	31.960

ANIMAL NUMBER	OVARIES
66	6.460
67	5.546
68	5.749
69	5.755
70	6.721

ATTACHMENT 1

WATER ANALYSES

- BACTERIOLOGICAL AND CHEMICAL ASSAYS
- CONTAMINANT ANALYSIS

RCC PROJECT 372881
FAT 45'169/A

BACTERIOLOGICAL ASSAY OF DRINKING WATER, FUELLINSDORF

Official Laboratory
Basel-Landschaft

Liestal, 15.03.94
Ref. No. 94030086
94030087

Locations:

1) Pumping station "Wanne", 35.A.3R

2) Pumping station "Wanne", 35.A.3U, UV-irradiated

Sampled on:	08.03.1994	
Sample:	1)	2)
Time of sampling	08.35 a.m.	08.35 a.m.
Water temperature (°C)	13.2	13.2
Air temperature (°C)	10.0	10.0
Weather condition prior to sampling	cloudy	
Weather condition during sampling	cloudy	

BACTERIOLOGICAL TEST:

Aerobic mesophilic bacteria (per ml)	22	1
E.coli (per 100 ml)	0	0
Enterococci (per 100 ml)	0	0

ASSESSMENT:

At the time of sampling, the tested bacteriological parameters met the requirements for drinking water according to article 260 of the "Eidg. Lebensmittelverordnung".

Official Laboratory
The Official Chemist

(signed Dr. W. Stutz)

RCC PROJECT 372881
FAT 45'169/A

CHEMICAL WATER ANALYSIS, FUELLINSDORF

Official Laboratory Basel-Landschaft	Liestal, 15.03.94 Ref. No. 94030086
Location:	Pumping station "Wanne", 35.A.3R

Date of sampling	08.03.94
Weather condition prior to sampling	cloudy
Weather condition during sampling	cloudy
Time of sampling	08.35 a.m.
Water temperature (°C)	13.2
Air temperature (°C)	10.0
Appearance	clear, colorless
Odor	not remarkable
Taste	not remarkable

Total hardness		fr.H°	34.0
Alkaline hardness		fr.H°	26.5
Non carbonate hardness		fr.H°	7.5
Conductivity at 20 °C		µS/cm	628.0
Oxygen demand (KMnO4 cons.)		mg/l	1.8
Free ammonia	NH4+	mg/l	<0.01
Nitrit	NO2-	mg/l	<0.002
Nitrate	NO3-	mg/l	23.3
Chloride	Cl-	mg/l	15.6
Calcium	Ca++	mg/l	122.5
Magnesium	Mg++	mg/l	8.4

The water sample meets the chemical requirements for drinking water according to article 260 of the "Eidg. Lebensmittelverordnung".

Official Laboratory
The Official Chemist

(signed Dr. W. Stutz)

RCC PROJECT 372881
FAT 45'169/A

CONTAMINANT ANALYSIS OF DRINKING WATER, BRL FUELLINSDORF

RCC Project: 374578

Date of sampling: 29.04.94

Sample: Tap water BRL Füllinsdorf, room 106

Parameter	Assay level mg/kg
Lindane	<0.005
Heptachlor	<0.005
Malathion	<0.5
DDT, total	<0.025
Dieldrin	<0.005
PCB's	<0.025
Cadmium	<0.02
Arsenic	<0.15
Lead	<0.25
Mercury	<0.05
Selenium	<0.15
Copper	<0.15
Nitrosamines (DMN, DEN, NPIP, NMORPH), total	<0.01

< 0.001 = less than 0.001 milligram per kilogram

June 06, 1994
signed K.Biedermann

ATTACHMENT 2

CHEMICAL ANALYSIS OF FOOD -

ASSAY FOR CONTAMINANTS

RCC

Umweltchemie AG

RCC PROJECT 372881
FAT 45'169/A

ANALYTICAL TEST REPORT

RCC Project 372508
12.04.94

Prepared for	Klingentalmühle AG CH-4303 Kaiseraugst
Attention of	Dr. Ch. Spirig
Materials tested	Kliba 343, Batch 74/94 08.04.1994
Test performed	AAS, GC, GC-MS, HPLC
Test results	See attached Table 1
Submitted	J. Walker
Issued by	K. Biedermann

May 06, 1994/noa

The undersigned confirms that analysis of Kliba feed (number 343, Batch 74/94, manufactured 08.04.1994) was performed, and that this certificate represents accurately the analysis results of the feed delivered.

Date: 09.05.94

KLINGENTALMÜHLE AG

CH-4452 Itingen/Basel Switzerland Telephone 061/975 11 11 Telex 966 136 rcc ch Telefax 061/971 52 66

RCC PROJECT 372881
FAT 45'169/A

RCC

ATTACHMENT

RCC Project 372508
12.04.94

Table 1 - Test Results

Kliba 343, Batch 74/94
08.04.1994

PARAMETER	ASSAY LEVEL mg/kg
Aflatoxins (B1, B2, G1, G2), total	< 0.001
Estrogens (DES, Hexestrol, Dienestrol), total	< 0.001
Lindane	< 0.005
Heptachlor	< 0.005
Malathion	< 0.5
DDT, total	< 0.025
Dieldrin	< 0.005
Cadmium	0.06
Arsenic	< 0.15
Lead	0.27
Mercury	< 0.05
Selenium	0.18
Copper	11
PCBs	< 0.025
Nitrosamines	
DMN	< 0.010
DEN	< 0.010
NPIP	< 0.010
NMORPH	< 0.010

< 0.001 = less than 0.001 milligram per kilogram

The original certificate of analysis has been archived by KLIBA of Kaiseraugst.

09.05.94

KLINGENTALMÜHLE AG

Ch. Spring

RCC
Umweltchemie AG

RCC PROJECT 372881
FAT 45'169/A

ANALYTICAL TEST REPORT

RCC Project 374117
28.04.94

Prepared for	Klingentalmühle AG CH-4303 Kaiseraugst
Attention of	Dr. Ch. Spirig
Materials tested	Kliba 343, Batch 75/94 26.04.1994
Test performed	AAS, GC, GC-MS, HPLC
Test results	See attached Table 1
Submitted	J. Walker
Issued by	K. Biedermann

.....
May 18, 1994/noa

The undersigned confirms that analysis of Kliba feed (number 343, Batch 75/94, manufactured 26.04.1994) was performed, and that this certificate represents accurately the analysis results of the feed delivered.

Date: 19.05.94

KLINGENTALMÜHLE AG

229

CH-4452 Itingen/Basel Switzerland Telephone 061/975 11 11 / Telex 966 136 rcc ch Telefax 061/971 52 66

RCC PROJECT 372881
FAT 45'169/A

RCC

ATTACHMENT

RCC Project 374117
28.04.94

Table 1 - Test Results

Kliba 343, Batch 75/94
26.04.1994

PARAMETER	ASSAY LEVEL mg/kg
Aflatoxins (B1, B2, G1, G2), total	< 0.001
Estrogens (DES, Hexestrol, Dienestrol), total	< 0.001
Lindane	< 0.005
Heptachlor	< 0.005
Malathion	< 0.5
DDT, total	< 0.025
Dieldrin	< 0.005
Cadmium	0.06
Arsenic	< 0.15
Lead	0.31
Mercury	< 0.05
Selenium	0.19
Copper	13
PCBs	< 0.025
Nitrosamines	
DMN	< 0.010
DEN	< 0.010
NPIP	< 0.010
NMORPH	< 0.010

< 0.001 = less than 0.001 milligram per kilogram

The original certificate of analysis has been archived by KLIBA of Kaiseraugst.

19.05.94

KLINGENTALMÜHLE AG

Ch. Spring

RCC PROJECT 372881
FAT 45'169/A

ATTACHMENT 3

CLINICAL LABORATORY INVESTIGATIONS -

REFERENCE VALUES FOR UNTREATED WISTAR HANIBM RATS

HISTORICAL DATA - HEMATOLOGY

STRAIN: RAT / Han-Ibm: WIST (SPF) (MALES)
DATA COLLECTION PERIOD: 05-SEP-89 TO 04-AUG-93

AGE: FROM 7 TO 9 WEEKS

PARAMETER	UNIT	N	MEAN	STAND.DEV	95% TOLERANCE LIMITS	
ERYTHROCYTES (RBC)	T/L	29	8.45	0.37	---	---
HEMOGLOBIN (HB)	MMOL/L	29	10.2	0.4	---	---
HEMATOCRIT (HCT)	L/L	29	0.50	0.03	---	---
MEAN CELL VOLUME (MCV)	FL	29	59.2	2.1	---	---
MEAN CELL HEMOGLOBIN (MCH)	FMOL	29	1.20	0.04	---	---
MEAN CELL HEMOGLOBIN CONC. (MCHC)	MMOL/L	29	20.4	0.7	---	---
THROMBOCYTES (PLATELETS)	G/L	29	1006	144	---	---
RETICULOCYTE COUNT.....						
RETICULOCYTE	%	19	3.73	0.57	---	---
RETICULOCYTE	T/L	19	0.3047	0.0441	---	---
RETICULOCYTE FLUORESCENCE (HFR)	%	19	4.0	2.3	---	---
RETICULOCYTE FLUORESCENCE (MFR)	%	19	36.2	4.3	---	---
RETICULOCYTE FLUORESCENCE (LFR)	%	19	59.9	5.9	---	---
NUCLEATED ERY./NORMOBLASTS (NEN)	/100 WBC	29	0.2	0.4	---	---
LEUKOCYTES, TOTAL (WBC)	G/L	29	7.9	2.6	---	---
DIFF.WBC COUNT (REL.).....						
BAND NEUTROPHIL (BAND)	1	29	0.00	0.00	---	---
SEG. NEUTROPHIL (SEG.)	1	29	0.11	0.04	---	---
EOSINOPHIL (EO.)	1	29	0.01	0.01	---	---
BASOPHIL (BASO.)	1	29	0.00	0.00	---	---
LYMPHOCYTE (LYMPH.)	1	29	0.87	0.04	---	---
MONOCYTE (MONO.)	1	29	0.01	0.01	---	---
PLASMA CELL (PLAS.)	1	29	0.00	0.00	---	---
DIFF.WBC COUNT (ABS.).....						
BAND NEUTROPHIL (BAND)	G/L	29	0.0	0.0	---	---
SEG. NEUTROPHIL (SEG.)	G/L	29	0.8	0.2	---	---
EOSINOPHIL (EO.)	G/L	29	0.1	0.1	---	---
BASOPHIL (BASO.)	G/L	29	0.0	0.0	---	---
LYMPHOCYTE (LYMPH.)	G/L	29	7.0	2.5	---	---
MONOCYTE (MONO.)	G/L	29	0.1	0.1	---	---
PLASMA CELL (PLAS.)	G/L	29	0.0	0.0	---	---
COAGULATION.....						
THROMBOPLASTIN TIME (PT)	SEC	30	12.2	0.6	---	---
PARTIAL THROMBOPLASTIN TIME (APTT	SEC	30	21.9	2.4	---	---

HISTORICAL DATA - HEMATOLOGY

STRAIN: RAT / Han-Ibm: WIST (SPF) (MALES) AGE: FROM 10 TO 12 WEEKS
DATA COLLECTION PERIOD: 05-SEP-89 TO 04-AUG-93

PARAMETER	UNIT	N	MEAN	STAND.DEV	95% TOLERANCE LIMITS	
ERYTHROCYTES (RBC)	T/L	336	9.14	0.46	8.21	10.15
HEMOGLOBIN (HB)	MMOL/L	336	10.6	0.4	9.7	11.6
HEMATOCRIT (HCT)	L/L	336	0.51	0.02	0.46	0.55
MEAN CELL VOLUME (MCV)	FL	326	55.5	2.5	51.2	60.4
MEAN CELL HEMOGLOBIN (MCH)	FMOL	326	1.16	0.04	1.08	1.24
MEAN CELL HEMOGLOBIN CONC. (MCHC)	MMOL/L	326	20.9	0.7	19.5	22.0
THROMBOCYTES (PLATELETS)	G/L	326	897	125	680	1109
RETICULOCYTE COUNT.....						
RETICULOCYTE	%	218	2.61	0.41	1.92	3.41
RETICULOCYTE	T/L	218	0.2327	0.0354	0.1731	0.3080
RETICULOCYTE FLUORESCENCE (HFR)	%	156	4.1	3.3	0.4	13.9
RETICULOCYTE FLUORESCENCE (MFR)	%	156	33.6	5.4	18.3	42.1
RETICULOCYTE FLUORESCENCE (LFR)	%	156	62.3	7.7	48.9	81.3
NUCLEATED ERY./NORMOBLASTS (NEN)	/100 WBC	326	0.2	0.4	0.0	1.0
HEINZ BODIES	o/oo	228	0	0	0	0
METHEMOGLOBIN (MET-HB)	%	245	1.0	0.2	0.6	1.5
LEUKOCYTES, TOTAL (WBC)	G/L	336	8.2	1.9	4.3	12.0
DIFF.WBC COUNT (REL.).....						
BAND NEUTROPHIL (BAND)	1	336	0.00	0.00	0.00	0.00
SEG. NEUTROPHIL (SEG.)	1	336	0.14	0.06	0.06	0.28
EOSINOPHIL (EO.)	1	336	0.01	0.01	0.00	0.03
BASOPHIL (BASO.)	1	336	0.00	0.00	0.00	0.00
LYMPHOCYTE (LYMPH.)	1	336	0.84	0.06	0.71	0.94
MONOCYTE (MONO.)	1	336	0.01	0.01	0.00	0.03
PLASMA CELL (PLAS.)	1	336	0.00	0.00	0.00	0.00
DIFF.WBC COUNT (ABS.).....						
BAND NEUTROPHIL (BAND)	G/L	336	0.0	0.0	0.0	0.0
SEG. NEUTROPHIL (SEG.)	G/L	336	1.1	0.4	0.4	2.1
EOSINOPHIL (EO.)	G/L	336	0.1	0.1	0.0	0.3
BASOPHIL (BASO.)	G/L	336	0.0	0.0	0.0	0.0
LYMPHOCYTE (LYMPH.)	G/L	336	6.9	1.8	3.6	10.9
MONOCYTE (MONO.)	G/L	336	0.1	0.1	0.0	0.3
PLASMA CELL (PLAS.)	G/L	336	0.0	0.0	0.0	0.0
COAGULATION.....						
THROMBOPLASTIN TIME (PT)	SEC	338	12.1	0.7	10.5	13.3
PARTIAL THROMBOPLASTIN TIME (APTT	SEC	323	21.7	3.1	15.3	26.7

HISTORICAL DATA - HEMATOLOGY

STRAIN: RAT / Han-Ibm: WIST (SPF) (MALES) AGE: FROM 13 TO 18 WEEKS
DATA COLLECTION PERIOD: 05-SEP-89 TO 04-AUG-93

PARAMETER	UNIT	N	MEAN	STAND.DEV	95% TOLERANCE LIMITS	
ERYTHROCYTES (RBC)	T/L	233	9.21	0.46	8.37	10.22
HEMOGLOBIN (HB)	MMOL/L	233	10.5	0.4	9.7	11.2
HEMATOCRIT (HCT)	L/L	233	0.50	0.02	0.46	0.55
MEAN CELL VOLUME (MCV)	FL	233	54.8	2.8	49.0	60.5
MEAN CELL HEMOGLOBIN (MCH)	FMOL	233	1.14	0.06	1.03	1.25
MEAN CELL HEMOGLOBIN CONC. (MCHC)	MMOL/L	233	20.8	0.6	19.5	21.8
THROMBOCYTES (PLATELETS)	G/L	233	906	129	633	1166
RETICULOCYTE COUNT.....						
RETICULOCYTE	%	155	2.68	0.41	2.00	3.58
RETICULOCYTE	T/L	155	0.2414	0.0379	0.1729	0.3161
RETICULOCYTE FLUORESCENCE (HFR)	%	121	3.2	2.1	0.5	7.3
RETICULOCYTE FLUORESCENCE (MFR)	%	121	31.6	5.1	20.2	39.5
RETICULOCYTE FLUORESCENCE (LFR)	%	121	65.2	6.6	55.4	79.0
NUCLEATED ERY./NORMOBLASTS (NEN)	/100 WBC	233	0.2	0.4	0.0	1.0
HEINZ BODIES	o/oo	129	0	0	0	0
METHEMOGLOBIN (MET-HB)	%	139	0.9	0.3	0.4	1.7
LEUKOCYTES, TOTAL (WBC)	G/L	233	7.7	2.1	3.4	12.4
DIFF.WBC COUNT (REL.).....						
BAND NEUTROPHIL (BAND)	1	233	0.00	0.00	0.00	0.01
SEG. NEUTROPHIL (SEG.)	1	233	0.16	0.06	0.06	0.31
EOSINOPHIL (EO.)	1	233	0.01	0.01	0.00	0.04
BASOPHIL (BASO.)	1	233	0.00	0.00	0.00	0.00
LYMPHOCYTE (LYMPH.)	1	233	0.82	0.06	0.68	0.93
MONOCYTE (MONO.)	1	233	0.01	0.01	0.00	0.03
PLASMA CELL (PLAS.)	1	233	0.00	0.00	0.00	0.00
DIFF.WBC COUNT (ABS.).....						
BAND NEUTROPHIL (BAND)	G/L	233	0.0	0.0	0.0	0.1
SEG. NEUTROPHIL (SEG.)	G/L	233	1.2	0.5	0.5	2.1
EOSINOPHIL (EO.)	G/L	233	0.1	0.1	0.0	0.3
BASOPHIL (BASO.)	G/L	233	0.0	0.0	0.0	0.0
LYMPHOCYTE (LYMPH.)	G/L	233	6.4	1.9	2.7	10.7
MONOCYTE (MONO.)	G/L	233	0.1	0.1	0.0	0.3
PLASMA CELL (PLAS.)	G/L	233	0.0	0.0	0.0	0.0
COAGULATION.....						
THROMBOPLASTIN TIME (PT)	SEC	229	12.0	0.9	10.5	14.0
PARTIAL THROMBOPLASTIN TIME (APTT	SEC	219	21.3	3.3	14.9	26.7

HISTORICAL DATA - HEMATOLOGY

STRAIN: RAT / Han-Ibm: WIST (SPF) (FEMALES) AGE: FROM 7 TO 9 WEEKS
DATA COLLECTION PERIOD: 05-SEP-89 TO 04-AUG-93

PARAMETER	UNIT	N	MEAN	STAND.DEV	95% TOLERANCE LIMITS	
ERYTHROCYTES (RBC)	T/L	74	7.90	0.41	---	---
HEMOGLOBIN (HB)	MMOL/L	74	9.6	0.4	---	---
HEMATOCRIT (HCT)	L/L	74	0.46	0.02	---	---
MEAN CELL VOLUME (MCV)	FL	74	58.8	1.8	---	---
MEAN CELL HEMOGLOBIN (MCH)	FMOL	74	1.22	0.04	---	---
MEAN CELL HEMOGLOBIN CONC. (MCHC)	MMOL/L	74	20.7	0.4	---	---
THROMBOCYTES (PLATELETS)	G/L	74	1097	174	---	---
RETICULOCYTE COUNT.....						
RETICULOCYTE	%	74	4.74	1.35	---	---
RETICULOCYTE	T/L	74	0.3581	0.0921	---	---
RETICULOCYTE FLUORESCENCE (HFR)	%	19	1.9	1.3	---	---
RETICULOCYTE FLUORESCENCE (MFR)	%	19	31.9	6.2	---	---
RETICULOCYTE FLUORESCENCE (LFR)	%	19	66.1	7.2	---	---
NUCLEATED ERY./NORMOBLASTS (NEN)	/100 WBC	74	0.1	0.4	---	---
HEINZ BODIES	o/oo	54	0	0	---	---
METHEMOGLOBIN (MET-HB)	%	54	1.1	0.2	---	---
LEUKOCYTES, TOTAL (WBC)	G/L	74	5.2	1.4	---	---
DIFF.WBC COUNT (REL.).....						
BAND NEUTROPHIL (BAND)	1	74	0.00	0.00	---	---
SEG. NEUTROPHIL (SEG.)	1	74	0.11	0.05	---	---
EOSINOPHIL (EO.)	1	74	0.01	0.01	---	---
BASOPHIL (BASO.)	1	74	0.00	0.00	---	---
LYMPHOCYTE (LYMPH.)	1	74	0.88	0.05	---	---
MONOCYTE (MONO.)	1	74	0.00	0.00	---	---
PLASMA CELL (PLAS.)	1	74	0.00	0.00	---	---
DIFF.WBC COUNT (ABS.).....						
BAND NEUTROPHIL (BAND)	G/L	74	0.0	0.0	---	---
SEG. NEUTROPHIL (SEG.)	G/L	74	0.6	0.3	---	---
EOSINOPHIL (EO.)	G/L	74	0.0	0.0	---	---
BASOPHIL (BASO.)	G/L	74	0.0	0.0	---	---
LYMPHOCYTE (LYMPH.)	G/L	74	4.6	1.3	---	---
MONOCYTE (MONO.)	G/L	74	0.0	0.0	---	---
PLASMA CELL (PLAS.)	G/L	74	0.0	0.0	---	---
COAGULATION.....						
THROMBOPLASTIN TIME (PT)	SEC	19	11.5	0.4	---	---
PARTIAL THROMBOPLASTIN TIME (APTT	SEC	19	19.9	3.1	---	---

HISTORICAL DATA - HEMATOLOGY

STRAIN: RAT / Han-Ibm: WIST (SPF) (FEMALES) AGE: FROM 10 TO 12 WEEKS
DATA COLLECTION PERIOD: 05-SEP-89 TO 04-AUG-93

PARAMETER	UNIT	N	MEAN	STAND.DEV	95% TOLERANCE LIMITS	
ERYTHROCYTES (RBC)	T/L	347	8.62	0.46	7.84	9.54
HEMOGLOBIN (HB)	MMOL/L	347	10.1	0.5	9.3	10.9
HEMATOCRIT (HCT)	L/L	347	0.48	0.03	0.44	0.53
MEAN CELL VOLUME (MCV)	FL	338	56.0	2.3	52.1	60.5
MEAN CELL HEMOGLOBIN (MCH)	FMOL	338	1.17	0.04	1.10	1.26
MEAN CELL HEMOGLOBIN CONC. (MCHC)	MMOL/L	338	20.9	0.7	19.4	22.0
THROMBOCYTES (PLATELETS)	G/L	338	925	122	704	1184
RETICULOCYTE COUNT.....						
RETICULOCYTE	%	228	2.84	0.53	2.00	3.94
RETICULOCYTE	T/L	228	0.2380	0.0428	0.1673	0.3260
RETICULOCYTE FLUORESCENCE (HFR)	%	164	5.1	4.1	0.5	17.0
RETICULOCYTE FLUORESCENCE (MFR)	%	164	33.2	5.5	23.1	42.5
RETICULOCYTE FLUORESCENCE (LFR)	%	164	61.7	8.5	44.3	75.7
NUCLEATED ERY./NORMOBLASTS (NEN)	/100 WBC	338	0.3	0.6	0.0	2.0
HEINZ BODIES	o/oo	225	0	0	0	0
METHEMOGLOBIN (MET-HB)	%	245	1.1	0.2	0.6	1.6
LEUKOCYTES, TOTAL (WBC)	G/L	347	5.2	1.7	2.4	8.8
DIFF.WBC COUNT (REL.).....						
BAND NEUTROPHIL (BAND)	1	347	0.00	0.00	0.00	0.00
SEG. NEUTROPHIL (SEG.)	1	347	0.14	0.06	0.05	0.29
EOSINOPHIL (EO.)	1	347	0.01	0.01	0.00	0.04
BASOPHIL (BASO.)	1	347	0.00	0.00	0.00	0.00
LYMPHOCYTE (LYMPH.)	1	347	0.84	0.06	0.69	0.94
MONOCYTE (MONO.)	1	347	0.01	0.01	0.00	0.03
PLASMA CELL (PLAS.)	1	347	0.00	0.00	0.00	0.00
DIFF.WBC COUNT (ABS.).....						
BAND NEUTROPHIL (BAND)	G/L	347	0.0	0.0	0.0	0.0
SEG. NEUTROPHIL (SEG.)	G/L	347	0.7	0.4	0.2	1.6
EOSINOPHIL (EO.)	G/L	347	0.1	0.1	0.0	0.2
BASOPHIL (BASO.)	G/L	347	0.0	0.0	0.0	0.0
LYMPHOCYTE (LYMPH.)	G/L	347	4.4	1.6	1.9	7.6
MONOCYTE (MONO.)	G/L	347	0.0	0.1	0.0	0.2
PLASMA CELL (PLAS.)	G/L	347	0.0	0.0	0.0	0.0
COAGULATION.....						
THROMBOPLASTIN TIME (PT)	SEC	331	12.2	0.7	10.5	13.5
PARTIAL THROMBOPLASTIN TIME (APTT	SEC	315	20.2	3.2	14.5	26.6

HISTORICAL DATA - HEMATOLOGY

STRAIN: RAT / Han-Ibm: WIST (SPF) (FEMALES) AGE: FROM 13 TO 18 WEEKS
DATA COLLECTION PERIOD: 05-SEP-89 TO 04-AUG-93

PARAMETER	UNIT	N	MEAN	STAND.DEV	95% TOLERANCE LIMITS	
ERYTHROCYTES (RBC)	T/L	229	8.51	0.44	7.82	9.30
HEMOGLOBIN (HB)	MMOL/L	229	10.3	0.4	9.4	11.0
HEMATOCRIT (HCT)	L/L	229	0.49	0.02	0.45	0.54
MEAN CELL VOLUME (MCV)	FL	229	58.1	2.5	53.7	62.5
MEAN CELL HEMOGLOBIN (MCH)	FMOL	229	1.21	0.05	1.11	1.30
MEAN CELL HEMOGLOBIN CONC. (MCHC)	MMOL/L	229	20.8	0.5	19.6	21.8
THROMBOCYTES (PLATELETS)	G/L	229	939	131	677	1200
RETICULOCYTE COUNT.....						
RETICULOCYTE	%	139	2.68	0.59	1.88	3.78
RETICULOCYTE	T/L	139	0.2221	0.0467	0.1607	0.3129
RETICULOCYTE FLUORESCENCE (HFR)	%	119	3.9	4.0	0.2	14.3
RETICULOCYTE FLUORESCENCE (MFR)	%	119	31.4	5.6	21.4	42.7
RETICULOCYTE FLUORESCENCE (LFR)	%	119	64.7	8.5	47.3	78.1
NUCLEATED ERY./NORMOBLASTS (NEN)	/100 WBC	229	0.2	0.6	0.0	2.0
HEINZ BODIES	o/oo	111	0	0	0	0
METHEMOGLOBIN (MET-HB)	%	121	1.0	0.3	0.7	1.7
LEUKOCYTES, TOTAL (WBC)	G/L	229	4.9	1.3	2.7	7.2
DIFF.WBC COUNT (REL.).....						
BAND NEUTROPHIL (BAND)	1	229	0.00	0.00	0.00	0.01
SEG. NEUTROPHIL (SEG.)	1	229	0.16	0.07	0.04	0.33
EOSINOPHIL (EO.)	1	229	0.01	0.01	0.00	0.04
BASOPHIL (BASO.)	1	229	0.00	0.00	0.00	0.00
LYMPHOCYTE (LYMPH.)	1	229	0.82	0.08	0.65	0.95
MONOCYTE (MONO.)	1	229	0.01	0.01	0.00	0.04
PLASMA CELL (PLAS.)	1	229	0.00	0.00	0.00	0.00
DIFF.WBC COUNT (ABS.).....						
BAND NEUTROPHIL (BAND)	G/L	229	0.0	0.0	0.0	0.0
SEG. NEUTROPHIL (SEG.)	G/L	229	0.8	0.4	0.2	2.0
EOSINOPHIL (EO.)	G/L	229	0.1	0.1	0.0	0.2
BASOPHIL (BASO.)	G/L	229	0.0	0.0	0.0	0.0
LYMPHOCYTE (LYMPH.)	G/L	229	4.0	1.2	1.9	6.2
MONOCYTE (MONO.)	G/L	229	0.0	0.1	0.0	0.2
PLASMA CELL (PLAS.)	G/L	229	0.0	0.0	0.0	0.0
COAGULATION.....						
THROMBOPLASTIN TIME (PT)	SEC	223	12.0	0.9	10.2	13.7
PARTIAL THROMBOPLASTIN TIME (APTT	SEC	209	19.9	3.6	13.5	26.9

HISTORICAL DATA - CLINICAL BIOCHEMISTRY

STRAIN: RAT / Han-Ibm: WIST (SPF) (MALES) AGE: FROM 7 TO 9 WEEKS
DATA COLLECTION PERIOD: 05-SEP-89 TO 01-JUN-93

PARAMETER	UNIT	N	MEAN	STAND.DEV	95% TOLERANCE LIMITS	
UREA	MMOL/L	30	5.99	0.91	---	---
CREATININE	µMOL/L	30	39	6	---	---
BILIRUBIN, TOTAL	µMOL/L	30	3.7	0.5	---	---
TRIGLYCERIDES	MMOL/L	30	0.65	0.23	---	---
ASPARTATE-AMINOTRANSFERASE (ASAT)	µKAT/L	30	1.34	0.15	---	---
ALANINE-AMINOTRANSFERASE (ALAT)	µKAT/L	30	0.47	0.12	---	---
LACTATE DEHYDROGENASE (LDH)	µKAT/L	30	2.41	1.71	---	---
CREATINE KINASE (CK)	µKAT/L	20	3.19	1.20	---	---
ALKALINE PHOSPHATASE (ALP)	µKAT/L	30	7.02	3.42	---	---
GAMMA-GLUTAMYLTRANSFERASE (G-GT)	NKAT/L	10	10.22	1.00	---	---
CALCIUM	MMOL/L	30	2.71	0.11	---	---
PHOSPHORUS	MMOL/L	30	2.43	0.30	---	---
SODIUM	MMOL/L	30	141.4	3.4	---	---
POTASSIUM	MMOL/L	30	3.20	0.28	---	---
CHLORIDE	MMOL/L	30	100.4	4.4	---	---
ALBUMIN	g/L	10	31.9	1.3	---	---
PROTEIN, TOTAL	g/L	30	65.0	2.6	---	---
A/G RATIO	-	10	1.03	0.03	---	---

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HISTORICAL DATA - CLINICAL BIOCHEMISTRY

STRAIN: RAT / Han-Ibm: WIST (SPF) (MALES)
DATA COLLECTION PERIOD: 05-SEP-89 TO 01-JUN-93

AGE: FROM 10 TO 12 WEEKS

PARAMETER	UNIT	N	MEAN	STAND.DEV	95% TOLERANCE LIMITS	
UREA	MMOL/L	338	6.67	1.80	4.31	11.14
CREATININE	µMOL/L	338	42	6	32	54
URIC ACID	µMOL/L	288	45.0	29.4	12.8	109.8
BILIRUBIN, TOTAL	µMOL/L	338	3.3	1.1	0.9	5.2
TRIGLYCERIDES	MMOL/L	328	0.69	0.30	0.28	1.31
PHOSPHOLIPIDS	MMOL/L	283	1.48	0.29	1.03	2.01
ASPARTATE-AMINOTRANSFERASE (ASAT)	µKAT/L	338	1.29	0.21	0.98	1.82
ALANINE-AMINOTRANSFERASE (ALAT)	µKAT/L	348	0.45	0.15	0.29	1.00
LACTATE DEHYDROGENASE (LDH)	µKAT/L	309	2.70	5.12	0.90	9.28
CREATINE KINASE (CK)	µKAT/L	299	2.96	2.65	1.49	10.77
ALKALINE PHOSPHATASE (ALP)	µKAT/L	348	4.55	1.35	2.84	7.71
GAMMA-GLUTAMYLTRANSFERASE (G-GT)	NKAT/L	278	9.02	4.17	1.68	20.69
CALCIUM	MMOL/L	348	2.72	0.13	2.47	2.95
PHOSPHORUS	MMOL/L	338	2.26	0.19	1.90	2.61
SODIUM	MMOL/L	348	141.7	3.4	136.3	148.6
POTASSIUM	MMOL/L	348	3.47	0.33	2.97	4.18
CHLORIDE	MMOL/L	348	102.5	2.9	96.7	109.2
ALBUMIN	g/L	303	31.2	1.7	28.2	34.7
PROTEIN, TOTAL	g/L	348	65.9	3.4	58.4	72.1
A/G RATIO	-	303	0.91	0.08	0.77	1.07

HISTORICAL DATA - CLINICAL BIOCHEMISTRY

STRAIN: RAT / Han-Ibm: WIST (SPF) (MALES)
DATA COLLECTION PERIOD: 05-SEP-89 TO 01-JUN-93

AGE: FROM 13 TO 18 WEEKS

PARAMETER	UNIT	N	MEAN	STAND.DEV	95% TOLERANCE LIMITS	
UREA	MMOL/L	238	6.36	1.19	4.67	9.89
CREATININE	µMOL/L	238	48	15	32	104
URIC ACID	µMOL/L	169	46.0	27.3	13.8	95.5
BILIRUBIN, TOTAL	µMOL/L	238	3.5	1.1	1.3	5.2
TRIGLYCERIDES	MMOL/L	233	0.72	0.47	0.21	1.56
PHOSPHOLIPIDS	MMOL/L	158	1.54	0.45	1.14	2.12
ASPARTATE-AMINOTRANSFERASE (ASAT)	µKAT/L	238	1.32	0.23	1.05	1.92
ALANINE-AMINOTRANSFERASE (ALAT)	µKAT/L	238	0.47	0.14	0.31	0.89
LACTATE DEHYDROGENASE (LDH)	µKAT/L	223	2.14	1.62	1.01	5.11
CREATINE KINASE (CK)	µKAT/L	218	2.47	2.31	1.22	5.85
ALKALINE PHOSPHATASE (ALP)	µKAT/L	238	3.41	0.95	1.93	6.11
GAMMA-GLUTAMYLTRANSFERASE (G-GT)	NKAT/L	164	9.10	3.67	3.26	17.79
CALCIUM	MMOL/L	268	2.65	0.13	2.42	2.89
PHOSPHORUS	MMOL/L	268	1.97	0.23	1.41	2.38
SODIUM	MMOL/L	237	140.9	2.5	136.7	146.2
POTASSIUM	MMOL/L	237	3.41	0.33	2.77	4.06
CHLORIDE	MMOL/L	227	102.6	2.6	98.2	109.0
ALBUMIN	g/L	172	31.0	1.8	27.8	34.2
PROTEIN, TOTAL	g/L	238	66.9	3.7	59.2	74.2
A/G RATIO	-	172	0.89	0.10	0.72	1.07

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HISTORICAL DATA - CLINICAL BIOCHEMISTRY

STRAIN: RAT / Han-Ibm: WIST (SPF) (FEMALES)
DATA COLLECTION PERIOD: 05-SEP-89 TO 01-JUN-93

AGE: FROM 7 TO 9 WEEKS

PARAMETER	UNIT	N	MEAN	STAND.DEV	95% TOLERANCE LIMITS	
UREA	MMOL/L	77	5.99	0.95	3.91	8.18
CREATININE	µMOL/L	77	39	5	32	52
URIC ACID	µMOL/L	57	64.0	12.0	---	---
BILIRUBIN, TOTAL	µMOL/L	77	3.4	0.5	2.5	4.8
TRIGLYCERIDES	MMOL/L	77	0.56	0.15	0.26	0.83
PHOSPHOLIPIDS	MMOL/L	57	1.75	0.22	---	---
ASPARTATE-AMINOTRANSFERASE (ASAT)	µKAT/L	77	1.31	0.12	1.00	1.55
ALANINE-AMINOTRANSFERASE (ALAT)	µKAT/L	77	0.26	0.09	0.16	0.60
LACTATE DEHYDROGENASE (LDH)	µKAT/L	77	2.19	0.75	1.28	4.41
CREATINE KINASE (CK)	µKAT/L	67	3.54	1.10	---	---
ALKALINE PHOSPHATASE (ALP)	µKAT/L	77	4.79	1.84	2.27	10.51
GAMMA-GLUTAMYLTRANSFERASE (G-GT)	NKAT/L	10	10.19	1.92	---	---
CALCIUM	MMOL/L	77	2.70	0.09	2.53	2.89
PHOSPHORUS	MMOL/L	77	2.27	0.18	1.86	2.56
SODIUM	MMOL/L	77	138.5	1.3	135.9	140.9
POTASSIUM	MMOL/L	77	3.25	0.31	2.67	3.89
CHLORIDE	MMOL/L	77	101.4	1.6	98.3	105.2
ALBUMIN	g/L	57	32.4	1.1	---	---
PROTEIN, TOTAL	g/L	77	64.4	2.8	60.7	71.8
A/G RATIO	-	57	1.05	0.05	---	---

HISTORICAL DATA - CLINICAL BIOCHEMISTRY

STRAIN: RAT / Han-Ibm: WIST (SPF) (FEMALES)
DATA COLLECTION PERIOD: 05-SEP-89 TO 01-JUN-93

AGE: FROM 10 TO 12 WEEKS

PARAMETER	UNIT	N	MEAN	STAND.DEV	95% TOLERANCE LIMITS	
UREA	MMOL/L	338	7.52	1.53	4.81	10.94
CREATININE	µMOL/L	338	49	6	37	60
URIC ACID	µMOL/L	287	50.6	23.8	21.7	108.1
BILIRUBIN, TOTAL	µMOL/L	337	4.3	10.8	1.4	5.9
TRIGLYCERIDES	MMOL/L	338	0.49	0.18	0.17	0.74
PHOSPHOLIPIDS	MMOL/L	282	1.64	0.33	1.06	2.36
ASPARTATE-AMINOTRANSFERASE (ASAT)	µKAT/L	338	1.34	1.66	0.99	1.79
ALANINE-AMINOTRANSFERASE (ALAT)	µKAT/L	348	0.37	0.23	0.23	0.78
LACTATE DEHYDROGENASE (LDH)	µKAT/L	308	2.56	3.39	0.89	9.35
CREATINE KINASE (CK)	µKAT/L	307	2.35	1.87	1.22	6.70
ALKALINE PHOSPHATASE (ALP)	µKAT/L	348	2.17	0.81	1.16	4.09
GAMMA-GLUTAMYLTRANSFERASE (G-GT)	NKAT/L	267	10.34	10.20	4.41	19.59
CALCIUM	MMOL/L	347	2.67	0.13	2.40	2.91
PHOSPHORUS	MMOL/L	338	1.80	0.26	1.30	2.33
SODIUM	MMOL/L	345	141.5	3.9	136.7	148.4
POTASSIUM	MMOL/L	345	3.23	0.33	2.67	3.93
CHLORIDE	MMOL/L	345	103.7	3.1	98.8	108.7
ALBUMIN	g/L	312	33.4	2.3	28.5	37.9
PROTEIN, TOTAL	g/L	347	68.1	4.0	58.6	76.1
A/G RATIO	-	312	0.97	0.10	0.80	1.18

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HISTORICAL DATA - CLINICAL BIOCHEMISTRY

STRAIN: RAT / Han-Ibm: WIST (SPF) (FEMALES)
DATA COLLECTION PERIOD: 05-SEP-89 TO 01-JUN-93

AGE: FROM 13 TO 18 WEEKS

PARAMETER	UNIT	N	MEAN	STAND.DEV	95% TOLERANCE LIMITS	
UREA	MMOL/L	232	7.73	1.44	5.73	10.74
CREATININE	µMOL/L	232	52	7	39	67
URIC ACID	µMOL/L	152	49.8	22.9	21.5	98.9
BILIRUBIN, TOTAL	µMOL/L	232	3.8	1.1	1.3	5.7
TRIGLYCERIDES	MMOL/L	217	0.50	0.15	0.20	0.78
PHOSPHOLIPIDS	MMOL/L	142	1.75	0.38	1.07	2.70
ASPARTATE-AMINOTRANSFERASE (ASAT)	µKAT/L	232	1.23	0.22	0.94	1.80
ALANINE-AMINOTRANSFERASE (ALAT)	µKAT/L	232	0.38	0.11	0.25	0.68
LACTATE DEHYDROGENASE (LDH)	µKAT/L	218	2.53	3.32	0.77	11.97
CREATINE KINASE (CK)	µKAT/L	203	2.23	2.49	0.99	7.00
ALKALINE PHOSPHATASE (ALP)	µKAT/L	232	1.61	0.59	0.85	3.19
GAMMA-GLUTAMYLTRANSFERASE (G-GT)	NKAT/L	172	10.16	4.04	3.81	19.48
CALCIUM	MMOL/L	262	2.66	0.14	2.41	2.95
PHOSPHORUS	MMOL/L	262	1.58	0.29	1.03	2.18
SODIUM	MMOL/L	230	140.7	2.4	136.3	145.5
POTASSIUM	MMOL/L	231	3.32	0.40	2.58	4.44
CHLORIDE	MMOL/L	220	104.2	2.5	99.6	108.5
ALBUMIN	g/L	157	34.0	2.1	29.3	38.4
PROTEIN, TOTAL	g/L	232	70.3	4.2	62.3	79.1
A/G RATIO	-	157	0.97	0.08	0.82	1.13

HISTORICAL DATA - URINALYSIS

STRAIN: RAT / Han-Ibm: WIST (SPF) (MALES)
DATA COLLECTION PERIOD: 05-SEP-89 TO 01-JUN-93

AGE: FROM 7 TO 9 WEEKS

PARAMETER	UNIT	N	MEAN	STAND.DEV	95% TOLERANCE LIMITS	
VOLUME 18h	ML	55	7.9	3.1	---	---
SPECIFIC GRAVITY	1	55	1.029	0.013	---	---
OSMOLALITY	MMOL/KG	40	924	571	---	---
pH	-	55	7	1	---	---

HISTORICAL DATA - URINALYSIS

STRAIN: RAT / Han-Ibm: WIST (SPF) (MALES) AGE: FROM 10 TO 12 WEEKS
DATA COLLECTION PERIOD: 05-SEP-89 TO 01-JUN-93

PARAMETER	UNIT	N	MEAN	STAND.DEV	95% TOLERANCE LIMITS	
VOLUME 18h	ML	314	6.4	2.5	2.0	11.0
SPECIFIC GRAVITY	1	328	1.045	0.021	1.022	1.092
OSMOLALITY	MMOL/KG	174	1254	372	627	2010
pH	-	328	7	1	6	9

HISTORICAL DATA - URINALYSIS

STRAIN: RAT / Han-Ibm: WIST (SPF) (MALES) AGE: FROM 13 TO 18 WEEKS
DATA COLLECTION PERIOD: 05-SEP-89 TO 01-JUN-93

PARAMETER	UNIT	N	MEAN	STAND.DEV	95% TOLERANCE LIMITS	
VOLUME 18h	ML	222	6.5	2.2	2.5	11.0
SPECIFIC GRAVITY	1	227	1.041	0.015	1.025	1.082
OSMOLALITY	MMOL/KG	90	1340	403	880	2102
pH	-	227	7	1	6	9

HISTORICAL DATA - URINALYSIS

STRAIN: RAT / Han-Ibm: WIST (SPF) (FEMALES)
DATA COLLECTION PERIOD: 05-SEP-89 TO 01-JUN-93

AGE: FROM 7 TO 9 WEEKS

PARAMETER	UNIT	N	MEAN	STAND.DEV	95% TOLERANCE LIMITS	
VOLUME 18h	ML	102	3.5	2.3	1.0	9.0
SPECIFIC GRAVITY	1	102	1.038	0.015	1.016	1.072
OSMOLALITY	MMOL/KG	87	1408	569	583	2560
pH	-	102	6	1	5	7

HISTORICAL DATA - URINALYSIS

STRAIN: RAT / Han-Ibm: WIST (SPF) (FEMALES)
DATA COLLECTION PERIOD: 05-SEP-89 TO 01-JUN-93

AGE: FROM 10 TO 12 WEEKS

PARAMETER	UNIT	N	MEAN	STAND.DEV	95% TOLERANCE LIMITS	
VOLUME 18h	ML	314	4.7	2.1	1.5	10.0
SPECIFIC GRAVITY	1	329	1.046	0.023	1.022	1.100
OSMOLALITY	MMOL/KG	175	1363	442	644	2438
pH	-	329	6	1	5	8

HISTORICAL DATA - URINALYSIS

STRAIN: RAT / Han-Ibm: WIST (SPF) (FEMALES)
DATA COLLECTION PERIOD: 05-SEP-89 TO 01-JUN-93

AGE: FROM 13 TO 18 WEEKS

PARAMETER	UNIT	N	MEAN	STAND.DEV	95% TOLERANCE LIMITS	
VOLUME 18h	ML	217	4.7	1.8	1.5	8.0
SPECIFIC GRAVITY	1	222	1.043	0.017	1.024	1.092
OSMOLALITY	MMOL/KG	84	1433	417	918	2600
pH	-	222	6	1	5	9

ATTACHMENT 4

DETERMINATION OF THE CONCENTRATIONS, HOMOGENEITY AND STABILITY OF FAT 45'169/A IN BI-DISTILLED WATER

RCC
UMWELTCHEMIE AG

PROJECT 372881

DETERMINATION OF CONCENTRATION, HOMOGENEITY
AND STABILITY OF FAT 45`169/A
IN BIDISTILLED WATER

SUBACUTE 28-DAY ORAL (GAVAGE) TOXICITY STUDY
IN THE RAT

REPORT

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GENERAL INFORMATION

GENERAL

RCC Project Number:	372881
Sponsor:	CIBA GEIGY AG Dr. B. Bruttel Produktesicherheit TF 5.31 CH-4002 Basel / Switzerland
Monitoring Scientist:	E. Rüdin RCC, Registration and Consulting Company Ldt CH-4452 Itingen / Switzerland
Test Article:	FAT 45`169/A
Testing Facility:	R C C UMWELTCHEMIE AG Department of Chemistry CH-4452 Itingen / Switzerland

PROJECT STAFF

Responsible for Analytics	K. Biedermann K. Biedermann Date: December 7, 1994/mma

ARCHIVING

R C C, CH-4452 Itingen	Protocol, raw data, copy of protocol analytical report and test article reference sample for at least 10 years. No data will be discarded without the sponsor´s consent.

GOOD LABORATORY PRACTICE

STATEMENT OF COMPLIANCE

PROJECT NUMBER:	372881
TEST ARTICLE:	FAT 45`169/A
RESPONSIBLE FOR ANALYTICS:	K. Biedermann
TITLE:	Determination of Concentration, Homogeneity and Stability of FAT 45`169/A in Bidistilled Water.

This study was conducted in compliance with Good Laboratory Practice Regulations.

Responsible for Analytics K. Biedermann

K. Biedermann

Date: December 7, 1994

QUALITY ASSURANCE UNIT

R C C UMWELTCHEMIE AG, CH-4452 ITINGEN / SWITZERLAND

STATEMENT

PROJECT NUMBER: 372881

TEST ARTICLE: FAT 45`169/A

RESPONSIBLE FOR ANALYTICS: K. Biedermann

TITLE: Determination of Concentration, Homogeneity and Stability of FAT 45`169/A in Bidistilled Water.

Study procedures were periodically inspected and this report was audited by the Quality Assurance Unit. The dates are given below.

Dates of QAU Inspections / Audits	Dates of Reports to the Study Director and to Management
17-JUN-94	17-JUN-94
30-JUN-94	30-JUN-94
01-DEC-94	01-DEC-94

Manager, Quality Assurance Unit Mrs. I. Wüthrich

I. Wüthrich

Date: December 1, 1994

ABSTRACT

This chemical analysis determined concentration, homogeneity and stability of FAT 45`169/A in bidistilled water.

Acclimatization/Pretest:

The mean concentrations of the homogeneity samples were found to be 96.8 %, 108.9 %, 105.5 % and 99.4 % of the nominal concentrations for dose groups 2 (1 mg/ml), 3 (5 mg/ml), 4 (20 mg/ml) and 5 (100 mg/ml), respectively. The homogeneity varied in the range from -1 % to +2 % of the mean concentrations.

FAT 45`169/A was found to be stable in bidistilled water at room temperature for at least two hours.

Administration/Treatment:

The mean concentrations of the homogeneity samples were found to be 108.1 %, 107.8 %, 109.9 % and 113.6 % of the nominal concentrations for dose groups 2 (1 mg/ml), 3 (5 mg/ml), 4 (20 mg/ml) and 5 (100 mg/ml), respectively. The homogeneity varied in the range from -5 % to +3 % of the mean concentrations.

FAT 45`169/A was found to be stable in bidistilled water at room temperature for at least two hours.

1 INTRODUCTION

This report describes the analytical method used and the results obtained for concentration, homogeneity and stability of FAT 45`169/A in bidistilled water. The analyses were performed by a HPLC method.

Analysis of homogeneity was performed by analyzing samples of each dose group from three different segments (top, middle, bottom) of the respective mixing container.

2 MATERIALS AND METHODS

2.1 TEST ARTICLE

(according to the information provided by the sponsor)

Identification:	FAT 45`169/A
Synonyma:	Reactive Red DER 7650
Batch number:	1/2, 94
Description:	dark red powder
Purity:	approx. 60 %
Stability of test article:	expiration date: April 1998
Stability of test article dilution:	Stable at room temperature for 2 hours (determined by RCC Umweltchemie AG)
Instructions for test article storage:	at room temperature in the dark
Safety precautions:	Gloves, goggles and face mask were sufficient to assure personnel health and safety.

2.2 SAMPLE STORAGE

Test article/vehicle mixtures were prepared, samples for analysis of concentration and homogeneity were collected and immediately thereafter delivered to the analytical laboratory, where they were either worked-up and analyzed by HPLC or kept deepfrozen prior to sample work-up and analysis by HPLC. Samples for analysis of stability were collected after storage of the test article/vehicle mixtures at room temperature for two hours. Then, they were delivered to the analytical laboratory followed by either sample work-up and analysis by HPLC or storage in a deepfreeze compartement prior to sample work-up and analysis by HPLC.

2.3 ANALYTICAL PROCEDURE

2.3.1 Standard Solutions

Stock solutions of the test article (see section 2.1) in solution A* with concentrations of 0.2 mg/ml and 0.207 mg/ml were prepared as follows: 20 mg and 20.7 mg portions of the test article were each weighed into a 100 ml volumetric flask and dissolved in about 70 ml of solution A* by treatment in an ultrasonic bath. Next, the volumetric flasks were filled to volume with solution A*. Finally, various standard solutions were prepared by respective dilution of these stock solutions with HPLC-eluent (see section 2.3.3) to yield concentrations in the range from 10 µg/ml to 207 µg/ml. These standard solutions were used to calibrate the HPLC.

2.3.2 Analysis of Samples

About 2 g (weighed to the third decimal place) of each test article/vehicle mixture was weighed into a 100 ml volumetric flask. Next, about 70 ml of solution A* was added and dissolution was achieved by treatment in an ultrasonic bath. Then, the volumetric flask was filled to volume with solution A*. Depending on the dose group, the latter sample solution was further diluted with HPLC-eluent (see section 2.3.3) to yield a concentration within the calibration range. Finally, a 10 µl aliquot was quantified by HPLC.

Solution A*: A gram of tetrabuthylammonium bromide (FLUKA 86860) was was weighed into a 1000 ml volumetric flask which was filled to volume with acetonitrile.
50 ml of Buffer (Baker 5656) was weighed into a 1000 ml volumetric flask which was filled to volume with bidistilled water.

2.3.3 HPLC-Determination

(Typical Operating Conditions)

Apparatus:	Merck L-6000	pump
	Merck L-4000	photometer
	Merck D-2000	integrator
	Merck 655A 40	sampling unit
Column:	Lichrospher RP-18; 5 µm; 125 x 4.6 mm	
Temperature:	Room temperature	
Eluent:	Acetonitrile	40 % v/v
	Bidistilled water (pH 7)	60 % v/v
	Tetrabutylammoium bromide (Fluka no.: 86860)	1 g/l
	Buffer (Baker 5656)	50 ml/l
Flow:	1.0 ml/min	
Detection:	UV, 254 nm	
Injection volume:	10 µl	

2.3.4 Evaluation of Results

Injected samples were quantified by peak area with reference to the calibration curves. The latter were obtained by correlation of the peak area (in counts) of the analytical standards with their corresponding concentration in µg/ml.

An example of a calibration curve is listed in Table 1 and typical chromatograms of standard solutions are shown in Figure 1. From these or similar curves, the concentration Y of FAT 45`169/A in µg/ml of an injected sample was calculated from equation 1.

$$Y = a + b \cdot X \qquad (1)$$

where

Y = µg/ml FAT 45`169/A in injected sample

a = y-axis intercept

b = slope

X = peak area of injected sample in counts

The concentrations of FAT 45`169/A in bidistilled water were calculated according to equation 2.

$$C = \frac{Y \cdot V \cdot D \cdot Q}{W \cdot 1000} \qquad (2)$$

where

C = Concentration of FAT 45`169/A in the vehicle (mg/ml)

Y = µg/ml of injected sample calculated by equation 1

V = Final volume (100 ml)

D = Dilution factor

W = Weight of sample (about 2 g, weighed to the third decimal place)

Q = Density of the test article/vehicle mixtures

The density of the test article/vehicle mixtures was assumed to be 1.0 g/ml.

3 RESULTS

The results obtained for concentration, homogeneity and stability of FAT 45`169/A in bidistilled water are summarized in the attached table on page 13.

The tabulated values represent rounded-off results obtained by calculations based on the exact raw data.

Acclimatization/Pretest:

The mean concentrations of the homogeneity samples were found to be 96.8 %, 108.9 %, 105.5 % and 99.4 % of the nominal concentrations for dose groups 2 (1 mg/ml), 3 (5 mg/ml), 4 (20 mg/ml) and 5 (100 mg/ml), respectively. The homogeneity varied in the range from -1 % to +2 % of the mean concentrations.

FAT 45`169/A was found to be stable in bidistilled water at room temperature for at least two hours.

Administration/Treatment:

The mean concentrations of the homogeneity samples were found to be 108.1 %, 107.8 %, 109.9 % and 113.6 % of the nominal concentrations for dose groups 2 (1 mg/ml), 3 (5 mg/ml), 4 (20 mg/ml) and 5 (100 mg/ml), respectively. The homogeneity varied in the range from -5 % to +3 % of the mean concentrations.

FAT 45`169/A was found to be stable in bidistilled water at room temperature for at least two hours.

An example of a calibration curve of FAT 45`169/A is listed in Table 1 and typical chromatograms of standard solutions and samples are shown in Figures 1 and 2, respectively.

Table 1: Example of a calibration curve

Standard concentration (Y) (µg/ml)	Peak area (counts) (X) before samples	after samples
10	49629	49469
20	99157	100148
50	247910	250798
100	497370	497325

$Y = -2.47\ E\text{-}2 + 2.01\ E\text{-}4 \cdot X$ $(R^2 = 0.999)$

where

Y = µg/ml FAT 45`169/A of injected sample

X = peak area of injected sample in counts

TEST ARTICLE IN VEHICLE STABILITY, CONTENT AND HOMOGENEITY

DATE OF PREPARATION: 09-JUN-94 Acclimatization/Pretest

Dose Group Time	Nominal mg/ml	Date of analysis		Concentrat. found mg/ml	% of Nom.	Mean % of Nom.	± Dev. in % of Mean
1-1							
0 Hour	0	17-JUN-94		0.000	---	---	---
2-1							
0 Hour	1	17-JUN-94	T	0.961	96.1	96.8	-1 / +1
0 Hour			M	0.976	97.6		
0 Hour			B	0.966	96.6		
2 Hour[s]			*	0.968	96.8	96.8	
3-1							
0 Hour	5	17-JUN-94	T	5.368	107.4	108.9	-1 / +1
0 Hour			M	5.465	109.3		
0 Hour			B	5.495	109.9		
2 Hour[s]			*	5.353	107.1	107.1	
4-1							
0 Hour	20	17-JUN-94	T	20.84	104.2	105.5	-1 / +2
0 Hour			M	21.00	105.0		
0 Hour			B	21.48	107.4		
2 Hour[s]			*	20.94	104.7	104.7	
5-1							
0 Hour	100	17-JUN-94	T	98.3	98.3	99.4	-1 / +2
0 Hour			M	101.0	101.0		
0 Hour			B	98.9	98.9		
2 Hour[s]			*	97.3	97.3	97.3	

DATE OF PREPARATION: 30-JUN-94 Administration/Treatment

Dose Group Time	Nominal mg/ml	Date of analysis		Concentrat. found mg/ml	% of Nom.	Mean % of Nom.	± Dev. in % of Mean
1-2							
0 Hour	0	30-JUN-94		---	---	---	---
2-2							
0 Hour	1	30-JUN-94	T	1.081	108.1	108.1	0 / +0
0 Hour			M	1.077	107.7		
0 Hour			B	1.085	108.5		
2 Hour[s]			*	1.093	109.3	109.3	
3-2							
0 Hour	5	30-JUN-94	T	5.364	107.3	107.8	0 / +0
0 Hour			M	5.393	107.9		
0 Hour			B	5.415	108.3		
2 Hour[s]			*	5.424	108.5	108.5	
4-2							
0 Hour	20	30-JUN-94	T	21.99	109.9	109.9	0 / +0
0 Hour			M	22.02	110.1		
0 Hour			B	21.93	109.6		
2 Hour[s]			*	21.86	109.3	109.3	
5-2							
0 Hour	100	30-JUN-94	T	116.2	116.2	113.6	-5 / +3
0 Hour			M	117.1	117.1		
0 Hour			B	107.4	107.4		
2 Hour[s]			*	107.5	107.5	107.5	

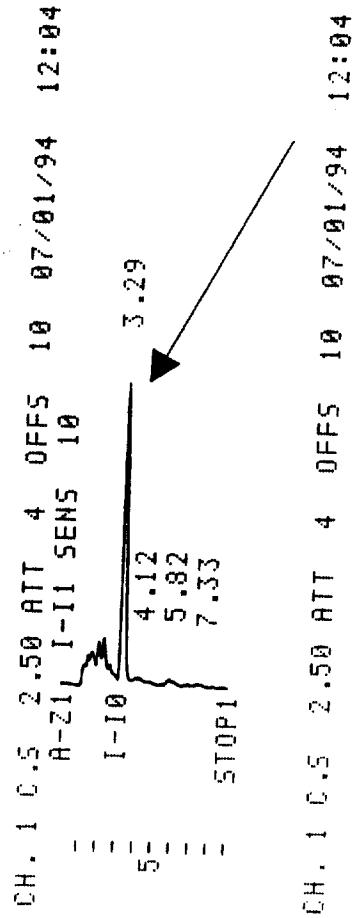
T : Top)
M : Middle) of mixing container
B : Bottom)

* Stability test over two hours at room temperature

Figure 1: Typical Chromatograms:

1. Standard solution 10 µg/ml (before samples)
2. Standard solution 100 µg/ml (before samples)

1.



2.

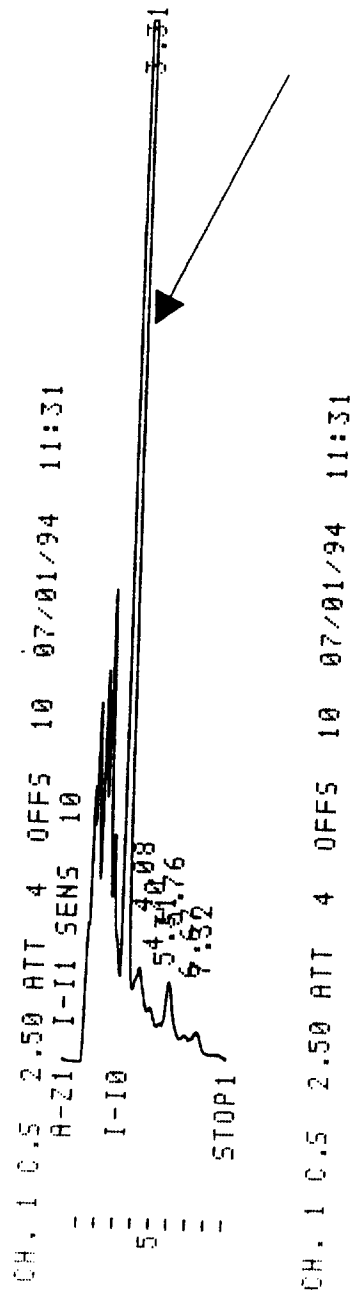
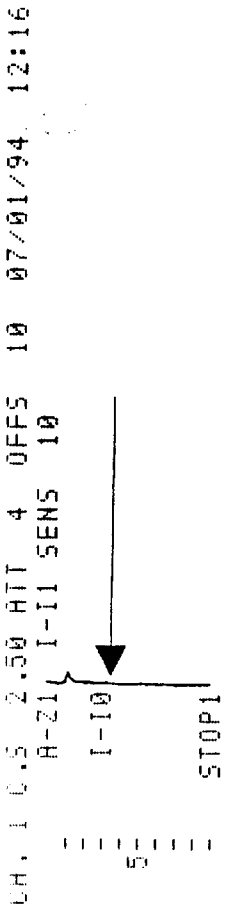


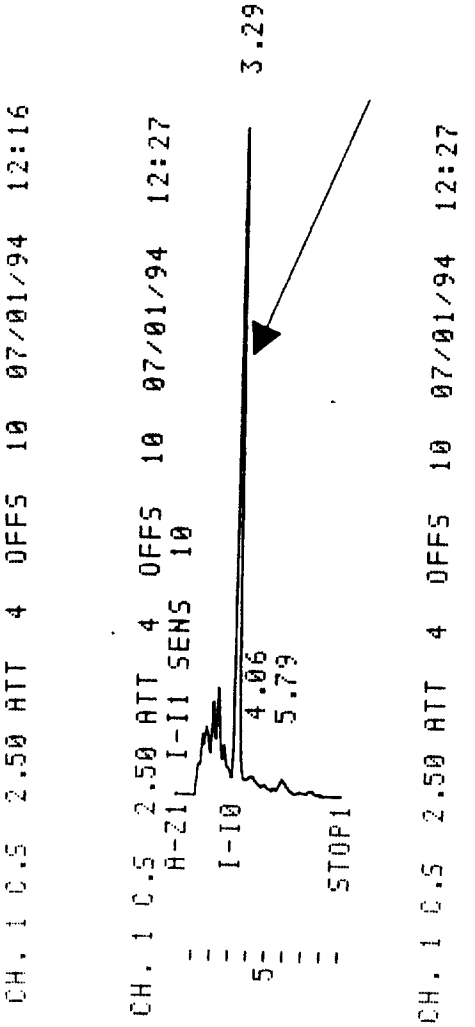
Figure 2: Typical Chromatograms:

1. Control sample
2. Sample, nominal 1 mg/ml
3. Sample, nominal 100 mg/ml, diluted 50x

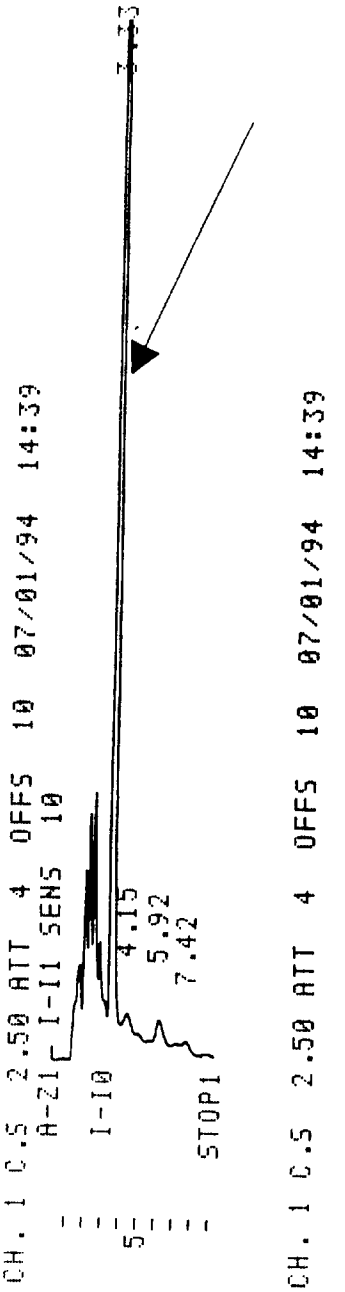
1.



2.



3.



RCC PROJECT 372881
FAT 45'169/A

ATTACHMENT 5

PATHOLOGY REPORT -

SUMMARY AND INDIVIDUAL DATA

November 26, 1994

Subacute 28-day Oral (Gavage) Toxicity Study in the Rat with FAT 45'169/A

(RCC Project No.: 372881)

Histopathology Report

Preclinical Safety Consultants Est.
7 Earning Street
Godmanchester
Cambridgeshire
PE18 8JD, ENGLAND

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TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL
SPONSOR : RCC AG

PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

COMPLIANCE WITH GOOD LABORATORY PRACTICE

All practices and procedures associated with the histopathological evaluation presented in this report comply with the requirements of the OECD Principles of Good Laboratory Practice (Environment monograph No. 45, OECD/GD (92)32, Paris 1992)

30.11.94

M.F. MARTLAND DrMedVet, MA, VetMB, MRCVS.
Veterinary Pathologist

All practices and procedures associated with the peer review of this report comply with the requirements of the OECD Principles of Good Laboratory Practice.

30.11.94

D.E. PRENTICE, MA, MVSc, VetMB, MRCVS, MRCPath
Reviewing Pathologist

Preclinical Safety (PCS) Consultants Est.

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TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL
SPONSOR : RCC AG

PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

QUALITY ASSURANCE STATEMENT

The facilities of Preclinical Safety (PCS) Consultants Est and the operating procedures used by this company are periodically inspected.

This report has been audited and is considered to be an accurate presentation of the histopathological procedures involved and of the study findings.

Date of audit: November 7, 1994.
Date of reporting findings to the histopathologist and to PCS Consultants Est management: November 7, 1994.

KW G. Shillam 11.12.94

KENNETH W.G. SHILLAM BSc, PhD, FIBiol.
Quality Assurance Consultant

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1 SUMMARY AND CONCLUSIONS

FAT 45'169/A in bi-distilled water vehicle was administered orally by gavage to groups of 5 male and 5 female rats for 28 days at levels of 0, 50, 200, and 1000 mg/kg/day. Further groups of 5 male and 5 female rats were treated for 28 days with 0 and 1000 mg/kg/day and were then allowed a 14 day test article free recovery period

This report details the histopathological examination of: adrenals, heart, kidneys, liver, lungs, spleen, stomach, testes and gross lesions from high dose and control animals, together with together with kidneys, lungs and gross lesions from animals in other groups, by Malcolm F. Martland (Preclinical Safety (PCS) Consultants Est consultant pathologist), and the peer review by David E. Prentice (managing consultant, PCS).

At 200 and 1000 mg/kg/day there were necropsy findings of general body discoloration and kidney discoloration (reddish).

At 1000 mg/kg/day there was histopathological evidence of nephrotoxicity in both sexes in the form of increased renal cortical tubular basophilia and degeneration. Increased severity of tubular hyaline droplets was apparent in the males and red tubular hyaline droplets were also present in the females. The kidney lesions were still apparent after a 14 day test article free recovery period.

At 1000 mg/kg/day clusters of foamy macrophages containing red pigment droplets were found in the lungs of two male rats. One male rat still showed the lesion after a 14 day test article free recovery period.

There were no other treatment-related histopathological findings.

2 INTRODUCTION

Histopathological slides from selected organs from high dose and control animals (plus gross lesions noted at necropsy in animals from the other treatment groups) in RCC project 372881 (conducted by RCC AG, CH-4452 Itingen/Switzerland) were examined by Malcolm F. Martland (Consultant Pathologist, Pre-Clinical Safety (PCS) Consultants Est.). The kidney and lung findings from selected animals were peer reviewed by David E. Prentice (Managing Consultant, PCS).

The following report details the procedures used, the results, and the conclusions drawn from the histopathological examination of materials from this study.

3 METHODS

3.1 STUDY DESIGN

35 male and 35 female rats were assigned to the following treatment groups:

Group	Sex	Dose (mg/kg/day)	Animal numbers	
			Terminal	Recovery
1	Males	0	1 - 5	6 - 10
	Females		36 - 40	41 - 45
2	Males	10	11 - 15	
	Females		46 - 50	
3	Males	50	16 - 20	
	Females		51 - 55	
4	Males	200	21 - 25	
	Females		56 - 60	
5	Males	1000	26 - 30	31 - 35
	Females		61 - 65	66 - 70

The test compound was administered orally by gavage in bi-distilled water vehicle for 28 days. Controls were treated with the vehicle only. Recovery animals were allowed a 14 day test article free period.

3.2 IN LIFE AND NECROPSY DATA

The in-life phase and necropsies of the project were performed by RCC. Necropsy data were entered onto the RCC Pathdata system, and were supplied to PCS on diskette for transfer onto the PCS Pathdata system. Organ weight data was supplied by RCC for information.

Necropsy findings are given in full in the INDIVIDUAL ANIMAL DATA SHEETS.

3.3 HISTOPATHOLOGY

Hematoxylin and Eosin (HE) stained sections were prepared and examined from the following list of tissues from all control and high dose animals:

adrenals,
heart,
kidneys,
liver,
lungs,
spleen,
stomach,
testes,
gross lesions.

Gross lesions, kidneys and lungs were also examined for all other animals. No examination was performed on other tissues from animals in other groups.

All pathological findings were entered directly onto the PATHDATA system. The codes and findings are explained and summarised in the SUMMARY TABLES (p.12), and described in text form in the INDIVIDUAL ANIMAL DATA SHEETS. Where findings have been abbreviated to fit the summary tables, they are given in full in the individual animal data sheets. Lesions were entered as present, or were graded in severity from grade 1 to grade 5.

3.4 PEER REVIEW

Peer review of the kidney and lung findings from selected animals was performed by Dr. D.E. Prentice. All peer reviewed tissues or animal are identified in the text of the individual animal data sheets by the entry "#" or "Peer review: Complete animal peer reviewed".

3.5 ARCHIVING

The histological sections have been returned to RCC for archiving. All Raw Data generated during the histopathological examination will be archived at the offices of PCS Consultants (see p. 3)for a period of at least 10 years and will not be disposed of without the sponsor's permission.

4 RESULTS

4.1 NECROPSY

Necropsy findings are summarised in the table INCIDENCE OF NECROPSY FINDINGS (P. 13) are given in full in the INDIVIDUAL ANIMAL DATA SHEETS (p. 39).

Treatment-related findings

General Observations	Discoloration (reddish) in group 5 (males 10/10, females 10/10).
Kidneys	Discoloration (reddish)in group 4 (males 5/5, females 5/5).
Mesenteric lymph nodes	Discoloration (reddish)in group 4 (males 5/5, females 5/5).

There were no histopathological counterparts to these findings.

There were no other treatment related necropsy findings.

4.2 HISTOPATHOLOGY

The incidence of histopathologic findings is given in the table NUMBER OF ANIMALS WITH MICROSCOPIC FINDINGS (p. 17). Gradings of kidney and lung lesions are also shown in the table SUMMARY INCIDENCE OF GRADINGS (p. 21). Findings for individual animals are listed in the TABLE OF INDIVIDUAL MICROSCOPIC FINDINGS (p. 25), and printed in full in the INDIVIDUAL ANIMAL DATA (p. 39). The following comments are made in summary.

Treatment-related findings

Terminal Necropsy (Groups 1,2,3,4 and 5)

Kidneys	Increased mean severity (mild to moderate) of cortical tubular hyaline droplets in group 5 males. Presence of mild cortical tubular hyaline droplet deposits in 5/5 group 5 females Increased incidence and mean severity (moderate to marked) of cortical tubular basophilia and degeneration in group 5 (Males 4/5; Females 4/5)
Lungs	Mild to moderate alveolar foamy macrophage accumulation with red pigment deposits in 2/5 group 5 males.

Recovery (Groups 1 and 5)

Kidneys — Marginally increased mean severity (minimal to moderate) of cortical tubular hyaline droplets in group 5 males.
Presence of minimal to mild cortical tubular hyaline droplet deposits in 4/5 group 5 females.
Increased incidence and mean severity (mild to moderate) of cortical tubular basophilia and degeneration in group 5 (Males 5/5; Females 5/5)

Lungs — Mild alveolar foamy macrophage accumulation with red pigment deposits in 1/5 group 5 male.

There were no other treatment related findings.

Incidental findings

A variety of other minor degenerative and inflammatory lesions were observed which fell within the expected range for rats of this age.

4.3 MORTALITY

There was one death of a control male rat on day 28. Cause of death could not be determined on the basis of this histopathological examination.

4.4 PEER REVIEW (Kidneys & Lungs)

The findings of the study pathologist and the peer reviewer were in agreement.

5. COMMENT

At 1000 mg/kg/day there was histopathological evidence of nephrotoxicity in the form of renal cortical tubular red hyaline droplets, tubular basophilia and degeneration. The tubular hyaline droplets were present at increased severity in the males compared with lower doses but in the females were present only in the high dose group. These hyaline droplets probably represent an accumulation of compound in the renal tubules which subsequently resulted in degenerative changes. The kidney lesions were still apparent after a 14 day test article free recovery period.

At 1000 mg/kg/day clusters of foamy macrophages containing red pigment droplets were found in the lungs of two male rats. In the absence of any accompanying inflammation these were considered to be due to a systemic accumulation of compound in the pulmonary macrophages rather than an inhalation reaction. One male rat still showed the lesion after a 14 day test article free recovery period.

TEST ARTICLE : FAT 45'169/A PATHOL. NO.: 37288 MAR
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE) DATE : 26-NOV-94
SPONSOR : RCC LTD. PDS PATHDATA SYSTEM TM

EXPLANATION OF CODES AND SYMBOLS

CODES AND SYMBOLS USED AT ANIMAL LEVEL

1 = MALE
2 = FEMALE
K0 = TERMINAL SACRIFICE GROUP
R1... = RECOVERY / POST-TREATMENT GROUP 1...
+ = INTERCURRENT DEATH/SACRIFICED MORIBUND
+1 = FOUND DEAD

CODES AND SYMBOLS USED AT ORGAN LEVEL:

G = GROSS FINDING EVALUATED HISTOLOGICALLY
* = COMMENT IN TEXT OF INDIVIDUAL ANIMAL DATA
' = HISTOLOGIC EXAMINATION NOT REQUIRED
- = ORGAN EXAMINED, NO PATHOLOGIC FINDINGS NOTED
(= ONLY ONE OF PAIRED ORGANS EXAMINED/PRESENT

CODES AND SYMBOLS USED AT FINDING LEVEL:

GRADE 1 = MINIMAL / VERY FEW / VERY SMALL
GRADE 2 = MILD / FEW / SMALL
GRADE 3 = MODERATE / MODERATE NUMBER / MODERATE SIZE
GRADE 4 = MARKED / MANY / LARGE
P = FINDING PRESENT, SEVERITY NOT SCORED
(= FINDING UNILATERAL IN PAIRED ORGANS

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.

PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

INCIDENCE OF NECROPSY FINDINGS BY ORGAN/GROUP/SEX

DOSE GROUP:	01		02		03		04	
SEX:	M	F	M	F	M	F	M	F
ORGAN/FINDING NO.ANIMALS:	10	10	5	5	5	5	5	5
GENERAL OBSERVATIONS :								
- DISCOLORATION								
KIDNEYS :								
- PELVIC DILATION				1		2	1	
- DISCOLORATION							5	5
STOMACH :								
- FOCUS/FOCI		1						1
LUNGS :								
- FOCUS/FOCI			1					
SEMINAL VESICLES :								
- DISCOLORATION	1							
OVARIES :								
- DISCOLORATION		1						1
UTERUS :								
- DISCOLORATION						1		1
- DISTENDED				1				
JEJUNUM :								
- DISCOLORATION	1					1	1	
RECTUM :								
- DISCOLORATION								1
SKIN :								
- AREAS WITH ALOPECIA	1	1						
EXORBITAL LACR.GLDS. :								
- FOCUS/FOCI					1			
THYMUS :								
- FOCUS/FOCI	1	1						1
MESENT. LYMPH NODE :								
- DISCOLORATION							5	5

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.

PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

INCIDENCE OF NECROPSY FINDINGS BY ORGAN/GROUP/SEX

	DOSE GROUP:	01		02		03		04	
	SEX:	M	F	M	F	M	F	M	F
ORGAN/FINDING	NO.ANIMALS:	10	10	5	5	5	5	5	5
MANDIBUL. LYMPH NODE :									
- FOCUS/FOCI				1					

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.
PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

INCIDENCE OF NECROPSY FINDINGS BY ORGAN/GROUP/SEX

DOSE GROUP:	01		05	
SEX:	M	F	M	F
ORGAN/FINDING NO.ANIMALS:	10	10	10	10
GENERAL OBSERVATIONS :				
- DISCOLORATION			10	10
KIDNEYS :				
- PELVIC DILATION			1	
- DISCOLORATION				
STOMACH :				
- FOCUS/FOCI		1		
LUNGS :				
- FOCUS/FOCI			1	
SEMINAL VESICLES :				
- DISCOLORATION	1			
OVARIES :				
- DISCOLORATION		1		
UTERUS :				
- DISCOLORATION				
- DISTENDED				
JEJUNUM :				
- DISCOLORATION	1			
RECTUM :				
- DISCOLORATION				
SKIN :				
- AREAS WITH ALOPECIA	1	1		
EXORBITAL LACR.GLDS. :				
- FOCUS/FOCI				
THYMUS :				
- FOCUS/FOCI	1	1		
MESENT. LYMPH NODE :				
- DISCOLORATION				

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.

PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

INCIDENCE OF NECROPSY FINDINGS BY ORGAN/GROUP/SEX

	DOSE GROUP:	01		05	
	SEX:	M	F	M	F
ORGAN/FINDING	NO.ANIMALS:	10	10	10	10
MANDIBUL. LYMPH NODE :					
- FOCUS/FOCI					

END OF SECTION

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.

PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

NUMBER OF ANIMALS WITH MICROSCOPIC FINDINGS BY ORGAN/GROUP/SEX
STATUS AT NECROPSY: K0, INCLUDING +

MALE

ORGAN/FINDING	SEX : DOSE GROUP: NO.ANIMALS:	01 5	02 5	03 5	04 5	05 5
CAUSE OF DEATH	NO. EXAM.:	1				
- NOT DETERMINABLE		1				
LIVER	NO. EXAM.:	5				5
- LYMPHOID FOCI		5				5
- DIFFUSE VACUOLATION		1				1
KIDNEYS	NO. EXAM.:	5	5	5	5	5
- TUBULE BASOPH.DEGEN.		1	1	1	3	5
- HYALINE DROPLETS		5	5	5	4	5
- HYDRONEPHROSIS				2	1	
- UROTHEL.HYPERPLASIA					1	
- LYMPHOID FOCI			1			
LUNGS	NO. EXAM.:	5	5	5	5	5
- FOAMY MACROPHAGES		2	4	3	3	3
- PIGMENT DEPOSITS						2
- INFLAMMATION				1		
- MINERALISED FOCI			1	1		
- ALVEOLAR HAEMORRHAGE						1
JEJUNUM	NO. EXAM.:	1			1	
- INFLAMMATION					1	
EXORBITAL LACR.GLDS.	NO. EXAM.:			1		
- HARDERIANISATION				1		
MESENT. LYMPH NODE	NO. EXAM.:				5	
- REACTIVE					2	
MANDIBUL. LYMPH NODE	NO. EXAM.:		1			2
- REACTIVE			1			

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.

PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

NUMBER OF ANIMALS WITH MICROSCOPIC FINDINGS BY ORGAN/GROUP/SEX
STATUS AT NECROPSY: K0, INCLUDING +

	SEX :					FEMALE
	DOSE GROUP:	01	02	03	04	05
ORGAN/FINDING	NO.ANIMALS:	5	5	5	5	5
HEART	NO. EXAM.:	5				5
- DEGENERATION		1				1
LIVER	NO. EXAM.:	5				5
- LYMPHOID FOCI		5				5
- DIFFUSE VACUOLATION		4				4
- HAEMATOPOIESIS		1				2
KIDNEYS	NO. EXAM.:	5	5	5	5	5
- TUBULE BASOPH.DEGEN.		1	2	4	2	5
- HYALINE DROPLETS						5
- MINERALISATION		4	3	4	4	4
STOMACH	NO. EXAM.:	5			1	5
- INFLAMMATION						1
LUNGS	NO. EXAM.:	5	5	5	5	5
- FOAMY MACROPHAGES		4	1	2	3	4
UTERUS	NO. EXAM.:		3	2	2	1
- HYDROMETRA			3	1	1	1
- INFLAMMATION				1		
- CYST(S)					1	
RECTUM	NO. EXAM.:				1	
- DISTENSION					1	
MANDIBUL. LYMPH NODE	NO. EXAM.:		1			1
- REACTIVE			1			

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.

PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

NUMBER OF ANIMALS WITH MICROSCOPIC FINDINGS BY ORGAN/GROUP/SEX
STATUS AT NECROPSY: R1

	SEX :			MALE
	DOSE GROUP:	01	05	
ORGAN/FINDING	NO.ANIMALS:	5	5	
HEART	NO. EXAM.:	5	5	
- DEGENERATION		1	1	
LIVER	NO. EXAM.:	5	5	
- LYMPHOID FOCI		5	4	
- DIFFUSE VACUOLATION		2	1	
- FOCAL NECROSIS			1	
KIDNEYS	NO. EXAM.:	5	5	
- TUBULE BASOPH.DEGEN.		1	5	
- HYALINE DROPLETS		5	4	
- HYDRONEPHROSIS			1	
STOMACH	NO. EXAM.:	5	5	
- INFLAMMATION		1		
LUNGS	NO. EXAM.:	5	5	
- FOAMY MACROPHAGES		2	4	
- PIGMENT DEPOSITS			1	
- MINERALISED FOCI			1	
ADRENAL GLANDS	NO. EXAM.:	5	5	
- CORTICAL VACUOLATION		1	1	

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.

PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

NUMBER OF ANIMALS WITH MICROSCOPIC FINDINGS BY ORGAN/GROUP/SEX
STATUS AT NECROPSY: R1

	SEX :			FEMALE
	DOSE GROUP:	01	05	
ORGAN/FINDING	NO.ANIMALS:	5	5	
HEART	NO. EXAM.:	5	5	
- DEGENERATION		1	2	
LIVER	NO. EXAM.:	5	5	
- LYMPHOID FOCI		5	4	
- FOCAL VACUOLATION			1	
- DIFFUSE VACUOLATION		5	4	
- HAEMATOPOIESIS		1		
- FOCAL NECROSIS			1	
- INFLAMMATION			1	
SPLEEN	NO. EXAM.:	5	5	
- HAEMATOPOIESIS		1		
KIDNEYS	NO. EXAM.:	5	5	
- TUBULE BASOPH.DEGEN.		1	5	
- HYALINE DROPLETS			4	
- MINERALISATION		5	3	
STOMACH	NO. EXAM.:	5	5	
- EROSION(S)		1		
LUNGS	NO. EXAM.:	5	5	
- FOAMY MACROPHAGES		2	2	

END OF SECTION

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.

PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

SUMMARY INCIDENCE OF GRADINGS BY ORGAN/GROUP/SEX
STATUS AT NECROPSY: K0, INCLUDING +

ORGAN/FINDING	SEX :					MALE
	DOSE GROUP:	01	02	03	04	05
	NO.ANIMALS:	5	5	5	5	5
KIDNEYS	NO. EXAM.:	5	5	5	5	5
- TUBULE BASOPH.DEGEN.	GRADE 1 :	1	1	1	2	1
	GRADE 2 :				1	
	GRADE 4 :					4
	TOTAL AFFECTED:	1	1	1	3	5
	MEAN GRADING :	0.2	0.2	0.2	0.8	3.4
- HYALINE DROPLETS	GRADE 1 :	3				
	GRADE 2 :	1	5	4	4	2
	GRADE 3 :	1		1		3
	TOTAL AFFECTED:	5	5	5	4	5
	MEAN GRADING :	1.6	2.0	2.2	1.6	2.6
LUNGS	NO. EXAM.:	5	5	5	5	5
- FOAMY MACROPHAGES	GRADE 1 :	2	3	2	2	1
	GRADE 2 :		1	1	1	1
	GRADE 3 :					1
	TOTAL AFFECTED:	2	4	3	3	3
	MEAN GRADING :	0.4	1.0	0.8	0.8	1.2
- PIGMENT DEPOSITS	GRADE 2 :					1
	GRADE 3 :					1
	TOTAL AFFECTED:					2
	MEAN GRADING :					1.0

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.

PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

SUMMARY INCIDENCE OF GRADINGS BY ORGAN/GROUP/SEX
STATUS AT NECROPSY: K0, INCLUDING +

FEMALE

ORGAN/FINDING	SEX :					
	DOSE GROUP:	01	02	03	04	05
	NO.ANIMALS:	5	5	5	5	5
KIDNEYS	NO. EXAM.:	5	5	5	5	5
- TUBULE BASOPH.DEGEN.	GRADE 1 :	1	1	3	2	
	GRADE 2 :		1	1		1
	GRADE 3 :					4
	TOTAL AFFECTED:	1	2	4	2	5
	MEAN GRADING :	0.2	0.6	1.0	0.4	2.8
- HYALINE DROPLETS	GRADE 2 :					5
	TOTAL AFFECTED:					5
	MEAN GRADING :					2.0
LUNGS	NO. EXAM.:	5	5	5	5	5
- FOAMY MACROPHAGES	GRADE 1 :	4	1	2	3	4
	TOTAL AFFECTED:	4	1	2	3	4
	MEAN GRADING :	0.8	0.2	0.4	0.6	0.8

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.

PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

SUMMARY INCIDENCE OF GRADINGS BY ORGAN/GROUP/SEX
STATUS AT NECROPSY: R1

	SEX :			MALE
	DOSE GROUP:	01	05	
ORGAN/FINDING	NO.ANIMALS:	5	5	
KIDNEYS	NO. EXAM.:	5	5	
- TUBULE BASOPH.DEGEN.	GRADE 2 :	1	3	
	GRADE 3 :		2	
	TOTAL AFFECTED:	1	5	
	MEAN GRADING :	0.4	2.4	
- HYALINE DROPLETS	GRADE 1 :	3	1	
	GRADE 2 :	2	2	
	GRADE 3 :		1	
	TOTAL AFFECTED:	5	4	
	MEAN GRADING :	1.4	1.6	
LUNGS	NO. EXAM.:	5	5	
- FOAMY MACROPHAGES	GRADE 1 :	2	3	
	GRADE 2 :		1	
	TOTAL AFFECTED:	2	4	
	MEAN GRADING :	0.4	1.0	
- PIGMENT DEPOSITS	GRADE 2 :		1	
	TOTAL AFFECTED:		1	
	MEAN GRADING :		0.4	

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.

PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

SUMMARY INCIDENCE OF GRADINGS BY ORGAN/GROUP/SEX
STATUS AT NECROPSY: R1

	SEX :		FEMALE
	DOSE GROUP:	01	05
ORGAN/FINDING	NO.ANIMALS:	5	5
KIDNEYS	NO. EXAM.:	5	5
- TUBULE BASOPH.DEGEN.	GRADE 1 :	1	
	GRADE 2 :		5
	TOTAL AFFECTED:	1	5
	MEAN GRADING :	0.2	2.0
- HYALINE DROPLETS	GRADE 1 :		2
	GRADE 2 :		2
	TOTAL AFFECTED:		4
	MEAN GRADING :		1.2
LUNGS	NO. EXAM.:	5	5
- FOAMY MACROPHAGES	GRADE 1 :	2	2
	TOTAL AFFECTED:	2	2
	MEAN GRADING :	0.4	0.4

END OF SECTION

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.

PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TABLE OF INDIVIDUAL MICROSCOPIC FINDINGS
DOSE GROUP : 01, 0 MG/KG

ANIMAL NUMBER :	1	2	3	4	5	6	7	8	9	10
	1K0	1K0	1+1	1K0	1K0	1R1	1R1	1R1	1R1	1R1
GENERAL OBSERVATIONS	'	'	'	'	'	'	'	'	'	'
PEER REVIEW	'	'	'	'	'	'	'	'	'	'
CAUSE OF DEATH	'	'	.	'	'	'	'	'	'	'
- NOT DETERMINABLE			P.							
HEART	-	-	-	-	-	-	-	.	-	-
- DEGENERATION	.	.	.	.	.	.	.	1.	.	.
LIVER	.	.	.	.	.	.	.	.	.	.
- LYMPHOID FOCI	1.	1.	1.	2.	1.	1.	2.	1.	2.	1.
- DIFFUSE VACUOLATION	.	1.	.	.	.	1.	1.	.	.	.
SPLEEN	-	-	-	-	-	-	-	-	-	-
KIDNEYS	*	*	*	*	*	*	*	*	*	*
- TUBULE BASOPH.DEGEN.	.	.	(1.	.	.	.	.	.	2.	.
- HYALINE DROPLETS	3.	1.	2.	1.	1.	1.	2.	1.	1.	2.
STOMACH	-	-	-	-	-	-	-	.	-	-
- INFLAMMATION	.	.	.	.	.	.	.	2.	.	.
LUNGS	-*	-*	*	-*	*	-	.	-	.	-
- FOAMY MACROPHAGES	.	.	1.	.	1.	.	1.	.	1.	.
TESTES	-	-	-	-	-	-	-	-	-	-
ADRENAL GLANDS	-	-	-	-	-	.	-	-	-	-
- CORTICAL VACUOLATION	.	.	.	.	.	2.	.	.	.	.
SEMINAL VESICLES	'	'	'	'	(-G	'	'	'	'	'
PROSTATE	'	'	'	'	'	'	'	'	'	'
DUODENUM	'	'	'	'	'	'	'	'	'	'
JEJUNUM	'	'	'	-G	'	'	'	'	'	'

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.

PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TABLE OF INDIVIDUAL MICROSCOPIC FINDINGS
DOSE GROUP : 01, 0 MG/KG

ANIMAL NUMBER :

	1	2	3	4	5	6	7	8	9	10
	1K0	1K0	1+1	1K0	1K0	1R1	1R1	1R1	1R1	1R1
RECTUM	'	'	'	'	'	'	'	'	'	'
SKIN	'	'	'	'	'	'	'	'	'	-G
EXORBITAL LACR.GLDS.	'	'	'	'	'	'	'	'	'	'
THYMUS	'	'	-G	'	'	'	'	'	'	'
LYMPH NODES	'	'	'	'	'	'	'	'	'	'
MESENT. LYMPH NODE	'	'	'	'	'	'	'	'	'	'
MANDIBUL. LYMPH NODE	'	'	'	'	'	'	'	'	'	'
THYROID GLAND	'	'	'	'	'	'	'	'	'	'

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.

PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TABLE OF INDIVIDUAL MICROSCOPIC FINDINGS
DOSE GROUP : 01, 0 MG/KG

ANIMAL NUMBER :	36	37	38	39	40	41	42	43	44	45
	2K0	2K0	2K0	2K0	2K0	2R1	2R1	2R1	2R1	2R1
GENERAL OBSERVATIONS	'	'	'	'	'	'	'	'	'	'
PEER REVIEW	'	'	'	'	'	'	'	'	'	'
CAUSE OF DEATH	'	'	'	'	'	'	'	'	'	'
HEART	-	-	.	-	-	-	.	-	-	-
- DEGENERATION	.	.	1.	.	.	.	1.	.	.	.
LIVER	.	.	.	.	.	.	.	.	.	.
- LYMPHOID FOCI	2.	1.	1.	1.	1.	1.	2.	1.	1.	1.
- DIFFUSE VACUOLATION	1.	1.	1.	.	1.	1.	1.	1.	2.	1.
- HAEMATOPOIESIS	.	.	1.	.	.	.	1.	.	.	.
SPLEEN	-	-	-	-	-	-	.	-	-	-
- HAEMATOPOIESIS	.	.	.	.	.	.	1.	.	.	.
KIDNEYS	*	-*	*	*	*	.	.	.	.	.
- TUBULE BASOPH.DEGEN.	.	.	.	(1.	.	.	.	(1.	.	.
- MINERALISATION	2.	.	(2.	2.	2.	2.	1.	2.	1.	(1.
STOMACH	-	-	-	-	-	-	-	-	-	G
- EROSION(S)	.	.	.	.	.	.	.	.	.	2.
LUNGS	.	-	.	.	.	.	-	-	-	.
- FOAMY MACROPHAGES	1.	.	1.	1.	1.	1.	.	.	.	1.
ADRENAL GLANDS	-	-	-	-	-	-	-	-	-	-
OVARIES	'	'	(-G	'	'	'	'	'	'	'
UTERUS	'	'	'	'	'	'	'	'	'	'
DUODENUM	'	'	'	'	'	'	'	'	'	'
JEJUNUM	'	'	'	'	'	'	'	'	'	'
RECTUM	'	'	'	'	'	'	'	'	'	'

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.

PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TABLE OF INDIVIDUAL MICROSCOPIC FINDINGS
DOSE GROUP : 01, 0 MG/KG

ANIMAL NUMBER :	36	37	38	39	40	41	42	43	44	45
	2K0	2K0	2K0	2K0	2K0	2R1	2R1	2R1	2R1	2R1
SKIN	'	'	'	-G	'	'	'	'	'	'
EXORBITAL LACR.GLDS.	'	'	'	'	'	'	'	'	'	'
THYMUS	'	'	'	'	'	'	'	'	-G	'
LYMPH NODES	'	'	'	'	'	'	'	'	'	'
MESENT. LYMPH NODE	'	'	'	'	'	'	'	'	'	'
MANDIBUL. LYMPH NODE	'	'	'	'	'	'	'	'	'	'
THYROID GLAND	'	'	'	'	'	'	'	'	'	'

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.

PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TABLE OF INDIVIDUAL MICROSCOPIC FINDINGS
DOSE GROUP : 02, 10 MG/KG

ANIMAL NUMBER :	11	12	13	14	15	46	47	48	49	50
	1K0	1K0	1K0	1K0	1K0	2K0	2K0	2K0	2K0	2K0
GENERAL OBSERVATIONS	'	'	'	'	'	'	'	'	'	'
PEER REVIEW	'	'	'	'	'	'	'	'	'	'
CAUSE OF DEATH	'	'	'	'	'	'	'	'	'	'
HEART	'	'	'	'	'	'	'	'	'	'
LIVER	'	'	'	'	'	'	'	'	'	'
SPLEEN	'	'	'	'	'	'	'	'	'	'
KIDNEYS	.	.	.	.	.	-	G	.	.	.
- TUBULE BASOPH.DEGEN.	1.	.	.	.	.	.	(1.	2.	.	.
- HYALINE DROPLETS	2.	2.	2.	2.	2.	.	.	.	.	.
- MINERALISATION	.	.	.	.	.	.	.	2.	1.	2.
- LYMPHOID FOCI	(1.	.	.	.	.	.	.	.	.	.
STOMACH	'	'	'	'	'	'	'	'	'	'
LUNGS	.	-	.	G	.	-*	-*	.	-	-
- FOAMY MACROPHAGES	1.	.	2.	1.	1.	.	.	1.	.	.
- MINERALISED FOCI	.	.	1.	.	.	.	.	.	.	.
TESTES	'	'	'	'	'					
ADRENAL GLANDS	'	'	'	'	'	'	'	'	'	'
SEMINAL VESICLES	'	'	'	'	'					
PROSTATE	'	'	'	'	'					
OVARIES						'	'	'	'	'
UTERUS						'	G	G	G	'
- HYDROMETRA							3.	3.	3.	
DUODENUM	'	'	'	'	'	'	'	'	'	'

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.
PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TABLE OF INDIVIDUAL MICROSCOPIC FINDINGS
DOSE GROUP : 02, 10 MG/KG

ANIMAL NUMBER :	11	12	13	14	15	46	47	48	49	50
	1K0	1K0	1K0	1K0	1K0	2K0	2K0	2K0	2K0	2K0
JEJUNUM										
RECTUM										
SKIN										
EXORBITAL LACR.GLDS.										
THYMUS										
LYMPH NODES										
MESENT. LYMPH NODE										
MANDIBUL. LYMPH NODE - REACTIVE					(G (2.			G 2.		
THYROID GLAND										

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.

PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TABLE OF INDIVIDUAL MICROSCOPIC FINDINGS
DOSE GROUP : 03, 50 MG/KG

ANIMAL NUMBER :	16	17	18	19	20	51	52	53	54	55
	1K0	1K0	1K0	1K0	1K0	2K0	2K0	2K0	2K0	2K0
GENERAL OBSERVATIONS	'	'	'	'	'	'	'	'	'	'
PEER REVIEW	'	'	'	'	'	'	'	'	'	'
CAUSE OF DEATH	'	'	'	'	'	'	'	'	'	'
HEART	'	'	'	'	'	'	'	'	'	'
LIVER	'	'	'	'	'	'	'	'	'	'
SPLEEN	'	'	'	'	'	'	'	'	'	'
KIDNEYS	G	.	G	.	.	.	.	.	.	.
- TUBULE BASOPH.DEGEN.	.	.	(1.	.	.	(1.	(1.	.	(2.	(1.
- HYALINE DROPLETS	2.	2.	2.	3.	2.	.	.	.	.	.
- HYDRONEPHROSIS	(2.	.	(2.	.	.	.	.	.	.	.
- MINERALISATION	.	.	.	.	.	2.	2.	1.	.	3.
STOMACH	'	'	'	'	'	'	'	'	'	'
LUNGS	.	.	.	.	-	-	.	-	.	-
- FOAMY MACROPHAGES	1.	2.	1.	.	.	.	1.	.	1.	.
- INFLAMMATION	.	1.	.	.	.	.	.	.	.	.
- MINERALISED FOCI	.	.	.	2.	.	.	.	.	.	.
TESTES	'	'	'	'	'					
ADRENAL GLANDS	'	'	'	'	'	'	'	'	'	'
SEMINAL VESICLES	'	'	'	'	'					
PROSTATE	'	'	'	'	'					
OVARIES						'	'	'	'	'
UTERUS						G	'	G	'	'
- HYDROMETRA						.		3.		
- INFLAMMATION						1.		.		

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.

PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TABLE OF INDIVIDUAL MICROSCOPIC FINDINGS
DOSE GROUP : 03, 50 MG/KG

ANIMAL NUMBER :	16	17	18	19	20	51	52	53	54	55
	1K0	1K0	1K0	1K0	1K0	2K0	2K0	2K0	2K0	2K0
DUODENUM	'	'	'	'	'	'	'	'	'	'
JEJUNUM	'	'	'	'	'	'	'	'	'	-G
RECTUM	'	'	'	'	'	'	'	'	'	'
SKIN	'	'	'	'	'	'	'	'	'	'
EXORBITAL LACR.GLDS.	(G	'	'	'	'	'	'	'	'	'
- HARDERIANISATION	(2.									
THYMUS	'	'	'	'	'	'	'	'	'	'
LYMPH NODES	'	'	'	'	'	'	'	'	'	'
MESENT. LYMPH NODE	'	'	'	'	'	'	'	'	'	'
MANDIBUL. LYMPH NODE	'	'	'	'	'	'	'	'	'	'
THYROID GLAND	'	'	'	'	'	'	'	'	'	'

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.

PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TABLE OF INDIVIDUAL MICROSCOPIC FINDINGS
DOSE GROUP : 04, 200 MG/KG

ANIMAL NUMBER :	21	22	23	24	25	56	57	58	59	60
	1K0	1K0	1K0	1K0	1K0	2K0	2K0	2K0	2K0	2K0
GENERAL OBSERVATIONS	'	'	'	'	'	'	'	'	'	'
PEER REVIEW	'	'	'	'	'	'	'	'	'	'
CAUSE OF DEATH	'	'	'	'	'	'	'	'	'	'
HEART	'	'	'	'	'	'	'	'	'	'
LIVER	'	'	'	'	'	'	'	'	'	'
SPLEEN	'	'	'	'	'	'	'	'	'	'
KIDNEYS	G	G	G	G	G	G	-G	G	G	G
- TUBULE BASOPH.DEGEN.	.	.	(2.	(1.	1.	.	.	(1.	(1.	.
- HYALINE DROPLETS	2.	2.	.	2.	2.	.	.	.	.	.
- HYDRONEPHROSIS	.	.	.	(3.	.	.	.	.	.	.
- MINERALISATION	.	.	.	.	.	1.	.	1.	2.	1.
- UROTHEL.HYPERPLASIA	.	.	.	(2.	.	.	.	.	.	.
STOMACH	'	'	'	'	'	'	'	-G	'	'
LUNGS	*	*	-*	*	-*	.	-*	-	.	.
- FOAMY MACROPHAGES	1.	1.	.	2.	.	1.	.	.	1.	1.
TESTES	'	'	'	'	'					
ADRENAL GLANDS	'	'	'	'	'	'	'	'	'	'
SEMINAL VESICLES	'	'	'	'	'					
PROSTATE	'	'	'	'	'					
OVARIES						'	'	'	(-G	'
UTERUS						'	G	G	'	'
- HYDROMETRA							.	2.		
- CYST(S)							P.	.		
DUODENUM	'	'	'	'	'	'	'	'	'	'

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.

PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TABLE OF INDIVIDUAL MICROSCOPIC FINDINGS
DOSE GROUP : 04, 200 MG/KG

ANIMAL NUMBER :	21	22	23	24	25	56	57	58	59	60
	1K0	1K0	1K0	1K0	1K0	2K0	2K0	2K0	2K0	2K0
JEJUNUM	'	'	'	G	'	'	'	'	'	'
- INFLAMMATION				2.						
RECTUM	'	'	'	'	'	G	'	'	'	'
- DISTENSION						P.				
SKIN	'	'	'	'	'	'	'	'	'	'
EXORBITAL LACR.GLDS.	'	'	'	'	'	'	'	'	'	'
THYMUS	'	'	'	'	'	'	'	'	-G	'
LYMPH NODES	'	'	'	'	'	'	'	'	'	'
MESENT. LYMPH NODE	G	-G	-G	G	-G	-G	-G	-G	-G	-G
- REACTIVE	2.	.	.	2.	.	.	.	.	.	.
MANDIBUL. LYMPH NODE	'	'	'	'	'	'	'	'	'	'
THYROID GLAND	'	'	'	'	'	'	'	'	'	'

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.
PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TABLE OF INDIVIDUAL MICROSCOPIC FINDINGS
DOSE GROUP : 05, 1000 MG/KG

ANIMAL NUMBER :	26	27	28	29	30	31	32	33	34	35
	1K0	1K0	1K0	1K0	1K0	1R1	1R1	1R1	1R1	1R1
GENERAL OBSERVATIONS	'G	'G	'G	'G	'G	'G	'G	'G	'G	'G
PEER REVIEW	'	'	'	.	'	'	'	'	'	'
- WHOLE ANIMAL				P.						
CAUSE OF DEATH	'	'	'	'	'	'	'	'	'	'
HEART	-	-	-	-	-	.	-	-	-	-
- DEGENERATION	.	.	.	.	.	1.	.	.	.	.
LIVER	.	.	.	.	.	.	.	.	G	.
- LYMPHOID FOCI	1.	1.	1.	1.	1.	2.	1.	1.	.	1.
- DIFFUSE VACUOLATION	.	1.	.	.	.	.	.	.	.	2.
- FOCAL NECROSIS	.	.	.	.	.	.	.	.	3.	.
SPLEEN	-	-	-	-	-	-	-	-	-	-
KIDNEYS	*	*	*	*	*	*	G	*	*	*
- TUBULE BASOPH.DEGEN.	4.	4.	4.	4.	(1.	2.	3.	2.	2.	3.
- HYALINE DROPLETS	3.	3.	2.	2.	3.	3.	2.	2.	1.	.
- HYDRONEPHROSIS	.	.	.	.	.	.	(3.	.	.	.
STOMACH	-G	-	-	-	-	-	-	-	-	-
LUNGS	*	-*	*	G	-	.	.	-	.	.
- FOAMY MACROPHAGES	1.	.	2.	3.	.	1.	1.	.	2.	1.
- PIGMENT DEPOSITS	.	.	2.	3.	.	.	.	.	2.	.
- MINERALISED FOCI	.	.	.	.	.	.	.	.	1.	.
- ALVEOLAR HAEMORRHAGE	1.	.	.	.	.	.	.	.	.	.
TESTES	-	-	-	-	-	-	-	-	-	-
ADRENAL GLANDS	-	-	-	-	-	.	-	-	-	-
- CORTICAL VACUOLATION	.	.	.	.	.	2.	.	.	.	.
SEMINAL VESICLES	'	'	'	'	'	'	'	'	'	'
PROSTATE	'	'	'	'	'	'	'	'	'	'

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.

PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TABLE OF INDIVIDUAL MICROSCOPIC FINDINGS
DOSE GROUP : 05, 1000 MG/KG

ANIMAL NUMBER :	26	27	28	29	30	31	32	33	34	35
	1K0	1K0	1K0	1K0	1K0	1R1	1R1	1R1	1R1	1R1
DUODENUM	'	'	'	'	'	'	'	'	'	'
JEJUNUM	'	'	'	'	'	'	'	'	'	'
RECTUM	'	'	'	'	'	'	'	'	'	'
SKIN	'	'	'	'	'	'	'	'	'	'
EXORBITAL LACR.GLDS.	'	'	'	'	'	'	'	'	'	'
THYMUS	'	'	'	'	'	'	'	'	'	'
LYMPH NODES	'	'	'	'	'	'	'	'	'	'
MESENT. LYMPH NODE	'	'	'	'	'	'	'	'	'	'
MANDIBUL. LYMPH NODE	'	(-G	'	'	(-G	'	'	'	'	'
THYROID GLAND	'	'	'	'	'	'	'	'	'	'

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.

PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TABLE OF INDIVIDUAL MICROSCOPIC FINDINGS
DOSE GROUP : 05, 1000 MG/KG

ANIMAL NUMBER :

	61	62	63	64	65	66	67	68	69	70
	2K0	2K0	2K0	2K0	2K0	2R1	2R1	2R1	2R1	2R1
GENERAL OBSERVATIONS	'G	'G	'G	'G	'G	'G	'G	'G	'G	'G
PEER REVIEW	.	.	.	.	.	.	.	.	.	.
CAUSE OF DEATH	'	'	'	'	'	'	'	'	'	'
HEART	-	.	-	-	-	-	-	.	.	-
- DEGENERATION	.	1.	.	.	.	.	.	1.	1.	.
LIVER	.	.	.	.	.	.	.	.	.	.
- LYMPHOID FOCI	1.	1.	2.	1.	1.	.	1.	2.	1.	1.
- FOCAL VACUOLATION	.	.	.	.	.	.	.	.	1.	.
- DIFFUSE VACUOLATION	2.	1.	2.	.	2.	1.	1.	.	1.	1.
- HAEMATOPOIESIS	.	1.	.	.	1.	.	.	.	.	.
- FOCAL NECROSIS	.	.	.	.	.	.	.	1.	.	.
- INFLAMMATION	.	.	.	.	.	.	.	.	1.	.
SPLEEN	-	-	-	-	-	-	-	-	-	-
KIDNEYS	*	*	*	*	*	.	.	.	.	.
- TUBULE BASOPH.DEGEN.	3.	3.	3.	3.	2.	2.	2.	2.	2.	2.
- HYALINE DROPLETS	2.	2.	2.	2.	2.	1.	2.	.	1.	2.
- MINERALISATION	2.	2.	.	(1.	2.	2.	.	2.	(1.	.
STOMACH	-	-	G	-	-	-	-	-	-	-
- INFLAMMATION	.	.	2.	.	.	.	.	.	.	.
LUNGS	*	*	*	*	-*	-	.	-	-	.
- FOAMY MACROPHAGES	1.	1.	1.	1.	.	.	1.	.	.	1.
ADRENAL GLANDS	-	-	-	-	-	-	-	-	-	-
OVARIES	'	'	'	'	'	'	'	'	'	'
UTERUS	'	'	'	'	G	'	'	'	'	'
- HYDROMETRA					3.					
DUODENUM	'	'	'	'	'	'	'	'	'	'

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.
PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TABLE OF INDIVIDUAL MICROSCOPIC FINDINGS
DOSE GROUP : 05, 1000 MG/KG

ANIMAL NUMBER :	61	62	63	64	65	66	67	68	69	70
	2K0	2K0	2K0	2K0	2K0	2R1	2R1	2R1	2R1	2R1
JEJUNUM	'	'	'	'	'	'	'	'	'	'
RECTUM	'	'	'	'	'	'	'	'	'	'
SKIN	'	'	'	'	'	'	'	'	'	'
EXORBITAL LACR.GLDS.	'	'	'	'	'	'	'	'	'	'
THYMUS	'	'	'	'	'	'	'	'	'	'
LYMPH NODES	'	'	'	'	'	'	'	'	'	'
MESENT. LYMPH NODE	'	'	'	'	'	'	'	'	'	'
MANDIBUL. LYMPH NODE	'	'	'	(-G	'	'	'	'	'	'
THYROID GLAND	'	'	'	'	'	'	'	'	'	'

END OF SECTION

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.

PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

ANIMAL HEADING DATA
DOSE GROUP : 01, 0 MG/KG

ANIMAL NUMBER	SEX M/F	DEFINED AND FINAL STATE OF NECROPSY		TEST DAYS	FIRST AND LAST DAY UNDER TEST		DATE OF NECROPSY
1	M	K0	K0	28	14-JUN-94	11-JUL-94	12-JUL-94
2	M	K0	K0	28	14-JUN-94	11-JUL-94	12-JUL-94
3	M	K0	+1	28	14-JUN-94	11-JUL-94	12-JUL-94
4	M	K0	K0	28	14-JUN-94	11-JUL-94	12-JUL-94
5	M	K0	K0	28	14-JUN-94	11-JUL-94	12-JUL-94
6	M	R1	R1	28	14-JUN-94	11-JUL-94	26-JUL-94
7	M	R1	R1	28	14-JUN-94	11-JUL-94	26-JUL-94
8	M	R1	R1	28	14-JUN-94	11-JUL-94	26-JUL-94
9	M	R1	R1	28	14-JUN-94	11-JUL-94	26-JUL-94
10	M	R1	R1	28	14-JUN-94	11-JUL-94	26-JUL-94
36	F	K0	K0	28	14-JUN-94	11-JUL-94	12-JUL-94
37	F	K0	K0	28	14-JUN-94	11-JUL-94	12-JUL-94
38	F	K0	K0	28	14-JUN-94	11-JUL-94	12-JUL-94
39	F	K0	K0	28	14-JUN-94	11-JUL-94	12-JUL-94
40	F	K0	K0	28	14-JUN-94	11-JUL-94	12-JUL-94
41	F	R1	R1	28	14-JUN-94	11-JUL-94	26-JUL-94
42	F	R1	R1	28	14-JUN-94	11-JUL-94	26-JUL-94
43	F	R1	R1	28	14-JUN-94	11-JUL-94	26-JUL-94
44	F	R1	R1	28	14-JUN-94	11-JUL-94	26-JUL-94
45	F	R1	R1	28	14-JUN-94	11-JUL-94	26-JUL-94

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.
PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 01, 0 MG/KG MALE

* STATE AT NECROPSY: K0
DAYS ON TEST : 28 * ANIMAL NO. : 1

* NECROPSY FINDINGS

NO NECROPSY FINDINGS NOTED

* MICROSCOPIC FINDINGS

LIVER:
-LYMPHOID FOCI, GRADE 1
KIDNEYS:
#
-HYALINE DROPLETS, GRADE 3
LUNGS:
#
ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS

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* STATE AT NECROPSY: K0
DAYS ON TEST : 28 * ANIMAL NO. : 2

* NECROPSY FINDINGS

NO NECROPSY FINDINGS NOTED

* MICROSCOPIC FINDINGS

LIVER:
-LYMPHOID FOCI, GRADE 1
-DIFFUSE VACUOLATION, GRADE 1
KIDNEYS:
#
-HYALINE DROPLETS, GRADE 1

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.
PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 01, 0 MG/KG MALE

CONT./FF. ANIMAL NO. : 2

LUNGS:
#
ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS

* STATE AT NECROPSY: K0/+1
DAYS ON TEST : 28
* ANIMAL NO. : 3

* NECROPSY FINDINGS

THYMUS:
FOCUS/FOCI, ISOLATED, D=1 MM, REDDISH.
ALL OTHER ORGANS WITHOUT NECROPSY FINDINGS

* MICROSCOPIC FINDINGS

CAUSE OF DEATH, CONTRIBUTORY FACTORS:
-NOT DETERMINABLE
LIVER:
-LYMPHOID FOCI, GRADE 1
KIDNEYS:
#
-TUBULAR BASOPHILIA/DEGENERATION, UNILATERAL, GRADE 1
-HYALINE DROPLETS, GRADE 2
LUNGS:
#
-FOAMY MACROPHAGE ACCUMULATIONS, GRADE 1
THYMUS:
PASSIVE CONGESTION.
ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.
PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 01, 0 MG/KG MALE

* STATE AT NECROPSY: K0
DAYS ON TEST : 28 * ANIMAL NO. : 4

* NECROPSY FINDINGS

JEJUNUM:
MUCOSA: DISCOLORATION, REDDISH.
ALL OTHER ORGANS WITHOUT NECROPSY FINDINGS

* MICROSCOPIC FINDINGS

LIVER:
-LYMPHOID FOCI, GRADE 2
KIDNEYS:
#
-HYALINE DROPLETS, GRADE 1
LUNGS:
#
JEJUNUM:
AUTOLYTIC.
ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS

---

* STATE AT NECROPSY: K0
DAYS ON TEST : 28 * ANIMAL NO. : 5

* NECROPSY FINDINGS

SEMINAL VESICLES:
RIGHT SIDE: DISCOLORATION, REDDISH.
ALL OTHER ORGANS WITHOUT NECROPSY FINDINGS

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.
PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 01, 0 MG/KG MALE

CONT./FF. ANIMAL NO. : 5

* MICROSCOPIC FINDINGS

LIVER:
-LYMPHOID FOCI, GRADE 1
KIDNEYS:
#
-HYALINE DROPLETS, GRADE 1
LUNGS:
#
-FOAMY MACROPHAGE ACCUMULATIONS, GRADE 1
SEMINAL VESICLES:
ONLY ONE OF PAIRED ORGANS EXAMINED/PRESENT
NO MICROSCOPIC FINDING CORRESPONDING TO GROSS OBSERVATION.
ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS

---

* STATE AT NECROPSY: R1
DAYS ON TEST : 28 * ANIMAL NO. : 6

* NECROPSY FINDINGS

NO NECROPSY FINDINGS NOTED

* MICROSCOPIC FINDINGS

LIVER:
-LYMPHOID FOCI, GRADE 1
-DIFFUSE VACUOLATION, GRADE 1
KIDNEYS:
#
-HYALINE DROPLETS, GRADE 1
ADRENAL GLANDS:
-CORTICAL VACUOLATION, GRADE 2
ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.

PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 01, 0 MG/KG

MALE

* STATE AT NECROPSY: R1
DAYS ON TEST : 28

* ANIMAL NO. : 7

* NECROPSY FINDINGS

NO NECROPSY FINDINGS NOTED

* MICROSCOPIC FINDINGS

LIVER:
-LYMPHOID FOCI, GRADE 2
-DIFFUSE VACUOLATION, GRADE 1
KIDNEYS:
#
-HYALINE DROPLETS, GRADE 2
LUNGS:
-FOAMY MACROPHAGE ACCUMULATIONS, GRADE 1
ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS

---

* STATE AT NECROPSY: R1
DAYS ON TEST : 28

* ANIMAL NO. : 8

* NECROPSY FINDINGS

NO NECROPSY FINDINGS NOTED

* MICROSCOPIC FINDINGS

HEART:
-DEGENERATION, GRADE 1
LIVER:
-LYMPHOID FOCI, GRADE 1

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.

PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 01, 0 MG/KG

MALE

CONT./FF. ANIMAL NO. : 8

KIDNEYS:
#
-HYALINE DROPLETS, GRADE 1
STOMACH:
-INFLAMMATION, GRADE 2
ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS

* STATE AT NECROPSY: R1
DAYS ON TEST : 28

* ANIMAL NO. : 9

* NECROPSY FINDINGS

NO NECROPSY FINDINGS NOTED

* MICROSCOPIC FINDINGS

LIVER:
-LYMPHOID FOCI, GRADE 2
KIDNEYS:
#
-TUBULAR BASOPHILIA/DEGENERATION, GRADE 2
-HYALINE DROPLETS, GRADE 1
LUNGS:
-FOAMY MACROPHAGE ACCUMULATIONS, GRADE 1
ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.

PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 01, 0 MG/KG MALE

* STATE AT NECROPSY: R1
DAYS ON TEST : 28 * ANIMAL NO. : 10

* NECROPSY FINDINGS

SKIN:
CERVICAL REGION: ALOPECIA, D=25X15 MM, MARKED.
ALL OTHER ORGANS WITHOUT NECROPSY FINDINGS

* MICROSCOPIC FINDINGS

LIVER:
-LYMPHOID FOCI, GRADE 1
KIDNEYS:
#
-HYALINE DROPLETS, GRADE 2
SKIN:
NO MICROSCOPIC FINDING CORRESPONDING TO GROSS OBSERVATION.
ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.
PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 01, 0 MG/KG FEMALE

* STATE AT NECROPSY: K0
DAYS ON TEST : 28 * ANIMAL NO. : 36

* NECROPSY FINDINGS

NO NECROPSY FINDINGS NOTED

* MICROSCOPIC FINDINGS

LIVER:
-LYMPHOID FOCI, GRADE 2
-DIFFUSE VACUOLATION, GRADE 1
KIDNEYS:
#
-MINERALISATION, GRADE 2
LUNGS:
-FOAMY MACROPHAGE ACCUMULATIONS, GRADE 1
ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS

---

* STATE AT NECROPSY: K0
DAYS ON TEST : 28 * ANIMAL NO. : 37

* NECROPSY FINDINGS

NO NECROPSY FINDINGS NOTED

* MICROSCOPIC FINDINGS

LIVER:
-LYMPHOID FOCI, GRADE 1
-DIFFUSE VACUOLATION, GRADE 1
KIDNEYS:
#

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.

PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 01, 0 MG/KG

FEMALE

CONT./FF. ANIMAL NO. : 37

ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS

* STATE AT NECROPSY: KO
DAYS ON TEST : 28

* ANIMAL NO. : 38

* NECROPSY FINDINGS

OVARIES:
RIGHT SIDE: DISCOLORATION, REDDISH.
ALL OTHER ORGANS WITHOUT NECROPSY FINDINGS

* MICROSCOPIC FINDINGS

HEART:
-DEGENERATION, GRADE 1
LIVER:
-LYMPHOID FOCI, GRADE 1
-DIFFUSE VACUOLATION, GRADE 1
-HAEMATOPOIESIS, GRADE 1
KIDNEYS:
#
-MINERALISATION, UNILATERAL, GRADE 2
LUNGS:
-FOAMY MACROPHAGE ACCUMULATIONS, GRADE 1
OVARIES:
ONLY ONE OF PAIRED ORGANS EXAMINED/PRESENT
PASSIVE CONGESTION.
ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.
PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 01, 0 MG/KG FEMALE

* STATE AT NECROPSY: K0
DAYS ON TEST : 28 * ANIMAL NO. : 39

* NECROPSY FINDINGS

SKIN:
THIGH, LEFT SIDE: ALOPECIA, D=35X20 MM, MARKED.
ALL OTHER ORGANS WITHOUT NECROPSY FINDINGS

* MICROSCOPIC FINDINGS

LIVER:
-LYMPHOID FOCI, GRADE 1
KIDNEYS:
#
-TUBULAR BASOPHILIA/DEGENERATION, UNILATERAL, GRADE 1
-MINERALISATION, GRADE 2
LUNGS:
-FOAMY MACROPHAGE ACCUMULATIONS, GRADE 1
SKIN:
NO MICROSCOPIC FINDING CORRESPONDING TO GROSS OBSERVATION.
ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS

---

* STATE AT NECROPSY: K0
DAYS ON TEST : 28 * ANIMAL NO. : 40

* NECROPSY FINDINGS

NO NECROPSY FINDINGS NOTED

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.

PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 01, 0 MG/KG

FEMALE

CONT./FF. ANIMAL NO. : 40

* MICROSCOPIC FINDINGS

LIVER:
-LYMPHOID FOCI, GRADE 1
-DIFFUSE VACUOLATION, GRADE 1
KIDNEYS:
#
-MINERALISATION, GRADE 2
LUNGS:
-FOAMY MACROPHAGE ACCUMULATIONS, GRADE 1
ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS

---

* STATE AT NECROPSY: R1
DAYS ON TEST : 28

* ANIMAL NO. : 41

* NECROPSY FINDINGS

NO NECROPSY FINDINGS NOTED

* MICROSCOPIC FINDINGS

LIVER:
-LYMPHOID FOCI, GRADE 1
-DIFFUSE VACUOLATION, GRADE 1
KIDNEYS:
-MINERALISATION, GRADE 2
LUNGS:
-FOAMY MACROPHAGE ACCUMULATIONS, GRADE 1
ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.
PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 01, 0 MG/KG FEMALE

* STATE AT NECROPSY: R1
DAYS ON TEST : 28 * ANIMAL NO. : 42

* NECROPSY FINDINGS

NO NECROPSY FINDINGS NOTED

* MICROSCOPIC FINDINGS

HEART:
-DEGENERATION, GRADE 1
LIVER:
-LYMPHOID FOCI, GRADE 2
-DIFFUSE VACUOLATION, GRADE 1
-HAEMATOPOIESIS, GRADE 1
SPLEEN:
-HAEMATOPOIESIS, GRADE 1
KIDNEYS:
-MINERALISATION, GRADE 1
STOMACH:
ORGAN EXAMINED, NO PATHOLOGIC FINDINGS NOTED
LUNGS:
ORGAN EXAMINED, NO PATHOLOGIC FINDINGS NOTED
ADRENAL GLANDS:
ORGAN EXAMINED, NO PATHOLOGIC FINDINGS NOTED

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.
PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 01, 0 MG/KG FEMALE

* STATE AT NECROPSY: R1
DAYS ON TEST : 28 * ANIMAL NO. : 43

* NECROPSY FINDINGS

NO NECROPSY FINDINGS NOTED

* MICROSCOPIC FINDINGS

LIVER:
-LYMPHOID FOCI, GRADE 1
-DIFFUSE VACUOLATION, GRADE 1
KIDNEYS:
-TUBULAR BASOPHILIA/DEGENERATION, UNILATERAL, GRADE 1
-MINERALISATION, GRADE 2
ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS

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* STATE AT NECROPSY: R1
DAYS ON TEST : 28 * ANIMAL NO. : 44

* NECROPSY FINDINGS

THYMUS:
FOCUS/FOCI, ISOLATED, D=1 MM, REDDISH.
ALL OTHER ORGANS WITHOUT NECROPSY FINDINGS

* MICROSCOPIC FINDINGS

LIVER:
-LYMPHOID FOCI, GRADE 1
-DIFFUSE VACUOLATION, GRADE 2
KIDNEYS:
-MINERALISATION, GRADE 1

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.

PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 01, 0 MG/KG FEMALE

CONT./FF. ANIMAL NO. : 44

THYMUS:
NO MICROSCOPIC FINDING CORRESPONDING TO GROSS OBSERVATION.
ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS

* STATE AT NECROPSY: R1
DAYS ON TEST : 28

* ANIMAL NO. : 45

* NECROPSY FINDINGS

STOMACH:
FUNDUS, MUCOSA: FOCUS/FOCI, D=3X1 MM, BLACK.
ALL OTHER ORGANS WITHOUT NECROPSY FINDINGS

* MICROSCOPIC FINDINGS

HEART:
ORGAN EXAMINED, NO PATHOLOGIC FINDINGS NOTED
LIVER:
-LYMPHOID FOCI, GRADE 1
-DIFFUSE VACUOLATION, GRADE 1
SPLEEN:
ORGAN EXAMINED, NO PATHOLOGIC FINDINGS NOTED
KIDNEYS:
-MINERALISATION, UNILATERAL, GRADE 1
STOMACH:
-EROSION(S), GRADE 2
LUNGS:
-FOAMY MACROPHAGE ACCUMULATIONS, GRADE 1
ADRENAL GLANDS:
ORGAN EXAMINED, NO PATHOLOGIC FINDINGS NOTED

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.

PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

ANIMAL HEADING DATA
DOSE GROUP : 02, 10 MG/KG

ANIMAL NUMBER	SEX M/F	DEFINED AND FINAL STATE OF NECROPSY		TEST DAYS	FIRST AND LAST DAY UNDER TEST		DATE OF NECROPSY
11	M	K0	K0	28	14-JUN-94	11-JUL-94	12-JUL-94
12	M	K0	K0	28	14-JUN-94	11-JUL-94	12-JUL-94
13	M	K0	K0	28	14-JUN-94	11-JUL-94	12-JUL-94
14	M	K0	K0	28	14-JUN-94	11-JUL-94	12-JUL-94
15	M	K0	K0	28	14-JUN-94	11-JUL-94	12-JUL-94
46	F	K0	K0	28	14-JUN-94	11-JUL-94	12-JUL-94
47	F	K0	K0	28	14-JUN-94	11-JUL-94	12-JUL-94
48	F	K0	K0	28	14-JUN-94	11-JUL-94	12-JUL-94
49	F	K0	K0	28	14-JUN-94	11-JUL-94	12-JUL-94
50	F	K0	K0	28	14-JUN-94	11-JUL-94	12-JUL-94

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.

PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 02, 10 MG/KG MALE

* STATE AT NECROPSY: KO
DAYS ON TEST : 28 * ANIMAL NO. : 11

* NECROPSY FINDINGS

NO NECROPSY FINDINGS NOTED

* MICROSCOPIC FINDINGS

KIDNEYS:
-TUBULAR BASOPHILIA/DEGENERATION, GRADE 1
-HYALINE DROPLETS, GRADE 2
-LYMPHOID FOCI, UNILATERAL, GRADE 1
LUNGS:
-FOAMY MACROPHAGE ACCUMULATIONS, GRADE 1

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* STATE AT NECROPSY: KO
DAYS ON TEST : 28 * ANIMAL NO. : 12

* NECROPSY FINDINGS

NO NECROPSY FINDINGS NOTED

* MICROSCOPIC FINDINGS

KIDNEYS:
-HYALINE DROPLETS, GRADE 2
LUNGS:
ORGAN EXAMINED, NO PATHOLOGIC FINDINGS NOTED

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.
PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 02, 10 MG/KG MALE

* STATE AT NECROPSY: K0
DAYS ON TEST : 28 * ANIMAL NO. : 13

* NECROPSY FINDINGS

NO NECROPSY FINDINGS NOTED

* MICROSCOPIC FINDINGS

KIDNEYS:
-HYALINE DROPLETS, GRADE 2
LUNGS:
-FOAMY MACROPHAGE ACCUMULATIONS, GRADE 2
-MINERALISED FOCI, OSTEOID, GRADE 1

---

* STATE AT NECROPSY: K0
DAYS ON TEST : 28 * ANIMAL NO. : 14

* NECROPSY FINDINGS

LUNGS:
LEFT LOBE: FOCUS/FOCI, D=5 MM, DARK RED.
ALL OTHER ORGANS WITHOUT NECROPSY FINDINGS

* MICROSCOPIC FINDINGS

KIDNEYS:
-HYALINE DROPLETS, GRADE 2
LUNGS:
-FOAMY MACROPHAGE ACCUMULATIONS, GRADE 1

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.
PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 02, 10 MG/KG MALE

* STATE AT NECROPSY: K0
DAYS ON TEST : 28 * ANIMAL NO. : 15

* NECROPSY FINDINGS

MANDIBULAR LYMPH NODE:
FOCUS/FOCI, ISOLATED, D=1 MM, DARK RED.
ALL OTHER ORGANS WITHOUT NECROPSY FINDINGS

* MICROSCOPIC FINDINGS

KIDNEYS:
-HYALINE DROPLETS, GRADE 2
LUNGS:
-FOAMY MACROPHAGE ACCUMULATIONS, GRADE 1
MANDIBULAR LYMPH NODE:
ONLY ONE OF PAIRED ORGANS EXAMINED/PRESENT
-REACTIVE, UNILATERAL, GRADE 2

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.
PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 02, 10 MG/KG FEMALE

* STATE AT NECROPSY: K0
DAYS ON TEST : 28 * ANIMAL NO. : 46

* NECROPSY FINDINGS

NO NECROPSY FINDINGS NOTED

* MICROSCOPIC FINDINGS

KIDNEYS:
ORGAN EXAMINED, NO PATHOLOGIC FINDINGS NOTED
LUNGS:
ORGAN EXAMINED, NO PATHOLOGIC FINDINGS NOTED
COLLAPSED SECTION, UNPERFUSED WITH FIXATIVE.

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* STATE AT NECROPSY: K0
DAYS ON TEST : 28 * ANIMAL NO. : 47

* NECROPSY FINDINGS

KIDNEYS:
BOTH SIDES: PELVIC DILATION.
UTERUS:
RIGHT HORN: DISTENDED, D=4 MM.
BOTH HORNS: CONTAINS FLUID.
ALL OTHER ORGANS WITHOUT NECROPSY FINDINGS

* MICROSCOPIC FINDINGS

KIDNEYS:
NO MICROSCOPIC FINDING CORRESPONDING TO GROSS OBSERVATION.
-TUBULAR BASOPHILIA/DEGENERATION, UNILATERAL, GRADE 1

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.
PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 02, 10 MG/KG FEMALE

CONT./FF. ANIMAL NO. : 47

LUNGS:
ORGAN EXAMINED, NO PATHOLOGIC FINDINGS NOTED
COLLAPSED SECTION, UNPERFUSED WITH FIXATIVE.
UTERUS:
-HYDROMETRA, GRADE 3

* STATE AT NECROPSY: KO
DAYS ON TEST : 28
* ANIMAL NO. : 48

* NECROPSY FINDINGS

UTERUS:
BOTH HORNS: DILATION, D=5 MM.
MANDIBULAR LYMPH NODE:
DISCOLORATION, REDDISH.
ALL OTHER ORGANS WITHOUT NECROPSY FINDINGS

* MICROSCOPIC FINDINGS

KIDNEYS:
-TUBULAR BASOPHILIA/DEGENERATION, GRADE 2
-MINERALISATION, GRADE 2
LUNGS:
-FOAMY MACROPHAGE ACCUMULATIONS, GRADE 1
UTERUS:
-HYDROMETRA, GRADE 3
MANDIBULAR LYMPH NODE:
-REACTIVE, GRADE 2

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.
PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 02, 10 MG/KG FEMALE

* STATE AT NECROPSY: K0
DAYS ON TEST : 28 * ANIMAL NO. : 49

* NECROPSY FINDINGS

UTERUS:
BOTH HORNS: DILATION, D=5 MM.
ALL OTHER ORGANS WITHOUT NECROPSY FINDINGS

* MICROSCOPIC FINDINGS

KIDNEYS:
-MINERALISATION, GRADE 1
LUNGS:
ORGAN EXAMINED, NO PATHOLOGIC FINDINGS NOTED
UTERUS:
-HYDROMETRA, GRADE 3

---

* STATE AT NECROPSY: K0
DAYS ON TEST : 28 * ANIMAL NO. : 50

* NECROPSY FINDINGS

NO NECROPSY FINDINGS NOTED

* MICROSCOPIC FINDINGS

KIDNEYS:
-MINERALISATION, GRADE 2
LUNGS:
ORGAN EXAMINED, NO PATHOLOGIC FINDINGS NOTED

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.

PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

ANIMAL HEADING DATA
DOSE GROUP : 03, 50 MG/KG

ANIMAL NUMBER	SEX M/F	DEFINED AND FINAL STATE OF NECROPSY		TEST DAYS	FIRST AND LAST DAY UNDER TEST		DATE OF NECROPSY
16	M	K0	K0	28	14-JUN-94	11-JUL-94	12-JUL-94
17	M	K0	K0	28	14-JUN-94	11-JUL-94	12-JUL-94
18	M	K0	K0	28	14-JUN-94	11-JUL-94	12-JUL-94
19	M	K0	K0	28	14-JUN-94	11-JUL-94	12-JUL-94
20	M	K0	K0	28	14-JUN-94	11-JUL-94	12-JUL-94
51	F	K0	K0	28	14-JUN-94	11-JUL-94	12-JUL-94
52	F	K0	K0	28	14-JUN-94	11-JUL-94	12-JUL-94
53	F	K0	K0	28	14-JUN-94	11-JUL-94	12-JUL-94
54	F	K0	K0	28	14-JUN-94	11-JUL-94	12-JUL-94
55	F	K0	K0	28	14-JUN-94	11-JUL-94	12-JUL-94

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.
PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 03, 50 MG/KG MALE

* STATE AT NECROPSY: K0
DAYS ON TEST : 28 * ANIMAL NO. : 16

* NECROPSY FINDINGS

KIDNEYS:
PELVIC DILATION.
EXORBITAL LACRIMAL GLANDS:
LEFT SIDE: FOCUS/FOCI, ISOLATED, D=1 MM, GRAY WHITE.
ALL OTHER ORGANS WITHOUT NECROPSY FINDINGS

* MICROSCOPIC FINDINGS

KIDNEYS:
-HYALINE DROPLETS, GRADE 2
-HYDRONEPHROSIS, UNILATERAL, GRADE 2
LUNGS:
-FOAMY MACROPHAGE ACCUMULATIONS, GRADE 1
EXORBITAL LACRIMAL GLANDS:
ONLY ONE OF PAIRED ORGANS EXAMINED/PRESENT
-HARDERIANISATION, MULTIFOCAL, UNILATERAL, GRADE 2

* STATE AT NECROPSY: K0
DAYS ON TEST : 28 * ANIMAL NO. : 17

* NECROPSY FINDINGS

NO NECROPSY FINDINGS NOTED

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.

PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 03, 50 MG/KG MALE

CONT./FF. ANIMAL NO. : 17

* MICROSCOPIC FINDINGS

KIDNEYS:
-HYALINE DROPLETS, GRADE 2
LUNGS:
-FOAMY MACROPHAGE ACCUMULATIONS, GRADE 2
-INFLAMMATION, GRADE 1

* STATE AT NECROPSY: K0
DAYS ON TEST : 28 * ANIMAL NO. : 18

* NECROPSY FINDINGS

KIDNEYS:
PELVIC DILATION.
ALL OTHER ORGANS WITHOUT NECROPSY FINDINGS

* MICROSCOPIC FINDINGS

KIDNEYS:
-TUBULAR BASOPHILIA/DEGENERATION, UNILATERAL, GRADE 1
-HYALINE DROPLETS, GRADE 2
-HYDRONEPHROSIS, UNILATERAL, GRADE 2
LUNGS:
-FOAMY MACROPHAGE ACCUMULATIONS, GRADE 1

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.
PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 03, 50 MG/KG MALE

* STATE AT NECROPSY: K0
DAYS ON TEST : 28 * ANIMAL NO. : 19

* NECROPSY FINDINGS

NO NECROPSY FINDINGS NOTED

* MICROSCOPIC FINDINGS

KIDNEYS:
-HYALINE DROPLETS, GRADE 3
LUNGS:
-MINERALISED FOCI, OSTEOID, GRADE 2

* STATE AT NECROPSY: K0
DAYS ON TEST : 28 * ANIMAL NO. : 20

* NECROPSY FINDINGS

NO NECROPSY FINDINGS NOTED

* MICROSCOPIC FINDINGS

KIDNEYS:
-HYALINE DROPLETS, GRADE 2
LUNGS:
ORGAN EXAMINED, NO PATHOLOGIC FINDINGS NOTED

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.
PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 03, 50 MG/KG FEMALE

* STATE AT NECROPSY: K0
DAYS ON TEST : 28 * ANIMAL NO. : 51

* NECROPSY FINDINGS

UTERUS:
RIGHT HORN: DILATION, D=4 MM.
RIGHT HORN: DISCOLORATION, REDDISH.
ALL OTHER ORGANS WITHOUT NECROPSY FINDINGS

* MICROSCOPIC FINDINGS

KIDNEYS:
-TUBULAR BASOPHILIA/DEGENERATION, UNILATERAL, GRADE 1
-MINERALISATION, GRADE 2
LUNGS:
ORGAN EXAMINED, NO PATHOLOGIC FINDINGS NOTED
UTERUS:
-INFLAMMATION, GRADE 1

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* STATE AT NECROPSY: K0
DAYS ON TEST : 28 * ANIMAL NO. : 52

* NECROPSY FINDINGS

NO NECROPSY FINDINGS NOTED

* MICROSCOPIC FINDINGS

KIDNEYS:
-TUBULAR BASOPHILIA/DEGENERATION, UNILATERAL, GRADE 1
-MINERALISATION, GRADE 2

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.

PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 03, 50 MG/KG FEMALE

CONT./FF. ANIMAL NO. : 52

LUNGS:
-FOAMY MACROPHAGE ACCUMULATIONS, GRADE 1

* STATE AT NECROPSY: K0
DAYS ON TEST : 28 * ANIMAL NO. : 53

* NECROPSY FINDINGS

UTERUS:
BOTH HORNS: DILATION, D=5 MM.
ALL OTHER ORGANS WITHOUT NECROPSY FINDINGS

* MICROSCOPIC FINDINGS

KIDNEYS:
-MINERALISATION, GRADE 1
LUNGS:
ORGAN EXAMINED, NO PATHOLOGIC FINDINGS NOTED
UTERUS:
-HYDROMETRA, GRADE 3

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.
PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 03, 50 MG/KG FEMALE

* STATE AT NECROPSY: K0
DAYS ON TEST : 28 * ANIMAL NO. : 54

* NECROPSY FINDINGS

NO NECROPSY FINDINGS NOTED

* MICROSCOPIC FINDINGS

KIDNEYS:
-TUBULAR BASOPHILIA/DEGENERATION, UNILATERAL, GRADE 2
LUNGS:
-FOAMY MACROPHAGE ACCUMULATIONS, GRADE 1

---

* STATE AT NECROPSY: K0
DAYS ON TEST : 28 * ANIMAL NO. : 55

* NECROPSY FINDINGS

JEJUNUM:
MUCOSA: DISCOLORATION, REDDISH.
ALL OTHER ORGANS WITHOUT NECROPSY FINDINGS

* MICROSCOPIC FINDINGS

KIDNEYS:
-TUBULAR BASOPHILIA/DEGENERATION, UNILATERAL, GRADE 1
-MINERALISATION, GRADE 3
LUNGS:
ORGAN EXAMINED, NO PATHOLOGIC FINDINGS NOTED
JEJUNUM:
ORGAN EXAMINED, NO PATHOLOGIC FINDINGS NOTED
AUTOLYTIC.
PASSIVE CONGESTION.

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.

PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 03, 50 MG/KG

FEMALE

CONT./FF. ANIMAL NO. : 55

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.

PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

ANIMAL HEADING DATA
DOSE GROUP : 04, 200 MG/KG

ANIMAL NUMBER	SEX M/F	DEFINED AND FINAL STATE OF NECROPSY		TEST DAYS	FIRST AND LAST DAY UNDER TEST		DATE OF NECROPSY
21	M	K0	K0	28	14-JUN-94	11-JUL-94	12-JUL-94
22	M	K0	K0	28	14-JUN-94	11-JUL-94	12-JUL-94
23	M	K0	K0	28	14-JUN-94	11-JUL-94	12-JUL-94
24	M	K0	K0	28	14-JUN-94	11-JUL-94	12-JUL-94
25	M	K0	K0	28	14-JUN-94	11-JUL-94	12-JUL-94
56	F	K0	K0	28	14-JUN-94	11-JUL-94	12-JUL-94
57	F	K0	K0	28	14-JUN-94	11-JUL-94	12-JUL-94
58	F	K0	K0	28	14-JUN-94	11-JUL-94	12-JUL-94
59	F	K0	K0	28	14-JUN-94	11-JUL-94	12-JUL-94
60	F	K0	K0	28	14-JUN-94	11-JUL-94	12-JUL-94

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.

PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 04, 200 MG/KG

MALE

* STATE AT NECROPSY: KO
DAYS ON TEST : 28 * ANIMAL NO. : 21

* NECROPSY FINDINGS

KIDNEYS:
BOTH SIDES: DISCOLORATION, REDDISH.
MESENTERIC LYMPH NODE:
DISCOLORATION, REDDISH.
ALL OTHER ORGANS WITHOUT NECROPSY FINDINGS

* MICROSCOPIC FINDINGS

KIDNEYS:
NO MICROSCOPIC FINDING CORRESPONDING TO GROSS OBSERVATION.
#
-HYALINE DROPLETS, GRADE 2
LUNGS:
#
-FOAMY MACROPHAGE ACCUMULATIONS, GRADE 1
MESENTERIC LYMPH NODE:
-REACTIVE, GRADE 2

---

* STATE AT NECROPSY: KO
DAYS ON TEST : 28 * ANIMAL NO. : 22

* NECROPSY FINDINGS

KIDNEYS:
BOTH SIDES: DISCOLORATION, REDDISH.
MESENTERIC LYMPH NODE:
DISCOLORATION, REDDISH.
ALL OTHER ORGANS WITHOUT NECROPSY FINDINGS

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.
PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 04, 200 MG/KG MALE

CONT./FF. ANIMAL NO. : 22

* MICROSCOPIC FINDINGS

KIDNEYS:
NO MICROSCOPIC FINDING CORRESPONDING TO GROSS OBSERVATION.
#
-HYALINE DROPLETS, GRADE 2
LUNGS:
#
-FOAMY MACROPHAGE ACCUMULATIONS, GRADE 1
MESENTERIC LYMPH NODE:
ORGAN EXAMINED, NO PATHOLOGIC FINDINGS NOTED
NO MICROSCOPIC FINDING CORRESPONDING TO GROSS OBSERVATION.

---

* STATE AT NECROPSY: K0
DAYS ON TEST : 28
* ANIMAL NO. : 23

* NECROPSY FINDINGS

KIDNEYS:
BOTH SIDES: DISCOLORATION, REDDISH.
MESENTERIC LYMPH NODE:
DISCOLORATION, REDDISH.
ALL OTHER ORGANS WITHOUT NECROPSY FINDINGS

* MICROSCOPIC FINDINGS

KIDNEYS:
NO MICROSCOPIC FINDING CORRESPONDING TO GROSS OBSERVATION.
#
-TUBULAR BASOPHILIA/DEGENERATION, UNILATERAL, GRADE 2
LUNGS:
ORGAN EXAMINED, NO PATHOLOGIC FINDINGS NOTED
#

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.

PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 04, 200 MG/KG MALE

CONT./FF. ANIMAL NO. : 23

MESENTERIC LYMPH NODE:
ORGAN EXAMINED, NO PATHOLOGIC FINDINGS NOTED
NO MICROSCOPIC FINDING CORRESPONDING TO GROSS OBSERVATION.

* STATE AT NECROPSY: K0
DAYS ON TEST : 28 * ANIMAL NO. : 24

* NECROPSY FINDINGS

KIDNEYS:
RIGHT SIDE: PELVIC DILATION.
BOTH SIDES: DISCOLORATION, REDDISH.
JEJUNUM:
MUCOSA: DISCOLORATION, REDDISH.
MESENTERIC LYMPH NODE:
DISCOLORATION, REDDISH.
ALL OTHER ORGANS WITHOUT NECROPSY FINDINGS

* MICROSCOPIC FINDINGS

KIDNEYS:
NO MICROSCOPIC FINDING CORRESPONDING TO GROSS OBSERVATION, "DISCOLORATION".
#
-TUBULAR BASOPHILIA/DEGENERATION, UNILATERAL, GRADE 1
-HYALINE DROPLETS, GRADE 2
-HYDRONEPHROSIS, UNILATERAL, GRADE 3
-UROTHELIAL HYPERPLLASIA, UNILATERAL, GRADE 2
LUNGS:
#
-FOAMY MACROPHAGE ACCUMULATIONS, GRADE 2

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.

PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 04, 200 MG/KG MALE

CONT./FF. ANIMAL NO. : 24

JEJUNUM:
-INFLAMMATION, GRADE 2
MESENTERIC LYMPH NODE:
-REACTIVE, GRADE 2

* STATE AT NECROPSY: K0
DAYS ON TEST : 28 * ANIMAL NO. : 25

* NECROPSY FINDINGS

KIDNEYS:
BOTH SIDES: DISCOLORATION, REDDISH.
MESENTERIC LYMPH NODE:
DISCOLORATION, REDDISH.
ALL OTHER ORGANS WITHOUT NECROPSY FINDINGS

* MICROSCOPIC FINDINGS

KIDNEYS:
NO MICROSCOPIC FINDING CORRESPONDING TO GROSS OBSERVATION.
#
-TUBULAR BASOPHILIA/DEGENERATION, GRADE 1
-HYALINE DROPLETS, GRADE 2
LUNGS:
ORGAN EXAMINED, NO PATHOLOGIC FINDINGS NOTED
COLLAPSED SECTION, UNPERFUSED WITH FIXATIVE.
#
MESENTERIC LYMPH NODE:
ORGAN EXAMINED, NO PATHOLOGIC FINDINGS NOTED
NO MICROSCOPIC FINDING CORRESPONDING TO GROSS OBSERVATION.

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.
PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 04, 200 MG/KG FEMALE

* STATE AT NECROPSY: KO
DAYS ON TEST : 28 * ANIMAL NO. : 56

* NECROPSY FINDINGS

KIDNEYS:
BOTH SIDES: DISCOLORATION, REDDISH.
RECTUM:
MUCOSA: DISCOLORATION, REDDISH.
MESENTERIC LYMPH NODE:
DISCOLORATION, REDDISH.
ALL OTHER ORGANS WITHOUT NECROPSY FINDINGS

* MICROSCOPIC FINDINGS

KIDNEYS:
NO MICROSCOPIC FINDING CORRESPONDING TO GROSS OBSERVATION.
#
-MINERALISATION, GRADE 1
LUNGS:
-FOAMY MACROPHAGE ACCUMULATIONS, GRADE 1
RECTUM:
-DISTENSION
MESENTERIC LYMPH NODE:
ORGAN EXAMINED, NO PATHOLOGIC FINDINGS NOTED
NO MICROSCOPIC FINDING CORRESPONDING TO GROSS OBSERVATION.

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.
PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 04, 200 MG/KG FEMALE

* STATE AT NECROPSY: KO
DAYS ON TEST : 28 * ANIMAL NO. : 57

* NECROPSY FINDINGS

KIDNEYS:
BOTH SIDES: DISCOLORATION, REDDISH.
UTERUS:
RIGHT HORN: WATERY CYST, D=4 MM.
MESENTERIC LYMPH NODE:
DISCOLORATION, REDDISH.
ALL OTHER ORGANS WITHOUT NECROPSY FINDINGS

* MICROSCOPIC FINDINGS

KIDNEYS:
ORGAN EXAMINED, NO PATHOLOGIC FINDINGS NOTED
NO MICROSCOPIC FINDING CORRESPONDING TO GROSS OBSERVATION.
#
LUNGS:
ORGAN EXAMINED, NO PATHOLOGIC FINDINGS NOTED
COLLAPSED SECTION, UNPERFUSED WITH FIXATIVE.
UTERUS:
-CYST(S)
MESENTERIC LYMPH NODE:
ORGAN EXAMINED, NO PATHOLOGIC FINDINGS NOTED
NO MICROSCOPIC FINDING CORRESPONDING TO GROSS OBSERVATION.

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.
PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 04, 200 MG/KG FEMALE

* STATE AT NECROPSY: K0
DAYS ON TEST : 28 * ANIMAL NO. : 58

* NECROPSY FINDINGS

KIDNEYS:
BOTH SIDES: DISCOLORATION, REDDISH.
STOMACH:
FUNDUS, MUCOSA: FOCUS/FOCI, ISOLATED, D=4X1 MM, REDDISH.
UTERUS:
RIGHT HORN: DISCOLORATION, REDDISH.
MESENTERIC LYMPH NODE:
DISCOLORATION, REDDISH.
ALL OTHER ORGANS WITHOUT NECROPSY FINDINGS

* MICROSCOPIC FINDINGS

KIDNEYS:
NO MICROSCOPIC FINDING CORRESPONDING TO GROSS OBSERVATION.
#
-TUBULAR BASOPHILIA/DEGENERATION, UNILATERAL, GRADE 1
-MINERALISATION, GRADE 1
STOMACH:
ORGAN EXAMINED, NO PATHOLOGIC FINDINGS NOTED
NO MICROSCOPIC FINDING CORRESPONDING TO GROSS OBSERVATION.
LUNGS:
ORGAN EXAMINED, NO PATHOLOGIC FINDINGS NOTED
UTERUS:
PASSIVE CONGESTION.
-HYDROMETRA, GRADE 2
MESENTERIC LYMPH NODE:
ORGAN EXAMINED, NO PATHOLOGIC FINDINGS NOTED
NO MICROSCOPIC FINDING CORRESPONDING TO GROSS OBSERVATION.

TEST ARTICLE : FAT 45'169/A PATHOL. NO.: 37288 MAR
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE) DATE : 26-NOV-94
SPONSOR : RCC LTD. PDS PATHDATA SYSTEM TM

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 04, 200 MG/KG FEMALE

* STATE AT NECROPSY: KO
DAYS ON TEST : 28 * ANIMAL NO. : 59

* NECROPSY FINDINGS

KIDNEYS:
BOTH SIDES: DISCOLORATION, REDDISH.
OVARIES:
RIGHT SIDE: DISCOLORATION, REDDISH.
THYMUS:
FOCUS/FOCI, SEVERAL, D=1 MM, REDDISH.
MESENTERIC LYMPH NODE:
DISCOLORATION, REDDISH.
ALL OTHER ORGANS WITHOUT NECROPSY FINDINGS

* MICROSCOPIC FINDINGS

KIDNEYS:
NO MICROSCOPIC FINDING CORRESPONDING TO GROSS OBSERVATION.
#
-TUBULAR BASOPHILIA/DEGENERATION, UNILATERAL, GRADE 1
-MINERALISATION, GRADE 2
LUNGS:
-FOAMY MACROPHAGE ACCUMULATIONS, GRADE 1
OVARIES:
ONLY ONE OF PAIRED ORGANS EXAMINED/PRESENT
ORGAN EXAMINED, NO PATHOLOGIC FINDINGS NOTED
PASSIVE CONGESTION.
THYMUS:
ORGAN EXAMINED, NO PATHOLOGIC FINDINGS NOTED
NO MICROSCOPIC FINDING CORRESPONDING TO GROSS OBSERVATION.
MESENTERIC LYMPH NODE:
ORGAN EXAMINED, NO PATHOLOGIC FINDINGS NOTED
NO MICROSCOPIC FINDING CORRESPONDING TO GROSS OBSERVATION.

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.
PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 04, 200 MG/KG FEMALE

* STATE AT NECROPSY: KO
DAYS ON TEST : 28 * ANIMAL NO. : 60

* NECROPSY FINDINGS

KIDNEYS:
BOTH SIDES: DISCOLORATION, REDDISH.
MESENTERIC LYMPH NODE:
DISCOLORATION, REDDISH.
ALL OTHER ORGANS WITHOUT NECROPSY FINDINGS

* MICROSCOPIC FINDINGS

KIDNEYS:
NO MICROSCOPIC FINDING CORRESPONDING TO GROSS OBSERVATION.
#
-MINERALISATION, GRADE 1
LUNGS:
-FOAMY MACROPHAGE ACCUMULATIONS, GRADE 1
MESENTERIC LYMPH NODE:
ORGAN EXAMINED, NO PATHOLOGIC FINDINGS NOTED
NO MICROSCOPIC FINDING CORRESPONDING TO GROSS OBSERVATION.

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.
PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

ANIMAL HEADING DATA
DOSE GROUP : 05, 1000 MG/KG

ANIMAL NUMBER	SEX M/F	DEFINED AND FINAL STATE OF NECROPSY		TEST DAYS	FIRST AND LAST DAY UNDER TEST		DATE OF NECROPSY
26	M	K0	K0	28	14-JUN-94	11-JUL-94	12-JUL-94
27	M	K0	K0	28	14-JUN-94	11-JUL-94	12-JUL-94
28	M	K0	K0	28	14-JUN-94	11-JUL-94	12-JUL-94
29	M	K0	K0	28	14-JUN-94	11-JUL-94	12-JUL-94
30	M	K0	K0	28	14-JUN-94	11-JUL-94	12-JUL-94
31	M	R1	R1	28	14-JUN-94	11-JUL-94	26-JUL-94
32	M	R1	R1	28	14-JUN-94	11-JUL-94	26-JUL-94
33	M	R1	R1	28	14-JUN-94	11-JUL-94	26-JUL-94
34	M	R1	R1	28	14-JUN-94	11-JUL-94	26-JUL-94
35	M	R1	R1	28	14-JUN-94	11-JUL-94	26-JUL-94
61	F	K0	K0	28	14-JUN-94	11-JUL-94	12-JUL-94
62	F	K0	K0	28	14-JUN-94	11-JUL-94	12-JUL-94
63	F	K0	K0	28	14-JUN-94	11-JUL-94	12-JUL-94
64	F	K0	K0	28	14-JUN-94	11-JUL-94	12-JUL-94
65	F	K0	K0	28	14-JUN-94	11-JUL-94	12-JUL-94
66	F	R1	R1	28	14-JUN-94	11-JUL-94	26-JUL-94
67	F	R1	R1	28	14-JUN-94	11-JUL-94	26-JUL-94
68	F	R1	R1	28	14-JUN-94	11-JUL-94	26-JUL-94
69	F	R1	R1	28	14-JUN-94	11-JUL-94	26-JUL-94
70	F	R1	R1	28	14-JUN-94	11-JUL-94	26-JUL-94

TEST ARTICLE : FAT 45'169/A PATHOL. NO.: 37288 MAR
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE) DATE : 26-NOV-94
SPONSOR : RCC LTD. PDS PATHDATA SYSTEM TM

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 05, 1000 MG/KG MALE

* STATE AT NECROPSY: KO
DAYS ON TEST : 28 * ANIMAL NO. : 26

* NECROPSY FINDINGS

GENERAL OBSERVATIONS:
DISCOLORATION, REDDISH.
STOMACH:
MUCOSA: DISCOLORATION, DARK RED.

* MICROSCOPIC FINDINGS

LIVER:
-LYMPHOID FOCI, GRADE 1
KIDNEYS:
#
-TUBULAR BASOPHILIA/DEGENERATION, GRADE 4
-HYALINE DROPLETS, GRADE 3
STOMACH:
NO MICROSCOPIC FINDING CORRESPONDING TO GROSS OBSERVATION.
LUNGS:
#
-FOAMY MACROPHAGE ACCUMULATIONS, GRADE 1
-ALVEOLAR HAEMORRHAGE, GRADE 1
ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.
PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 05, 1000 MG/KG MALE

* STATE AT NECROPSY: KO
DAYS ON TEST : 28 * ANIMAL NO. : 27

* NECROPSY FINDINGS

GENERAL OBSERVATIONS:
DISCOLORATION, REDDISH.
MANDIBULAR LYMPH NODE:
DISCOLORATION, DARK RED.

* MICROSCOPIC FINDINGS

LIVER:
-LYMPHOID FOCI, GRADE 1
-DIFFUSE VACUOLATION, GRADE 1
KIDNEYS:
#
-TUBULAR BASOPHILIA/DEGENERATION, GRADE 4
-HYALINE DROPLETS, GRADE 3
LUNGS:
#
MANDIBULAR LYMPH NODE:
ONLY ONE OF PAIRED ORGANS EXAMINED/PRESENT
NO MICROSCOPIC FINDING CORRESPONDING TO GROSS OBSERVATION.
ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.

PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 05, 1000 MG/KG

MALE

* STATE AT NECROPSY: KO
DAYS ON TEST : 28 * ANIMAL NO. : 28

* NECROPSY FINDINGS

GENERAL OBSERVATIONS:
DISCOLORATION, REDDISH.

* MICROSCOPIC FINDINGS

LIVER:
-LYMPHOID FOCI, GRADE 1
KIDNEYS:
#
-TUBULAR BASOPHILIA/DEGENERATION, GRADE 4
-HYALINE DROPLETS, GRADE 2
LUNGS:
#
-FOAMY MACROPHAGE ACCUMULATIONS, GRADE 2
-MACROPHAGE PIGMENT DEPOSITS, GRADE 2
ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS

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* STATE AT NECROPSY: KO
DAYS ON TEST : 28 * ANIMAL NO. : 29

* NECROPSY FINDINGS

GENERAL OBSERVATIONS:
DISCOLORATION, REDDISH.
LUNGS:
FOCUS/FOCI, SEVERAL, D=5 MM, DARK RED.

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.
PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 05, 1000 MG/KG MALE

CONT./FF. ANIMAL NO. : 29

* MICROSCOPIC FINDINGS

PEER REVIEW:
-WHOLE ANIMAL PEER REVIEWED
LIVER:
-LYMPHOID FOCI, GRADE 1
KIDNEYS:
#
-TUBULAR BASOPHILIA/DEGENERATION, GRADE 4
-HYALINE DROPLETS, GRADE 2
LUNGS:
#
-FOAMY MACROPHAGE ACCUMULATIONS, GRADE 3
-MACROPHAGE PIGMENT DEPOSITS, GRADE 3
ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS

---

* STATE AT NECROPSY: K0
DAYS ON TEST : 28 * ANIMAL NO. : 30

* NECROPSY FINDINGS

GENERAL OBSERVATIONS:
DISCOLORATION, REDDISH.
MANDIBULAR LYMPH NODE:
DISCOLORATION, REDDISH.

* MICROSCOPIC FINDINGS

LIVER:
-LYMPHOID FOCI, GRADE 1
KIDNEYS:
#
-TUBULAR BASOPHILIA/DEGENERATION, UNILATERAL, GRADE 1

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.
PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 05, 1000 MG/KG MALE

CONT./FF. ANIMAL NO. : 30

-HYALINE DROPLETS, GRADE 3
MANDIBULAR LYMPH NODE:
ONLY ONE OF PAIRED ORGANS EXAMINED/PRESENT
NO MICROSCOPIC FINDING CORRESPONDING TO GROSS OBSERVATION.
ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS

---

* STATE AT NECROPSY: R1
DAYS ON TEST : 28
* ANIMAL NO. : 31

* NECROPSY FINDINGS

GENERAL OBSERVATIONS:
DISCOLORATION, REDDISH.

* MICROSCOPIC FINDINGS

HEART:
-DEGENERATION, GRADE 1
LIVER:
-LYMPHOID FOCI, GRADE 2
SPLEEN:
ORGAN EXAMINED, NO PATHOLOGIC FINDINGS NOTED
KIDNEYS:
#
-TUBULAR BASOPHILIA/DEGENERATION, GRADE 2
-HYALINE DROPLETS, GRADE 3
STOMACH:
ORGAN EXAMINED, NO PATHOLOGIC FINDINGS NOTED
LUNGS:
-FOAMY MACROPHAGE ACCUMULATIONS, GRADE 1
TESTES:
ORGAN EXAMINED, NO PATHOLOGIC FINDINGS NOTED

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.
PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 05, 1000 MG/KG MALE

CONT./FF. ANIMAL NO. : 31

ADRENAL GLANDS:
-CORTICAL VACUOLATION, GRADE 2

* STATE AT NECROPSY: R1
DAYS ON TEST : 28 * ANIMAL NO. : 32

* NECROPSY FINDINGS

GENERAL OBSERVATIONS:
DISCOLORATION, REDDISH.
KIDNEYS:
RIGHT SIDE: PELVIC DILATION.

* MICROSCOPIC FINDINGS

LIVER:
-LYMPHOID FOCI, GRADE 1
KIDNEYS:
#
-TUBULAR BASOPHILIA/DEGENERATION, GRADE 3
-HYALINE DROPLETS, GRADE 2
-HYDRONEPHROSIS, UNILATERAL, GRADE 3
LUNGS:
-FOAMY MACROPHAGE ACCUMULATIONS, GRADE 1
ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.
PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 05, 1000 MG/KG MALE

* STATE AT NECROPSY: R1
DAYS ON TEST : 28 * ANIMAL NO. : 33

* NECROPSY FINDINGS

GENERAL OBSERVATIONS:
DISCOLORATION, REDDISH.

* MICROSCOPIC FINDINGS

LIVER:
-LYMPHOID FOCI, GRADE 1
KIDNEYS:
#
-TUBULAR BASOPHILIA/DEGENERATION, GRADE 2
-HYALINE DROPLETS, GRADE 2
ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS

---

* STATE AT NECROPSY: R1
DAYS ON TEST : 28 * ANIMAL NO. : 34

* NECROPSY FINDINGS

GENERAL OBSERVATIONS:
DISCOLORATION, REDDISH.
LIVER:
CAUDATE LOBE: FOCUS/FOCI, D=8 MM, YELLOWISH, TAN.

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.
PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 05, 1000 MG/KG MALE

CONT./FF. ANIMAL NO. : 34

* MICROSCOPIC FINDINGS

LIVER:
-FOCAL NECROSIS, TORSION, GRADE 3
KIDNEYS:
#
-TUBULAR BASOPHILIA/DEGENERATION, GRADE 2
-HYALINE DROPLETS, GRADE 1
LUNGS:
-FOAMY MACROPHAGE ACCUMULATIONS, GRADE 2
-MACROPHAGE PIGMENT DEPOSITS, GRADE 2
-MINERALISED FOCI, OSTEOID, GRADE 1
ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS

---

* STATE AT NECROPSY: R1
DAYS ON TEST : 28
* ANIMAL NO. : 35

* NECROPSY FINDINGS

GENERAL OBSERVATIONS:
DISCOLORATION, REDDISH.

* MICROSCOPIC FINDINGS

LIVER:
-LYMPHOID FOCI, GRADE 1
-DIFFUSE VACUOLATION, GRADE 2
KIDNEYS:
#
-TUBULAR BASOPHILIA/DEGENERATION, GRADE 3
LUNGS:
-FOAMY MACROPHAGE ACCUMULATIONS, GRADE 1

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.

PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 05, 1000 MG/KG MALE

CONT./FF. ANIMAL NO. : 35

ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS

TEST ARTICLE : FAT 45'169/A PATHOL. NO.: 37288 MAR
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE) DATE : 26-NOV-94
SPONSOR : RCC LTD. PDS PATHDATA SYSTEM TM

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 05, 1000 MG/KG FEMALE

* STATE AT NECROPSY: K0
DAYS ON TEST : 28 * ANIMAL NO. : 61

* NECROPSY FINDINGS

GENERAL OBSERVATIONS:
DISCOLORATION, REDDISH.

* MICROSCOPIC FINDINGS

LIVER:
-LYMPHOID FOCI, GRADE 1
-DIFFUSE VACUOLATION, GRADE 2
KIDNEYS:
#
-TUBULAR BASOPHILIA/DEGENERATION, GRADE 3
-HYALINE DROPLETS, GRADE 2
-MINERALISATION, GRADE 2
LUNGS:
#
-FOAMY MACROPHAGE ACCUMULATIONS, GRADE 1
ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS

---

* STATE AT NECROPSY: K0
DAYS ON TEST : 28 * ANIMAL NO. : 62

* NECROPSY FINDINGS

GENERAL OBSERVATIONS:
DISCOLORATION, REDDISH.

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.
PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 05, 1000 MG/KG FEMALE

CONT./FF. ANIMAL NO. : 62

* MICROSCOPIC FINDINGS

HEART:
-DEGENERATION, GRADE 1
LIVER:
-LYMPHOID FOCI, GRADE 1
-DIFFUSE VACUOLATION, GRADE 1
-HAEMATOPOIESIS, GRADE 1
SPLEEN:
ORGAN EXAMINED, NO PATHOLOGIC FINDINGS NOTED
KIDNEYS:
#
-TUBULAR BASOPHILIA/DEGENERATION, GRADE 3
-HYALINE DROPLETS, GRADE 2
-MINERALISATION, GRADE 2
STOMACH:
ORGAN EXAMINED, NO PATHOLOGIC FINDINGS NOTED
LUNGS:
#
-FOAMY MACROPHAGE ACCUMULATIONS, GRADE 1
ADRENAL GLANDS:
ORGAN EXAMINED, NO PATHOLOGIC FINDINGS NOTED
ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS

---

* STATE AT NECROPSY: KO
DAYS ON TEST : 28 * ANIMAL NO. : 63

* NECROPSY FINDINGS

GENERAL OBSERVATIONS:
DISCOLORATION, REDDISH.

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.

PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 05, 1000 MG/KG FEMALE

CONT./FF. ANIMAL NO. : 63

STOMACH:
MUCOSA: DISCOLORATION, DARK RED.

* MICROSCOPIC FINDINGS

HEART:
ORGAN EXAMINED, NO PATHOLOGIC FINDINGS NOTED
LIVER:
-LYMPHOID FOCI, GRADE 2
-DIFFUSE VACUOLATION, GRADE 2
SPLEEN:
ORGAN EXAMINED, NO PATHOLOGIC FINDINGS NOTED
KIDNEYS:
#
-TUBULAR BASOPHILIA/DEGENERATION, GRADE 3
-HYALINE DROPLETS, GRADE 2
STOMACH:
-INFLAMMATION, GRADE 2
LUNGS:
#
-FOAMY MACROPHAGE ACCUMULATIONS, GRADE 1
ADRENAL GLANDS:
ORGAN EXAMINED, NO PATHOLOGIC FINDINGS NOTED
ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.

PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 05, 1000 MG/KG FEMALE

* STATE AT NECROPSY: KO
DAYS ON TEST : 28 * ANIMAL NO. : 64

* NECROPSY FINDINGS

GENERAL OBSERVATIONS:
DISCOLORATION, DARK RED.
MANDIBULAR LYMPH NODE:
DISCOLORATION, DARK RED.

* MICROSCOPIC FINDINGS

LIVER:
-LYMPHOID FOCI, GRADE 1
KIDNEYS:
#
-TUBULAR BASOPHILIA/DEGENERATION, GRADE 3
-HYALINE DROPLETS, GRADE 2
-MINERALISATION, UNILATERAL, GRADE 1
LUNGS:
#
-FOAMY MACROPHAGE ACCUMULATIONS, GRADE 1
MANDIBULAR LYMPH NODE:
ONLY ONE OF PAIRED ORGANS EXAMINED/PRESENT
NO MICROSCOPIC FINDING CORRESPONDING TO GROSS OBSERVATION.
ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.
PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 05, 1000 MG/KG FEMALE

* STATE AT NECROPSY: KO
DAYS ON TEST : 28 * ANIMAL NO. : 65

* NECROPSY FINDINGS

GENERAL OBSERVATIONS:
DISCOLORATION, REDDISH.
UTERUS:
BOTH HORNS: DILATION, D=5 MM.

* MICROSCOPIC FINDINGS

LIVER:
-LYMPHOID FOCI, GRADE 1
-DIFFUSE VACUOLATION, GRADE 2
-HAEMATOPOIESIS, GRADE 1
KIDNEYS:
#
-TUBULAR BASOPHILIA/DEGENERATION, GRADE 2
-HYALINE DROPLETS, GRADE 2
-MINERALISATION, GRADE 2
LUNGS:
#
UTERUS:
-HYDROMETRA, GRADE 3
ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.
PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 05, 1000 MG/KG FEMALE

* STATE AT NECROPSY: R1
DAYS ON TEST : 28 * ANIMAL NO. : 66

* NECROPSY FINDINGS

GENERAL OBSERVATIONS:
DISCOLORATION, REDDISH.

* MICROSCOPIC FINDINGS

LIVER:
-DIFFUSE VACUOLATION, GRADE 1
KIDNEYS:
-TUBULAR BASOPHILIA/DEGENERATION, GRADE 2
-HYALINE DROPLETS, GRADE 1
-MINERALISATION, GRADE 2
ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS

---

* STATE AT NECROPSY: R1
DAYS ON TEST : 28 * ANIMAL NO. : 67

* NECROPSY FINDINGS

GENERAL OBSERVATIONS:
DISCOLORATION, REDDISH.

* MICROSCOPIC FINDINGS

LIVER:
-LYMPHOID FOCI, GRADE 1
-DIFFUSE VACUOLATION, GRADE 1
KIDNEYS:
-TUBULAR BASOPHILIA/DEGENERATION, GRADE 2
-HYALINE DROPLETS, GRADE 2

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.
PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 05, 1000 MG/KG FEMALE

CONT./FF. ANIMAL NO. : 67

LUNGS:
-FOAMY MACROPHAGE ACCUMULATIONS, GRADE 1
ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS

* STATE AT NECROPSY: R1
DAYS ON TEST : 28
* ANIMAL NO. : 68

* NECROPSY FINDINGS

GENERAL OBSERVATIONS:
DISCOLORATION, REDDISH.

* MICROSCOPIC FINDINGS

HEART:
-DEGENERATION, GRADE 1
LIVER:
-LYMPHOID FOCI, GRADE 2
-FOCAL NECROSIS, GRADE 1
KIDNEYS:
-TUBULAR BASOPHILIA/DEGENERATION, GRADE 2
-MINERALISATION, GRADE 2
ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.

PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 05, 1000 MG/KG FEMALE

* STATE AT NECROPSY: R1
DAYS ON TEST : 28 * ANIMAL NO. : 69

* NECROPSY FINDINGS

GENERAL OBSERVATIONS:
DISCOLORATION, REDDISH.

* MICROSCOPIC FINDINGS

HEART:
-DEGENERATION, GRADE 1
LIVER:
-LYMPHOID FOCI, GRADE 1
-FOCAL VACUOLATION, GRADE 1
-DIFFUSE VACUOLATION, GRADE 1
-INFLAMMATION, GRADE 1
KIDNEYS:
-TUBULAR BASOPHILIA/DEGENERATION, GRADE 2
-HYALINE DROPLETS, GRADE 1
-MINERALISATION, UNILATERAL, GRADE 1
ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS

---

* STATE AT NECROPSY: R1
DAYS ON TEST : 28 * ANIMAL NO. : 70

* NECROPSY FINDINGS

GENERAL OBSERVATIONS:
DISCOLORATION, REDDISH.

TEST ARTICLE : FAT 45'169/A
TEST SYSTEM : RAT, 28 DAYS, ORAL (GAVAGE)
SPONSOR : RCC LTD.

PATHOL. NO.: 37288 MAR
DATE : 26-NOV-94
PDS PATHDATA SYSTEM TM

TEXT OF GROSS AND MICROSCOPIC FINDINGS
DOSE GROUP : 05, 1000 MG/KG FEMALE

CONT./FF. ANIMAL NO. : 70

* MICROSCOPIC FINDINGS

LIVER:
-LYMPHOID FOCI, GRADE 1
-DIFFUSE VACUOLATION, GRADE 1
KIDNEYS:
-TUBULAR BASOPHILIA/DEGENERATION, GRADE 2
-HYALINE DROPLETS, GRADE 2
LUNGS:
-FOAMY MACROPHAGE ACCUMULATIONS, GRADE 1
ALL OTHER PROTOCOL TISSUES WITHOUT PATHOLOGIC FINDINGS

END OF SECTION
LAST PAGE OF REPORT

RCC PROJECT 372881
FAT 45'169/A

ATTACHMENT 6

SUMMARY OF RESULTS ACCORDING TO JAPANESE CHEMICAL SUBSTANCE LAW

(APRIL 1, 1987; MHW - MINISTRY OF HEALTH AND WELFARE)

TWENTY-EIGHT-DAY REPEATED DOSE TOXICITY TEST

Administration period of the test substance		from 14-JUN-1994 to 11-JUL-1994					
Animal species/strain		Rat, HanIbm: WIST (SPF)	Number of animals per group				
Route of administration		Oral (gavage)	Male:10 (Gr.1+5) Female:10 (Gr.1+5) Male: 5 (Gr.2+3+4) Female: 5 (Gr.2+3+4)				
Purity of the test substance (%)		Control group includ. recovery group	The lowest dose group	Intermediate dose group I	Intermediate dose group II	The highest dose group including recovery group	
approx. 60%	Dose levels mg/kg	0	10	50	200	1000	
						T	R
Mortality		1*	None	None	None	None	None
General appearance		2*	Normal	Normal	Normal	Normal	Normal
Body weight		Normal	Normal	Normal	Normal	Normal	Normal
Food consumption		Normal	Normal	Normal	Normal	Normal	Normal
Ophthalmoscopy		Normal	Normal	Normal	Normal	Normal	Normal
Urinalysis		Normal	Normal	Normal	Normal	3*	4*
Blood biochemistry		Normal	Normal	Normal	5*	6*	7*
Blood morphology		Normal	Normal	Normal	Normal	Normal	Normal
Organ weight		Normal	Normal	Normal	Normal	8*	Normal
Necropsy		Normal	Normal	Normal	9*	10*	Normal
Histology		Normal	Normal	Normal	Normal	11*	12*
Others		----	----	----	----	----	----
No-observed-adverse-effect level (mg/kg)		200 mg/kg body weight/day					
Change(s) by which "No-observed-adverse-effect level is estimated		Reddish discoloration of the kidneys and mesenteric lymph nodes noted at terminal necropsy					

T = During or at the end of the treatment period
R = During or at the end of the recovery period

* For explanations see on the following page.

1 * = Control male no. 3 died during narcosis for blood sampling on day of schedule necropsy.

2 * = Alopecia on the chest wall and front paws was noted in control male no. 10. This finding was first noted at week two of treatment and lasted until the end of the recovery period.

3 * = Slight increase by 1% in specific gravity in male animals.
Slight increase by 43% of the osmolality in male animals.
Slight increase in urine protein (score) in male animals.
Slight increase in urine bilirubin (score) in male animals.
Slight increase in occult blood (score) in male and female animals.
The urine showed a light orange to light red discoloration.

4 * = Slight increase in occult blood (score) in male and female animals.
Slight orange to orange discoloration of the urine

5 * = Slightly decreased glucose level by 20% in females.

6 * = All plasma samples of the animals at the end of the treatment showed a pink to deep pink discoloration.
Slightly decreased glucose level by 17% in females
Slightly decreased urea level by 15% in females
Slightly increased creatinine level by 19% in males
Markedly increased uric acid by 101 to 248% on average in both sexes
Markedly increased bilirubin by 278 to 543% on average in both sexes
Slightly increased total cholesterol level by 37% in males.
Slightly increased phospholipid level by 28% in males.
Slightly increased albumin level by 8% in females.

7 * = Increase of creatinine and bilirubin levels.

8 * = Slight increase of the kidneys and liver weights in males.

9 * = Reddish discoloration of the kidneys and of the mesenteric lymph nodes.

10 * = General body discoloration (reddish) in all animals

11 * = There was histopathological evidence of nephrotoxicity in both sexes in the form of increased renal cortical tubular basophilia and degeneration. Increased severity of tubular hyaline droplets was apparent in the males and red tubular hyaline droplets were also present in the females.
In addition, cluster of foamy macrophages containing red pigment droplets were found in the lungs of two male rats.

12 * = The kidneys lesions were still apparent after a 14-day treatment free recovery period.
One male still showed cluster of foamy macrophages containing red pigment droplets in the lungs after the 14-day recovery period.

OTHERS

Testing institution	Name and Address	RCC, Research & Consulting Company Ltd., P.O. Box, CH-4452 Itingen/Switzerland Tel: 061/975.11.11
Study director	Name Title	Dr. A. Dotti Signature:
Test dates	from	06-JUN-1994 to 26-JUL-1994

Remark:

"Study Director" is defined in Article 5 of "Standards Concerning Testing Facilities Stipulated in Article 3 of the Order Prescribing the Items of the Test Relating to the New Chemical Substances" which is stipulated in "Concerning Testing Facilities Stipulated in Article 3 of the Order Prescribing the Items of the Testing Relating to the New Chemical Substances (Notification No. 37 of the Planning and Coordination Bureau, Environment Agency, No. 229 of the Pharmaceutical Affairs Bureau, Ministry of Health and Welfare & No. 85 (1984) of the Basic Industries Bureau, Ministry of International Trade and Industry, March 31, 1984)".

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

Anthony Di Battista
Manager, Regulatory Affairs & Toxic Substances Compliance
Toxicology, Regulatory Auditing & Compliance
CIBA-GEIGY Corporation
444 Saw Mill River Road
Ardsley, New York 10502-2699

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

JAN 30 1995

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

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

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

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

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

Sincerely,

Terry R. O'Bryan

Terry R. O'Bryan
Risk Analysis Branch

Enclosure 13309 A

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Triage of 8(e) Submissions

Date sent to triage: MAY 0 9 1995

NON-CAP CAP

Submission number: 133094A

TSCA Inventory: Y N D

Study type (circle appropriate):

Group 1 - Dick Clements (1 copy total)

ECO AQUATO

Group 2 - Ernie Falke (1 copy total)

ATOX SBTOX SEN w/NEUR

Group 3 - Elizabeth Margosches (1 copy each)

STOX CTOX EPI RTOX GTOX

STOX/ONCO CTOX/ONCO IMMUNO CYTO NEUR

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

Notes:

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

For Contractor Use Only

entire document: 0 1 2 **pages** — **pages** 1,2

Notes:

Contractor reviewer : PDR **Date:** 2/9/95

CECATS\TRIAGE TRACKING DB/ :RY FORM

CECATS DATA:
Submission # 8EHQ- 0195 - 13309 (3) SEQ. A

TYPE: (INT.) SUPP FLWP

SUBMITTER NAME: Ciba - Geigy Corporation

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

DISPOSITION:
(0639) REFER TO CHEMICAL SCREENING
0678 CAP NOTICE

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

SUB. DATE: 01/13/95 OTS DATE: 01/19/95 CSRAD DATE: 01/25/95

CHEMICAL NAME: CAS#

FAT 45'169/A — Confident

Naphthalenesulfonic acid, azo substituted — "

naphthalene amino triazinyl amino phenyl azo substituted

naphthalene amino substituted triazin

INFORMATION TYPE:		P F C	INFORMATION TYPE:		P F C	INFORMATION TYPE:		P F C
0201	ONCO (HUMAN)	01 02 04	0216	EPI/CLIN	01 02 04	0241	IMMUNO (ANIMAL)	01 02 04
0202	ONCO (ANIMAL)	01 02 04	0217	HUMAN EXPOS (PROD CONTAM)	01 02 04	0242	IMMUNO (HUMAN)	01 02 04
0203	CELL TRANS (IN VITRO)	01 02 04	0218	HUMAN EXPOS (ACCIDENTAL)	01 02 04	(0243)	CHEM/PHYS PROP	01 02 04
0204	MUTA (IN VITRO)	01 02 04	0219	HUMAN EXPOS (MONITORING)	01 02 04	0244	CLASTO (IN VITRO)	01 02 04
0205	MUTA (IN VIVO)	01 02 04	0220	ECO/AQUA TOX	01 02 04	0245	CLASTO (ANIMAL)	01 02 04
0206	REPRO/TERATO (HUMAN)	01 02 04	0221	ENV. OCCC/REL/FATE	01 02 04	0246	CLASTO (HUMAN)	01 02 04
0207	REPRO/TERATO (ANIMAL)	01 02 04	0222	EMER INCI OF ENV CONTAM	01 02 04	0247	DNA DAM/REPAIR	01 02 04
0208	NEURO (HUMAN)	01 02 04	0223	RESPONSE REQEST DELAY	01 02 04	(0248)	PROD/USE/PROC	01 02 04
0209	NEURO (ANIMAL)	01 02 04	(0224)	PROD/COMP/CHEM ID	01 02 (04)	0251	MSDS	01 02 04
0210	ACUTE TOX. (HUMAN)	01 02 04	0225	REPORTING RATIONALE	01 02 04	0299	OTHER	01 02 04
0211	CHR. TOX. (HUMAN)	01 02 04	0226	CONFIDENTIAL	01 02 04			
0212	ACUTE TOX. (ANIMAL)	01 02 04	0227	ALLERG (HUMAN)	01 02 04			
(0213)	SUB ACUTE TOX (ANIMAL)	01 02 04	0228	ALLERG (ANIMAL)	01 02 04			
0214	SUB CHRONIC TOX (ANIMAL)	01 02 04	0239	METAB/PHARMACO (ANIMAL)	01 02 04			
0215	CHRONIC TOX (ANIMAL)	01 02 04	0240	METAB/PHARMACO (HUMAN)	01 02 04			

TRIAGE DATA:	NON-CBI INVENTORY	ONGOING REVIEW	SPECIES	TOXICOLOGICAL CONCERN:	USE:	PRODUCTION:
	YES	YES (DROP/REFER)	RAT	(LOW)	Dye	
	NO	NO (CONTINUE)		MED		
	(DETERMINE)	REFER:		HIGH		

COMMENTS: Non-Cap, PMN (P94-178)

-CPSS- 1004951453

0 0 0 0 0 0 0 0 0 0 0
> <ID NUMBER>
8(E)-13309A

> <TOX CONCERN>
L

> <COMMENT>
SUBACUTE ORAL TOXICITY IN RATS IS LOW CONCERN. THE NOAEL WAS DETERMINED TO BE 200 MG/KG. ANIMALS (5/SEX/DOSE) WERE EXPOSED TO TEST MATERIAL FOR 28 DAYS. NO MORTALITY WAS NOTED WHEN ANIMALS WERE EXPOSED TO DOSE LEVELS OF 0, 10, 50, 200 AND 1000 MG/KG. HISTOPATHOLOGICAL EXAM REVEALED EVIDENCE OF NEPHROTOXICITY, RENAL CORTICAL TUBULAR BASOPHILIA AND DEGENERATION WERE ALSO NOTED WITH INCREASING SEVERITY OF TUBULAR HYALINE DROPLETS IN THE HIGH DOSE GROUP (1000 MG/KG). CHANGES IN KIDNEY AND LIVER WEIGHTS PLUS CLINICAL CHEMISTRY PARAMETERS WERE OBSERVED.

$$$$