FDA 檢驗測試報告

STUDY REPORT

13-Week GLP Toxicity Study of the Odorox® Boss™ Hydroxyl Processor Air Cleansing Machine in Rats

Study Number: CB10-5065-R-TX

Testing Facility:

Comparative Biosciences, Inc.
786 Lucerne Drive
Sunnyvale, CA 94085

Sponsor:

HGI Industries Inc.
2055 High Ridge Road
Boynton Beach, FL 33426

Test Article:

Odorox® Boss™ Hydroxyl Processor air cleansing machine

Comparative Biosciences, Inc.

KEY STUDY PERSONNEL AND DATES

13-Week GLP Toxicity Study of the Odorox® Boss™ Hydroxyl Processor Air Cleansing Machine in Rats

Study Number: CB10-5065-R-TX

Key Study Personnel:

Study Director:	Robin Dean, PhD
Lead Biologist	Lucy Jawed, BS, BA
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Ophthalmologist:	Kristina Burling, DVM, Diplomate, ACVO Animal Eye Specialists of San Jose
Study Pathologist:	Carol Meschter, PhD, DVM, DACVP
Scientific Writer:	Peter Margolis, PhD
Quality Assurance:	Jeanette Jacobs, BS (to 10 June 2011) Matthew Knox, BA (from 10 June 2011)
Odorox® Processor™ Hydroxyl Performance Monitoring	Mark E. Mino, General Manager, HGI Industries, Inc.

Study Dates:

Study Initiation:	1 March 2011
Initiation of Treatment:	2 – 4 March 2011 (Cohorts 1 – 3)
Terminal Bleed and Necropsy:	1 – 3 June 2011 (Cohorts 1 – 3)
End of In-life:	3 June 2011
Report Issued:	15 February 2012

Sponsor and Sponsor's Representative:

HGI Industries, Inc.
2055 High Ridge Road
Boynton Beach, FL 33426

Sponsor's Representative:	Connie Araps, PhD (561) 735-3701 caraps@bellsouth.net

QUALITY ASSURANCE STATEMENT

CBI Study Number: CB11-5065-R-TX / H-11-1016
Sponsor: HGI Industries Inc
Study Director: Robin Dean, PhD
Pathologist: Carol Meschter, DVM, PhD, DACVP
Study Title: 13-Week Toxicity Study of the Boss Hydroxyl Odor Processor ® Air Cleansing Machine in Rats

Date of Inspection	Phase Inspected	Date reported to Study Director	Date reported to Management
27-Jan-11	Receipt of Test Article Device	1-Feb-11	18-Feb-11
14-Feb-11	Receipt of Test Article Device	16-Feb-11	18-Feb-11
21-Mar-11	Body Weights/Room Inspection	22-Mar-11	25-Mar-11
30-Mar-11	Food Consumption	4-Apr-11	6-Arp-11
31-Mar-11	Functional Observation Battery Test	4-Apr-11	6-Apr-11
26-Apr-11	Body Weights/Room Inspection	27-Apr-11	9-May-11
11-May-11	Food Consumption	11-May-11	13-May-11
27-May-11	Ophthalmologic Exam	2-Jun-11	14-Jun-11
27-May-11	Review of Raw Data	27-May-11	22-Jun-11
27-May-11	Necropsy	2-Jun-11	14-Jun-11
14-Jun-11	Gross Trimming Wet Tissue	15-Jun-11	16-Jun-11
18-July-11	Sectioning Paraffin Blocks	25-Jul-11	25-Jul-11
22-Jul-11	Gross Trimming Wet Tissue	25-Jul-11	25-Jul-11
25-Aug-11	Draft Study and Pathology Report	26-Aug-11	30-Aug-11

Matthew Knox 2/15/12

Matthew Knox, BS
Quality Assurance Associate I
Comparative Biosciences, Inc.

Date

COMPLIANCE STATEMENT

I, the undersigned Study Director, hereby declare that this report constitutes a true and faithful account of the results of this study to the best of my knowledge. This study was conducted in compliance with the US Food and Drug Administration's Good Laboratory Practices regulations (21 CFR Part 58), with this protocol as amended, and with Testing Facility Standard Operating Procedures. (Note: The air exchange rate in the room with the HGI machine was decreased slightly below the lower end of the recommended range.)

Robin Dean — 15 Feb 2012

Robin Dean, PhD
Study Director

Date

Carol Meschter — 15 Feb 12

Carol Meschter, DVM, PhD, DACVP
Study Pathologist
President & CEO

Date

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(This report consists of 60 pages plus 4 appendices, which is numbered separately.)

SUMMARY

The objective of this study was to evaluate the potential toxicity in rats exposed to hydroxyl radicals and other compounds that may be released into the air as a result of operation of two Odorox® Boss™ Hydroxyl Processor air cleansing machines. An electrochemical sensor was used to initially adjust the hydroxyl output of the machines to a desired level, where it was maintained for the duration of the study. The output was monitored remotely throughout the study. This study was conducted at Comparative Biosciences, Inc. (CBI; Sunnyvale, CA). The study was conducted in compliance with the US Food and Drug Administration's Good Laboratory Practices regulations (21 CFR Part 58), with this protocol as amended, and with Testing Facility Standard Operating Procedures. The study was initiated on 1 March 2011. Treatment was begun on 2 – 4 March 2011 (for Cohorts 1 – 3, respectively); terminal bleeds and necropsies were performed on 1 – 3 June 2011, for cohorts 1 – 3, respectively. The in-life phase was completed on 3 June 2011; this report was issued on 15 February 2012.

The study consisted of two groups of Sprague-Dawley rats: a treated group (20 males and 20 females) housed for 13 weeks in a room in which two Odorox® Boss™ Hydroxyl Processor air cleansing machines were operating continuously for 13 weeks; and a control group (10 males and 10 females) housed for the same period in a different room under similar housing conditions, but not exposed to the Odorox® Boss™ Hydroxyl Processor machine operation. The air exchange in the treatment room was 7.4 changes/hr and that in the control room was 10.8 changes/hr; this difference was not considered significant. Both groups underwent the same evaluations and tests, including the following: Clinical observations were recorded once daily, with special attention to the eyes, nose, and respiratory system; Body weights and food consumption were measured once weekly; Behavioral tests, functional observational battery (FOB) tests, were performed four times during the course of the study, including a pre-treatment test and three other times at regular intervals following the start of treatment. The FOB tests included a focus on respiration, eyes, neurotoxicity, and mucous membranes. Ophthalmological examinations were performed on all animals by a veterinary ophthalmologist once prior to the start of treatment and again prior to sacrifice. Hematology and clinical chemistry analyses were performed at necropsy. Gross necropsies were performed, including specified organ weights. A complete set of tissues was evaluated by a board-certified veterinary pathologist, with special attention to the skin, eyes, nasal turbinates, larynx/pharynx, and respiratory system.

Summary of In-Life Study Results:

No mortality or unscheduled deaths occurred during the study. No abnormal clinical observations were seen in animals exposed to the operation of the Odorox® Boss™ Hydroxyl Processor air cleansing machines. Rough coat, a mild form of piloerection, was the only clinical observation that may have been related to treatment. It was also noted that treated animals appeared to be more alert during the day-light hours than untreated animals after about a week or two of treatment. No changes in food consumption or weight gain were noted. There were no treatment-related changes in ophthalmology, neurological or behavioral changes as evaluated by the functional observational battery tests. Some statistically significant differences were found in some hematological and clinical chemistry parameters, which were not considered to have toxicological significance. Males exposed to the test article exhibited a decrease in pituitary weight and an increase in testes/ epididymides weight. Histological evaluation found no evidence of abnormalities in the pituitary or testes/epididymides. Thus, during the 13-week in-life phase of the study, output of hydroxyl ions, oxidants, ozone, and reaction by-products from the continuously operating Odorox® Boss™ Hydroxyl Processor air cleansing machines appeared to be well tolerated by the animals under the conditions used in this study.

Summary of Pathology Results:

In general, there were no histopathologic differences between the control rats and the rats exposed to air modified by two continuously operating Odorox® Boss™ Hydroxyl Processor air cleansing machines. Special attention was paid to the skin, eyes, nasal turbinates, larynx/pharynx, and respiratory system. There were no changes in these organs and they appeared to be within normal limits in both the control and treated animals. There were however, a number of neoplasms. A hepatobiliary carcinoma was found in one control male. Three females in the Odorox Hydroxyl Processor®-exposed group were found to have three different neoplasms; a renal carcinoma, a hemagiosarcoma and a thymic epithelioma. The incidences of neoplasms in the control vs. treated groups were 1/20 and 3/40, which was statistically indistinguishable. This suggests that the tumors were spontaneously occurring and not related to exposure to air processed by the Odorox® Boss™ Hydroxyl Processor air cleansing machines.

Study Toxicology Summary:

The in-life phase of the study failed to reveal any significant changes in observable behavior or health, appetite or weight gain, ophthalmology, neurological measures or other behaviors (as measured by FOB test), or biologically relevant changes in hematology or clinical chemistry. In males, small testes (noted in one control male) is not an uncommon finding in some male rats. The significant pituitary weight differences between the two groups in males probably are within the normal range of variability and since there were no pathological findings in the treated pituitaries, the weight differences are not considered biologically significant. No histopathological differences were found between the control rats and those that were housed in a room with two Odorox® Boss™ Hydroxyl Processor air cleansing machines running continuously for 13 weeks. There were some tumors found in both the treated and control rats at roughly the same frequency of occurrence. The tumors were thought to arise spontaneously or be idiosyncratic in etiology, and therefore, not thought to be related to exposure to air processed by the Odorox® Boss™ Hydroxyl Processor air cleansing machines. Thus, the results of this study indicate that the output of hydroxyl radicals, oxidants, ozone and reaction by-products by the two Odoroox® Boss Hydroxyl Processor™ air cleansing machines was well tolerated by Sprague Dawley rats and did not induce any detectable toxicity under the conditions used in this study.

1. INTRODUCTION

The objective of this study was to evaluate the potential toxicity in rats exposed to hydroxyl radicals and other compounds that were released into the air as a result of operation of the Odorox® Boss™ Hydroxyl Processor air cleansing machines. This study was conducted at Comparative Biosciences, Inc. (CBI; Sunnyvale, CA). The study was conducted in compliance with the US Food and Drug Administration's Good Laboratory Practices regulations (21 CFR Part 58), with this protocol as amended, and with Testing Facility Standard Operating Procedures. The study was initiated on 1 March 2011. Treatment was initiated on 2 – 4 March 2011 (for Cohorts 1 – 3, respectively); terminal bleeds and necropsies were performed on 1 – 3 June 2011, respectively. The in-life phase was completed on 3 June 2011; this report is issued on 15 February 2012.

2. EXPERIMENTAL DESIGN

The study protocol and amendments are attached in Appendix A. There were two amendments to the protocol, neither of which significantly altered the study procedure. The first addressed changes in the study personnel; the second changed the name of the test article, which was incorrect in the approved protocol. Two deviations (see Appendix B) from Testing Facility SOPs were noted during the study. Neither deviation was thought to significantly affect the quality or integrity of the study.

The experimental design is summarized in Table 1. The study consisted of two groups of Sprague-Dawley (SD) rats: a treated group (20 males and 20 females) housed for 13 weeks in a room in which two Odorox® Boss™ Hydroxyl Processor air cleansing machines were operating continuously; and a control group (10 males and 10 females) housed for the same time period in a different room, under similar housing conditions, but not exposed to air modified by the Odorox® Boss™ Hydroxyl Processor® air cleansing machine operation. Both groups underwent the same evaluations and tests, including the following: Clinical observations were recorded once daily, with special attention to the eyes, nose, and respiratory system. Body weights and food consumption were measured once weekly. Functional observational battery (FOB) tests were conducted four times during the course of the study, including a pre-treatment test and three times during the study, (at regular intervals following the start of treatment). The FOB tests were focused on respiration, eyes, neurotoxicity, and mucous membranes. Ophthalmological examinations were performed on all animals by a veterinary ophthalmologist once prior to the start of treatment and again prior to sacrifice. Prior to necropsy, blood was collected for hematology and clinical chemistry analysis. At sacrifice, gross necropsies were performed, including specified organ weights. Tissues specified in the study protocol were collected, processed and evaluated histopathologically by a board-certified veterinary pathologist, with special attention to the skin, eyes, nasal turbinates, larynx/pharynx, and respiratory system.

Table 1. Summary of Study Design

Group	Animal No. (males/females)	Treatment	Sacrifice
1	101-110/151-160	Room without Odorox® Boss™ Hydroxyl Processor machines (similar housing conditions)	Week 13
2	201-220/251-270	Room with Odorox® Boss™ Hydroxyl Processor machines running continuously	Week 13

Note: Volume of Group 1 room was 1802.6 ft^3
Volume of Group 2 room was 1646.9 ft^3

3. MATERIALS AND METHODS

3.1. Test and Control Articles

3.1.1. Test Article

The test article, the Odorox® Boss™ Hydroxyl Processor air cleansing machine, produces airborne hydroxyl radicals, ozone and other compounds (combined oxides) by photolysis of ambient water vapor in the air. These products are designed to cleanse the air and exposed surfaces by reacting with and decomposing inorganic and organic compounds, bacteria, viruses, mold, and mildew producing volatile organic and inorganic compounds which circulate in the air. Volatile organic compounds and inorganic compounds are produced by the reaction, which also circulate in the air. Thus, animals are exposed to the reaction by-products as well as the hydroxyl radicals, ozone and oxidants generated by the HGI machines. The HGI equipment was received in good condition at the Testing Facility on the indicated dates.

Table 2. Test Articles/Machines

Item	Serial No.	Logged Usage on Receipt	Date of Receipt	Logged Usage on Return
Odorox® Boss™ Hydroxyl Processor	ODHG001293	1.4 hr	14 Feb 2011	2655.2 hr
Odorox® Boss™ Hydroxyl Processor	ODHG001295	148.7 hr	14 Feb 2011	2812.3 hr
Back-up	ODHG001266	44.5 hr	14 Feb 2011	44.6 hr*
Back-up	ODHG001294	286.7 hr	14 Feb 2011	286.8 hr*
Odorox® control box with blue modem cable "W3"	n/a	n/a	27 Jan 2011	n/a

*Bach-up machines were never used, so small logged usage must be due to moving machines around.

Two Odorox® Boss™ Hydroxyl Processor air cleansing machines were set up on either end of an animal room. The hydroxyl output and fan speed were adjusted prior to start of study by Jeff Chalpan, an HGI employee. See Section 3.2. for more detail about setting up the HGI machines.

3.1.2. Control Article

There was no formal control article. Control animals (Group 1) were housed in a room similar to the room with the test articles, maintained at approximately the same temperature, humidity and air exchange rate as the room in which the test article was operating. Air exchange rates were 10.8 changes/hr in the control room and 7.4 changes/hr in the room with the test article. This small difference was not expected to have any effect on the outcome of the study. Air supplied to both rooms was 100% fresh outdoor air. The room housing the control rats was slightly larger than the test room (1802.6 cubic feet vs. 1646.90 cubic feet, control and treated rooms, respectively).

3.2. Device Preparation/Operation

The test articles were installed and operated according to the Sponsor's instructions. The Odorox® Boss™ Hydroxyl Processor air cleansing machines were adjusted to the desired hydroxyl output and fan setting by Jeff Chalpan (from HGI) prior to start of the study. The processors were set on high to maximize the hydroxyl radical/oxidant concentration and the fans were set on low to provide the desired air flow and minimize the fan noise. During the study, the performance of the Odorox® Boss™ Hydroxyl Processor air cleansing machines was monitored continuously remotely by the Sponsor via an Ethernet data line connected to the stand-alone monitoring device. The sampling line connected to the monitoring unit sampled air from the middle of the rack on which the animal cages were placed. Live monitoring provided concurrent quantification of the output of the machines and demonstrated that the operation of the machines was within machine specifications throughout the study. Over the testing period the average oxidant level measured was 0.1236 parts per million (ppm) with a SD of 0.01829 ppm. The HGI monitoring report, describing in detail how the monitoring was conducted and summarizing the results, is attached to this study report as Appendix C.

3.3. Test System

Thirty-six male (160 – 180 g each) and 36 female (140 – 160 g each) Sprague-Dawley rats (*Rattus norvegicus*), 6 – 7 weeks old on arrival, were purchased from Simonsen Laboratories (Gilroy, CA) for use in the study. Rats were selected for the study since these animals are an accepted species frequently used in pre-clinical evaluation of devices intended for human use.

3.3.1. Institutional Animal Care and Use Committee Approval

A research proposal was approved by the Institutional Animal Care and Use Committee of CBI for this study.

3.3.2. Receipt and Acclimation

All 72 rats were received at the Testing Facility on 18 February 2011. Animals were received in good condition. Animals were acclimated for nine days following arrival. During the acclimation period, the animals were observed at least once daily for clinical signs of abnormality. No signs were observed. On 28 February 2011, the animals were examined by Carol Meschter, PhD, DVM, DACVP. Oral malocclusion was observed in three of the animals; the remaining rats were judged to be in good health and were released for use in the study.

3.3.3. Identification

Animals were arbitrarily assigned sequential temporary identification numbers after receipt at the Testing Facility. The study number and the temporary identification number were displayed on each cage card during the acclimation period. Upon assignment to a study group, animals were assigned "permanent" identification numbers, which were displayed on cage cards and coded on individual animals by tail marks using permanent ink.

3.3.4. Environment and Husbandry

3.3.4.1. Temperature and Relative Humidity

Controls were set to maintain the temperature of the animal rooms at 64° to 79°F and the relative humidity (RH) was generally between 30% to 70%. These environmental parameters were monitored and recorded daily. There were no excursions from the expected temperature range during the acclimation or treatment phases. Following the start of treatment (via test article machine exposure; see Sections 3.1. and 3.2.), the RH fell as low as 22% in the room housing the experimental animals (Group 2) on 21 separate days. In the room housing the control animals (Group 1), RH fell as low as 17% on 28 separate days. While these occasions represented excursions from the 30-70% RH range, these events were not thought to significantly affect the study.

The air exchange rate in the study rooms was adjusted down slightly from the range recommended (10 – 15 fresh air changes per hour) in the National Research Council's *Guide for Care and Use of Laboratory Animals*, National Academy Press, 1996) to ensure that animals were exposed to the desired concentrations of hydroxyls, ozone, etc. generated by the machine. It was thought that a high air exchange rate would remove the air modified by the Odorox® Boss™ Hydroxyl Processor air cleansing machines (hydroxyl radicals and other oxidation products) from the room too rapidly to allow sufficient exposure of the rats. At start of the study, the air exchange rate in the Group–2 room was 7.4 changes/hr and in the control room it was 10.8 changes/hr. Air exchange rates in the two rooms were left at these settings for the duration of the study. The room with the HGI machines was approximately 1646.9 cubic feet in volume while the control room was approximately 1802.6 cubic feet in volume. The slight differences in room volume and air exchange rate were not thought to affect the results of the study.

3.3.4.2. Light Cycle

Twelve hours of light (fluorescent light) and twelve hours of dark were provided in the animal rooms. Lights were turned on at approximately 0700 hours and turned off at approximately 1900 hours each day. (Pacific Standard Time)

3.3.4.3. Feed

LabDiet® 5002 Certified Rodent Diet (Purina Mills, Inc., St. Louis, MO) was fed *ad libitum* throughout the acclimation and treatment periods. Records of lot number(s) and Certificate(s) of Analysis are maintained by the Testing Facility. There are no known contaminants that are reasonably expected to be present in the diet that are known to be capable of interfering with the purpose or conduct of the study.

3.3.4.4. Water

Fresh water from Sunnyvale Municipal Water Supply was provided *ad libitum* to the animals via individual bottles. The water supply is periodically monitored by the City of Sunnyvale and by the Testing Facility for chlorine content and bacterial contamination. Results of these analyses are maintained on file at the Testing Facility. There are no known contaminants that are reasonably expected to be present in the water that are known to be capable of interfering with the purpose or conduct of the study.

3.3.4.5. Husbandry

Throughout the study, animals were pair-housed in plastic "shoe-box" static cages with wire tops in rooms dedicated to rats. General procedures for animal housing and husbandry were conducted according to Testing Facility SOPs and met all regulations concerning use of animals in research including the US Department of Agriculture regulations (9 CFR Ch.1) implementing the Animal Welfare Act (7 USC 2131 *et seq.*) and the recommendations of the National Research Council's *Guide for Care and Use of Laboratory Animals* (National Academy Press, 1996).

3.3.4.6. Sanitation

All animal enclosures and equipment were cleaned and sanitized according to Testing Facility SOP.

3.3.5. Final Selection and Group Assignment

On 28 February 2011 (study Day -2, -3, or -4, depending on cohort), all animals were weighed, subjected to veterinary check (see Section 3.3.2.), and assessed by FOB (see Section 3.9.). On the following day (1 March 2011), animals were subjected to ophthalmological examination (see Section 3.8.), and a total of sixty animals (30 males, 30 females) were selected for use in the study. Animals were selected based on moderate body weight and normal clinical, behavioral, and ophthalmological presentation. Two males and one female were excluded at the veterinary check, two males were excluded for ophthalmological reasons, and two males and one female were excluded for possible behavioral (FOB) abnormalities. Animals that were approved to be on study were randomized using an Excel function and assigned to the two study groups.

3.4. Treatment

3.4.1. Dose Administration

Formally speaking, there was no dose administration, but animals were maintained in rooms lacking (Group 1) or containing (Group 2) operating test article devices (Odorox® Boss™ Hydroxyl Processor air cleansing machines) from the start of the treatment phase to the end of in-life.

3.4.2. Treatment Cohorts

To facilitate testing and necropsies, animals were entered into the treatment phase as three separate cohorts at one day intervals, starting on 2 – 4 March 2011 for Cohorts 1 – 3, respectively. Cohorts were composed as follows: Cohort 1, Rats 201 - 210 and 251 – 260; Cohort 2, Rats 211 – 220 and 261 – 270; Cohort 3, all animals of Group 1 (Rats 101 – 110 and 151 – 160).

Note that, because of cohort assignment, data collected on a single calendar date actually may correspond to one of three sequential study days, depending on the respective cohort. For clarity in data analysis and presentation, data for a single calendar date are pooled and presented (e.g., plotted) as for the animals of Cohort 2 (i.e., actual study day may be ± 1 day from that shown).

3.5. Clinical Observations

Clinical observations, including overt signs of toxic or pharmacologic effect(s), were conducted at least once daily for each animal during the acclimation and treatment periods. All abnormal clinical signs were recorded. Clinical observations were inadvertently not done on three different days (See Deviation No. 1.).

3.6. Body Weights

The animals were weighed within two days prior to start of treatment, once weekly thereafter, and at sacrifice. Due to error in the carcass weight measurement of one cohort at necropsy, the carcass weights were not used in body weight analysis. There were weekly body weights before the start of the study and weekly for 13 weeks during treatment. These weights were used for analysis and statistical comparisons. The final week-13 body weight (Day 88) was used in the normalization of organ weights to body weights (See Deviation No. 2.).

3.7. Food Consumption

Food consumption (FC) was measured once weekly beginning at the start of treatment. FC was calculated as grams (g) per animal per day for each weekly interval (FC/animal/week). Data were expressed as a mean for the pair-housed animals.

3.8. Ophthalmology

All animals received an ophthalmological examination by a board-certified veterinary ophthalmologist during the acclimation period (within three days prior to the start of treatment) and again within three days prior to sacrifice. Two males were excluded from inclusion into the study based on the pre-treatment ophthalmological examination.

3.9. Functional Observational Battery (FOB) Behavioral Testing

Functional observation battery (FOB) testing was performed on all animals four times during the 13-week study. The first test occurred within two days prior to start of treatment; the remaining tests were performed at approximately regular intervals throughout the treatment phase. The individual tests that comprise the FOB test were described in an appendix to the protocol (see Appendix A of this report). Two males and one female were excluded from use in the study based on possible abnormal behavior in the pre-treatment FOB assessment.

3.10. Clinical Pathology

Immediately prior to sacrifice, terminal cardiocentesis was performed on each animal according to Testing Facility SOP. The resulting whole blood and serum samples were submitted to Quality Veterinary Laboratories (QVL, Davis, CA) for assessment of hematology and clinical chemistry parameters. The parameters to be evaluated were presented as an appendix to the protocol (see Study Protocol in Appendix A of this report).

3.11. Necropsy

The animals were euthanized on the respective Study Day 91, according to Testing Facility SOP. Specified organs were weighed, and tissues were collected for histopathological evaluation (Appendix B of Study Protocol, Appendix A of this report). The specified organs and tissues were listed as an appendix to the protocol (see Appendix A of this report). Tissues were fixed in 10% neutral buffered formalin, NBF, (except eyes and testes, which were fixed in modified Davidson's solution for approximately 24 hours, then transferred to 10% NBF).

3.12. Histopathology

Fixed tissues were dehydrated, embedded in paraffin, sectioned at 3 – 5 µm, and stained with hematoxylin and eosin (H&E). Tissue slides were evaluated histopathologically via light microscopy by a board-certified veterinary pathologist.

3.13. Statistical Analysis

Calculations and descriptive statistics (means, standard deviations) were performed using Excel® (Office 2007; Microsoft, Redmond, WA). Where appropriate, inferential statistical analysis was performed using Excel® or Prism 5 (GraphPad; San Diego, CA). Continuous normal data were analyzed using the Student t-test (with Welch's correction in case of non-homogeneous variance as determined by an F-test). Categorical (non-continuous) data (e.g., FOB scores, histopathology severity scores) were analyzed using non-parametric tests. P values of ≤0.05 were considered statistically significant. Summary tables, graphic displays, and other appropriate techniques were employed as deemed necessary. Clinical observation data are presented as text or in tabular form.

3.14. Storage Locations

The following records, together with any other records deemed necessary by the Study Director and study monitor(s), were retained at the Testing Facility in accordance with 21 CFR Part 58.195:

Personnel records, approved and dated study protocol and associated documentation, test/control article records, pretest animal records, in-life animal records, feed and water analysis documentation, post-mortem animal records, and relevant formal correspondence with the Sponsor are on file.

Following completion of the study treatment phase, all equipment was returned to the Sponsor by a shipment leaving the Testing Facility on 15 June 2011. The fate of the remaining biological samples (including histology specimens) will be determined per agreement with or consultation with the Sponsor. Original raw data, or exact copies, will be stored at the Testing Facility for at least ten years.

4. RESULTS

4.1. Acclimation

Clinical observations were recorded daily throughout the acclimation phase. Two males and one female were excluded from the study by the veterinarian at the pre-study health examination. All other animals were released for use in the study at the end of the acclimation period. Five more rats were excluded from inclusion in the study prior to group assignment, based on results of the ophthalmological examination, and the pre-treatment FOB test.

4.2. Mortality

There was no mortality during the acclimation or treatment phases of the study.

4.3. Clinical Observations

Daily clinical observations are summarized in Tables 5A and B. All of the Group-2 (Odorox® Boss™ Hydroxyl Processor exposed) animals, both male and female, displayed rough coats (mild form of piloerection) from the fifth week (Day 29 or 30) through the rest of the study period. This sign was not observed in the Group-1 (control) animals. Piloerection is a commonly seen sign of stress in rats. In this case it might be due to ongoing exposure to greater air movement and/or noise or vibration generated by the test article's blowers. It was noted by the research associates working in the room with the Odorox® Boss™ Hydroxyl Processor air cleansing machines that there was a "strange smell" in the room. Thus, there may have been other stress-producing factors for rats that weren't readily detected by humans. Among the Group-2 animals, 17 of 20 males (85%) and 7 of 20 females (35%) displayed evidence of generally mild chromodacryorrhea, i.e. red staining generally on eyelids around one or both eyes, occasionally the nose or pink staining on fur of the head, neck or back (presumably transferred by grooming) on one or more days. Among the Group–1 animals, similar signs were seen in 8 of 10 (80%) males and 9 of 10 (90%) females. These signs were most frequently observed in the final days of the study and were generally mild when noted. Chromodacryorrhea is often seen in rats; since the stains were seen in animals of both groups, at similar frequencies of occurrence, and were generally mild, the sign is unlikely to be test article-related. A single Group-1 male had a kinked tail from Day 59 on (likely caught in cage top). All but three of the animals exhibited one or more of these signs during the course of the three-month study; no other observations were noted.

In addition to the individual daily clinical observations, "group observations" were made periodically throughout the study by the study director. The first observation occurred after animals had been on study about a week and no obvious differences were noted between the control and treated groups. By Study Day 45, 46, and 47 (for cohorts 3, 2, and 1, respectively) the treated animals appeared more alert than the control group. An observer in front of their cages was enough to catch their attention. Light tapping with a finger on the front of the cage was sufficient to bring approximately 85–90% of the animals to the front of the cage to investigate. An observer standing in front of the control cages seldom elicited any curious behavior on the part of control rats. Tapping on the front of their cages occasionally caused them to raise their head from a curled sleeping posture, but generally they resumed that sleeping posture as soon as they saw it was just a person. This same trend of Group–2 animals appearing more alert and more interested in their surroundings during the daylight hours continued for the remainder of the observations on Study Days 49, 50, and 51; Study Days 56, 57, and 58; Study Days 59, 60, and 61; and Study Days 73, 74, and 75 (all for cohorts 3, 2, and 1, respectively). During the conduct of one of the mid-study FOB tests, there seemed to be a greater background noise produced by Group–2 rats moving around in their home cages than was noted in the control room during control rat FOB testing the same day. The same observation was made during the final FOB test on Study Days 87, 88, or 89 (for Cohort 3, 2, and 1, respectively). The apparent increased alertness in Group 2 didn't translate into greater locomotor activity during the FOB test, possibly because testing was done in a different cage than the home cage, since animals were pair housed and tested individually.

4.4. Body Weights

Both groups displayed gains in body weight over the course of the study, both as raw body weight (Tables 6A and 6B) and when normalized to the pre–exposure value (Tables 7A and 7B (See Figures 1 and 2). Differences between the groups were statistically significant only for the males and only intermittently; on Days 4, 25, and 91 (for normalized weights), indicating that these differences were not biologically significant. An apparent increase in body weight, seen on Day 91 (i.e., at sacrifice) in both males and females of Group 2, was determined to be due to an error in weighing Cohort–1 carcasses at necropsy (see Deviation 2, Appendix B). The Day 91 (carcass) weights therefore, were not used in body weight data analysis. The weekly body weights (pre-study and for 13 weeks while on study) were used for assessing body weight changes. Instead, the Day 88 body weights (i.e., for Week 13) were used to determine the body-weight normalized organ weights (Table 16A and 16B) for males and females, respectively. Animals in the two groups gained a comparable amount of body weight during the 13 weeks of the study. No significant differences in body weight were noted between the two groups. Thus, treatment did not affect the body weight or weight gain of treated animals under conditions used in this experiment.

4.5. Food Consumption

Average food consumption, calculated as g/rat/day over the weekly measurement period (g per rat per day, food consumed by two rats over interval/2) is shown in Tables 8A and 8B for males and females, respectively and plotted in Figures 3 and 4 (group mean ± standard deviation). Figure 4 shows that there was more variability in average food consumption in females of both the control and treated group. The reason for this is unclear. Food consumption did not significantly differ between the two groups during the course of the study (the sole exception was during the first week in the males).

4.6. Ophthalmology

Ophthalmological assessments are summarized in Tables 9A and 9B, for males and females, respectively. There were no findings in either the control or the treated group prior to onset of treatment. At the end of treatment a slightly defective blink and resultant epiphora, was noted in one control male, No. 109. There were no findings in the treated males. There were no findings in females of either group prior to start of study. In females at the end of treatment, there were no findings in any control animals. Three of the treated females had some minor findings: No. 260 had a bilateral increased nuclear density; No. 258 had a bilateral increased nuclear density and pinpoint opacity in the lens; and No. 264 was found to have an increased nuclear density and pinpoint opacity in the lens of the right eye only. The incidence of ophthalmological abnormalities was slightly higher in the treated females than in treated males (15% vs. 0 %) while in males the incidence of ophthalmological abnormalities was higher in the untreated animals 5% vs. 0%. These minor findings are fairly common low-frequency incidental findings in rats of this strain and age and are within the normal range of variation expected and are probably not related to the treatment. It is unclear why most of the ophthalmological abnormalities in this study were seen in females. The different size control and treatment groups may have contributed to there being more animals with minor common ophthalmological findings in the larger treatment group.

4.7. FOB Testing

Functional observation battery (FOB) assessments are summarized in Tables 10A and 10B, for males and females, respectively. No evidence of behavioral or neurological abnormalities was found. Almost all parameters assessed throughout the study were "N" for normal or the numerical rating corresponding to normal for any given test. There were four parameters that varied somewhat throughout the FOB testing: generally mild piloerection (rough coat), chromodacryorrhea, i.e., red staining around eyes, nose or on fur, grip strength, and response to being picked up.

During pre-study FOB testing none of the animals exhibited any obvious piloerection, but 19 of 20 Group–2 males and 11 of 20 Group–2 females exhibited mild signs of piloerection (rough coat is a mild form) on 31 March 2011 (Study Day 27–29, depending upon cohort); decreasing to 7 of 20 Group–2 males and 0 of 20 Group–2 females on 2 May 2011 (Study Days 59–61 depending upon cohort) and only 1 of 20 males and no females on the final FOB test on Study Day 87–89, (depending upon cohort). None of the control males or females ever showed any piloerection (rough coat). Since piloerection is frequently a sign of stress (environmental or otherwise), this might simply reflect the animals feeling less stress with each successive FOB test. Alternatively, the treated group might have been slightly more stressed during the early part of the study but acclimated to whatever stressed them initially (possibly air movement or the sound of the machines running).

No chromodacryorrhea was noted during pre-study FOB testing in males or females of control or treated rats. On Study Days 27, 28, and 29 (for cohort 3, 2, and 1, respectively), no control or treated males showed any chromodacryorrhea, while 2 of 10 control females and 0 of 20 treated females showed (generally mild crustiness on eyelids). The FOB test conducted on Study Day 59, 60, or 61 (for cohorts 3, 2, and 1, respectively) showed 1 of 10 control males and two different control females as well as 10 of 20 treated males and females showed signs of mild chromodacryorrhea. At the final FOB test (Study Day 87–89, depending upon cohort), all animals appeared normal, with no obvious chromodacryorrhea present. Because there was a higher incidence in the treated animals, it might be related to treatment, or possibly stress. Chromodacryorrhea, when present, appeared to be short-lived and frequently gone or less pronounced by the end of the study. There was no cumulative effect over the course of the study.

Response to picking up was a variable response ranging from the most common, little resistance, sits quietly to struggles/runs away from handler. There is always a range of responses to being picked up in animals. There was a clear trend of improvement during the study, with animals showing less resistance over the FOB trials, with most animals having mild reactions by the last FOB. This trend is frequently seen in FOB tests when the test article has no neurological effects and the animals remain calm.

Grip-strength is the last parameter that varied among animals. The longest grip strength was generally recorded during the first pre-study FOB: means; 15.6 sec. in Group–1 females and 10.4 sec. in Group–2 females; 11.6 sec. in Group–1 males and 7.2 sec. in Group–2 males. These values recorded prior to start of the study are primarily a reflection of individual differences in the animals and how acclimated they are to handling. Females normally have longer/higher grip strength due to lower body weights. The mean values generally decreased in subsequent FOB tests as animals became accustomed to the testing procedures and there were no neurological effects produced by the treatment which might affect grip strength. The decreased grip strength in both the treated and control groups argues against a treatment-related effect and suggests the observed decrease in grip strength was probably a result of acclimation to the testing procedures. Thus, exposure to air treated by two Boss Hydroxyl Odor Processor® machines running continuously for 13 weeks did not appear to induce any behavioral or neurological abnormalities as measured by the FOB tests under the conditions of this study.

4.8. Clinical Pathology

4.8.1. Hematology

Hematology results are provided in Tables 11 and 12 for males and females, respectively. Parameters are summarized below. Rat 253 had a hemangiosarcoma. It had elevated WBC; decreased RBC, HGB, HCT, and increased RDW; increased PLT and MPV; increased relative and absolute neutrophil counts, and decreased relative lymphocytes. This is a typical finding in hemangiosarcoma. This animal was excluded from statistical analysis.

There were some statistically significant differences found between treated and control males and females for a few hematological parameters: in males, HGB ($P<.05$), MCHC ($P<0.01$), MPV ($P<0.001$), percent reticulocytes ($P<0.05$), and number of reticulocytes ($P<0.01$); in females, WBC ($P<0.01$), MCHC ($P<0.01$) and MPV ($P<0.05$). The individual values for all these parameters were within the normal range, with the exception of some animals that were found to have tumors as noted below. Because healthy animals fell within the normal range and there were no histopathological findings to support a cause for any abnormality, these “statistically significant” findings were not thought to have biological relevance.

WBCs: The total number of WBCs was significantly elevated in Boss Hydroxyl Odor Processor® air cleansing machine exposed (Group 2), females, but not in Group-2 males. Differential counts revealed significant changes only in the numbers (though not proportions) of lymphocytes and monocytes in the treated females. These changes were not considered biologically relevant, except in Animal 253 (the rat with the hemangiosarcoma). It had elevated WBC; decreased RBC, HGB, HCT, and increased RDW; increased PLT and MPV; increased relative and absolute neutrophil counts, and decreased relative lymphocytes (i.e., 253's WBC count = 17.8 x 10^3/µL, group mean =7.9).

RBCs: Although the proportion and number of reticulocytes were significantly decreased in treated males, changes in total RBC numbers were not significant in either males or females. The only parameters that displayed significant changes in both males and females were mean corpuscular hemoglobin concentration (MCHC; decreased in treated animals) and mean platelet volume (MPV; increased in treated males and females). These changes are not considered biologically relevant. No elevations or significant decreases were noted in animals with pathological findings.

Table 3. Hematological Parameter Summary

		WBC	RBC	HGB	HCT	MCV	MCH	MCHC	RDW	PLT	MPV	%RETIC	#RETIC
Group		x10^3 /uL	X10^6/uL	g /dL	%	fL	pg	g / dL	%	x10^3 /uL	fL		x10^9/L
1 M	Mean	10.8	9.13	15.7	52.6	57.6	17.2	29.9	11.5	872	7.4	2.7	243.4
	StdDev	3.3	0.39	0.7	2.7	1.9	0.4	0.4	0.4	125	0.3	0.4	31.9
2 M	Mean	9.4	8.89	15.1	51.5	57.9	17.0	29.4	11.3	796	8.3	2.3	206.5
	StdDev	1.7	0.46	0.7	2.4	1.7	0.6	0.6	0.4	133	0.5	0.2	20.4
1 vs. 2	**P value**	**NS**	**NS**	**<0.05**	**NS**	**NS**	**NS**	**<0.01**	**NS**	**NS**	**<0.001**	**<0.05**	**<0.01**
1 F	Mean		7.9	14.8	48.1	60.7	18.6	30.7	10.1	803	8.0	2.8	218.8
	StdDev	1.0	0.2	0.4	1.4	0.9	0.4	0.4	0.5	54	0.6	0.3	22.9
2 F	Mean	7.9	7.8	14.3	47.6	61.0	18.3	30.0	10.4	798	8.7	2.8	212.0
	StdDev	2.8	0.6	1.1	3.7	1.4	0.5	0.7	0.7	355	0.6	0.7	35.1
1 vs. 2	**P value**	**<0.01**	**NS**	**NS**	**NS**	**NS**	**NS**	**<0.01**	**NS**	**NS**	**<0.05**	**NS**	**NS**

WBC= white blood cell count, RBC = red blood cell count HGB= hemoglobin
HTC=hematocrit MCV=mean corpuscular volume MCH= mean corpuscular hemoglobin
MCHC=mean cellular [HGB] RDW- RBC distrib. width PLT = platelets
MPV=mean platelet volume % RETIC = % reticulocytes, # RETIC = number of reticulocytes

Some elevated hematological parameters were found in some animals with tumors. Control Animal 107, with a hepatic carcinoma, was found to have elevated: WBCs (13.2 $x10^3/\mu L$), platelets (1095 x $10^3/\mu L$), reticulocytes (312.5 x $10^9/L$), and eosinophyls (0.40 x $10^3/\mu L$). Animal 267, a treated female that was found to have a renal carcinoma, had 14% neutrophyls (1.11 x $10^3/\mu L$). Another treated female, No. 261, that was found to have a thymic epithelioma, appeared to have hematological parameters that were within normal limits. In males, the elevated percentage and number of reticulocytes in control male No. 107 (one of the animals with a tumor) probably contributed to significant differences between control and treated males for those two parameters being elevated. Other statistically significant differences in hematological parameters between Group 1 and Group 2 have no obvious explanation or histological findings to support a treatment-related effect, and therefore, are not thought to have any biological significance.

4.8.2. Clinical Chemistry

Clinical chemistry results are provided in Tables 13A and 13B for males and females, respectively. Parameters with significant changes in either sex are summarized below. Significant changes were seen in both males and females for albumin, protein, alkaline phosphatase, creatinine, calcium, glucose, and globulin; in males for blood urea nitrogen and phosphorus; and in females for potassium. For most of these clinical chemistry parameters, mean values were decreased in the Group–2 animals (Odorox® Boss™ Hydroxyl Processor air cleansing machine exposed animals). Altered values for the parameters in animals with tumors didn't explain or correlate with those parameters that appeared to have significant changes in Group–1 vs Group–2 animals. For most of the parameters where there were statistically significant differences between groups, the majority of individual values in both Groups 1 and 2 (male and female) fell within the normal range of values. For calcium, both males and females of Group 2 each had five individuals with values below the normal range, while Group–1 animals (male and female) were all within the normal range. This suggests a possible treatment-related effect. The biological significance of the other parameters that have statistically significant changes, where individual values for Groups 1 and 2 are mostly within the normal range, is unclear. The lack of pathological findings in any organs or tissues (other than the tumors), suggests that the statistically significant findings are probably not biologically or toxicologically meaningful.

Table 4. Clinical Chemistry Parameter Summary

Group		ALB g/dL	TP g/dL	ALP U/L	BUN mg/dL	CREAT mg/dL	CA mg/dL	GLU mg/dL	PHOS mg/dL	K mEq/L	GLOB g/dL
1 M	Mean	3.2	6.4	241	18	0.4	9.8	122	6.5	6.0	3.2
1 M	StdDev	0.3	0.5	46	2	0.1	1.5	19	0.7	0.4	0.3
2 M	Mean	2.9	5.7	185	15	0.3	7.3	106	5.6	6.4	2.8
2 M	StdDev	0.3	0.7	49	2	0.1	2.3	18	0.9	0.6	0.4
1 vs. 2	**P value**	**<0.05**	**<0.01**	**<0.01**	**<0.05**	**<0.01**	**<0.01**	**<0.05**	**<0.01**	**NS**	**<0.01**
1 F	Mean	3.6	6.7	222	16	0.5	10.5	124	5.4	5.9	3.1
1 F	StdDev	0.2	0.4	36	2	0.0	1.1	14	0.6	0.4	0.2
2 F	Mean	3.2	5.9	185	15	0.4	7.9	111	5.6	6.4	2.7
2 F	StdDev	0.3	0.5	42	2	0.1	1.8	13	0.7	0.5	0.3
1 vs. 2	**P value**	**<0.001**	**<0.001**	**<0.05**	**NS**	**<0.001**	**<0.001**	**<0.05**	**NS**	**<0.01**	**<0.001**

ALB= albumen TP= total protein ALP= Alkaline phosphatase BUN= blood urea nitrogen
CREAT= creatinine CA = calcium GLU= glucose PHOS= phosphorus
K=potassium GLOB=globulins

4.9. Necropsy Observations

Necropsy observations are summarized in Table 14. An unusually small left testis was noted in one control male (107). One Group-2 male (No. 209) displayed unequally sized thyroids. Both observations are frequently naturally occurring observations in rats and not believed to be related to the test article. A small mass was noted on the liver of Group-1 male (No. 107); histopathological examination of this liver subsequently revealed hepatic biliary carcinoma. A single Group-2 female (No. 253) exhibited fusion of several abdominal organs (spleen, pancreas, liver) and had white nodes on its spleen. (The spleen and pancreas weights for this animal were excluded from organ weight analysis, because the weight of these organs were clearly outliers.) During histopathological examination, it was determined that Animal 253 had a hemangioma sarcoma in its spleen. Female 267 was noted to have a small white pea-sized mass on the right kidney, which was determined by the pathologist to be renal carcinoma. No abnormal necropsy observations were made in the remaining tumor-bearing animal, (Group 2, Female 261).

4.10. Organ Weights

Organ weights were recorded at necropsy and are presented as raw values (Tables 15A and 15B) and normalized to body weight (Tables 16A and 16B, using the Day-88 body weight (see Section 4.4. and Deviation 2 in Appendix B) and to brain weight (Tables 17A and 17B). Boss Hydroxyl Odor Processor® air cleansing machine-exposed males exhibited significant decreases in the weight of the pituitary (raw, body weight-normalized, brain weight-normalized); significant increases were seen in the weight of the testes/epididymes (raw, brain weight-normalized). Boss machine-exposed females did not exhibit significant changes in any raw or normalized organ weights. Small testes or unequally sized testes in rodents are not uncommon. Histological evaluation revealed no abnormalities in either the testes or the pituitary, so it is unlikely that either of these effects were test article/treatment-related. It is possible that the smaller size of the control group contributed to the apparent difference in these organ weights.

4.11. Histopathology

Pathology results are summarized in Table 18, and the pathologist's report (including individual animal data) is provided in Appendix D.

5. DISCUSSION AND CONCLUSIONS

The objective of this study was to evaluate the potential toxicity in rats exposed to hydroxyl radicals and other compounds that may be released into the air as a result of operation of the Boss Hydroxyl Odor Processor® air cleansing machine.

Summary of In-Life Study Results:

No mortality or unscheduled deaths occurred during the study. No abnormal clinical observations were seen in animals exposed to hydroxyl ions and other compounds generated by operation of the Odorox® Boss™ Hydroxyl Processor air cleansing machine. Rough coat, a mild form of piloerection, was the only clinical observation that may have been related to treatment. It was also noted the treated animals appeared to be more alert during the day time than the untreated animals after about a week or two of treatment. No changes in food consumption or weight gain were noted. There were no treatment-related changes in ophthalmology, neurological or behavioral changes as evaluated by the functional observational battery tests. There were some statistically significant differences found in some hematological and clinical chemistry parameters, but individual values were within the normal range for rats, so the statistical differences are not believed to have any biological significance. Odorox® Boss™ Hydroxyl Processor air cleansing machine exposed males exhibited a decrease in pituitary weight and an increase in testes/epididymes weight. Histological evaluation failed to find any evidence supporting abnormalities in hematology, clinical chemistry, in the pituitary or the testes/epididymis. Thus, during the 13-week in-life phase of the study, operation of two Odorox® Boss™ Hydroxyl Processor air cleansing machines appeared to be well tolerated by the animals under the conditions used in this study and the output of material achieved by the two Odorox® machines operating during the study.

Summary of Pathology Results

In general, there were no histopathologic differences between the control rats and the rats exposed to two continuously operating Odorox® Boss™ Hydroxyl Processor air cleansing machines. Special attention was paid to the skin, eyes, nasal turbinates, larynx/pharynx, and respiratory system. There were no changes in these organs and they appeared to be within normal limits in both the control and treated animals. There were, however, a number of neoplasms. There was a hepatobiliary carcinoma in one control male and a renal carcinoma, a hemagiosarcoma and a thymic epithelioma in three females in the Boss Hydroxyl Odor Processor® machine group. The incidences were 1 of 20 and 3 of 40, which is statistically indistinguishable. This suggests that the tumors were spontaneously occurring and not related to exposure to air processed by the Odorox® Boss™ Hydroxyl Processor air cleansing machines.

The histopathologic findings from this study indicate that the Odorox® Boss™ Hydroxyl Processor air cleansing machine was well tolerated under the conditions used in this study and not associated with adverse effects on the eyes, skin or respiratory system in particular.

Study Toxicology Summary

The in-life phase of the study failed to reveal any changes in: observable behavior or health, appetite or weight gain, ophthalmology, neurological measures or other behaviors (as measured by FOB test), or biologically relevant changes in hematology or clinical chemistry. In males, significant organ weight changes in pituitary and testes may be related to the different sizes of the two groups and are probably not biologically significant. No histopathological differences were found between the control rats and those that were housed in a room with two Odorox® Boss™ Hydroxyl Processor air cleansing machines running continuously for 13 weeks. There were some neoplastic tumors found in both the treated and control rats, but they were not thought to be related to exposure to air processed by the Odorox® Boss™ Hydroxyl Processor air cleansing machines. Thus, the results of this study indicate that the Odorox® Boss™ Hydroxyl Processor air cleansing machine was well tolerated by SD rats and did not induce any detectable toxicity under the conditions used in this experiment.

Table 5A. Clinical Observations, Males

		Study day(s) on which indicated sign was observed			
Group	Animal No.	Rough coat	Chromo-dacryorrhea*	Kinked tail	NSO
1	101				x
	102		14-16, 31-75, 84-sac		
	103		16		
	104		77-sac		
	105				x
	106		88-sac		
	107		88-sac	59-sac	
	108		59-75		
	109		88-sac		
	110		88-sac		
2	201	30-sac	90		
	202	30-sac	90		
	203	30-sac	18		
	204	30-sac	9-13		
	205	30-sac	90		
	206	30-sac	90		
	207	30-sac	75-sac		
	208	30-sac	90		
	209	30-sac	90		
	210	30-sac			
	211	29-sac	89-sac		
	212	29-sac			
	213	29-sac	89-sac		
	214	29-sac	89-sac		
	215	29-sac	89-sac		
	216	29-sac	89-sac		
	217	29-sac	89-sac		
	218	29-sac			
	219	29-sac	89-sac		
	220	29-sac	89-sac		

* Chromodacryorrhea: As evidenced by any of the following: Red staining of fur around one or both eyes; dried blood on cheek(s) and/or nostril(s), mild stain on forehead/cheek(s)/ear(s)/nose; dark red stain on lower back fur.

Table 5B. Clinical Observations, Females

		Study day(s) on which indicated sign was observed			
Group	Animal No.	Rough coat	Chromo-dacryorrhea*	Kinked tail	NSO
1	151		88-sac		
	152		88-sac		
	153		88-sac		
	154		88-sac		
	155		88-sac		
	156		88-sac		
	157		88-sac		
	158		88-sac		
	159		88-sac		
	160				x
2	251	30-sac	90		
	252	30-sac	90		
	253	30-sac	90		
	254	30-sac	90		
	255	30-sac			
	256	30-sac	61-76, 78, 90		
	257	30-sac	90		
	258	30-sac			
	259	30-sac	61-77		
	260	30-sac			
	261	29-sac			
	262	29-sac			
	263	29-sac			
	264	29-sac			
	265	29-sac			
	266	29-sac			
	267	29-sac			
	268	29-sac			
	269	29-sac			
	270	29-sac			

* See preceding table.

Table 6A. Body Weight, Males

		Body Weight (g) on Indicated Study Day													
Group	Animal No.	-3	4	11	18	25	32	39	46	53	60	67	74	81	88
1	101	227.2	266.8	288.4	304.1	318.9	334.0	338.9	349.3	354.5	363.9	377.0	384.0	392.5	392.7
	102	239.0	284.9	320.9	351.2	374.2	398.9	407.5	430.7	433.7	445.4	459.2	464.2	477.0	480.2
	103	238.8	275.1	303.0	328.4	341.7	357.9	366.7	380.4	380.7	394.1	397.6	403.0	410.3	407.4
	104	240.0	286.4	318.4	348.5	364.3	382.8	394.3	409.7	412.9	422.6	433.2	444.2	450.0	453.6
	105	217.7	252.2	281.4	303.7	315.3	328.2	342.1	356.3	361.3	373.7	377.9	380.3	393.5	392.9
	106	238.1	286.1	322.9	348.1	363.8	380.3	393.4	411.3	415.2	430.1	430.1	435.6	448.2	449.1
	107	242.9	286.0	328.1	355.2	373.8	399.3	406.7	427.8	429.2	444.1	449.5	460.1	465.8	466.4
	108	236.8	273.4	305.3	331.2	348.4	365.8	374.2	385.7	386.7	396.5	405.3	412.1	415.6	420.3
	109	244.4	283.2	318.6	344.4	357.7	373.9	382.6	393.7	396.6	395.0	417.1	416.1	427.7	434.8
	110	236.3	270.7	306.2	334.2	346.1	355.5	368.9	378.8	378.1	410.5	399.6	406.4	414.8	416.7
	Mean	**236.1**	**276.5**	**309.3**	**334.9**	**350.4**	**367.7**	**377.5**	**392.4**	**394.9**	**407.6**	**414.7**	**420.6**	**429.5**	**431.4**
	StdDev	**7.9**	**11.2**	**15.4**	**18.6**	**20.7**	**24.4**	**24.2**	**27.7**	**27.4**	**27.9**	**28.2**	**29.5**	**29.4**	**30.4**
2	201	225.5	274.3	290.1	318.3	336.3	346.4	348.6	357.9	367.5	376.4	387.1	384.9	396.3	396.9
	202	228.0	264.6	305.3	334.1	356.5	374.5	381.9	398.6	409.1	418.6	420.5	425.2	433.6	440.0
	203	230.6	279.2	307.5	335.6	354.5	355.2	376.2	391.2	398.3	411.6	415.5	423.8	431.1	439.3
	204	235.4	282.7	317.7	345.3	373.7	381.6	395.9	410.6	418.1	430.6	435.4	446.4	449.7	457.7
	205	239.8	280.9	311.6	341.1	361.3	371.6	383.3	398.6	402.5	419.7	425.4	429.8	440.3	440.7
	206	237.3	274.5	301.5	323.3	341.4	350.2	357.3	374.8	380.4	395.3	403.8	409.5	415.8	416.8
	207	252.6	298.3	335.7	372.1	396.1	415.4	426.1	440.2	449.8	462.1	463.6	473.2	485.1	479.4
	208	233.0	281.2	316.4	345.6	366.4	378.4	390.1	407.1	410.1	424.1	434.2	436.6	449.5	450.3
	209	232.8	271.1	306.5	331.7	342.6	356.3	366.3	375.2	379.7	390.1	403.8	407.5	418.4	420.0
	210	236.3	277.7	299.4	328.1	347.5	358.4	369.2	383.2	388.1	399.6	404.9	407.1	419.9	421.9
	211	230.2	275.1	304.9	336.9	362.1	374.7	384.1	400.9	408.4	424.4	429.0	431.7	440.7	448.2
	212	246.6	296.1	331.1	365.3	387.9	398.2	405.9	420.9	427.3	443.1	443.1	441.5	444.3	452.3
	213	236.7	281.9	316.7	347.5	362.1	376.4	392.1	403.6	409.8	424.0	425.5	432.1	438.1	444.6
	214	248.4	292.4	316.8	345.9	364.1	383.0	378.4	395.0	389.9	399.2	403.0	407.7	418.9	422.6
	215	227.2	271.2	304.6	338.9	358.4	373.3	387.2	401.4	409.4	423.4	431.2	436.9	449.0	446.2
	216	240.3	287.1	323.6	354.4	381.6	402.0	419.9	442.1	450.4	468.6	471.2	476.7	489.5	493.2
	217	234.7	277.4	310.2	341.8	364.4	369.4	386.0	402.2	406.4	422.2	433.1	437.7	444.9	454.5
	218	240.4	297.0	344.3	378.6	402.3	415.9	435.3	455.4	463.3	476.6	484.6	490.5	496.2	508.7
	219	215.8	251.1	268.9	294.1	312.2	324.1	326.8	344.8	348.5	360.3	366.8	371.6	377.6	380.9
	220	240.1	287.6	313.1	332.6	346.3	357.9	354.5	370.2	378.9	380.6	389.1	390.9	404.7	409.0
	Mean	**235.6**	**280.1**	**311.3**	**340.6**	**360.9**	**373.1**	**383.3**	**398.7**	**404.8**	**417.5**	**423.5**	**428.1**	**437.2**	**441.2**
	StdDev	**8.4**	**11.4**	**16.2**	**18.8**	**21.1**	**22.9**	**26.3**	**27.5**	**28.4**	**30.2**	**28.8**	**30.1**	**29.8**	**30.7**
1 vs. 2	P value	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS

Table 6B. Body Weight, Females

		Body Weight (g) on Indicated Study Day													
Group	Animal No.	-3	4	11	18	25	32	39	46	53	60	67	74	81	88
1	151	192.7	197.4	218.2	229.8	237.8	248.0	260.2	272.6	270.8	276.7	267.2	275.2	284.3	283.5
	152	168.1	186.2	214.8	208.7	211.6	213.1	235.1	236.9	237.2	251.0	254.9	249.3	254.7	244.6
	153	189.1	205.8	247.5	247.3	244.8	259.8	288.1	283.4	272.4	287.1	287.1	289.3	298.8	324.4
	154	174.1	185.6	195.3	209.7	206.0	213.5	218.2	221.6	229.6	225.5	234.1	235.8	235.4	242.5
	155	178.9	184.7	201.5	210.3	220.3	226.4	225.4	256.1	234.5	239.0	236.7	244.1	242.8	245.3
	156	180.5	193.3	204.7	219.6	223.3	231.5	242.2	238.1	255.8	261.6	261.4	263.9	268.7	274.2
	157	176.7	192.0	191.5	210.4	215.5	218.5	226.1	227.1	234.0	236.2	233.2	240.2	237.0	247.2
	158	186.2	199.9	216.6	243.4	240.6	245.5	255.5	279.2	265.1	284.4	286.5	303.3	297.7	314.6
	159	176.7	196.2	212.2	219.7	227.6	230.4	245.5	250.6	246.1	253.4	249.1	255.6	255.1	261.7
	160	177.4	178.5	179.1	196.9	200.4	198.7	211.6	215.2	217.3	224.3	221.5	226.3	225.4	227.3
	Mean	**180.0**	**192.0**	**208.1**	**219.6**	**222.8**	**228.5**	**240.8**	**248.1**	**246.3**	**253.9**	**253.2**	**258.3**	**260.0**	**266.5**
	StdDev	**7.4**	**8.2**	**18.6**	**16.1**	**15.0**	**18.6**	**22.9**	**24.3**	**18.9**	**23.2**	**22.6**	**24.6**	**26.4**	**32.4**
2	251	176.1	195.1	213.6	220.7	234.2	231.5	240.5	248.9	249.7	252.6	245.1	254.4	265.6	266.2
	252	170.0	188.7	199.3	210.6	216.4	220.3	217.6	228.5	226.9	233.7	232.6	234.1	244.5	247.7
	253	188.8	210.5	219.6	227.4	245.3	243.1	241.1	249.8	245.2	250.4	247.9	244.5	253.3	289.3
	254	174.8	192.3	200.4	209.8	214.8	216.5	219.2	219.5	220.2	227.4	222.3	229.7	234.0	228.4
	255	187.8	198.3	209.7	213.7	221.1	235.9	232.5	244.0	242.3	257.3	243.1	247.2	253.9	257.3
	256	185.2	202.0	205.9	225.5	222.9	224.1	240.1	238.3	242.6	242.9	235.0	243.7	240.8	249.4
	257	198.3	230.9	232.5	237.8	244.0	261.7	277.8	296.1	288.9	289.8	279.5	280.9	285.4	285.3
	258	180.3	187.6	202.2	206.7	208.7	215.5	214.7	223.5	225.6	227.2	226.3	231.5	233.0	235.6
	259	179.6	193.5	200.8	216.7	218.0	226.8	225.7	230.7	233.5	238.6	240.0	241.2	242.1	249.0
	260	175.3	190.4	195.2	209.6	207.5	218.2	212.9	216.9	215.5	222.9	219.9	219.4	229.2	229.0
	261	181.2	193.9	201.3	225.4	231.9	221.0	216.2	230.3	231.8	235.5	242.5	243.7	242.8	239.9
	262	190.5	206.6	222.9	218.4	221.8	251.4	245.0	248.5	250.8	256.2	265.4	258.5	258.4	268.7
	263	169.9	183.4	195.9	196.8	213.9	221.4	222.4	232.2	223.5	236.1	237.9	262.2	243.2	250.4
	264	179.1	195.5	222.7	246.4	238.7	256.1	244.9	257.0	263.7	265.4	261.7	278.8	271.1	272.5
	265	192.1	211.3	218.3	232.4	229.8	241.0	236.0	249.4	243.7	249.2	246.1	246.6	255.8	245.9
	266	183.2	186.5	214.3	233.2	235.5	242.3	243.7	255.9	254.9	270.5	265.2	265.5	269.8	261.7
	267	188.8	210.4	222.7	228.8	241.3	252.1	252.3	259.6	259.5	263.1	267.4	262.8	273.4	273.0
	268	188.8	215.1	213.9	225.0	231.4	244.0	258.1	249.5	247.3	254.8	252.9	270.2	270.5	258.2
	269	184.9	197.2	216.4	228.8	238.2	238.6	239.1	242.8	242.1	253.6	248.2	247.3	249.6	253.4
	270	173.4	201.3	206.1	205.9	207.5	240.5	226.3	214.4	223.8	221.6	249.1	244.0	239.2	250.0
	Mean	**182.4**	**199.5**	**210.7**	**221.0**	**226.1**	**235.1**	**235.3**	**241.8**	**241.6**	**247.4**	**246.4**	**250.3**	**252.8**	**255.5**
	StdDev	**7.8**	**11.7**	**10.5**	**12.3**	**12.4**	**14.1**	**16.5**	**18.8**	**17.5**	**17.5**	**15.7**	**16.3**	**15.6**	**16.8**
1 vs. 2	P value	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS

Table 7A. Normalized Body Weight, Males

		Normalized Body Weight (%) on Indicated Study Day													
Group	Animal No.	-3	4	11	18	25	32	39	46	53	60	67	74	81	88
1	101	100	117	127	134	140	147	149	154	156	160	166	169	173	173
	102	100	119	134	147	157	167	171	180	181	186	192	194	200	201
	103	100	115	127	138	143	150	154	159	159	165	166	169	172	171
	104	100	119	133	145	152	160	164	171	172	176	181	185	188	189
	105	100	116	129	140	145	151	157	164	166	172	174	175	181	180
	106	100	120	136	146	153	160	165	173	174	181	181	183	188	189
	107	100	118	135	146	154	164	167	176	177	183	185	189	192	192
	108	100	115	129	140	147	154	158	163	163	167	171	174	176	177
	109	100	116	130	141	146	153	157	161	162	162	171	170	175	178
	110	100	115	130	141	146	150	156	160	160	174	169	172	176	176
	Mean	**100**	**117**	**131**	**142**	**148**	**156**	**160**	**166**	**167**	**173**	**176**	**178**	**182**	**183**
	StdDev	**0**	**2**	**3**	**4**	**5**	**7**	**7**	**8**	**8**	**9**	**9**	**9**	**9**	**10**
2	201	100	122	129	141	149	154	155	159	163	167	172	171	176	176
	202	100	116	134	147	156	164	168	175	179	184	184	186	190	193
	203	100	121	133	146	154	154	163	170	173	178	180	184	187	191
	204	100	120	135	147	159	162	168	174	178	183	185	190	191	194
	205	100	117	130	142	151	155	160	166	168	175	177	179	184	184
	206	100	116	127	136	144	148	151	158	160	167	170	173	175	176
	207	100	118	133	147	157	164	169	174	178	183	184	187	192	190
	208	100	121	136	148	157	162	167	175	176	182	186	187	193	193
	209	100	116	132	142	147	153	157	161	163	168	173	175	180	180
	210	100	118	127	139	147	152	156	162	164	169	171	172	178	179
	211	100	120	132	146	157	163	167	174	177	184	186	188	191	195
	212	100	120	134	148	157	161	165	171	173	180	180	179	180	183
	213	100	119	134	147	153	159	166	171	173	179	180	183	185	188
	214	100	118	128	139	147	154	152	159	157	161	162	164	169	170
	215	100	119	134	149	158	164	170	177	180	186	190	192	198	196
	216	100	119	135	147	159	167	175	184	187	195	196	198	204	205
	217	100	118	132	146	155	157	164	171	173	180	185	186	190	194
	218	100	124	143	157	167	173	181	189	193	198	202	204	206	212
	219	100	116	125	136	145	150	151	160	161	167	170	172	175	177
	220	100	120	130	139	144	149	148	154	158	159	162	163	169	170
	Mean	**100**	**119**	**132**	**145**	**153**	**158**	**163**	**169**	**172**	**177**	**180**	**182**	**186**	**187**
	StdDev	**0**	**2**	**4**	**5**	**6**	**7**	**9**	**9**	**10**	**11**	**10**	**11**	**11**	**11**
1 vs. 2	**P value**	**N/A**	**<0.05**	**NS**	**NS**	**<0.05**	**NS**	**NS**	**NS**	**NS**	**NS**	**NS**	**NS**	**NS**	**NS**

Table 7B. Normalized Body Weight, Females

		Normalized Body Weight (%) on Indicated Study Day													
Group	Animal No.	-3	4	11	18	25	32	39	46	53	60	67	74	81	88
1	151	100	102	113	119	123	129	135	141	141	144	139	143	148	147
	152	100	111	128	124	126	127	140	141	141	149	152	148	152	146
	153	100	109	131	131	129	137	152	150	144	152	152	153	158	172
	154	100	107	112	120	118	123	125	127	132	130	134	135	135	139
	155	100	103	113	118	123	127	126	143	131	134	132	136	136	137
	156	100	107	113	122	124	128	134	132	142	145	145	146	149	152
	157	100	109	108	119	122	124	128	129	132	134	132	136	134	140
	158	100	107	116	131	129	132	137	150	142	153	154	163	160	169
	159	100	111	120	124	129	130	139	142	139	143	141	145	144	148
	160	100	101	101	111	113	112	119	121	122	126	125	128	127	128
	Mean	**100**	**107**	**116**	**122**	**124**	**127**	**134**	**138**	**137**	**141**	**141**	**143**	**144**	**148**
	StdDev	**0**	**4**	**9**	**6**	**5**	**7**	**9**	**10**	**7**	**9**	**10**	**10**	**11**	**14**
2	251	100	111	121	125	133	131	137	141	142	143	139	144	151	151
	252	100	111	117	124	127	130	128	134	133	137	137	138	144	146
	253	100	111	116	120	130	129	128	132	130	133	131	130	134	153
	254	100	110	115	120	123	124	125	126	126	130	127	131	134	131
	255	100	106	112	114	118	126	124	130	129	137	129	132	135	137
	256	100	109	111	122	120	121	130	129	131	131	127	132	130	135
	257	100	116	117	120	123	132	140	149	146	146	141	142	144	144
	258	100	104	112	115	116	120	119	124	125	126	126	128	129	131
	259	100	108	112	121	121	126	126	128	130	133	134	134	135	139
	260	100	109	111	120	118	124	121	124	123	127	125	125	131	131
	261	100	107	111	124	128	122	119	127	128	130	134	134	134	132
	262	100	108	117	115	116	132	129	130	132	134	139	136	136	141
	263	100	108	115	116	126	130	131	137	132	139	140	154	143	147
	264	100	109	124	138	133	143	137	143	147	148	146	156	151	152
	265	100	110	114	121	120	125	123	130	127	130	128	128	133	128
	266	100	102	117	127	129	132	133	140	139	148	145	145	147	143
	267	100	111	118	121	128	134	134	138	137	139	142	139	145	145
	268	100	114	113	119	123	129	137	132	131	135	134	143	143	137
	269	100	107	117	124	129	129	129	131	131	137	134	134	135	137
	270	100	116	119	119	120	139	131	124	129	128	144	141	138	144
	Mean	**100**	**109**	**116**	**121**	**124**	**129**	**129**	**132**	**132**	**136**	**135**	**137**	**139**	**140**
	StdDev	**0**	**4**	**4**	**5**	**5**	**6**	**6**	**7**	**7**	**7**	**7**	**8**	**7**	**8**
1 vs. 2	**P value**	**N/A**	**NS**	**NS**	**NS**	**NS**	**NS**	**NS**	**NS**	**NS**	**NS**	**NS**	**NS**	**NS**	**NS**

Figure 1. Normalized Body Weight Trends, Males

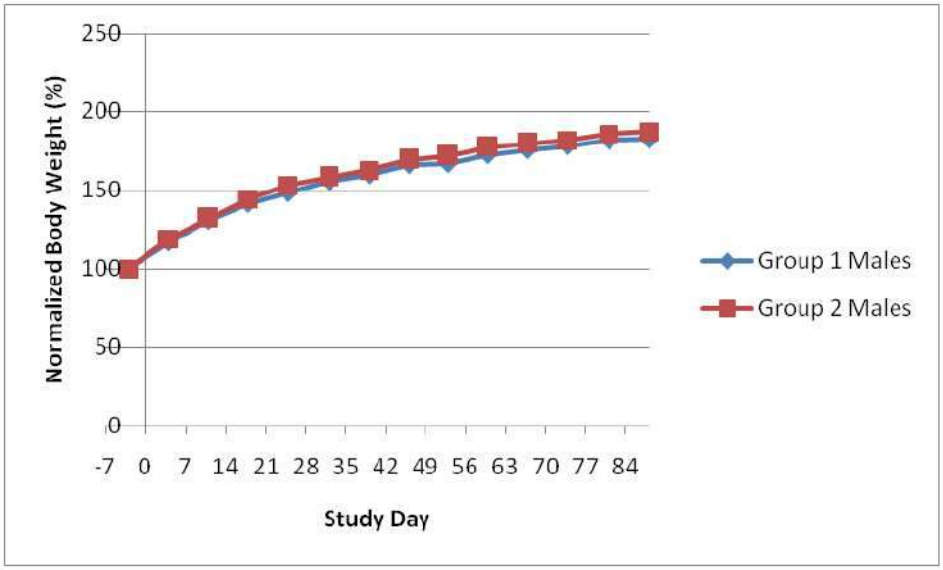


Figure 2. Normalized Body Weight Trends, Females

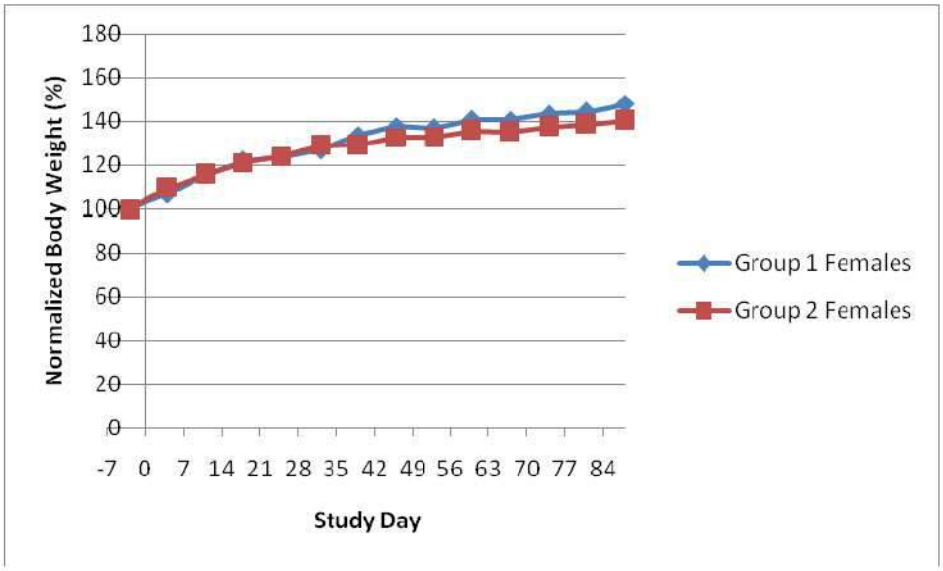


Table 8A. Food Consumption, Males

		Average Daily FC (g/rat/day) for Week Ending on Indicated Study Day												
Group	Animal No.	6	13	20	27	34	41	48	55	62	69	76	83	89
1	101-102	21.9	22.9	23.0	24.0	24.9	26.3	18.7	26.8	32.2	29.6	26.2	31.1	24.9
	103-104	22.5	23.7	23.7	23.3	24.6	24.9	25.4	24.9	23.3	23.4	25.4	22.8	24.1
	105-106	21.8	23.1	24.0	24.1	22.7	26.6	27.1	30.7	25.9	23.8	23.6	22.0	23.7
	107-108	21.2	22.7	22.7	23.0	22.4	22.2	22.3	21.9	22.0	21.7	22.4	21.3	20.8
	109-110	21.8	22.5	23.4	22.7	21.5	22.7	21.8	21.8	22.4	21.5	22.5	21.8	21.8
	Mean	**21.8**	**23.0**	**23.3**	**23.4**	**23.2**	**24.6**	**23.1**	**25.2**	**25.2**	**24.0**	**24.0**	**23.8**	**23.1**
	StdDev	**0.5**	**0.4**	**0.5**	**0.6**	**1.5**	**2.0**	**3.3**	**3.7**	**4.2**	**3.3**	**1.7**	**4.1**	**1.7**
2	201-202	22.0	22.3	22.4	23.4	22.7	22.2	21.6	22.7	22.0	21.7	22.8	21.7	21.8
	203-204	22.6	22.5	23.8	23.4	22.3	23.0	22.8	22.9	22.7	22.1	22.4	22.1	22.3
	205-206	22.2	22.3	23.3	22.6	21.6	23.5	22.5	22.1	22.8	22.3	23.9	20.9	21.8
	207-208	24.3	23.9	25.5	25.2	25.2	24.6	24.4	23.3	24.3	22.4	23.3	23.7	22.8
	209-210	20.7	21.0	22.7	21.0	20.0	21.3	20.8	21.3	21.0	19.6	21.5	21.3	20.9
	211-212	23.0	23.7	24.0	23.8	22.7	22.4	23.4	23.5	23.4	21.8	22.2	21.6	22.3
	213-214	23.2	22.9	23.7	23.0	23.4	23.4	22.5	22.8	21.6	21.1	21.9	22.1	22.1
	215-216	23.5	23.3	24.0	20.9	24.2	24.0	24.1	24.3	24.4	22.6	23.5	23.3	23.7
	217-218	24.9	26.9	26.3	25.9	23.7	26.4	26.0	26.4	23.8	24.0	25.2	24.7	24.8
	219-220	22.0	21.4	20.6	21.8	21.9	20.8	20.5	19.8	20.4	19.5	20.6	20.1	20.6
	Mean	**22.8**	**23.0**	**23.6**	**23.1**	**22.8**	**23.2**	**22.9**	**22.9**	**22.6**	**21.7**	**22.7**	**22.2**	**22.3**
	StdDev	**1.2**	**1.7**	**1.6**	**1.6**	**1.5**	**1.6**	**1.7**	**1.8**	**1.4**	**1.4**	**1.3**	**1.4**	**1.2**
1 vs. 2	**P value**	**<0.05**	**NS**	**NS**	**NS**	**NS**	**NS**	**NS**	**NS**	**NS**	**NS**	**NS**	**NS**	**NS**

Table 8B. Food Consumption, Females

		Average Daily FC (g/rat/day) for Week Ending on Indicated Study Day												
Group	Animal No.	6	13	20	27	34	41	48	55	62	69	76	83	89
1	151-152	15.1	23.4	14.4	16.4	16.9	18.2	16.6	16.1	17.0	17.6	16.4	17.2	16.9
	153-154	15.6	17.3	14.8	16.1	16.2	18.2	14.8	16.1	16.6	15.5	17.0	17.6	18.1
	155-156	14.7	14.9	15.5	16.4	15.4	17.1	16.7	17.9	14.5	15.5	17.4	16.0	17.1
	157-158	16.7	16.0	17.7	25.9	27.1	21.6	15.8	25.4	32.3	25.9	25.0	23.5	31.5
	159-160	26.7	30.2	32.2	16.3	24.8	28.3	27.1	34.7	26.3	25.9	22.4	25.5	23.6
	Mean	**17.7**	**20.4**	**18.9**	**18.2**	**20.1**	**20.7**	**18.2**	**22.0**	**21.3**	**20.1**	**19.7**	**20.0**	**21.4**
	StdDev	**5.1**	**6.4**	**7.5**	**4.3**	**5.4**	**4.6**	**5.0**	**8.1**	**7.6**	**5.4**	**3.8**	**4.2**	**6.2**
2	251-252	16.9	20.2	27.3	17.7	17.7	22.3	28.3	23.3	26.0	28.3	17.1	25.9	19.2
	253-254	15.9	15.8	19.7	17.5	20.4	18.7	22.9	27.1	30.7	23.8	23.0	16.5	18.0
	255-256	14.7	15.3	15.7	14.8	16.2	15.8	16.1	16.4	16.1	14.9	15.7	16.1	16.8
	257-258	16.9	13.8	15.3	15.7	16.6	17.8	16.3	17.9	15.0	12.7	14.9	14.7	14.8
	259-260	15.2	17.8	26.9	13.3	15.7	19.0	22.6	21.5	20.7	24.2	18.6	23.0	22.4
	261-262	15.9	16.1	18.2	15.3	15.9	15.6	16.4	15.4	16.9	14.9	16.3	15.1	16.9
	263-264	29.6	19.5	18.2	18.5	19.7	18.4	17.9	18.1	17.3	17.3	18.5	17.2	19.8
	265-266	15.4	25.1	37.1	23.2	27.5	21.8	26.5	23.7	18.6	13.6	21.6	20.1	21.2
	267-268	17.0	14.7	18.6	20.8	25.6	24.2	24.1	23.0	16.7	25.8	21.5	23.5	21.9
	269-270	17.3	14.1	17.4	18.3	17.9	19.1	21.2	28.1	24.6	26.8	20.6	28.6	28.9
	Mean	**17.5**	**17.2**	**21.4**	**17.5**	**19.3**	**19.3**	**21.2**	**21.5**	**20.3**	**20.2**	**18.8**	**20.1**	**20.0**
	StdDev	**4.4**	**3.5**	**6.9**	**2.9**	**4.1**	**2.8**	**4.4**	**4.4**	**5.2**	**6.1**	**2.8**	**4.9**	**4.0**
1 vs. 2	**P value**	**NS**	**NS**	**NS**	**NS**	**NS**	**NS**	**NS**	**NS**	**NS**	**NS**	**NS**	**NS**	**NS**

Figure 3. Average Daily FC Trends During Each Week (g/rat/day), Males

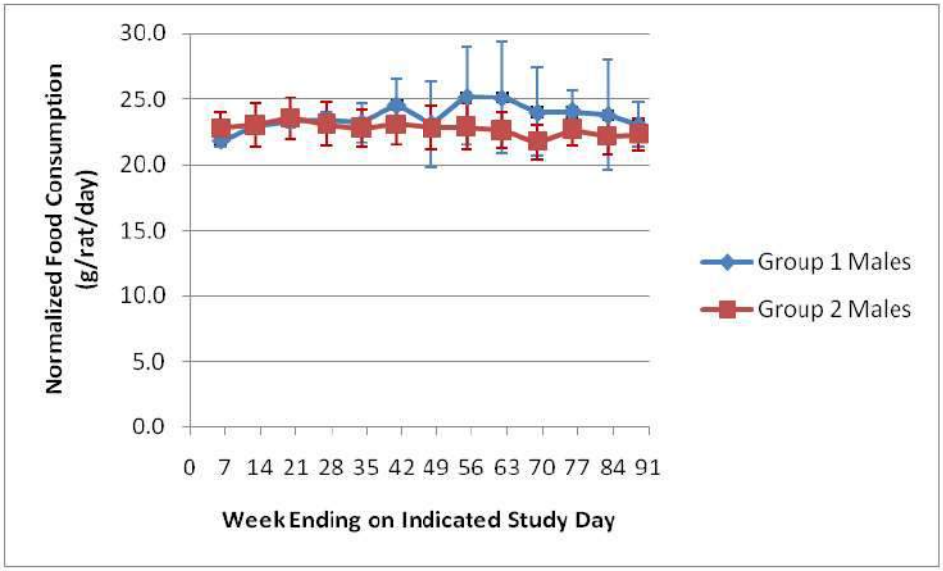


Figure 4. Average Daily FC Trends During Each Week (g/rat/day), Females

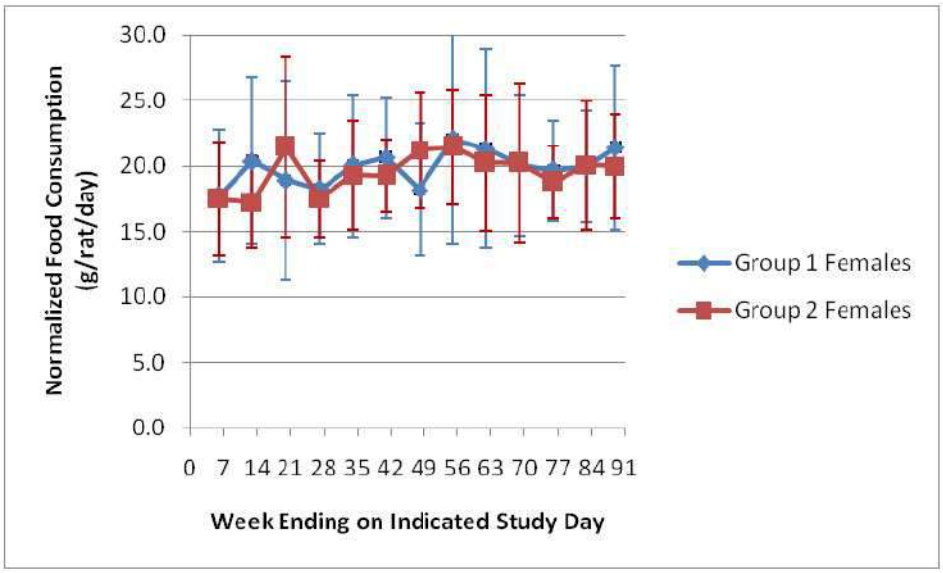


Table 9A. Ophthalmology Summary, Males

Group	Animal No.	Pre-study Findings 1 March 2011		End-Study Findings 27 May 2011	
		OD	OS	OD	OS
1	101	N	N	N	N
	102	N	N	N	N
	103	N	N	N	N
	104	N	N	N	N
	105	N	N	N	N
	106	N	N	N	N
	107	N	N	N	N
	108	N	N	N	N
	109	N	N	Normal globe, slight defective blink, epiphora	N
	110	N	N	N	N
2	201	N	N	N	N
	202	N	N	N	N
	203	N	N	N	N
	204	N	N	N	N
	205	N	N	N	N
	206	N	N	N	N
	207	N	N	N	N
	208	N	N	N	N
	209	N	N	N	N
	210	N	N	N	N
	211	N	N	N	N
	212	N	N	N	N
	213	N	N	N	N
	214	N	N	N	N
	215	N	N	N	N
	216	N	N	N	N
	217	N	N	N	N
	218	N	N	N	N
	219	N	N	N	N
	220	N	N	N	N

Table 9B. Ophthalmology Summary, Females

Group	Animal No.	Pre-study Findings 1 March 2011		End-Study Findings 27 May 2011	
		OD	OS	OD	OS
1	151	N	N	N	N
	152	N	N	N	N
	153	N	N	N	N
	154	N	N	N	N
	155	N	N	N	N
	156	N	N	N	N
	157	N	N	N	N
	158	N	N	N	N
	159	N	N	N	N
	160	N	N	N	N
2	251	N	N	N	N
	252	N	N	N	N
	253	N	N	N	N
	254	N	N	N	N
	255	N	N	N	N
	256	N	N	N	N
	257	N	N	N	N
	258	N	N	Increased nuclear. density, pinpoint opacity in lens	Increased nuclear density, pinpoint opacity in lens
	259	N	N	N	N
	260	N	N	Increased nuclear density	Increased nuclear density
	261	N	N	N	N
	262	N	N	N	N
	263	N	N	N	N
	264	N	N	Increased nuclear. density, pinpoint opacity in lens	N
	265	N	N	N	N
	266	N	N	N	N
	267	N	N	N	N
	268	N	N	N	N
	269	N	N	N	N
	270	N	N	N	N

Table 10A. FOB Testing Summary For Variable Parameters, Males

Animal	Response to picking up				Chromodacryorrhea				Grip strength				Piloerection			
No.	3/1/'11	3/31/'11	5/2/'11	5/28/'11	3/1/'11	3/31/'11	5/2/'11	5/28/'11	3/1/'11	3/31/'11	5/2/'11	5/28/'11	3/1/'11	3/31/'11	5/2/'11	5/28/'11
101	3	1	1	1	1	1	1	1	2	1	9	1	N	N	N	N
102	1	1	1	1	1	1	1	1	10	3	2	1	N	N	N	N
103	1	1	1	1	1	1	1	1	9.4	3	4	3	N	N	N	N
104	2	2	1	1	1	1	1	1	16.5	4	5	4	N	N	N	N
105	3	3	1	1	1	1	1	1	57.5	2	3	4	N	N	N	N
106	3	6	1	2	1	1	1	1	2.1	1	2	1	N	N	N	N
107	3	3	1	1	1	1	1	1	2.3	7	8	5	N	N	N	N
108	1	1	2	2	1	1	2	1	3.1	4	2	2	N	N	N`	N
109	3	1	1	1	1	1	1	1	10	4	2	2	N	N	N`	N
110	1	1	1	1	1	1	1	1	3.1	3	2	3	N	N	N	N
Mean	2.1	2.0	1.1	1.2	1.0	1.0	1.1	1.0	11.6	3.2	3.9	2.6	N	N	N	N
SD	1.0	1.6	0.3	0.4	0.0	0.0	0.3	0.0	16.8	1.8	2.6	1.4	NA	NA	NA	NA
201	1	1	1	1	1	1	1	1	24.2	11	3	2	N	mild	N	N
202	1	1	1	1	1	1	1	1	2.7	8	2	4	N	mild	N	N
203	1	1	1	1	3	1	1	1	5.8	3	1	2	N	mild	mild	N
204	1	1	1	1	1	2	1	1	2.3	3	1	1	N	mild	mild	mild
205	4	1	1	1	1	1	1	1	3.5	3	2	3	N	mild	mild	N
206	3	2	1	1	1	1	1	1	6.9	1	3	1	N	mild	mild	N
207	3	2	2	3	1	1	2 mild	1	8.7	2	3	1	N	mild	mild	N
208	3	1	1	1	1	1	2 mild	1	3.4	2	3	2	N	N	mild	N
209	3	1	1	1	1	1	2 mild	1	3.1	2	2	1	N	mild	mild	N
210	1	2	1	1	1	1	2 mild	1	4.6	3	1	2	N	mild	N	N
211	1	1	1	1	1	1	2 mild	1	34.1	3	2	3	N	mild	N	N
212	3	1	2	1	1	1	2 mild	1	3.1	1	1	2	N	mild	N	N
213	1	1	1	1	1	1	1	1	2.5	2	2	1	N	mild	N	N
214	1	1	1	1	1	1	1	1	8.9	2	4	3	N	mild	N	N
215	3	1	1	1	1	1	2 mild	1	6.8	7	1	5	N	mild	N	N
216	3	1	1	1	1	1	1	1	9	1	1	1	N	mild	N	N
217	1	1	1	1	2	1	1	1	2.5	2	2	4	N	mild	N	N
218	3	2	1	1	1	1	2 mild	1	7.3	2	1	2	N	mild	N	N
219	3	1	1	1	1	1	2 mild	1	1.9	3	2	2	N	mild	N	N
220	3	1	2	1	1	1	2 mild	1	3.1	4	1	3	N	mild	N	N
	2.2	1.2	1.2	1.1	1.2	1.1	1.5	1.0	7.2	3.3	1.9	2.3	N	19/20m	7/20m	1m
	1.1	0.4	0.4	0.4	0.5	0.2	0.5	0.0	8.0	2.6	0.9	1.2				

Table 10B. FOB Testing Summary For Variable Parameters, Females

Animal	Response to picking up				Chromodacryorrhea				Grip strength				Piloerection			
No.	3/1/'11	3/31/'11	5/2/'11	5/28/'11	3/1/'11	3/31/'11	5/2/'11	5/28/'11	3/1/'11	3/31/'11	5/2/'11	5/28/'11	3/1/'11	3/31/'11	5/2/'11	5/28/'11
151	3	1	2	1	1	1	1	1	5.2	1	4	7	N	N	N	N
152	1	5	1	1	1	1	1	1	40.8	7	5	11	N	N	N	N
153	1	1	2	2	1	2	1	1	10.2	4	8	1	N	N	N	N
154	1	1	1	1	1	1	2	1	14.8	8	7	7	N	N	N	N
155	1	1	21	1	1	1	1	1	11.6	18	3	15	N	N	N	N
156	1	1	1	1	1	1	1	1	32.8	18	8	6	N	N	N	N
157	1	2	1	2	1	2	1	1	10.9	6	4	6	N	N	N	N
158	1	1	2	1	1	1	1	1	8.9	5	1	1	N	N	N`	N
159	3	1	1	2	1	1	2	1	5.4	2	1	1	N	N	N`	N
160	1	1	1	1	1	1	1	1	2.2	5	5	17	N	N	N	N
Mean	1.2	1.7	1.3	1.4	1.0	1.2	1.2	1.0	15.6	7.4	4.6	7.2				
SD	0.6	1.3	0.5	0.5	0.0	0.0	0.4	0	12.5	6.0	2.5	5.7				
251	1	1	1	2	1	1	2 mild	1	11.2	3	1	2	N	mild	N	N
252	1	1	1	1	1	1	2 mild	1	7.1	4	9	1	N	mild	N	N
253	1	1	1	1	1	1	2	1	6.7	9	3	5	N	mild	N	N
254	1	1	2	1	1	1	2 mild	1	32.2	3	9	18	N	mild	N	N
255	1	1	1	1	1	1	2 mild	1	5.2	23	10	40	N	mild	N	N
256	1	1	1	1	1	1	1	1	12.3	2	1	15	N	mild	N	N
257	1	1	1	1	1	1	2 mild	1	10.5	4	3	8	N	N	N	N
258	1	1	1	1	1	1	2 mild	!	3.7	6	4	6	N	N	N	N
259	1	1	2	1	1	1	1	1	6.6	2	1	1	N	mild	N	N
260	1	1	1	1	1	1	2 mild	1	8.3	2	18	13	N	mild	N	N
261	1	1	1	2	1	1	2 mild	1	11.8	4	1	19	N	mild	N	N
262	1	1	1	1	1	1	2 mild	1	13.1	3	3	3	N	mild	N	N
263	1	1	1	1	1	1	2 mild	1	4.3	3	5	3	N	mild	N	N
264	1	1	2	2	1	2	1	1	7.2	6	6	3	N	mild	N	N
265	1	1	1	1	1	1	2	1	15.7	5	2	2	N	mild	N	N
266	3	2	1	1	1	1	2 mild	1	13.1	4	3	2	N	mild	N	N
267	1	1	2	1	1	1	2 slight	1	4.9	2	8	3	N	mild	N	N
268	1	2	1	1	1	1	2 slight	1	14	4	7	2	N	mild	N	N
269	1	1	1	1	1	1	2 mild	1	5.6	9	4	7	N	mild	N	N
270	3	1	1	1	1	1	2 mild	1	14.8	5	10	2	N	mild	N	N
Mean	1.2	1.1	1.2	1.1	1.0	1.1	17/20	1.0	10.4.	5.2	5.4	7.8		18/20		
SD	1.1	0.4	0.4	0.4	0	0.2	0.5	0.0	6.4	2.6	0.9	1.2				

Note: since FOB test done out of home cage, findings might be different that daily in-cage observations.

Table 11. Hematology, Males

Group	Animal No.	WBC x10³ /uL	RBC X10⁶/uL	HGB g /dL	HCT %	MCV fL	MCH pg	MCHC g / dL	RDW %	PLT x10³ /uL	MPV fL	%RETIC	#RETIC x10⁹/L
1	101	14.8	9.69	16.6	55.1	56.9	17.2	30.2	11.6	897	7.2	2.4	232.2
	102	9.0	8.79	15.2	51.4	58.5	17.3	29.6	11.8	813	7.0	2.9	251.1
	103	7.8	8.89	15.9	54.7	61.6	17.9	29.1	10.8	889	8.1	2.9	261.1
	104	12.0	8.64	14.9	49.2	57.0	17.3	30.3	11.5	964	7.7	2.3	196.1
	105	16.0	8.97	15.1	49.2	54.8	16.8	30.6	11.9	979	7.1	2.9	257.4
	106	8.2	9.74	16.3	54.7	56.2	16.7	29.8	11.2	713	7.3	2.2	214.8
	107	13.2	8.78	14.8	49.5	56.4	16.9	29.9	11.7	1095	7.2	3.6	312.5
	108	9.8	9.21	15.9	53.2	57.8	17.2	29.8	11.0	737	7.6	2.4	223.5
	109	11.3	9.19	15.6	52.5	57.1	17.0	29.7	12.0	913	7.2	2.8	254.0
	110	5.6	9.44	16.8	56.3	59.7	17.8	29.8	11.2	724	7.6	2.4	231.0
	Mean	**10.8**	**9.13**	**15.7**	**52.6**	**57.6**	**17.2**	**29.9**	**11.5**	**872**	**7.4**	**2.7**	**243.4**
	StdDev	**3.3**	**0.39**	**0.7**	**2.7**	**1.9**	**0.4**	**0.4**	**0.4**	**125**	**0.3**	**0.4**	**31.9**
2	201	11.0	9.52	16.2	54.6	57.4	17.0	29.6	11.8	568	8.7	2.2	205.3
	202	8.6	8.46	15.3	51.3	60.6	18.1	29.9	11.1	504	8.2	2.1	174.4
	203	10.7	9.43	14.8	51.3	54.4	15.7	28.9	11.5	737	8.7	2.2	212.1
	204	10.2	8.65	14.7	51.2	59.2	17.0	28.7	11.1	698	8.2	2.4	207.4
	205	7.3	8.99	15.5	54.1	60.1	17.2	28.6	11.1	722	8.3	2.1	192.2
	206	9.5	8.14	14.0	47.3	58.2	17.2	29.5	11.0	657	7.7	2.3	189.4
	207	10.9	8.66	15.2	50.0	57.8	17.5	30.3	10.9	858	7.5	2.1	181.8
	208	10.9	9.02	15.4	53.1	58.9	17.0	29.0	11.5	823	7.9	2.1	193.7
	209	7.0	9.25	16.1	54.4	58.8	17.4	29.7	11.4	818	7.9	2.2	201.0
	210	14.0	9.89	16.4	56.7	57.3	16.6	29.0	11.7	909	8.7	2.4	239.6
	211	8.1	9.29	15.6	52.4	56.4	16.8	29.7	11.8	842	8.2	2.6	243.0
	212	10.6	9.11	14.6	51.0	55.9	16.0	28.6	11.1	1070	8.1	2.0	180.1
	213	8.0	8.28	13.6	46.5	56.2	16.4	29.3	11.0	863	8.6	2.4	200.4
	214	8.4	9.03	14.8	50.6	56.0	16.4	29.2	12.3	897	8.0	2.2	199.1
	215	7.0	8.40	15.2	49.8	59.2	18.1	30.6	11.4	720	8.0	2.4	203.6
	216	9.8	8.54	14.6	48.9	57.2	17.0	29.8	11.8	928	8.2	2.6	223.1
	217	9.3	8.87	15.3	51.5	58.0	17.2	29.6	11.0	DNR	9.8	2.8	249.3
	218	9.3	8.42	15.1	51.3	61.0	17.9	29.3	11.2	852	8.6	2.6	220.4
	219	8.1	9.21	15.6	52.8	57.3	16.9	29.5	11.2	868	8.5	2.2	204.2
	220	10.3	8.72	14.4	50.9	58.3	16.6	28.4	10.9	789	8.3	2.4	209.4
	Mean	**9.4**	**8.89**	**15.1**	**51.5**	**57.9**	**17.0**	**29.4**	**11.3**	**796**	**8.3**	**2.3**	**206.5**
	StdDev	**1.7**	**0.46**	**0.7**	**2.4**	**1.7**	**0.6**	**0.6**	**0.4**	**133**	**0.5**	**0.2**	**20.4**
1 vs. 2	**P value**	**NS**	**NS**	**<0.05**	**NS**	**NS**	**NS**	**<0.01**	**NS**	**NS**	**<0.001**	**<0.05**	**<0.01**

Table 11. Hematology, Males (cont'd)

Group	Animal No.	%NEUT %	%LYMPHS %	%MONO %	%EOS %	%BASO %	%BANDS %	#NEUT x10³ /uL	#LYMPHS x10³ /uL	#MONO x10³ /uL	#EOS x10³ /uL	#BASO x10³ /uL	#BANDS x10³ /uL
1	101	8	87	3	2	1	0	1.19	12.90	0.44	0.30	0.15	0.00
	102	15	81	2	3	1	0	1.35	7.27	0.18	0.27	0.09	0.00
	103	11	86	1	2	1	0	0.85	6.67	0.08	0.16	0.08	0.00
	104	13	80	5	2	1	0	1.56	9.58	0.60	0.24	0.12	0.00
	105	10	86	2	2	1	0	1.60	13.76	0.32	0.32	0.16	0.00
	106	15	80	2	3	0	0	1.23	6.56	0.16	0.25	0.00	0.00
	107	8	86	2	3	1	0	1.06	11.37	0.26	0.40	0.13	0.00
	108	7	88	2	2	1	0	0.68	8.58	0.20	0.20	0.10	0.00
	109	10	86	2	2	1	0	1.13	9.73	0.23	0.23	0.11	0.00
	110	10	86	2	2	0	0	0.56	4.82	0.11	0.11	0.00	0.00
	Mean	**11**	**85**	**2**	**2**	**1**	**0**	**1.12**	**9.12**	**0.26**	**0.25**	**0.09**	**0.00**
	StdDev	**3**	**3**	**1**	**0**	**0**	**0**	**0.34**	**2.91**	**0.16**	**0.08**	**0.06**	**0.00**
2	201	13	81	3	3	1	0	1.44	8.94	0.33	0.33	0.11	0.00
	202	11	85	2	2	1	0	0.94	7.28	0.17	0.17	0.09	0.00
	203	13	81	3	2	0	0	1.39	8.69	0.32	0.21	0.00	0.00
	204	11	84	2	2	1	0	1.12	8.58	0.20	0.20	0.10	0.00
	205	15	81	2	2	1	0	1.10	5.91	0.15	0.15	0.07	0.00
	206	10	83	4	3	0	0	0.95	7.91	0.38	0.29	0.00	0.00
	207	8	87	2	3	0	0	0.87	9.49	0.22	0.33	0.00	0.00
	208	8	87	2	2	1	0	0.87	9.49	0.22	0.22	0.11	0.00
	209	11	84	2	3	0	0	0.77	5.87	0.14	0.21	0.00	0.00
	210	8	87	2	2	1	0	1.12	12.17	0.28	0.28	0.14	0.00
	211	13	83	2	2	0	0	1.05	6.68	0.16	0.16	0.00	0.00
	212	9	87	3	1	1	0	0.95	9.18	0.32	0.11	0.11	0.00
	213	10	86	2	2	1	0	0.80	6.91	0.16	0.16	0.08	0.00
	214	15	80	3	2	0	0	1.26	6.70	0.25	0.17	0.00	0.00
	215	13	78	5	5	0	0	0.91	5.45	0.35	0.35	0.00	0.00
	216	11	85	2	2	1	0	1.08	8.32	0.20	0.20	0.10	0.00
	217	27	69	2	1	2	0	2.52	6.43	0.19	0.09	0.19	0.00
	218	8	88	2	2	1	0	0.74	8.16	0.19	0.19	0.09	0.00
	219	8	86	3	2	0	0	0.65	6.97	0.24	0.16	0.00	0.00
	220	8	88	2	1	1	0	0.82	9.02	0.21	0.10	0.10	0.00
	Mean	**12**	**84**	**3**	**2**	**1**	**0**	**1.07**	**7.91**	**0.23**	**0.20**	**0.06**	**0.00**
	StdDev	**4**	**4**	**1**	**1**	**1**	**0**	**0.40**	**1.62**	**0.07**	**0.08**	**0.06**	**0.00**
1 vs. 2	P value	NS	NS	NS	NS	NS	N/A	NS	NS	NS	NS	NS	N/A

Table 11. Hematology, Males (cont'd)

			RBC Morphology			WBC Morphology				Platelet Comments		
Group	Animal No.	Reason for manual differential (if applicable)	Anisocytosis*	Poikilocytosis*	Polychromasia*	Reactive lymphs*	Mast cells present	Tissue cells present	Macrophages present	Automated platelet count confirmed by slide review	Platelets clumped; actual count may be higher	Platelet count invalid due to clot in tube
1	101		sl		sl					X		
	102				sl					X		
	103				sl					X		
	104		sl		sl		X			X		
	105				sl					X		
	106				sl		X				X	
	107				sl					X		
	108		sl		sl		X				X	
	109		sl		sl					X		
	110				sl					X		
2	201b		sl		sl		X				X	
	202		sl		sl						X	
	203				sl						X	
	204		sl		sl					X		
	205				sl					X		
	206	Due to possible mast cell interference	sl		sl		X			X		
	207	Due to possible mast cell interference	sl		sl					X		
	208				sl					X		
	209				sl						X	
	210		sl		sl						X	
	211		sl		sl						X	
	212				sl					X		
	213				sl					X		
	214		sl		sl					X		
	215		sl		sl					X		
	216		sl		sl					X		
	217				sl						Platelet count invalid due to platelet clumps	
	218				sl					X		
	219		sl		sl					X		
	220				sl					X		

* Ranked as slight (sl), moderate (mod), or marked (mkd).
X, parameter applies to this sample.

Table 12. Hematology, Females

Group	Animal No.	WBC x10³ /uL	RBC X10⁶/uL	HGB g /dL	HCT %	MCV fL	MCH pg	MCHC g / dL	RDW %	PLT x10³ /uL	MPV fL	%RETIC	#RETIC x10⁹/L
1	151	5.4	8.05	15.2	49.4	61.3	18.9	30.9	10.1	806	7.3	2.5	201.1
	152	5.7	7.84	15.0	47.5	60.6	19.1	31.5	9.6	874	7.8	2.8	222.9
	153	5.4	7.97	14.7	48.1	60.4	18.5	30.6	11.3	790	7.2	3.2	256.0
	154	6.5	8.10	14.9	48.7	60.2	18.4	30.5	10.4	788	7.4	2.2	177.2
	155	5.2	7.66	14.6	46.8	61.1	19.1	31.3	9.8	903	7.9	3.1	237.0
	156	3.4	8.11	15.5	50.8	62.6	19.2	30.6	10.2	820	8.2	2.7	216.5
	157	5.7	7.97	14.3	47.5	59.6	18.0	30.2	9.7	730	8.6	2.5	197.8
	158	6.1	7.86	14.3	47.4	60.3	18.2	30.2	9.8	809	8.3	3.0	235.4
	159	4.7	7.56	14.1	46.1	61.1	18.7	30.6	9.9	754	9.0	2.8	212.1
	160	7.0	8.22	15.0	48.9	59.4	18.3	30.7	10.2	754	8.4	2.8	231.9
	Mean	**5.5**	**7.9**	**14.8**	**48.1**	**60.7**	**18.6**	**30.7**	**10.1**	**803**	**8.0**	**2.8**	**218.8**
	StdDev	**1.0**	**0.2**	**0.4**	**1.4**	**0.9**	**0.4**	**0.4**	**0.5**	**54**	**0.6**	**0.3**	**22.9**
2	251	4.5	8.08	14.8	46.5	57.6	18.3	31.8	9.9	664	7.7	2.7	214.2
	252	8.7	9.11	15.5	53.6	58.8	17.1	29.0	10.4	521	8.4	2.4	218.7
	253	17.8	5.76	10.0	34.6	60.1	17.4	29.0	12.7	2207	10.5	4.8	275.7
	254	7.9	8.35	15.1	50.2	60.2	18.1	30.0	10.0	652	8.5	2.1	177.7
	255	6.3	7.75	14.2	48.5	62.6	18.3	29.3	10.2	639	8.8	1.8	141.9
	256	10.4	7.53	14.4	47.4	62.9	19.2	30.5	11.0	612	8.9	3.9	291.0
	257	7.4	8.11	15.0	51.4	63.3	18.5	29.2	10.1	674	8.5	2.5	201.6
	258	8.8	8.03	14.7	50.0	62.3	18.3	29.3	10.2	746	8.5	2.5	196.7
	259	9.2	7.39	13.6	45.4	61.4	18.4	30.0	10.4	701	8.2	3.2	234.9
	260	5.4	7.47	14.1	45.3	60.6	18.8	31.1	10.3	582	8.8	2.9	218.1
	261	6.4	7.42	14.0	46.8	63.0	18.9	30.0	10.6	1059	8.3	2.4	177.5
	262	9.3	8.12	15.0	49.8	61.3	18.4	30.0	10.1	779	8.2	2.6	214.2
	263	7.6	8.04	14.7	48.8	60.7	18.2	30.0	10.8	830	8.3	2.4	189.2
	264	7.8	7.97	14.5	47.8	60.0	18.2	30.3	10.1	727	8.6	3.0	236.1
	265	6.0	7.98	14.2	48.4	60.6	17.9	29.5	10.0	824	8.4	2.6	208.3
	266	6.7	7.62	13.5	45.7	60.0	17.7	29.6	9.6	883	9.1	2.3	175.7
	267	7.9	8.18	15.4	50.1	61.3	18.9	30.8	11.1	553	8.5	2.7	218.7
	268	5.3	7.75	14.7	47.6	61.4	18.9	30.8	10.0	669	9.1	2.8	213.4
	269	7.1	7.67	14.0	46.9	61.2	18.2	29.8	10.0	780	9.2	2.4	184.7
	270	8.5	7.95	14.5	48.1	60.6	18.3	30.2	10.2	854	8.7	3.2	252.0
	Mean	**7.9**	**7.8**	**14.3**	**47.6**	**61.0**	**18.3**	**30.0**	**10.4**	**798**	**8.7**	**2.8**	**212.0**
	StdDev	**2.8**	**0.6**	**1.1**	**3.7**	**1.4**	**0.5**	**0.7**	**0.7**	**355**	**0.6**	**0.7**	**35.1**
1 vs. 2	**P value**	**<0.01**	**NS**	**NS**	**NS**	**NS**	**NS**	**<0.01**	**NS**	**NS**	**<0.05**	**NS**	**NS**

Table 12. Hematology, Females (cont'd)

Group	Animal No.	%NEUT %	%LYMPHS %	%MONO %	%EOS %	%BASO %	%BANDS %	#NEUT x10³ /uL	#LYMPHS x10³ /uL	#MONO x10³ /uL	#EOS x10³ /uL	#BASO x10³ /uL	#BANDS x10³ /uL
1	151	7	90	2	1	0	0	0.38	4.85	0.11	0.05	0.00	0.00
	152	7	87	2	3	0	0	0.40	4.94	0.11	0.17	0.00	0.00
	153	9	87	1	2	1	0	0.49	4.69	0.05	0.11	0.05	0.00
	154	13	81	3	2	1	0	0.85	5.29	0.20	0.13	0.07	0.00
	155	6	90	1	2	1	0	0.31	4.65	0.05	0.10	0.05	0.00
	156	18	75	2	4	1	0	0.62	2.57	0.07	0.14	0.03	0.00
	157	11	82	3	3	0	0	0.62	4.63	0.17	0.17	0.00	0.00
	158	5	91	2	2	0	0	0.30	5.51	0.12	0.12	0.00	0.00
	159	9	87	2	1	1	0	0.42	4.10	0.09	0.05	0.05	0.00
	160	8	89	1	1	1	0	0.56	6.21	0.07	0.07	0.07	0.00
	Mean	**9**	**86**	**2**	**2**	**1**	**0**	**0.49**	**4.74**	**0.10**	**0.11**	**0.03**	**0.00**
	StdDev	**4**	**5**	**1**	**1**	**1**	**0**	**0.17**	**0.96**	**0.05**	**0.04**	**0.03**	**0.00**
2	251	6	91	1	1	0	0	0.27	4.10	0.05	0.05	0.00	0.00
	252	7	88	3	2	0	0	0.61	7.61	0.26	0.17	0.00	0.00
	253	45	49	3	3	0	0	8.00	8.71	0.53	0.53	0.00	0.00
	254	5	91	2	2	0	0	0.39	7.14	0.16	0.16	0.00	0.00
	255	11	86	1	2	0	0	0.69	5.43	0.06	0.13	0.00	0.00
	256	6	91	2	2	1	0	0.62	9.43	0.21	0.21	0.10	0.00
	257	6	91	2	1	1	0	0.44	6.72	0.15	0.07	0.07	0.00
	258	9	86	2	2	1	0	0.79	7.58	0.18	0.18	0.09	0.00
	259	7	89	3	1	0	0	0.64	8.16	0.28	0.09	0.00	0.00
	260	8	88	3	1	0	0	0.43	4.74	0.16	0.05	0.00	0.00
	261	9	86	2	2	1	0	0.58	5.52	0.13	0.13	0.06	0.00
	262	6	89	2	2	1	0	0.56	8.25	0.19	0.19	0.09	0.00
	263	11	84	2	2	0	0	0.84	6.40	0.15	0.15	0.00	0.00
	264	11	85	2	1	1	0	0.85	6.60	0.16	0.08	0.08	0.00
	265	6	89	1	3	1	0	0.36	5.36	0.06	0.18	0.06	0.00
	266	6	90	2	2	0	0	0.40	5.99	0.13	0.13	0.00	0.00
	267	14	81	2	2	1	0	1.11	6.40	0.16	0.16	0.08	0.00
	268	6	90	2	1	1	0	0.32	4.75	0.11	0.05	0.05	0.00
	269	9	87	2	1	0	0	0.64	6.19	0.14	0.07	0.00	0.00
	270	6	90	2	2	1	0	0.51	7.61	0.17	0.17	0.08	0.00
	Mean	**10**	**86**	**2**	**2**	**1**	**0**	**0.95**	**6.63**	**0.17**	**0.15**	**0.04**	**0.00**
	StdDev	**9**	**9**	**1**	**1**	**1**	**0**	**1.67**	**1.43**	**0.10**	**0.10**	**0.04**	**0.00**
1 vs. 2	**P value**	**NS**	**NS**	**NS**	**NS**	**NS**	**N/A**	**NS**	**<0.001**	**<0.05**	**NS**	**NS**	**N/A**

Table 12. Hematology, Females (cont'd)

			RBC Morphology			WBC Morphology				Platelet Comments		
Group	Animal No.	Reason for manual differential (if applicable)	Anisocytosis*	Poikilocytosis*	Polychromasia*	Reactive lymphs*	Mast cells present	Tissue cells present	Macrophages present	Automated platelet count confirmed by slide review	Platelets clumped; actual count may be higher	Platelet count invalid due to clot in tube
1	151	Due to instrument flags			sl					X		
	152				sl					X		
	153				sl					X		
	154				sl					X		
	155				sl					X		
	156		sl		sl					X		
	157				sl						X	
	158	Due to instrument flags			sl		X			X		
	159				sl					X		
	160				sl					X		
2	251				sl						X	
	252				sl						X	
	253	Due to large lymphocytes	mod		mod	mod				X		
	254				sl		rare			X		
	255				sl					X		
	256				sl					X		
	257				sl					X		
	258				sl		X				X	
	259	Due to possible mast cell interference			sl						X	
	260	Due to possible mast cell interference			sl		X				X	
	261				sl					X		
	262				sl					X		
	263				sl					X		
	264		sl		sl					X		
	265				sl					X		
	266				sl					X		
	267				sl		X	X			X	
	268						X			X		
	269				sl		X			X		
	270				sl		X			X		

* Ranked as slight (sl), moderate (mod), or marked (mkd).
X, parameter applies to this sample.

Table 13A. Clinical Chemistry, Males

Group	Animal No.	ALB g/dL	TP g/dL	ALP U/L	ALT U/L	AST U/L	TBIL mg/dL	BUN mg/dL	CREAT mg/dL	CA mg/dL	CHOL mg/dL	GLU mg/dL	PHOS mg/dL	NA mEq/L	K mEq/L	Cl mEq/L	TRIG mg/dL	GLOB g/dL	A/G Ratio	LIP	ICT	HEM
1	101	3.3	6.8	346	114	216	0.2	23	0.5	10.6	175	162	7.3	149	5.3	101	188	3.5	0.9	N	N	1+
	102	3.4	7.0	233	68	103	0.1	16	0.4	11.5	150	146	7.0	152	6.1	97	157	3.6	0.9	N	N	1+
	103	3.1	6.1	187	50	74	0.2	16	0.4	9.7	83	117	6.3	153	5.8	105	140	3.0	1.0	N	N	1+
	104	3.4	6.7	206	105	219	0.2	20	0.5	11.0	175	115	6.8	150	6.4	102	233	3.3	1.0	N	N	1+
	105	2.8	5.7	246	49	66	0.1	17	0.3	8.9	137	110	5.3	151	5.4	110	111	2.9	1.0	N	N	1+
	106	3.1	6.3	232	50	112	0.1	17	0.4	8.8	122	116	6.6	150	6.2	103	190	3.2	1.0	N	N	1+
	107	3.0	5.9	214	53	75	0.1	14	0.4	7.7	110	106	5.4	149	6.3	107	107	2.9	1.0	N	N	N
	108	3.5	6.8	235	63	113	0.1	18	0.5	11.3	129	134	6.8	152	6.2	100	94	3.3	1.1	N	N	N
	109	2.9	5.7	224	57	84	0.1	19	0.4	7.4	162	111	7.2	152	6.7	104	203	2.8	1.0	N	N	1+
	110	3.5	6.9	290	69	81	0.1	18	0.4	10.6	95	103	6.0	154	5.7	100	120	3.4	1.0	N	N	1+
	Mean	**3.2**	**6.4**	**241**	**68**	**114**	**0.1**	**18**	**0.4**	**9.8**	**134**	**122**	**6.5**	**151**	**6.0**	**103**	**154**	**3.2**	**1.0**			
	StdDev	**0.3**	**0.5**	**46**	**23**	**57**	**0.0**	**2**	**0.1**	**1.5**	**32**	**19**	**0.7**	**2**	**0.4**	**4**	**47**	**0.3**	**0.1**			
2	201*	2.7	5.1	171	60	90	QNS	12	QNS	4.5	93	75	6.0	QNS	QNS	QNS	108	2.4	1.1	N	N	N
	202	2.4	4.9	136	35	43	0.1	17	0.3	4.6	120	100	5.0	150	7.1	104	107	2.5	1.0	N	N	1+
	203	2.6	5.1	129	42	65	0.1	13	0.3	7.0	60	93	5.2	145	5.2	109	96	2.5	1.0	N	N	N
	204	2.9	5.6	148	71	85	0.1	14	0.3	6.9	107	84	5.1	152	6.9	102	138	2.7	1.1	N	N	N
	205	2.4	4.6	121	55	74	0.1	14	0.3	2.8**	75	78	4.4	153	6.8	110	53	2.2	1.1	N	N	N
	206	2.9	5.8	187	61	78	0.1	16	0.3	7.4	130	92	5.7	150	6.3	104	98	2.9	1.0	N	N	N
	207	2.3	4.3	173	42	77	0.1	11	0.2	4.7	66	86	4.7	149	5.8	113	50	2.0	1.2	N	N	N
	208	2.4	5.0	105	38	47	0.1	14	0.2	3.8	149	95	4.2	153	6.8	107	232	2.6	0.9	N	N	N
	209	3.0	6.2	247	51	111	0.1	15	0.3	7.7	144	109	4.4	148	5.8	102	118	3.2	0.9	N	N	1+
	210	3.1	6.0	191	62	76	0.1	16	0.3	6.0	130	109	4.4	154	5.9	100	217	2.9	1.1	N	N	N
	211	3.1	6.4	175	56	74	0.2	18	0.4	8.2	151	114	6.0	153	7.5	101	281	3.3	0.9	N	N	1+
	212	3.3	6.5	229	51	102	0.1	15	0.4	9.0	144	117	6.6	154	7.4	102	140	3.2	1.0	N	N	1+
	213	3.3	6.2	226	47	86	0.1	14	0.3	8.9	117	110	5.8	153	6.8	104	158	2.9	1.1	N	N	N
	214	3.2	6.7	287	101	139	0.2	20	0.4	11.3	216	121	7.1	150	6.2	101	259	3.5	0.9	N	N	1+
	215	3.0	5.7	242	58	82	0.1	16	0.4	8.1	104	119	5.3	150	6.0	107	90	2.7	1.1	N	N	N
	216	3.1	6.2	138	48	64	0.1	17	0.4	8.8	122	121	6.2	149	6.3	102	109	3.1	1.0	N	N	N
	217	3.3	6.4	237	204	451	0.1	18	0.4	10.9	138	142	7.5	150	6.0	100	135	3.1	1.1	N	N	1+
	218	2.9	5.9	163	45	69	0.1	16	0.4	8.6	129	127	5.6	152	6.4	101	124	3.0	1.0	N	N	N
	219	3.1	5.8	216	39	59	0.1	13	0.3	7.5	110	110	5.9	151	6.1	106	108	2.7	1.1	N	N	N
	220	3.2	6.1	169	47	67	0.1	14	0.3	8.5	124	116	6.5	155	6.6	102	166	2.9	1.1	N	N	N
	Mean	**2.9**	**5.7**	**185**	**61**	**97**	**0.1**	**15**	**0.3**	**7.3**	**121**	**106**	**5.6**	**151**	**6.4**	**104**	**139**	**2.8**	**1.0**			
	StdDev	**0.3**	**0.7**	**49**	**37**	**86**	**0.0**	**2**	**0.1**	**2.3**	**34**	**18**	**0.9**	**2**	**0.6**	**4**	**63**	**0.4**	**0.1**			
1 vs. 2	**P value**	**<0.05**	**<0.01**	**<0.01**	**NS**	**NS**	**NS**	**<0.05**	**<0.01**	**<0.01**	**NS**	**<0.05**	**<0.01**	**NS**	**NS**	**NS**	**NS**	**<0.01**	**NS**	**N/A**	**N/A**	**N/A**

* Panel by dilution. QNS = Quantity not sufficient to run test.
** Unable to recheck due to sample volume.

Table 13B. Clinical Chemistry, Females

Group	Animal No.	ALB g/dL	TP g/dL	ALP U/L	ALT U/L	AST U/L	TBIL mg/dL	BUN mg/dL	CREAT mg/dL	CA mg/dL	CHOL mg/dL	GLU mg/dL	PHOS mg/dL	NA mEq/L	K mEq/L	Cl mEq/L	TRIG mg/dL	GLOB g/dL	A/G Ratio	LIP	ICT	HEM
1	151	3.8	7.1	166	60	120	0.1	17	0.5	11.6	86	131	5.2	153	6.0	102	48	3.3	1.2	N	N	1+
	152	3.6	6.8	266	60	90	0.1	18	0.5	10.3	98	125	5.7	149	5.5	101	59	3.2	1.1	N	N	1+
	153	3.5	6.8	265	60	91	0.1	18	0.5	10.2	98	126	5.7	151	5.6	103	61	3.3	1.1	N	N	1+
	154	3.3	6.4	209	55	82	0.1	16	0.5	9.0	140	104	4.8	152	6.5	103	102	3.1	1.1	N	N	1+
	155	3.7	6.9	241	66	99	0.1	19	0.5	11.6	80	122	6.6	146	6.1	101	134	3.2	1.2	N	N	N
	156	3.8	7.1	215	53	104	0.1	17	0.5	11.3	127	136	4.9	153	6.1	101	42	3.3	1.2	N	N	1+
	157	3.3	6.2	240	45	83	0.1	14	0.4	9.7	97	109	5.4	149	5.2	107	70	2.9	1.1	N	N	N
	158	3.5	6.6	224	107	185	0.1	19	0.5	11.4	114	137	5.9	150	6.2	103	81	3.1	1.1	N	N	N
	159	3.4	6.1	231	41	72	0.1	12	0.4	8.6	96	106	4.4	150	6.1	104	58	2.7	1.3	N	N	N
	160	3.9	7.1	161	50	102	0.1	14	0.4	11.2	83	147	5.1	148	5.6	98	44	3.2	1.2	N	N	N
	Mean	**3.6**	**6.7**	**222**	**60**	**103**	**0.1**	**16**	**0.5**	**10.5**	**102**	**124**	**5.4**	**150**	**5.9**	**102**	**70**	**3.1**	**1.2**			
	StdDev	**0.2**	**0.4**	**36**	**18**	**32**	**0.0**	**2**	**0.0**	**1.1**	**19**	**14**	**0.6**	**2**	**0.4**	**2**	**29**	**0.2**	**0.1**			
2	251	3.6	6.4	245	59	86	0.2	16	0.3	10.6	85	116	6.6	142	4.9	103	69	2.8	1.3	N	N	N
	252	2.9	5.3	130	40	103	0.1	12	0.3	4.7	106	87	4.8	149	6.6	108	65	2.4	1.2	N	N	N
	253	2.3	5.8	273	51	75	0.1	15	0.3	7.8	97	109	5.9	144	7.1	100	75	3.5	0.7	N	N	N
	254	3.3	5.8	175	41	62	0.1	15	0.3	7.5	62	97	6.3	148	6.7	105	47	2.5	1.3	N	N	N
	255	3.1	5.7	179	41	92	0.1	15	0.3	5.9	101	96	5.2	153	6.7	105	114	2.6	1.2	N	N	N
	256	3.3	6.3	165	52	73	0.1	14	0.4	7.5	100	110	5.2	156	6.7	105	96	3.0	1.1	N	N	1+
	257	2.6	5.0	146	34	61	0.1	14	0.3	6.1	95	91	4.9	156	5.9	109	64	2.4	1.1	N	N	N
	258	2.9	5.2	196	40	67	0.1	20	0.3	4.4	86	98	5.1	161	7.2	114	88	2.3	1.3	N	N	1+
	259	3.2	5.6	175	43	79	0.1	16	0.3	8.5	86	129	5.5	155	6.0	105	67	2.4	1.3	N	N	N
	260	3.5	6.1	201	44	85	0.1	15	0.3	7.8	120	126	5.4	157	6.2	108	53	2.6	1.3	N	N	N
	261	3.0	5.6	175	49	66	0.1	15	0.3	7.2	115	100	5.1	153	6.6	105	50	2.6	1.2	N	N	N
	262	3.4	6.4	179	65	93	0.1	16	0.4	8.7	123	121	5.9	152	7.0	99	92	3.0	1.1	N	N	N
	263	3.5	6.7	248	65	100	0.1	17	0.5	10.6	117	109	6.6	154	6.7	101	156	3.2	1.1	N	N	1+
	264	2.9	5.3	156	75	106	0.1	13	0.3	6.3	107	117	4.7	151	6.2	105	67	2.4	1.2	N	N	N
	265	3.5	6.5	267	56	74	0.1	18	0.4	8.7	110	119	4.7	153	6.4	102	87	3.0	1.2	N	N	1+
	266	3.3	6.1	146	56	103	0.1	17	0.4	9.5	92	116	6.8	150	6.1	101	75	2.8	1.2	N	N	N
	267	3.2	6.0	142	55	97	0.1	16	0.4	8.6	87	115	6.5	151	6.5	102	67	2.8	1.1	N	N	N
	268	3.6	6.5	175	122	179	0.1	17	0.5	10.1	70	133	5.5	151	6.0	99	47	2.9	1.2	N	N	N
	269	3.2	6.0	138	40	55	0.1	13	0.3	8.0	127	118	5.2	151	6.9	101	66	2.8	1.1	N	N	N
	270	3.2	5.8	179	54	92	0.1	15	0.4	9.0	69	121	6.7	150	6.1	102	103	2.6	1.2	N	N	N
	Mean	**3.2**	**5.9**	**185**	**54**	**87**	**0.1**	**15**	**0.4**	**7.9**	**98**	**111**	**5.6**	**152**	**6.4**	**104**	**77**	**2.7**	**1.2**			
	StdDev	**0.3**	**0.5**	**42**	**19**	**27**	**0.0**	**2**	**0.1**	**1.8**	**18**	**13**	**0.7**	**4**	**0.5**	**4**	**26**	**0.3**	**0.1**			
1 vs. 2	**P value**	**<0.001**	**<0.001**	**<0.05**	**NS**	**NS**	**NS**	**NS**	**<0.001**	**<0.001**	**NS**	**<0.05**	**NS**	**NS**	**<0.01**	**NS**	**NS**	**<0.001**	**NS**	**N/A**	**N/A**	**N/A**

* Panel by dilution. QNS = Quantity not sufficient to run test.
** Unable to recheck due to sample volume.

Table 14. Necropsy Observations

	Males		Females	
Group	Animal No.	Comments	Animal No.	Comments
1	101	NSO	151	NSO
	102	NSO	152	NSO
	103	NSO	153	NSO (brain &spleen cut in half)
	104	NSO	154	NSO
	105	NSO	155	NSO
	106	NSO	156	NSO
	107	L testis abnormally small. Pea-sized mass on small lobe of liver	157	NSO
	108	NSO	158	NSO
	109	NSO	159	NSO
	110	NSO	160	NSO (L eye nicked at necropsy)
2	201	NSO	251	NSO
	202	NSO	252	NSO
	203	NSO	253	Fusion of spleen, pancreas, and one lobe of liver. White nodular spots on spleen
	204	NSO	254	NSO
	205	NSO	255	NSO
	206	NSO (R adrenal nicked)	256	NSO
	207	NSO	257	NSO
	208	R thyroid smaller than L	258	NSO (L thyroid lost at necropsy)
	209	NSO	259	NSO
	210	NSO	260	NSO
	211	NSO	261	NSO
	212	NSO	262	NSO
	213	NSO	263	NSO
	214	NSO	264	NSO
	215	NSO	265	NSO
	216	NSO	266	NSO
	217	NSO	267	White pea-sized mass on R kidney
	218	NSO	268	NSO
	219	NSO (Lens of L eye fell out at necropsy)	269	NSO
	220	NSO (R adrenal nicked at necropsy)	270	NSO

Table 15A. Organ Weights, Males

		Weight (g)											
Group	Animal No.	Day-88 Body Wt	Adrenal glands (pr)	Brain	Heart	Kidneys (pr)	Liver	Pituitary gland	Prostate + urinary bladder	Testes/ epididymes (pr)	Spleen	Thymus	Thyroid/ parathyroid (pr)
1	101	392.7	0.0437	1.9354	1.5711	3.4877	18.8350	0.0116	1.0510	4.2265	0.7996	0.3616	0.0125
	102	480.2	0.0618	1.9604	1.9115	4.2411	21.2550	0.0165	1.1571	5.3396	0.8930	0.3471	0.0241
	103	407.4	0.0797	1.7485	1.5252	3.7400	17.1460	0.0112	1.3129	5.4974	0.6946	0.1457	0.0121
	104	453.6	0.0470	1.9740	1.5683	4.1878	21.0387	0.0143	1.4687	5.0710	0.8843	0.2735	0.0197
	105	392.9	0.0621	1.9443	1.4042	3.4029	17.4570	0.0138	1.0995	5.6377	0.9480	0.2036	0.0109
	106	449.1	0.0331	2.0352	1.6011	3.6362	18.6504	0.0134	1.5243	4.8386	0.7129	0.3798	0.0209
	107	466.4	0.0807	2.0335	1.6338	3.4314	19.3437	0.0125	1.3392	3.4508	0.7789	0.2442	0.0225
	108	420.3	0.0431	1.9322	1.4269	3.1460	15.3092	0.0130	1.4633	4.7484	0.9120	0.2407	0.0214
	109	434.8	0.0511	1.8654	1.7433	3.7117	22.6547	0.0126	0.9958	5.1073	0.9013	0.2453	0.0178
	110	416.7	0.0746	1.9974	1.4896	3.2296	14.7959	0.0122	1.5491	5.4421	0.6264	0.3123	0.0154
	Mean	**431.4**	**0.0577**	**1.9426**	**1.5875**	**3.6214**	**18.6486**	**0.0131**	**1.2961**	**4.9359**	**0.8151**	**0.2754**	**0.0177**
	StdDev	**30.4**	**0.0167**	**0.0849**	**0.1509**	**0.3664**	**2.5548**	**0.0015**	**0.2066**	**0.6690**	**0.1093**	**0.0745**	**0.0047**
2	201	396.9	0.0566	1.8569	1.4938	3.0632	14.8145	0.0120	1.5476	7.4401	0.7751	0.2688	0.0197
	202	440.0	0.0864	1.9128	1.5860	3.7000	16.6950	0.0132	1.5477	6.8776	0.7677	0.1689	0.0262
	203	439.3	0.0532	1.9265	1.5714	3.4350	18.4386	0.0145	1.0006	5.0631	0.8382	0.4571	0.0190
	204	457.7	0.0881	1.9476	1.8920	4.2396	18.8703	0.0124	1.5617	6.2738	0.8153	0.3166	0.0244
	205	440.7	0.0433	1.9793	1.5871	3.1334	15.4643	0.0127	1.0554	5.0648	0.8110	0.2711	0.0203
	206	416.8	0.0278	1.8584	1.4054	3.2426	17.5740	0.0110	1.1808	5.3547	0.8054	0.3116	0.0200
	207	479.4	0.0537	2.0110	1.7278	3.8041	16.0950	0.0132	0.9784	5.3836	0.8876	0.3192	0.0176
	208	450.3	0.0705	1.9274	1.6493	3.8952	19.1562	0.0128	1.4776	6.0108	0.8941	0.2665	0.0163
	209	420.0	0.0455	1.8813	1.3857	3.2339	16.5236	0.0114	1.2807	4.7415	0.6069	0.2733	0.0164
	210	421.9	0.0650	1.7821	1.5298	2.9661	15.4095	0.0087	1.2014	6.1318	0.7933	0.3510	0.0177
	211	448.2	0.0641	1.9638	1.5573	4.0609	20.3457	0.0111	1.1305	5.8488	0.7863	0.2436	0.0182
	212	452.3	0.0431	2.0924	1.5042	2.8562	17.5746	0.0118	1.3646	4.7249	0.7650	0.4976	0.0201
	213	444.6	0.0807	1.9309	1.5838	3.9272	19.5456	0.0121	1.3850	6.1069	0.8024	0.2495	0.0192
	214	422.6	0.0573	2.1892	1.7293	4.2588	20.0857	0.0114	1.6421	5.3746	0.8860	0.3328	0.0169
	215	446.2	0.0400	1.9423	1.5836	3.6773	15.5444	0.0128	1.4911	5.0767	0.6635	0.3760	0.0194
	216	493.2	0.0760	2.0742	1.7882	3.8244	20.2608	0.0143	1.4948	7.1206	1.0044	0.2921	0.0181
	217	454.5	0.0450	2.0414	1.6646	3.7219	18.4142	0.0128	1.4044	4.7705	0.8774	0.3256	0.0233
	218	508.7	0.0934	2.0527	1.6420	4.0051	19.4476	0.0122	1.5009	6.3778	1.0221	0.2137	0.0216
	219	380.9	0.0456	1.7569	1.5329	3.3078	15.1141	0.0068	1.0843	5.1401	0.8996	0.2947	0.0163
	220	409.0	0.1230	1.9200	1.6322	3.9288	18.9107	0.0081	1.3600	5.6356	0.8079	0.1736	0.0200
	Mean	**441.2**	**0.0629**	**1.9524**	**1.6023**	**3.6141**	**17.7142**	**0.0118**	**1.3345**	**5.7259**	**0.8255**	**0.3002**	**0.0195**
	StdDev	**30.7**	**0.0229**	**0.1045**	**0.1214**	**0.4277**	**1.8726**	**0.0019**	**0.2064**	**0.8030**	**0.0970**	**0.0810**	**0.0027**
T test	**P value**	**NS**	**NS**	**NS**	**NS**	**NS**	**NS**	**<0.05**	**NS**	**<0.01**	**NS**	**NS**	**NS**

Table 15B. Organ Weights, Females

		Weight (g)										
Group	Animal No.	Day-88 Body Wt	Adrenal glands (pr)	Brain	Heart	Kidneys (pr)	Liver	Pituitary gland	Ovaries (pr)	Spleen	Thymus	Thyroid/ parathyroid (pr)
1	151	283.5	0.0762	1.8138	1.1194	2.2678	9.7880	0.0161	0.1156	0.6664	0.1949	0.0212
	152	244.6	0.0699	1.7070	1.0038	1.7835	8.0289	0.0151	0.1682	0.5420	0.1699	0.0114
	153	324.4	0.0756	1.8539	1.1384	2.1818	10.6638	0.0138	0.1726	0.6723	0.2968	0.0164
	154	242.5	0.0720	1.7553	0.9006	1.9025	8.1093	0.0137	0.1206	0.6602	0.1532	0.0184
	155	245.3	0.0634	1.8653	0.9846	2.0819	10.8639	0.0135	0.0828	0.6708	0.2879	0.0089
	156	274.2	0.0688	1.7052	0.9787	1.8538	7.5640	0.0131	0.0978	0.4922	0.2243	0.0105
	157	247.2	0.0748	1.8728	0.9491	1.9144	8.0771	0.0116	0.1399	0.4591	0.1904	0.0126
	158	314.6	0.0499	1.9062	1.2122	2.4581	12.6621	0.0154	0.1185	0.6858	0.2541	0.0221
	159	261.7	0.0857	1.8111	1.0582	2.2235	8.9202	0.0170	0.1874	0.5454	0.1942	0.0192
	160	227.3	0.0783	1.6503	1.0318	2.0198	8.1658	0.0177	0.0946	0.4868	0.2297	0.0192
	Mean	**266.5**	**0.0715**	**1.7941**	**1.0377**	**2.0687**	**9.2843**	**0.0147**	**0.1298**	**0.5881**	**0.2195**	**0.0160**
	StdDev	**32.4**	**0.0097**	**0.0855**	**0.0953**	**0.2133**	**1.6606**	**0.0019**	**0.0359**	**0.0912**	**0.0482**	**0.0048**
2	251	266.2	0.0572	1.9338	1.0181	1.6628	8.4637	0.0154	0.1073	0.5118	0.2991	0.0192
	252	247.7	0.0746	1.8304	1.0140	1.8665	9.0460	0.0100	0.0978	0.5250	0.2639	0.0160
	253	289.3	0.0850	1.7620	1.3458	2.2791	14.0114*	0.0094	0.1453	1.5152*	0.1671	0.0100
	254	228.4	0.0673	1.7873	0.9949	1.7731	8.5153	0.0139	0.0769	0.5303	0.1916	0.0160
	255	257.3	0.0734	1.9592	1.0610	1.8815	9.5757	0.0119	0.0958	0.4978	0.2638	0.0220
	256	249.4	0.0868	1.8471	1.0234	1.9661	9.7213	0.0173	0.0822	0.5823	0.1950	0.0200
	257	285.3	0.0571	1.8179	0.9236	1.6427	9.0969	0.0132	0.0956	0.5208	0.2273	0.0129
	258	235.6	0.1081	1.8016	0.9994	2.2384	10.0343	0.0173	0.2103	0.6477	0.2370	0.0055
	259	249.0	0.0546	1.7899	0.9424	1.8387	9.1293	0.0126	0.1025	0.5831	0.3063	0.0126
	260	229.0	0.0862	1.7281	0.9642	2.0096	8.1191	0.0129	0.1712	0.4406	0.1775	0.0142
	261	239.9	0.0560	1.7782	1.0220	1.9495	8.0798	0.0129	0.0916	0.5132	0.2148	0.0158
	262	268.7	0.1128	1.7944	1.1601	2.1667	10.3145	0.0137	0.1512	0.6498	0.2249	0.0147
	263	250.4	0.0686	1.9108	0.9900	1.9614	9.8608	0.0116	0.1321	0.5783	0.1765	0.0136
	264	272.5	0.0974	1.7328	1.1350	2.1880	10.0032	0.0133	0.2004	0.6943	0.1961	0.0235
	265	245.9	0.0580	1.8560	1.0950	2.0052	8.8643	0.0160	0.0779	0.4980	0.2369	0.0151
	266	261.7	0.0664	1.7404	0.9749	3.4190	10.3477	0.0074	0.1554	0.5628	0.2450	0.0149
	267	273.0	0.0603	1.8621	1.2042	1.9157	9.2044	0.0122	0.1402	0.7172	0.2877	0.0180
	268	258.2	0.0673	1.8261	1.0492	1.8049	8.2014	0.0127	0.0839	0.5453	0.2071	0.0157
	269	253.4	0.1030	1.7284	0.9920	2.1481	8.4245	0.0164	0.1134	0.5230	0.1840	0.0145
	270	250.0	0.0678	1.7040	1.0728	1.9633	10.5718	0.0113	0.0746	0.5740	0.2168	0.0150
	Mean	**255.5**	**0.0754**	**1.8095**	**1.0491**	**2.0340**	**9.2407**	**0.0131**	**0.1203**	**0.5629**	**0.2259**	**0.0155**
	StdDev	**16.8**	**0.0183**	**0.0706**	**0.1001**	**0.3708**	**0.8092**	**0.0026**	**0.0411**	**0.0713**	**0.0415**	**0.0040**
T test	**P value**	**NS**	**NS**	**NS**	**NS**	**NS**	**NS**	**NS**	**NS**	**NS**	**NS**	**NS**

* Outlier (excluded from analysis)

Table 16A. Organ Weights (Normalized to Body Weight), Males

		Weight as Percentage of Body Weight											
Group	Animal No.	Day-88 Body Wt	Adrenal glands (pr)	Brain	Heart	Kidneys (pr)	Liver	Pituitary gland	Prostate + urinary bladder	Testes/ epididymes (pr)	Spleen	Thymus	Thyroid/ parathyroid (pr)
1	101	100.0	0.0111	0.4928	0.4001	0.8881	4.7963	0.0030	0.2676	1.0763	0.2036	0.0921	0.0032
	102	100.0	0.0129	0.4082	0.3981	0.8832	4.4263	0.0034	0.2410	1.1120	0.1860	0.0723	0.0050
	103	100.0	0.0196	0.4292	0.3744	0.9180	4.2086	0.0027	0.3223	1.3494	0.1705	0.0358	0.0030
	104	100.0	0.0104	0.4352	0.3457	0.9232	4.6382	0.0032	0.3238	1.1179	0.1950	0.0603	0.0043
	105	100.0	0.0158	0.4949	0.3574	0.8661	4.4431	0.0035	0.2798	1.4349	0.2413	0.0518	0.0028
	106	100.0	0.0074	0.4532	0.3565	0.8097	4.1528	0.0030	0.3394	1.0774	0.1587	0.0846	0.0047
	107	100.0	0.0173	0.4360	0.3503	0.7357	4.1474	0.0027	0.2871	0.7399	0.1670	0.0524	0.0048
	108	100.0	0.0103	0.4597	0.3395	0.7485	3.6424	0.0031	0.3482	1.1298	0.2170	0.0573	0.0051
	109	100.0	0.0118	0.4290	0.4009	0.8537	5.2104	0.0029	0.2290	1.1746	0.2073	0.0564	0.0041
	110	100.0	0.0179	0.4793	0.3575	0.7750	3.5507	0.0029	0.3718	1.3060	0.1503	0.0749	0.0037
	Mean	**100.0**	**0.0134**	**0.4518**	**0.3680**	**0.8401**	**4.3216**	**0.0030**	**0.3010**	**1.1518**	**0.1897**	**0.0638**	**0.0041**
	StdDev	**0.0**	**0.0040**	**0.0295**	**0.0237**	**0.0687**	**0.5020**	**0.0003**	**0.0474**	**0.1908**	**0.0286**	**0.0170**	**0.0009**
2	201	100.0	0.0143	0.4679	0.3764	0.7718	3.7326	0.0030	0.3899	1.8746	0.1953	0.0677	0.0050
	202	100.0	0.0196	0.4347	0.3605	0.8409	3.7943	0.0030	0.3518	1.5631	0.1745	0.0384	0.0060
	203	100.0	0.0121	0.4385	0.3577	0.7819	4.1973	0.0033	0.2278	1.1525	0.1908	0.1041	0.0043
	204	100.0	0.0192	0.4255	0.4134	0.9263	4.1229	0.0027	0.3412	1.3707	0.1781	0.0692	0.0053
	205	100.0	0.0098	0.4491	0.3601	0.7110	3.5090	0.0029	0.2395	1.1493	0.1840	0.0615	0.0046
	206	100.0	0.0067	0.4459	0.3372	0.7780	4.2164	0.0026	0.2833	1.2847	0.1932	0.0748	0.0048
	207	100.0	0.0112	0.4195	0.3604	0.7935	3.3573	0.0028	0.2041	1.1230	0.1851	0.0666	0.0037
	208	100.0	0.0157	0.4280	0.3663	0.8650	4.2541	0.0028	0.3281	1.3348	0.1986	0.0592	0.0036
	209	100.0	0.0108	0.4479	0.3299	0.7700	3.9342	0.0027	0.3049	1.1289	0.1445	0.0651	0.0039
	210	100.0	0.0154	0.4224	0.3626	0.7030	3.6524	0.0021	0.2848	1.4534	0.1880	0.0832	0.0042
	211	100.0	0.0143	0.4382	0.3475	0.9060	4.5394	0.0025	0.2522	1.3050	0.1754	0.0544	0.0041
	212	100.0	0.0095	0.4626	0.3326	0.6315	3.8856	0.0026	0.3017	1.0446	0.1691	0.1100	0.0044
	213	100.0	0.0182	0.4343	0.3562	0.8833	4.3962	0.0027	0.3115	1.3736	0.1805	0.0561	0.0043
	214	100.0	0.0136	0.5180	0.4092	1.0078	4.7529	0.0027	0.3886	1.2718	0.2097	0.0788	0.0040
	215	100.0	0.0090	0.4353	0.3549	0.8241	3.4837	0.0029	0.3342	1.1378	0.1487	0.0843	0.0043
	216	100.0	0.0154	0.4206	0.3626	0.7754	4.1080	0.0029	0.3031	1.4438	0.2036	0.0592	0.0037
	217	100.0	0.0099	0.4492	0.3662	0.8189	4.0515	0.0028	0.3090	1.0496	0.1930	0.0716	0.0051
	218	100.0	0.0184	0.4035	0.3228	0.7873	3.8230	0.0024	0.2950	1.2537	0.2009	0.0420	0.0042
	219	100.0	0.0120	0.4612	0.4024	0.8684	3.9680	0.0018	0.2847	1.3495	0.2362	0.0774	0.0043
	220	100.0	0.0301	0.4694	0.3991	0.9606	4.6236	0.0020	0.3325	1.3779	0.1975	0.0424	0.0049
	Mean	**100.0**	**0.0143**	**0.4436**	**0.3639**	**0.8202**	**4.0201**	**0.0027**	**0.3034**	**1.3021**	**0.1873**	**0.0683**	**0.0044**
	StdDev	**0.0**	**0.0052**	**0.0247**	**0.0256**	**0.0905**	**0.3825**	**0.0004**	**0.0484**	**0.1955**	**0.0203**	**0.0186**	**0.0006**
T test	**P value**	**N/A**	**NS**	**NS**	**NS**	**NS**	**NS**	**<0.01**	**NS**	**NS**	**NS**	**NS**	**NS**

Table 16B. Organ Weights (Normalized to Body Weight), Females

		Weight as Percentage of Body Weight										
Group	Animal No.	Day-88 Body Wt	Adrenal glands (pr)	Brain	Heart	Kidneys (pr)	Liver	Pituitary gland	Ovaries (pr)	Spleen	Thymus	Thyroid/ parathyroid (pr)
1	151	100.0	0.0269	0.6398	0.3949	0.7999	3.4526	0.0057	0.0408	0.2351	0.0687	0.0075
	152	100.0	0.0286	0.6979	0.4104	0.7291	3.2825	0.0062	0.0688	0.2216	0.0695	0.0047
	153	100.0	0.0233	0.5715	0.3509	0.6726	3.2872	0.0043	0.0532	0.2072	0.0915	0.0051
	154	100.0	0.0297	0.7238	0.3714	0.7845	3.3440	0.0056	0.0497	0.2722	0.0632	0.0076
	155	100.0	0.0258	0.7604	0.4014	0.8487	4.4288	0.0055	0.0338	0.2735	0.1174	0.0036
	156	100.0	0.0251	0.6219	0.3569	0.6761	2.7586	0.0048	0.0357	0.1795	0.0818	0.0038
	157	100.0	0.0303	0.7576	0.3839	0.7744	3.2674	0.0047	0.0566	0.1857	0.0770	0.0051
	158	100.0	0.0159	0.6059	0.3853	0.7813	4.0248	0.0049	0.0377	0.2180	0.0808	0.0070
	159	100.0	0.0327	0.6921	0.4044	0.8496	3.4086	0.0065	0.0716	0.2084	0.0742	0.0073
	160	100.0	0.0344	0.7260	0.4539	0.8886	3.5925	0.0078	0.0416	0.2142	0.1011	0.0084
	Mean	**100.0**	**0.0273**	**0.6797**	**0.3913**	**0.7805**	**3.4847**	**0.0056**	**0.0489**	**0.2215**	**0.0825**	**0.0060**
	StdDev	**0.0**	**0.0053**	**0.0660**	**0.0296**	**0.0721**	**0.4565**	**0.0010**	**0.0135**	**0.0315**	**0.0166**	**0.0017**
2	251	100.0	0.0215	0.7264	0.3825	0.6246	3.1795	0.0058	0.0403	0.1923	0.1124	0.0072
	252	100.0	0.0301	0.7390	0.4094	0.7535	3.6520	0.0040	0.0395	0.2119	0.1065	0.0065
	253	100.0	0.0294	0.6091	0.4652	0.7878	N/A	0.0032	0.0502	N/A	0.0578	0.0035
	254	100.0	0.0295	0.7825	0.4356	0.7763	3.7282	0.0061	0.0337	0.2322	0.0839	0.0070
	255	100.0	0.0285	0.7614	0.4124	0.7312	3.7216	0.0046	0.0372	0.1935	0.1025	0.0086
	256	100.0	0.0348	0.7406	0.4103	0.7883	3.8979	0.0069	0.0330	0.2335	0.0782	0.0080
	257	100.0	0.0200	0.6372	0.3237	0.5758	3.1885	0.0046	0.0335	0.1825	0.0797	0.0045
	258	100.0	0.0459	0.7647	0.4242	0.9501	4.2590	0.0073	0.0893	0.2749	0.1006	0.0023
	259	100.0	0.0219	0.7188	0.3785	0.7384	3.6664	0.0051	0.0412	0.2342	0.1230	0.0051
	260	100.0	0.0376	0.7546	0.4210	0.8776	3.5455	0.0056	0.0748	0.1924	0.0775	0.0062
	261	100.0	0.0233	0.7412	0.4260	0.8126	3.3680	0.0054	0.0382	0.2139	0.0895	0.0066
	262	100.0	0.0420	0.6678	0.4317	0.8064	3.8387	0.0051	0.0563	0.2418	0.0837	0.0055
	263	100.0	0.0274	0.7631	0.3954	0.7833	3.9380	0.0046	0.0528	0.2310	0.0705	0.0054
	264	100.0	0.0357	0.6359	0.4165	0.8029	3.6709	0.0049	0.0735	0.2548	0.0720	0.0086
	265	100.0	0.0236	0.7548	0.4453	0.8155	3.6048	0.0065	0.0317	0.2025	0.0963	0.0061
	266	100.0	0.0254	0.6650	0.3725	1.3065	3.9540	0.0028	0.0594	0.2151	0.0936	0.0057
	267	100.0	0.0221	0.6821	0.4411	0.7017	3.3716	0.0045	0.0514	0.2627	0.1054	0.0066
	268	100.0	0.0261	0.7072	0.4064	0.6990	3.1764	0.0049	0.0325	0.2112	0.0802	0.0061
	269	100.0	0.0406	0.6821	0.3915	0.8477	3.3246	0.0065	0.0448	0.2064	0.0726	0.0057
	270	100.0	0.0271	0.6816	0.4291	0.7853	4.2287	0.0045	0.0298	0.2296	0.0867	0.0060
	Mean	**100.0**	**0.0296**	**0.7108**	**0.4109**	**0.7982**	**3.6481**	**0.0052**	**0.0471**	**0.2219**	**0.0886**	**0.0061**
	StdDev	**0.0**	**0.0075**	**0.0502**	**0.0312**	**0.1452**	**0.3270**	**0.0012**	**0.0165**	**0.0253**	**0.0163**	**0.0015**
T test	**P value**	**N/A**	**NS**	**NS**	**NS**	**NS**	**NS**	**NS**	**NS**	**NS**	**NS**	**NS**

* Outlier (excluded from analysis)

Table 17A. Organ Weights (Normalized to Brain Weight), Males

			Weight as Fraction of Brain Weight										
Group	Animal No.	Day-88 Body Wt	Adrenal glands (pr)	Brain	Heart	Kidneys (pr)	Liver	Pituitary gland	Prostate + urinary bladder	Testes/ epididymes (pr)	Spleen	Thymus	Thyroid/ parathyroid (pr)
1	101		0.0226	1.0000	0.8118	1.8021	9.7318	0.0060	0.5430	2.1838	0.4131	0.1868	0.0065
	102		0.0315	1.0000	0.9751	2.1634	10.8422	0.0084	0.5902	2.7237	0.4555	0.1771	0.0123
	103		0.0456	1.0000	0.8723	2.1390	9.8061	0.0064	0.7509	3.1441	0.3973	0.0833	0.0069
	104		0.0238	1.0000	0.7945	2.1215	10.6579	0.0072	0.7440	2.5689	0.4480	0.1386	0.0100
	105		0.0319	1.0000	0.7222	1.7502	8.9786	0.0071	0.5655	2.8996	0.4876	0.1047	0.0056
	106		0.0163	1.0000	0.7867	1.7867	9.1639	0.0066	0.7490	2.3775	0.3503	0.1866	0.0103
	107		0.0397	1.0000	0.8034	1.6874	9.5125	0.0061	0.6586	1.6970	0.3830	0.1201	0.0111
	108		0.0223	1.0000	0.7385	1.6282	7.9232	0.0067	0.7573	2.4575	0.4720	0.1246	0.0111
	109		0.0274	1.0000	0.9345	1.9898	12.1447	0.0068	0.5338	2.7379	0.4832	0.1315	0.0095
	110		0.0373	1.0000	0.7458	1.6169	7.4076	0.0061	0.7756	2.7246	0.3136	0.1564	0.0077
	Mean		**0.0298**	**1.0000**	**0.8185**	**1.8685**	**9.6168**	**0.0067**	**0.6668**	**2.5515**	**0.4204**	**0.1410**	**0.0091**
	StdDev		**0.0091**	**0.0000**	**0.0841**	**0.2154**	**1.3903**	**0.0007**	**0.0994**	**0.4044**	**0.0591**	**0.0352**	**0.0023**
2	201		0.0305	1.0000	0.8045	1.6496	7.9781	0.0065	0.8334	4.0067	0.4174	0.1448	0.0106
	202		0.0452	1.0000	0.8292	1.9343	8.7280	0.0069	0.8091	3.5956	0.4013	0.0883	0.0137
	203		0.0276	1.0000	0.8157	1.7830	9.5710	0.0075	0.5194	2.6281	0.4351	0.2373	0.0099
	204		0.0452	1.0000	0.9715	2.1768	9.6890	0.0064	0.8019	3.2213	0.4186	0.1626	0.0125
	205		0.0219	1.0000	0.8018	1.5831	7.8130	0.0064	0.5332	2.5589	0.4097	0.1370	0.0103
	206		0.0150	1.0000	0.7562	1.7448	9.4565	0.0059	0.6354	2.8813	0.4334	0.1677	0.0108
	207		0.0267	1.0000	0.8592	1.8916	8.0035	0.0066	0.4865	2.6771	0.4414	0.1587	0.0088
	208		0.0366	1.0000	0.8557	2.0210	9.9389	0.0066	0.7666	3.1186	0.4639	0.1383	0.0085
	209		0.0242	1.0000	0.7366	1.7190	8.7831	0.0061	0.6808	2.5203	0.3226	0.1453	0.0087
	210		0.0365	1.0000	0.8584	1.6644	8.6468	0.0049	0.6741	3.4408	0.4451	0.1970	0.0099
	211		0.0326	1.0000	0.7930	2.0679	10.3604	0.0057	0.5757	2.9783	0.4004	0.1240	0.0093
	212		0.0206	1.0000	0.7189	1.3650	8.3993	0.0056	0.6522	2.2581	0.3656	0.2378	0.0096
	213		0.0418	1.0000	0.8202	2.0339	10.1225	0.0063	0.7173	3.1627	0.4156	0.1292	0.0099
	214		0.0262	1.0000	0.7899	1.9454	9.1749	0.0052	0.7501	2.4551	0.4047	0.1520	0.0077
	215		0.0206	1.0000	0.8153	1.8933	8.0031	0.0066	0.7677	2.6138	0.3416	0.1936	0.0100
	216		0.0366	1.0000	0.8621	1.8438	9.7680	0.0069	0.7207	3.4329	0.4842	0.1408	0.0087
	217		0.0220	1.0000	0.8154	1.8232	9.0204	0.0063	0.6880	2.3369	0.4298	0.1595	0.0114
	218		0.0455	1.0000	0.7999	1.9511	9.4742	0.0059	0.7312	3.1070	0.4979	0.1041	0.0105
	219		0.0260	1.0000	0.8725	1.8827	8.6027	0.0039	0.6172	2.9257	0.5120	0.1677	0.0093
	220		0.0641	1.0000	0.8501	2.0463	9.8493	0.0042	0.7083	2.9352	0.4208	0.0904	0.0104
	Mean		**0.0323**	**1.0000**	**0.8213**	**1.8510**	**9.0691**	**0.0060**	**0.6834**	**2.9427**	**0.4231**	**0.1538**	**0.0100**
	StdDev		**0.0118**	**0.0000**	**0.0546**	**0.1921**	**0.7840**	**0.0009**	**0.0984**	**0.4538**	**0.0468**	**0.0405**	**0.0014**
T test	**P value**		**NS**	**N/A**	**NS**	**NS**	**NS**	**<0.05**	**NS**	**<0.05**	**NS**	**NS**	**NS**

Table 17B. Organ Weights (Normalized to Brain Weight), Females

			Weight as Fraction of Brain Weight									
Group	Animal No.	Day-88 Body Wt	Adrenal glands (pr)	Brain	Heart	Kidneys (pr)	Liver	Pituitary gland	Ovaries (pr)	Spleen	Thymus	Thyroid/ parathyroid (pr)
1	151		0.0420	1.0000	0.6172	1.2503	5.3964	0.0089	0.0637	0.3674	0.1075	0.0117
	152		0.0409	1.0000	0.5880	1.0448	4.7035	0.0088	0.0985	0.3175	0.0995	0.0067
	153		0.0408	1.0000	0.6141	1.1769	5.7521	0.0074	0.0931	0.3626	0.1601	0.0088
	154		0.0410	1.0000	0.5131	1.0839	4.6199	0.0078	0.0687	0.3761	0.0873	0.0105
	155		0.0340	1.0000	0.5279	1.1161	5.8242	0.0072	0.0444	0.3596	0.1543	0.0048
	156		0.0403	1.0000	0.5740	1.0871	4.4358	0.0077	0.0574	0.2886	0.1315	0.0062
	157		0.0399	1.0000	0.5068	1.0222	4.3128	0.0062	0.0747	0.2451	0.1017	0.0067
	158		0.0262	1.0000	0.6359	1.2895	6.6426	0.0081	0.0622	0.3598	0.1333	0.0116
	159		0.0473	1.0000	0.5843	1.2277	4.9253	0.0094	0.1035	0.3011	0.1072	0.0106
	160		0.0474	1.0000	0.6252	1.2239	4.9481	0.0107	0.0573	0.2950	0.1392	0.0116
	Mean		**0.0400**	**1.0000**	**0.5786**	**1.1522**	**5.1561**	**0.0082**	**0.0723**	**0.3273**	**0.1222**	**0.0089**
	StdDev		**0.0062**	**0.0000**	**0.0476**	**0.0934**	**0.7369**	**0.0013**	**0.0198**	**0.0440**	**0.0249**	**0.0026**
2	251		0.0296	1.0000	0.5265	0.8599	4.3767	0.0080	0.0555	0.2647	0.1547	0.0099
	252		0.0408	1.0000	0.5540	1.0197	4.9421	0.0055	0.0534	0.2868	0.1442	0.0087
	253		0.0482	1.0000	0.7638	1.2935	N/A	0.0053	0.0825	N/A	0.0948	0.0057
	254		0.0377	1.0000	0.5566	0.9921	4.7643	0.0078	0.0430	0.2967	0.1072	0.0090
	255		0.0375	1.0000	0.5415	0.9603	4.8876	0.0061	0.0489	0.2541	0.1346	0.0112
	256		0.0470	1.0000	0.5541	1.0644	5.2630	0.0094	0.0445	0.3153	0.1056	0.0108
	257		0.0314	1.0000	0.5081	0.9036	5.0041	0.0073	0.0526	0.2865	0.1250	0.0071
	258		0.0600	1.0000	0.5547	1.2425	5.5697	0.0096	0.1167	0.3595	0.1315	0.0031
	259		0.0305	1.0000	0.5265	1.0273	5.1005	0.0070	0.0573	0.3258	0.1711	0.0070
	260		0.0499	1.0000	0.5580	1.1629	4.6983	0.0075	0.0991	0.2550	0.1027	0.0082
	261		0.0315	1.0000	0.5747	1.0963	4.5438	0.0073	0.0515	0.2886	0.1208	0.0089
	262		0.0629	1.0000	0.6465	1.2075	5.7482	0.0076	0.0843	0.3621	0.1253	0.0082
	263		0.0359	1.0000	0.5181	1.0265	5.1606	0.0061	0.0691	0.3026	0.0924	0.0071
	264		0.0562	1.0000	0.6550	1.2627	5.7729	0.0077	0.1157	0.4007	0.1132	0.0136
	265		0.0313	1.0000	0.5900	1.0804	4.7760	0.0086	0.0420	0.2683	0.1276	0.0081
	266		0.0382	1.0000	0.5602	1.9645	5.9456	0.0043	0.0893	0.3234	0.1408	0.0086
	267		0.0324	1.0000	0.6467	1.0288	4.9430	0.0066	0.0753	0.3852	0.1545	0.0097
	268		0.0369	1.0000	0.5746	0.9884	4.4912	0.0070	0.0459	0.2986	0.1134	0.0086
	269		0.0596	1.0000	0.5739	1.2428	4.8742	0.0095	0.0656	0.3026	0.1065	0.0084
	270		0.0398	1.0000	0.6296	1.1522	6.2041	0.0066	0.0438	0.3369	0.1272	0.0088
	Mean		**0.0418**	**1.0000**	**0.5807**	**1.1288**	**5.1087**	**0.0072**	**0.0668**	**0.3112**	**0.1247**	**0.0085**
	StdDev		**0.0109**	**0.0000**	**0.0609**	**0.2314**	**0.5160**	**0.0014**	**0.0239**	**0.0422**	**0.0211**	**0.0021**
T test	**P value**		**NS**	**N/A**	**NS**	**NS**	**NS**	**NS**	**NS**	**NS**	**NS**	**NS**

* Outlier (excluded from analysis)

Table 18. Histopathology Findings

Group	Animal No.	Treatment	Tumor
1	107M	Normal Air	Hepatic biliary carcinoma
2	267F	Boss Hydroxyl Odor Processor® Air Cleansing Machine	Renal Carcinoma
2	253F	Boss Hydroxyl Odor Processor® Air Cleansing Machine	Hemangiosarcoma
2	261F	Boss Hydroxyl Odor Processor® Air Cleansing Machine	Thymic epithelioma

ABBREVIATIONS

Units are SI (metric) unless otherwise stated. Not all abbreviations are used in all reports.

Abbreviations (A-N)		Abbreviations (N-Z)	
ANOVA	analysis of variance	NSL	no significant lesion
APHIS	Animal and Plant Health Inspection Service (USDA)	NSO	no significant observations
AUC	area under the curve	NTP	National Toxicology Program
BSA	bovine serum albumin	OECD	Organization for Economic Co-operation and Development
BSL-1, BL-1	biosafety level 1	P value	probability value
BW	body weight	PBS	phosphate-buffered saline
CBI	Comparative Biosciences, Inc.	PD	pharmacodynamic
CDER	Center for Drug Evaluation and Research (FDA)	PHS	Public Health Service
CFR	Code of Federal Regulations	PI	principal investigator
C_{max}	maximum concentration	PK	pharmacokinetic
CofA	Certificate of Analysis	QA	Quality Assurance
concn	Concentration	QAU	Quality Assurance Unit
%CV	coefficient of variation (percentage)	QD	once daily
EPA	Environmental Protection Agency	RH	relative humidity
ERY	Erythema	sac	sacrifice
°F	degrees Fahrenheit	SC, SQ	subcutaneous
FD	found dead	sec, s	second
FDA	Food and Drug Administration	SEM	standard error of the mean
GLP	Good Laboratory Practices	SOP	Standard Operating Procedure
H&E	hematoxylin and eosin (staining)	StdDev	standard deviation
hr	Hour	TK	toxicokinetic
IACUC	Institutional Animal Care and Use Committee	TS	terminal sacrifice
ICH	International Conference on Harmonization	USC	United States Code
min	Minute	USDA	United States Department of Agriculture
N/A	not applicable	USP	United States Pharmacopeia
NBF	neutral buffered formalin	vol.	volume
NC	not calculated		
ND	no data or not determined	w/v	weight-to-volume ratio
NIEHS	National Institute of Environmental Health Sciences	wk	week
no., No.	Number		
NOAEL	no observable adverse effect level		
NOEL	no observable effect level		
NS	not significant (P >0.05, unless otherwise specified)		

APPENDIX A: Study Protocol and Amendments

This Appendix consists of 21 pages, including this cover page.

Comparative Biosciences Inc.

STUDY PROTOCOL

13-Week GLP Toxicity Study of the Boss Hydroxyl Odor Processor ® Air Cleansing Machine in Rats

Study Number: CB10-5065-R-TX

Testing Facility:
Comparative Biosciences Inc.
786 Lucerne Drive
Sunnyvale, CA 94085

Sponsor:
HGI Industries Inc.
2055 High Ridge Road
Boynton Beach, Florida 33426
Sponsor Representative: Connie Araps, Ph.D.

Sponsor's Test Article:
Boss Hydroxyl Odor Processor ® air cleansing machine

TABLE OF CONTENTS

APPROVALS

13-Week Toxicity Study of the Boss Hydroxyl Odor Processor® Air Cleansing Machine in Rats

Study Number: CB10-5065-R-TX

Sponsor:
HGI Industries Inc.
2055 High Ridge Road
Boynton Beach, Florida 33426
877-735-3701
Sponsor Representative: Connie Araps, Ph.D.
Tel: (561) 498-4986
caraps@bellsouth.net

Sponsor's Test Article:
Boss Hydroxyl Odor Processor® air cleansing machine

Approved, Comparative Biosciences, Inc.:

Jeanette Jacobs, BS
Quality Assurance — 01 Mar 11 Date

Carol Meschter, DVM, PhD, DACVP
President & CEO — 3/1/11 Date

Robin Dean, PhD
Study Director — 01 March 2011 Date

Approved Sponsor

Connie Araps, PhD
Sponsor's Representative — 3-1-11 Date

13-Week Toxicity Study of the Boss Hydroxyl Odor Processor® Air Cleansing Machine in Rats

Study Number: CB10-5065-R-TX

1. TITLE

13-Week Toxicity Study of the Boss Hydroxyl Odor Processor ® Air Cleansing Machine in Rats

2. STUDY OBJECTIVE

The objective of this study is to evaluate the potential toxicity in rats exposed to hydroxyl radicals and other compounds that may be released into the air as a result of operation of the Boss Hydroxyl Odor Processor ® air cleansing unit.

3. SPONSOR AND SPONSOR'S REPRESENTATIVE

Sponsor:
HGI Industries Inc.
2055 High Ridge Road
Boynton Beach, Florida 33426

Sponsor's Representative: Connie Araps, PhD
(561) 498-4986
caraps@bellsouth.net

4. TESTING FACILITY

4.1. Testing Facility

Comparative Biosciences, Inc.
786 Lucerne Drive
Sunnyvale, CA 94085

4.2. Other Test Sites

Clinical Pathology:

Quality Veterinary Laboratories (QVL)
2121 Second Street, No. 104
Davis, CA 95618
Joan Shewmaker, CLS, MT (ASCP)
(530) 759-8533

(530) 759-8553 fax

Ophthalmology:

Animal Eye Specialists
903 Dell Ave.
Campbell, CA 95008
Kristina Burling, DVM, Diplomate, ACVO
(408) 871-2100
(408) 871-2233 fax

Boss Hydroxyl Odor Processor® Performance Monitoring:

Mark Mino, HGI General Manager
HGI Industries, Inc. 2055 High Ridge Rd.
Boynton Beach, FL 334426
561-735-3701

4.3. Study Team

Study Director:	Robin Dean, PhD
Attending Veterinarian:	Carolyn Reed, VMD, DACLAM
Study Pathologists:	Carol Meschter, DVM, PhD, DACVP
Quality Assurance:	Jeanette Jacobs, BS
Scientific Writer:	Peter Margolis, PhD
Clinical Pathology:	Joan Shewmaker, CLS, MT (ASCP) Quality Veterinary Laboratories (QVL)
Ophthalmologist:	Kristina Burling, DVM, Diplomate, ACVO Animal Eye Specialists of San Jose
Boss Hydroxyl Odor Processor Performance Monitoring	Mark Mino, HGI Industries, Inc, Gen, Manager

5. REGULATORY STATUS OF PROJECT

This study will be conducted in compliance with the US Food and Drug Administration's Good Laboratory Practices regulations (21 CFR Part 58), with this protocol, and with Testing Facility Standard Operating Procedures (note: The air exchange rate in the room with the HGI machine was decreased slightly below the lower end of the recommended range.)

6. TEST SYSTEM

Species: Outbred rat (*Rattus norvegicus*)

Strain/Stock: Sprague-Dawley/Simonsen Albino,

Vendor: Simonsen Laboratories (Gilroy) or other approved vendor

Age: approximately 6-7 weeks of age upon receipt.

Sex: Males and Females,

Body weight range: Approximately 160-180 g (M) and 140-160g (F) upon receipt

Justification for use: Rats are an accepted species frequently used in pre-clinical evaluation of drugs and devices intended for human use.

Number required for study: approximately 30 males and 30 females, plus spares

7. ANIMAL CARE, HOUSING, AND ENVIRONMENTAL CONDITIONS

7.1 Institutional Animal Care and Use Committee Approval

This study will be conducted according to a research proposal approved by the Institutional Animal Care and Use Committee of Comparative Biosciences, Inc.

7.2. Receipt and Acclimation

Animals will be acclimated for approximately seven (7) days after receipt at Comparative Biosciences, Inc., according to Testing Facility SOP. Animals will be observed daily during the acclimation period for clinical signs of abnormality. If, in the opinion of the Study Director or veterinarian the health status of any animal is questionable, that animal will be excluded from the study.

7.3. Drop outs and Replacements

Extra animals may be ordered from the vendor. Any animal determined to be unfit for the study during the acclimation period may be excluded from the study. If an animal is excluded, any data already collected on that animal will be retained. After dosing, an animal may be replaced on Day 0 at the option of the Study Director. Any data already acquired on the replaced animal will be retained. Records of the reasons for the replacement will be maintained and explained in the study report. No replacements will be permitted after Day 0.

7.4. Environment and Husbandry

7.4.1.Temperature and Humidity

Temperature controls will be set to maintain room temperature within the range of 64-79°F. Relative humidity in the facility is generally within the range of 30-70%. These environmental parameters will be monitored and daily minima and maxima recorded. Any excursions from these ranges will be noted in the study report. The Air exchange rate was decreased in the room containing the HGI machines to 7.4 exchanges per hour (slightly below the Guide for the Care and Use of Animals recommendations) and the control room was lowered to 10.8 air exchanges/hr, still within the Guide recommended range.

7.4.2.Light Cycle

Twelve hours of light and twelve hours of dark will be provided in the animal rooms. A fluorescent light source will be used, with lights turned on at approximately 0700 hours and turned off at approximately 1900 hours each day.

7.4.3.Feed

LabDiet® 5002 Certified Rodent Diet (Purina Mills, Inc., St. Louis, MO) or other approved diet will be provided *ad libitum* throughout the acclimation and treatment phases Lot number(s) and Certificate(s) of Analysis will be maintained by the Testing Facility. There are no known contaminants that are reasonably expected to be present in the diet that are known to be capable of interfering with the purpose or conduct of the study.

7.4.4.Water

Fresh water from the Sunnyvale Municipal Water Supply will be provided *ad libitum* to the animals via water bottles. The water supply is periodically tested by the City of Sunnyvale for chemical and bacterial contamination. In addition, the Testing Facility tests water from its own taps for bacteria at least once a year. Results of these analyses (City and Testing Facility) will be maintained on file at the Testing Facility. There are no known contaminants that are reasonably expected to be present in the water that are known to be capable of interfering with the purpose or conduct of the study.

7.4.5.Husbandry

All animals will be pair housed in plastic static cages (wire tops) in a room dedicated to rats. General procedures for animal housing and husbandry will be conducted according to Testing Facility SOPs and will meet all regulations concerning use of animals in research including the U.S. Department of Agriculture regulations (9 CFR Ch. 1) implementing the Animal Welfare Act (7 USC 2131 *et seq.*) and the recommendations of the National Research Council's *Guide for Care and Use of Laboratory Animals* (National Academy Press, 1996). Note: there was one deviation from the guide, the number of air exchanges in the room where the HGI machine was operating was slightly below the recommended number, 7.4/hr instead of 10-15/hr.

7.4.6.Animal Identification

Animals will be arbitrarily assigned sequential temporary animal identification numbers after receipt at the Testing Facility. The study number and temporary identification number will be displayed on each cage card during the acclimation period. Upon allocation to a study group, animals will be assigned "permanent" identification numbers as described in Section 9.2. Permanent identification numbers will be displayed on cage cards and coded on individual rats by ear tags or tail marks (refreshed regularly).

8. TEST AND CONTROL ARTICLES

8.1. **Test Article/Machine:** The Test Article, Boss Hydroxyl Odor Processor ® air cleansing machine, produces airborne hydroxyl radicals and other compounds (combined oxides) by photolysis of ambient water vapor. It is designed to cleanse the air and exposed surfaces by reacting with and decomposing organic compounds, bacteria, viruses, mold and mildew.

8.1.1. **Source:** HGI Industries, Inc. (Boynton Beach, FL).

8.1.2. **Lot Number:** The lot number or other appropriate identification will be recorded and included in the study report.

8.1.3. **Storage:** Room temperature

8.1.4. **Expiration Date:** NA

8.1.5. **Dose Preparation:** None required

8.1.6. **Dose Analysis**: Boss Hydroxyl Odor Processor ® operation will be monitored continuously during the study remotely by the Sponsor via a data line connected to a stand-alone monitoring device. This will provide concurrent verification of the output of the machine. It should also demonstrate that the operation of the machine is constant and uniform throughout the study. A report associated with this monitoring will be provided by the Sponsor to be appended to the study report.

8.1.7. **Characterization:** The Sponsor will provide evidence of the identity, strength, purity, stability, and uniformity of the test article operation, as applicable, which will be appended to the final report. These "specifications/calibration" can be compared to the real-time monitoring (described above) to demonstrate stable operation/hydroxyl radical and combined oxides output for 13 weeks or the length of the study.

8.1.8. **Special Handling:** Standard laboratory precautions.

8.2. **Control Article**: Normal room air (room without a Boss Hydroxyl Odor Processor ® machine operating**),** approximately the same temperature, and humidity as room with the Boss Hydroxyl Odor Processor ® machine running. The air exchange rate was measured in the room housing the control animals and was found to be slightly higher than in the experimental room **(**10.8 exchanges/hr in control room and 7.4 in the room with the HGI machine running.) This small difference was not thought to have any effect on the outcome of the study.

9. EXPERIMENTAL DESIGN

The study will consist of two groups: a treated group (20 males and 20 females) to be housed for at least 13 weeks in a room in which the Boss Hydroxyl Odor Processor ® air cleansing machine is operating; and a control group (10 males and 10 females) housed for the same time period in a different room, not exposed to the Boss Hydroxyl Odor Processor ® machine operation, under normal animal housing conditions. The air exchange rate will be slightly higher in the control room than in the room with the HGI machine operating. The study design is outlined in Table 1. Both groups will undergo the same evaluations and tests. Clinical observations will be performed once-daily. Since the machine generates hydroxyl ions and other oxides which might irritate eyes, nose and respiratory system, close examination of these should be performed during daily clinical observations. Body weight and food consumption will be measured once weekly. During the course of the study four functional observational battery (F.O.B.) tests will be performed on animals, with a focus on respiration, eyes, neurotoxicity and mucous membranes (Appendix C). The first F.O.B. test will occur within three days prior to start of the study and the others will be approximately equally spaced throughout the study. An ophthalmological exam will be performed

on all animals by a veterinary ophthalmologist during the acclimation period and again prior to necropsy. Prior to necropsy, blood will be collected for hematology and clinical chemistry analysis. At sacrifice, gross necropsies will be performed, including specified organ weights (Appendix B). A complete set of tissues will be collected and fixed for histopathological evaluation, with focus on skin, eyes, nasal turbinates, larynx/pharynx and respiratory system. (Appendix B).

Table 1. Summary of Study Design

Group	Animal No. (M/F)	Treatment	Sacrifice
1	101-110/151-160	Room without Boss Hydroxyl Odor Processor ® Machines (normal housing conditions)	Week 13
2	201-220/251-270	Room with Boss Hydroxyl Odor Processor ® Machines running continuously	Week 13

9.1. Rationale for Selection of Dose and Route

Operation of the Boss Hydroxyl Odor Processor ® machine will duplicate anticipated exposure to air containing hydroxyl radicals and other compounds (combined oxides), etc. generated by the device as expected in clinical/normal use.

9.2. Final Selection and Randomization of Animals

No earlier than three (3) days prior to start of study, the animals will be examined by a qualified veterinarian. Animals not excluded for health reasons will be weighed and any outliers set aside (these animals may be used as replacements). Animals will be selected for the study based on normal clinical presentation (veterinary and ophthalmological exams) and moderate body weight. Animals may or may not be randomized using computer software. Details of any randomization procedure will be filed with the raw data and described in study report.

Animals not used for the study may be placed in the spare animal colony or euthanized, at the option of the Study Director. Any data already gathered on these animals will be retained with the raw data, but not necessarily included in the final report.

9.3. Animal Identification

Upon assignment to a study group, each animal will be uniquely identified with tail marks or ear tags. A cage card displaying the animals' permanent identification numbers and the study number will be displayed throughout the in-life period. The animal identification numbers and their groups are shown in Table 1.

9.4. Dosing Cohorts

Study will be run and animals necropsied as approximately three cohorts, generally staggered by a day or two. Cohort composition will be described in detail in the Study Report.

9.5. Dose Administration

Not applicable.

9.6. Adverse Reactions

No adverse reactions are anticipated. Any animals experiencing adverse reactions will receive supportive veterinary care if, in the opinion of the Study Director and the veterinarian, such treatment will not interfere with the purpose or conduct of the study. Moribund animals will be euthanized after veterinary consultation. Animals in extreme pain or distress may be euthanized by qualified personnel without veterinary consultation.

9.7. Animals that Die on Study

If an animal dies on study or is judged to be moribund and euthanized, it will be submitted for gross necropsy according to Testing Facility SOPs. An attempt will be made to determine if the death or moribund condition was test article-related. Tissues will be fixed for histopathological examination. The Sponsor will be notified promptly.

10. OBSERVATIONS, MEASUREMENTS, AND SAMPLES

10.1. Clinical Observations

Clinical observations, including overt signs of toxic or pharmacologic effect(s), will be recorded at least once daily during the acclimation and in-life study periods. All signs of clinical abnormality will be recorded.

10.2. Body Weights

The animals will be weighed within 3 days prior to start of study, once weekly thereafter, and at necropsy.

10.3. Food Consumption

Food consumption (per cage) will be measured once weekly.

10.4. Ophthalmology

All animals will receive an ophthalmological examination by a board-certified veterinary ophthalmologist during the acclimation period prior to inclusion in study and again within approximately three days prior to sacrifice. Note: timing may vary slightly due to availability of veterinary ophthalmologist.

10.5. .F.O.B. Testing

F.O.B. testing will be performed on all animals four times during the 13-week study. The first test will occur within three days prior to start of study and the remaining tests will be performed approximately evenly spaced throughout the study. The individual tests that comprise the F.O.B. test are listed in Appendix C, along with a more detailed description of the individual tests.

10.6. Clinical Pathology

Assessment of hematology and clinical chemistry parameters will be performed on blood samples collected immediately prior to necropsy for all groups. The parameters to be evaluated are presented in Appendix A.

10.7. Necropsy

The animals will be euthanized at end of study (unless previously euthanized as described in Section 9.6.), according to Testing Facility SOP. Specified organs will be weighed and tissues collected for histopathological evaluation (Appendix B). Tissues will be fixed in 10% neutral buffered formalin (except eyes and testes, which are to be fixed in modified Davidson's solution). Note: necropsies of different cohorts may be on different days.

10.8. Histopathology

The tissues indicated in Appendix B will be examined histopathologically. Tissues will be dehydrated, embedded in paraffin, sectioned at 3-5 μm, and stained with hematoxylin and eosin. Slides will be evaluated via light microscopy by board-certified veterinary pathologist. Additional tissues may be added at the discretion of the pathologist or as requested by the Sponsor.

11. DATA PRESENTATION AND STATISTICAL ANALYSIS

11.1. Data Presentation

Data will be presented as raw data and in summary tables and/or displays as appropriate.

11.2. Statistical Analysis

P-values of ≤0.05 will be considered statistically significant.

11.2.1 Continuous Normal Data

11.2.1.1 Two groups: Continuous normal data will be analyzed using the Student t-test (with Welch's correction in case of non-homogeneous variance as determined by an F-test).

11.2.1.2 More than two groups: Bartlett's Test for Equal Variances will be used to determine homogeneity of the data from the multiple groups. In the case of homogeneous variance, analysis of variance (ANOVA) will be used followed by a suitable post-test if the ANOVA is significant. For non-homogeneous variance, the Kruskal-Wallis (non-parametric) test will be used, followed by Dunn's post-test if the Kruskal-Wallis test is significant.

11.2.2 Categorical Data: Histopathology lesion data will be analyzed by the Study Pathologist. Histopathology severity scores may be analyzed statistically using non-parametric tests. Clinical observation data will be presented as text or in tabular form.

11.2.3 Other Methods: Summary tables, descriptive statistics (e.g., means, standard deviations), graphic displays, and other appropriate statistical tests and

techniques will be employed as deemed necessary. Results having a probability of 0.05 or less ($P \leq 0.05$) will be considered statistically significant.

12. RECORDS AND REPORTS

12.1. Study Records

The following records, together with any other records deemed necessary by the Study Director and study monitor(s), will be retained at the Testing Facility in accordance with 21 CFR Part 58.195:

Personnel records, approved and dated study protocol and associated documentation, test/control article records, pretest animal records, in-life animal records, feed and water analysis documentation, post-mortem animal records, and relevant formal correspondence with the Sponsor.

12.2. Final Report

The draft report (Version 1) will be generated within twelve weeks following sacrifice. A final report will be issued within four weeks after the Sponsor's comments on the draft report (Version 1) are received by the Study Director. Extensive comments may require additional drafts. A draft final report will be automatically finalized by the Testing Facility if the Sponsor has not responded to a draft within ninety (90) days after the document was issued to the Sponsor. A final report can only be modified by a written amendment signed by the Study Director.

The final report will include a copy of the final study protocol (and any/all amendments), a summary of the raw data collected during the in-life period, a summary of clinical pathology results, and the pathologist's report. A report prepared by the Sponsor summarizing results of the Boss Hydroxyl Odor Processor ® monitoring data will also be included in the final study report as an appendix.

13. MONITORING OF STUDY

This study will be conducted in compliance with the US Food and Drug Administration's Good Laboratory Practices regulations (21 CFR Part 58) with this protocol, and with Testing Facility Standard Operating Procedures. Critical phases will be inspected by the Testing Facility Quality Assurance Unit. The Sponsor may monitor the study during normal business hours by appointment with the Study Director.

14. ADMINISTRATIVE PROCEDURES

14.1. Amendments to the Protocol

Any modification to the approved protocol will be documented as an amendment to the protocol. Such modifications will be made jointly by the Sponsor and Comparative Biosciences, Inc., prior to the action being carried out. Amendments may be implemented by telephone agreement and formalized later. Reasons for any amendment(s) will be documented and signed by the Sponsor and Study Director. Amendments will be maintained

with the study protocol. The study protocol will be the controlling document in case of discrepancies between the protocol and the SOPs of Comparative Biosciences, Inc.

14.2. Deviations from the Protocol

All protocol deviations will be documented and brought to the attention of the Study Director, according to Testing Facility SOP. Any deviation judged reasonably by the Study Director to have possible impact on the outcome of the study or interpretation of the data will be communicated to the Sponsor as soon as possible and corrective actions will be determined. All deviations will be summarized in the final report.

14.3. Termination of the Study

The Sponsor or Comparative Biosciences, Inc. may terminate the study prematurely. If a study is terminated, the appropriate party will be notified by telephone and then in writing as to the reason and timing of study termination.

14.4. Test/Control Article/Device Accountability

The Sponsor shall provide complete instructions of handling, storage, biohazard nature, and operation of the Boss Hydroxyl Odor Processor ® machines . Comparative Biosciences Inc. will maintain complete records of the test machine operation and will return the test machines according to the Sponsor's written and/or spoken instructions. Sponsor will monitor operation of their machine remotely via a data line connected directly to the operating Boss Hydroxyl Odor Processor ®. At least two backup Boss Hydroxyl Odor Processor ® machines will be supplied by the Sponsor in case of failure of the primary unit.

14.5. Independent Audits

The Sponsor may arrange for an independent audit of the Testing Facility and/or any of its subcontractors. Any such audit shall be conducted by appointment during regular business hours and the Sponsor shall ensure that the independent auditor(s) comply with Testing Facility procedures and policies.

14.6. Histology/Biological Specimen Archival

The Testing Facility will not serve as a permanent archive for histology and/or other biological specimens generated by the study. These archival materials will be collected, inventoried, appropriately packaged, and forwarded via courier to the Sponsor, or a facility designated by the Sponsor, following distribution of the final report. Upon request, the Testing Facility will arrange for archival at an independent facility.

14.7. Material Safety Data Sheets (MSDS)

The Sponsor will provide an MSDS or equivalent for the test device, supplied to the Testing Facility. This information should including stability and uniformity of operation over the duration of the study.

14.8. Confidentiality

All information obtained during conduct of the study will be considered confidential. At no time will the nature or the study, study protocol, or study data be disclosed by Comparative Biosciences, Inc., to any third party without written consent from the Sponsor, except as may be required by regulatory authorities. Likewise, Sponsor will treat all correspondence from Comparative Biosciences, Inc., except the final report, but including draft reports, as confidential information.

APPENDIX A

Hematology Panel
Total Leukocyte Count (WBC)
Erythrocyte count (RBC)
Hemoglobin (HGB)
Hematocrit (HCT)
Mean Corpuscular Volume (MCV)
Mean Corpuscular Hemoglobin (MCH)
Mean Corpuscular Hemoglobin Concentration (MCHC)
Red Cell Distribution Width (RDW)
Platelet Count (PLT)
Mean Platelet Volume (MPV)
Differential Leukocyte Count – Absolute and Relative
Reticulocyte Count (RETIC) – Absolute and %

Serum Chemistry Panel
Blood Urea Nitrogen (BUN)
Creatinine (CREAT)
Glucose (GLUC)
Serum Aspartate Aminotransferase (AST)
Serum Alanine Aminotransferase (ALT)
Alkaline Phosphatase (ALP)
Bilirubin, Total (BILI-T)
Sodium (Na)
Potassium (K)
Chloride (Cl)
Calcium (Ca)
Phosphorus (P)
Total Protein (TP)
Albumin (ALB)
Globulin (GLOB)
Albumin/Globulin Ratio (A/G Ratio)
Triglycerides
Cholesterol (CHOL)

APPENDIX B

Tissues to Be Collected at Necropsy

Tissue/Specimen	Tissue Collection	Organ Weight	Histopathologic Evaluation
Adrenal glands (paired)	√	√	√
Aorta (thoracic)	√		√
Bladder, urinary	√		√
Bone			
Femur	√		√
Sternum	√		√
Bone marrow			
Femur	√		√
Sternum	√		√
Bone Marrow Smear	√		√
Brain (cerebrum, cerebellum, brain stem)	√	√	√
Esophagus	√		√
Eyes with optic nerve, conjunctiva, and lids	√		√
Harderian/lacrimal gland	√		√
Heart	√	√	√
Injection site (if any)	NA		NA
Kidneys (paired)	√	√	√
Large intestine			
Cecum	√		√
Colon	√		√
Rectum	√		√
Larynx/pharynx	√		√
Liver	√	√	√
Lungs with bronchi	√		√
Lymph nodes (mandibular, mesenteric)	√		√
Macroscopic lesions	√		√
Mammary gland (inguinal)	√		√
Nostrils +nasal turbinates	√		√
Pancreas	√		√
Pituitary gland	√	√	√
Reproductive--female			
Cervix/Uterus	√		√
Ovaries (paired)	√	√	√
Oviducts (paired)	√		√
Vagina	√		√
Reproductive--male			
Epididymis	√		√
Prostate	√	√	√
Seminal Vesicles	√		√
Testes (paired)	√	√	√
Salivary gland	√		√

APPENDIX B (continued)

Tissues to Be Collected at Necropsy

Tissue/Specimen	Tissue Collection	Organ Weight	Histopathologic Evaluation
Sciatic nerve	√		√
Skeletal muscle	√		√
Skin & subcutis (inguinal)	√		√
Small intestine			
Duodenum	√		√
Jejunum	√		√
Ileum	√		√
Spinal cord (cervical, lumbar, thoracic, w/ vertebrae)	√		√
Spleen	√	√	√
Stomach	√		√
Thymus	√	√	√
Thyroid/parathyroid	√	√	√
Tongue	√		√
Trachea	√		√
Zymbal's Gland	-		-

APPENDIX C.: FOB Test Parameters and Data Collection

Study No.									
Tester									
Recorder									
Animal #					Animal #				
Test time (week)	pre-study	~4 weeks	~8 weeks	12-13 weeks	Test time	pre-study	~4 weeks	~8 weeks	12-13 weeks
Date									
Home cage (3 min)									
1. Body position									
2. Respiration									
3. Piloerection									
4. Locomotor activity									
5. Gait									
6. Abnormal behavior (describe)									
7. Response to blunt object									
Hand-Held responses									
1. Response to holding									
2. Palpebral closure (1-4, N to. closed)									
3. Lacrimation									
4. Porphyrin-staining around eyes (1-4, N to severe)									
5.Conjunctiva (Normal /red, degree of)									
6. Blink reflex (y/n)									
7. Clicker reflex									
8. Tail-pinch response (y/n, rapid-sluggish)									
9. Righting reflex (drop from ~ 30 cm upside down)									
10. Grip strength (time rat hangs onto dowel)									

Functional Observational Battery (FOB) Tests

Home Cage Behavior (3 min. Observation)

1.Body Position
- N, Normal
- A, asleep
- R, rearing, standing on hind legs
- L, lying on side
- F, animal's abdomen flattened on bottom of cage
- C, catalepsy (trance-like state, generally immobile, frequently abnormal posture

2. Respiration
- N, normal
- S, shallow
- D, difficulty breathing or labored breathing
- SD, severe difficulty breathing, wheezing, mouth open while trying to breathe

3.Piloerection
- N, none,
- P, Piloerection present (describe location and severity, mild, moderate or severe)

4.Locomotor Activity
- N, normal
- I, immobile, not moving at all or hardly at all, describe
- S, slow infrequent movement
- V, vigorous rapid movement

5.Gait
- N, normal
- D, animal drags body, abdomen frequently touching floor, body wobbling
- DH, animal drags hind limbs, unable to support weight on hind legs
- H, Body hunched, back rounded
- T, Walks on tiptoes
- A, Ataxia, loss of motor coordination, body sways animal lurches while trying to walk

6. Abnormal Behavior (anything abnormal, not covered above- describe)

7.Response to blunt object (like eraser end of pencil, put close to animal's head)
- I, no reaction, ignores it
- N, normal reaction, slow approach sniffs, probably backs off or walks away
- T, Twitches (generally away, but can bump into object)
- V, violent overreaction, jumping biting, squeaking and even attack

Hand-Held Responses (Pick up and hold animal to complete these tests)

1.Response to picking up.
- 1. Easy, rat sits quietly, little resistance
- 2. Vocalization without much other resistance
- 3. Moderately difficult, rat rears and follows hand
- 4. Rat flinches (with/without vocalization)
- 5. Difficult rat runs around cage trying to avoid being picked up
- 6. Very difficult, may try to bite with/without squealing

2.Palpebral closure
- 1 or N, eyelids wide open –normal
- 2. Eyelids slightly closed
- 3. Eyelids half closed
- 4, eyelids completely closed

3. Lacrimation
- 1/N, normal, no noticeable lacrimation
- 2, Excess lacrimation at margin
- 3, Persistent dampness
- 4, dampness extends beyond margin, may have red tinge

4. Porphyrin staining around eyes
- 1/N, none
- 2, slight red tinge to tears and slight crustiness to edge of lids.
- 3, moderate dried blood-like crustiness on lids, generally upper or lower, but can be both
- 4, extreme accumulation of dried blood-like crustiness around all lids.

5.Conjunctiva appearance
- N, normal
- A, abnormal, describe (ie mod. Red)

6. Blink Reflex
- yes/no

7. Clicker reflex
- yes/no and describe (i.e. brisk with jump)

8. Tail Pinch
- yes/no

9.Righting reflex (drop upside down ~ 30 cm off surface)
- Yes -lands on feet, generally all four
- No, doesn't land on feet, maybe on side, rarely on back

10.Grip strength: Time in seconds that animal is able to grip the dowel before losing grip and falling
- # of seconds (~120 sec. max)

Protocol Amendment

Comparative Biosciences Inc.

Study No.: CB10-5065-R-TX	Sponsor: HGI Industries, Inc.
Title: 13-Week GLP Toxicity Study of the Boss Hydroxyl Odor Processor® Air Cleansing Machine in Rats	
Effective Date: 30 June 2011	

Amendment No. 1

Page 5, Section 4.3 Study Team

Change:
Insert: Lead Biologist under Study Director.

To read:
"Lead Biologist Lucy Jawed, B.S., B.A."

Justification:
Inadvertently omitted from the signed protocol.

Page 5, Section 4.3 Study Team

Change:
"Quality Assurance Jeanette Jacobs, B.S."

To read:
"Quality Assurance Jeanette Jacobs, B.S. (to June 10, 2011)
Quality Assurance Matthew Knox, B.A. (from June 10, 2011 on)"

Justification:
Matthew Knox was appointed to the QA position after Jeanette Jacob's departure from CBI.

Approved by:

Sponsor: [signature]	Date: 7-1-11
Study Director: Robin Daam	Date: July 1, 2011

Protocol Amendment

Comparative Biosciences Inc.

Study No.: CB10-5065-R-TX	Sponsor: HGI Industries
Title: 13-Week GLP Toxicity Study of the Boss Hydroxyl Processor Air Cleansing Machine in Rats	
Effective Date: 9 November 2011	

Amendment No. 2

Throughout report:

Change: Name of test article from "Boss Hydroxyl Odor Processor® Air Cleansing Machine".

To read:"Odorox® Boss™ Hydroxyl Processor Air Cleansing Machine" everywhere it appears in the text of the report. The name appears on many pages, frequently in multiple places on many pages. It should be changes in all those places.

Note: When it appears as a title, on pages 1 and 2, all words will be capitalized, whereas in other places within the text "air cleansing machine" generally won't be capitalized.

Justification:
The name of the test article was incorrect in the protocol, but was not caught by anyone. The Sponsor wishes to change the name of the test article in the report, so the name must be changed in the approved Study Protocol by amendment.

Approved by:

Sponsor: Annie Brupe	Date: 11-10-11
Study Director: Robin Dean	Date: 9 Nov 2011

APPENDIX B: Summary of Deviations

This Appendix consists of 2 pages, including this cover page.

Summary of Deviations

Deviation No. 1.

Description. Clinical observations were inadvertently not done on three days, 21 March (Study Days 17–19 for cohorts 3, 2, and 1, respectively); 27 March (Study Days 23–25, for cohorts 3, 2, and 1, respectively); and 7 April 2011 (Study Days 34–36 for cohorts 3, 2, and 1, respectively).

Known or potential effect on study results. Clinical observation records were present for the days preceding and the days following those that were missing. It is unlikely that significant clinical observations occurred on one day only. Therefore, it is unlikely that this deviation had any impact on the study results or their interpretation.

Corrective action. Meet with RAs that failed to perform Clinical Observations and discuss problem.

Deviation No. 2.

Description. Body weights of animals in Cohort 1 apparently increased 55-60 g at necropsy. This was attributed to failure to tare the balance used on that day.

Known or potential effect on study results. Body weights showed a steady increase throughout the study, which had slowed to a few grams per week in both males and females. The last weekly weighing was performed on Day 88, only three days prior to necropsy. Therefore, Day-88 body weights were used to calculate the organ weights normalized to body weight. This deviation was thought to have had no significant effect on the results or interpretation of the study.

Corrective action. The individual responsible for the error was re-trained in proper use of the balance.

APPENDIX C: Monitoring Report for Test Article/Machine

This Appendix consists of 6 pages, including this cover page.

HGI Report - Odorox® Boss™ Hydroxyl Processor Air Cleansing Machine Operation During Comparative Biosciences Toxicology Study CB10-5065-R-TX

January 7, 2012

Section 1 - Purpose:

The purpose of the studies described herein was to measure the concentrations of hydroxyl radicals and ozone produced by the two Odorox® Boss™ Hydroxyl Processor Air Cleansing Machines used in toxicology study CB10-5065-R-TX and to confirm that the machines were operating according to their specifications.

Section 2 - Introduction:

The Odorox® Boss™ Hydroxyl Processor Air Cleansing Machines are used in indoor environments to cleanse the air of volatile organic compounds that produce odors and to kill bacteria, viruses, mold and mildew. They do this by circulating ambient air through a photolysis chamber where quartz optics generate a range of ultra violet (UV) radiation that interacts with the water vapor, oxygen and trace gases present in ambient air to produce hydroxyl radicals and ozone. These oxidants react with the volatile organic compounds in ambient air to decompose them through a series of oxidation steps which create oxidized organic by-products. The purpose of the toxicology study is to determine if the chemicals and by-products produced by the test article have adverse health effects.

Section 3 - Participants:

Laboratory studies to measure the primary chemical oxidants – hydroxyl radicals and ozone - produced by the Odorox® Boss™ Hydroxyl Processor air cleansing machines were conducted at the Lovelace Respiratory Research Institute (LRRI) by Dr. Jacob MacDonald and his team. The data produced was analyzed and reported by both Dr. MacDonald and an independent expert in the field of atmospheric physical chemistry and hydroxyl radical formation and reaction, Dr. David Crosley and Dr. Connie Araps a chemist with expertise in organic free radical chemistry. Mr. Mark Mino and Mr. Jeff Chalpan, HGI employees, provided expertise in the areas of equipment engineering, data acquisition and analysis for the purpose of validating machine performance during the toxicology studies.

Section 4 – Study Design

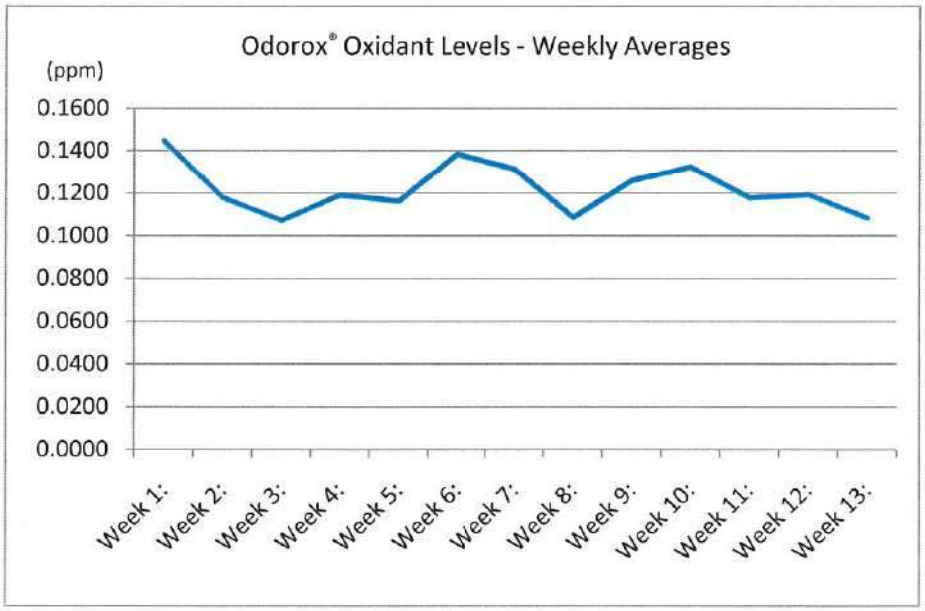
In order to measure the Odorox® Boss™ Hydroxyl Processor Air Cleansing Machines' hydroxyl radical and ozone output an ultra-clean room and special analytical equipment is required, as hydroxyl radicals are too short lived to measure in a normal laboratory environment. These studies were conducted at the Lovelace Respiratory Research Institute and are described herein in Appendix 1. From these results, the correlation between hydroxyl radical and oxidant formation was determined. Since the ratio of hydroxyl

radical to ozone formation remains constant during machine operation, measured ozone concentration is a valid means of confirming that the test article is running to specifications.

Section 5 - Materials and Methods:

The amount of Odorox® oxidants produced during animal testing was monitored continuously using a direct reading instrument, a model Polytron 7000 Series Controller and Pump module with an OV-1 (P/N 63 10 290) DrägerSensor® manufactured by Dräger. The inlet of the sampling device was placed at a height of approximately 30 inches, in the center of the rack of rat cages, which was in the center of the test room. Mr. Jeff Chalpan installed the testing equipment and monitored the output remotely via electronic data transmission. This device is an industry standard ozone meter.

The sensor ozone/oxidant data stream was sampled every thirty (30) seconds and the sampled ozone/oxidant level measurements were recorded. The total Odorox® oxidants were plotted for each 24 hour period (EST). The data is summarized below as weekly averages.



	Average Oxidant Levels (ppm)
Week 1:	0.1443 ppm
Week 2:	0.1177 ppm
Week 3:	0.1070 ppm
Week 4:	0.1189 ppm
Week 5:	0.1161 ppm
Week 6:	0.1383 ppm
Week 7:	0.1313 ppm
Week 8:	0.1085 ppm
Week 9:	0.1258 ppm
Week 10:	0.1323 ppm
Week 11:	0.1178 ppm
Week 12:	0.1193 ppm
Week 13:	0.1082 ppm

Over the testing period (13 weeks), the average Odorox® oxidant level was 0.1236 parts per million (ppm), with a median of 0.1213 ppm and a Standard Deviation of 0.01829 ppm. These measurements correspond to a steady state Odorox® hydroxyl radical formation by each machine of ~2 x 10^6 molecules/cm^3 if distributed uniformly within the treatment space) based on studies conducted by Dr. J. MacDonald at LRRI and analysis provided by Dr. David Crosley; both individuals being independent, third party experts in the field of atmospheric hydroxyl radical measurements and chemistry. These studies are summarized in Appendix 1. Normal operating oxidant levels are 0.03 to 0.1 ppm, as the OSHA guidelines for continuous 8-hour exposure is 0.1ppm. It was our goal to expose the test animals to slightly higher than normal test article operating conditions which are always below the OSHA limit.

Section 6 - Conclusion

The oxidant levels measured confirmed that hydroxyl radicals were being formed by the Odorox® Boss™ Hydroxyl Processor air cleansing machines during the toxicology study and that the machines were operating within specifications. The amount of oxidants and by-products produced were set to be greater than what would be expected in actual occupied spaces such as a hospital, school or office setting where the machine might be used and thus provides a valid test of the possible toxicity of the output of the machine.

Appendix 1

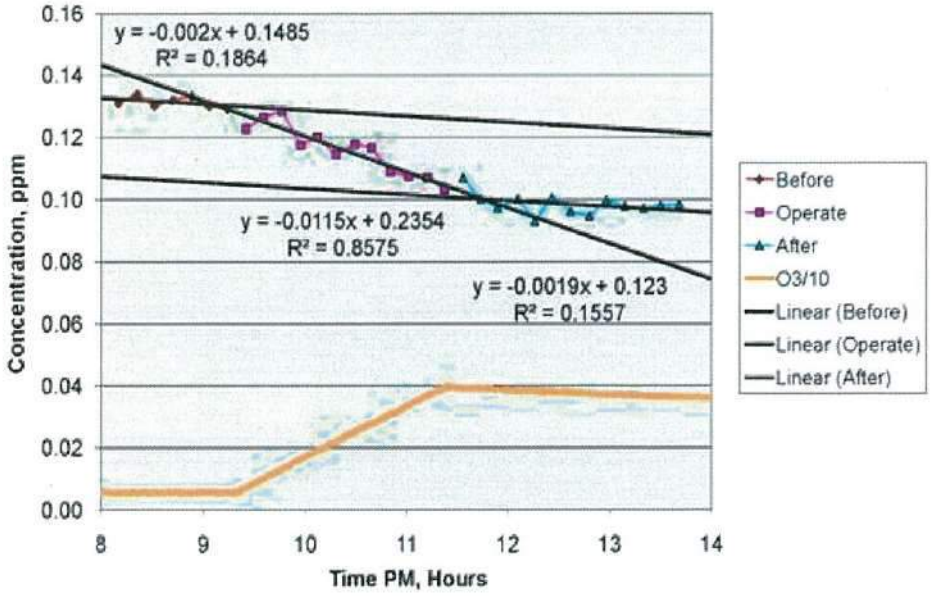
Odorox® Boss™ Hydroxyl Processor Air Cleansing Machine Hydroxyl Radical and Ozone Studies

The measurement of hydroxyl radical and ozone formation by the Odorox® Boss™ Hydroxyl Processor air cleansing machine (test article) was conducted at the Lovelace Respiratory Research Institute by Dr. Jacob MacDonald and his research team in a specially designed Teflon room (120,000 cubic liters). The room was purged of background organics to less than 8 ppb by filtering ambient air running at a very low level through HEPA and charcoal filters. A tracer gas, CCL4, was also used to enable sampling through a gas chromatograph and other sensors for measurement of the n-heptane used as the control volatile organic compound. N-heptane reacts rapidly with hydroxyl radicals but does not react with ozone. Since these are the only oxidants produced under the controlled test conditions, the consumption rate of the n-heptane would be equal to the production rate of the hydroxyl radical after correction for the dilution rate. This is a published method for measuring hydroxyl radical formation based on kinetic data published by Finlayson and Pitts and analyzed by Crosley[1,2]. An ozone detector inside the chamber was used to measure total oxidant formation. Reactions were run at night to minimize photolysis outside of the Boss™ machine.

A quantity of n-heptane was introduced into the room and equilibrated to create a concentration of 120 ppb. A base-line measurement of this concentration was recorded in Table 1. Note the slow reduction in n-heptane concentration resulting from introduction of the tracer gas (3-4% dilution rate). The Boss™ machine was then run for 2.48 hours (with two optics on and the fan set at low), so that it produced hydroxyl radicals which reacted with the n-heptane as evidenced by increased loss of n-heptane during this period. Also noted in Table 1 was the formation of ozone. After the Boss™ machine was turned off, the loss of n-heptane returned to the original rate associated with dilution, since hydroxyl radicals were no longer being produced.

Dr. David Crosley independently analyzed the data and confirmed that the measured disappearance of the n-heptane of 18 percent correlated well with the published reaction rate coefficient for hydroxyl radicals and n-heptane of 7×10^{-12} cm^3s^{-1} (Finlayson-Pitts and Pitts)[2]. He calculated the hydroxyl radical production rate to be 2×10^{13}/cm or a theoretical steady state concentration around the room of 2×10^6/cm, which is similar to that found in nature. The measured formation rate of ozone was essentially the same at 1×10^{13}/cm. This rate of formation will remain constant for the Boss™ system provided that the same number of optics and the same fan speed is used (two optics, low fan). The ratio of hydroxyl radical formation and ozone formation will also remain the same.

Heptane Treatment with Boss Odorox OH Generator



1. D. R. Crosley, The Measurement of OH and HO_2 in the Atmosphere, J. Atm. Sci. 52, 3299 (1995).

2. B. J. Finlayson Pitts and J. N. Pitts, Jr., *The Chemistry of the Upper and Lower Atmosphere*, Academic Press, San Diego, 1999.

2-9-2012
Dr. Connie Araps Date

2/9/2012
Mr. Mark Mino Date

2/9/2012
Mr. Jeff Chalpan Date

APPENDIX D: Pathology Report

This Appendix consists of 44 pages, including this cover page.

PATHOLOGY REPORT

13-Week GLP Toxicity Study of the Boss Hydroxyl Odor Processor ® Air Cleansing Machine in Rats

CBI Accession Number: H-11-1016

CBI Study Number: CB10-5065-R-TX

Testing Facility

Comparative Biosciences, Inc.
786 Lucerne Drive
Sunnyvale, CA 94085

Sponsor

HGI Industries Inc.
2055 High Ridge Road
Boynton Beach, FL 33426
Sponsor Representative: Connie Araps, Ph.D.

Sponsor's Test Article

Boss Hydroxyl Odor Processor ® air cleansing machine

1. TABLE OF CONTENTS

2. QUALITY ASSURANCE STATEMENT

Histology Laboratory: Comparative Biosciences, Inc.
CBI Accession No.: H-11-1016
Pathologist: Carol Meschter, DVM, PhD, DACVP
Study Title: 13-Week GLP Toxicity Study of the Boss Hydroxyl Odor Processor ® Air Cleansing Machine in Rats

Performing (In-life) Laboratory: Comparative Biosciences, Inc.
CBI Study No: CB10-5065-R-TX
Study Director: Robin Dean, PhD

Sponsor: HGI Industries Inc.

Date of Inspection	Phase Inspected	Date reported to Study Director	Date reported to Management
27-Jan-11	Receipt of Test Article Device	1-Feb-11	18-Feb-11
14-Feb-11	Receipt of Test Article Device	16-Feb-11	18-Feb-11
21-Mar-11	Body Weights/Room Inspection	22-Mar-11	25-Mar-11
30-Mar-11	Food Consumption	4-Apr-11	6-Arp-11
31-Mar-11	Functional Observation Battery Test	4-Apr-11	6-Apr-11
26-Apr-11	Body Weights/Room Inspection	27-Apr-11	9-May-11
11-May-11	Food Consumption	11-May-11	13-May-11
27-May-11	Ophthalmologic Exam	2-Jun-11	14-Jun-11
27-May-11	Review of Raw Data	27-May-11	22-Jun-11
27-May-11	Necropsy	2-Jun-11	14-Jun-11
14-Jun-11	Gross Trimming Wet Tissue	15-Jun-11	16-Jun-11
18-July-11	Sectioning Paraffin Blocks	25-Jul-11	25-Jul-11
22-Jul-11	Gross Trimming Wet Tissue	25-Jul-11	25-Jul-11
25-Aug-11	Draft Study and Pathology Report	26-Aug-11	30-Aug-11

Matthew Knox 2/2/12

Matthew Knox, BA
Quality Assurance Unit
Comparative Biosciences, Inc.

Date

3. COMPLIANCE STATEMENT

13-Week GLP Toxicity Study of the Boss Hydroxyl Odor Processor ® Air Cleansing Machine in Rats

CBI Accession Number: H-11-1016

CBI Study No.: CB10-5065-R-TX

Sponsor:	HGI Industries Inc. 2055 High Ridge Road Boynton Beach, FL 33426
Histopathology Laboratory:	Comparative Biosciences, Inc. 786 Lucerne Drive Sunnyvale, CA 94085

I, the undersigned pathologist, hereby declare that this report constitutes a true and faithful account of the results of this study, to the best of my knowledge. The histopathologic phase of this study was conducted in compliance with the study protocol, with Comparative Biosciences, Inc., Standard Operating Procedures (SOPs), and with the Good Laboratory Practices regulations (GLPs) of the United States Food and Drug Administration (US FDA; 21 CFR Part 58).

Carol Meschter 2 Feb 12

Carol Meschter, DVM, PhD, DACVP — Date
Study Pathologist

4. SUMMARY

The objective of this study was to evaluate the potential toxicity in rats of exposure to hydroxyl radicals and other compounds that may be released by operation of the Boss Hydroxyl Odor Processor® air cleansing machine. In general, there were no histopathologic differences between the rats exposed to normal air and the Boss Hydroxyl Odor Processor®. Special attention was paid to the eyes, eyelids, conjunctiva, tongue, larynx, pharynx, trachea, and lungs. There were no changes in these organs and they appeared to be within normal limits in both the control and treated animals. There were, however, four neoplasms: a hepatobiliary carcinoma in one control male, and a renal carcinoma, a hemangiosarcoma, and a thymic epithelioma in three females in the test group. The incidences are 1/20 and 3/40, which are statistically indistinguishable. This suggests that the tumors were spontaneously occurring and not related exposure to the Boss Hydroxyl Odor Processor® air cleansing machine. The histopathologic findings from this study indicate that the Boss Hydroxyl Odor Processor® air cleansing machine was well tolerated under the conditions of this study and not associated with effects on the eyes, skin or respiratory system in particular.

5. INTRODUCTION

The Sponsor is developing the test article, the Boss Hydroxyl Odor Processor ® air cleansing machine, for potential clinical applications in maintaining "clean" air conditions for medical and other environments. The Boss Hydroxyl Odor Processor® air cleansing machine releases hydroxyl radicals and other compounds into the air during operation. The objective of this study was to evaluate the potential toxicity of such compounds in rats exposed to the cleansing unit in operation. Specifically, two groups of Sprague-Dawley rats were maintained at the Testing Facility: a treated group housed for 13 weeks in a room in which the Boss Hydroxyl Odor Processor® air cleansing machine was operating; and a control group housed for the same period in a different room, under normal animal housing conditions, but not exposed to the Boss Hydroxyl Odor Processor® machine. At the end of the in-life period, the animals were euthanized, and tissues were evaluated histopathologically.

6. EXPERIMENTAL DESIGN

The study consisted of two groups of Sprague-Dawley rats: a treated group (20 males and 20 females) housed for 13 weeks in a room in which the Boss Hydroxyl Odor Processor® air cleansing machine was operating; and a control group (10 males and 10 females) housed for the same period in a different room under similar housing conditions but not exposed to the Boss Hydroxyl Odor Processor® machine. Both groups underwent the same evaluations and tests, including the following: Clinical observations were recorded once daily, with special attention to the eyes, nose, and respiratory system. Body weights and food consumption were measured once weekly. Functional observational batteries (FOBs) were assessed four times during the course of the study, including once pre-treatment and three times following the start of treatment. The FOBs included a focus on respiration, eyes, neurotoxicity, and mucous membranes. Ophthalmological examinations were performed on all animals by a veterinary ophthalmologist once prior to the start of treatment and again prior to sacrifice. Prior to necropsy, blood was collected for hematology and clinical chemistry analysis. Gross necropsies were performed, including specified organ weights. A complete set of tissues was collected, for histopathological evaluation by a board-certified veterinary pathologist.

Table 1. Experimental Design.

Group	Animal No. (males/females)	Treatment	Sacrifice
1	101-110/151-160	*Room without Boss Hydroxyl Odor Processor® Machines	Week 13
2	201-220/251-270	**Room with two Boss Hydroxyl Odor Processor® Machines	Week 13

*normal housing conditions. **machines running continuously.

7. IN-LIFE PHASE

The in-life phase was conducted at the Testing Facility as CBI Study CB10-5065-R-TX. At the end of the in-life phase, tissues were fixed in 10% neutral buffered formalin (NBF), except for eyes and testes, which were fixed overnight in modified Davidson's solution before being transferred to 10% NBF.

8. HISTOPATHOLOGY PHASE

8.1. Tissues Submitted

Fixed tissues (Table 2) from a total of 60 animals were submitted to the CBI Histology Laboratory for processing and microscopic examination.

Table 2. Tissues Examined Histopathologically.

Tissue	Tissue	Tissue
Adrenal gland	Large intestine (cecum, colon, rectum)	Sciatic (peripheral) nerve
Aorta	Larynx, pharynx	Skeletal muscle (hindlimb)
Bladder, Urinary	Liver	Skin & subcutis (inguinal)
Bone & bone marrow (femur)	Lungs with bronchi	Small intestine (duodenum, jejunum, ileum)
Bone & bone marrow (sternum)	Lymph nodes (mesenteric, mandibular)	Spinal cord (cervical, thoracic, lumbar)
Bone marrow smear*	Macroscopic lesion(s)	Spleen
Brain (cerebrum, cerebellum, mid-brain)	Mammary gland area (inguinal skin area)	Stomach
Esophagus	Nasal passages (3 levels)	Thymus
Eye with optic nerve	Pancreas	Thyroid with parathyroid
Eyelids	Pituitary gland	Tongue
Heart	Reproductive, female (cervix/uterus, ovary, oviduct, vagina)	Trachea
Kidney	Reproductive, male (epididymis, prostate, seminal vesicle, testis)	
Lacrimal gland	Salivary gland	

* Bone marrow smear examined only if deemed appropriate based on hematology finding or examination of marrow sections from the sternum.

8.2. Tissue Preparation

Fixed tissues were gross trimmed, processed, oriented and embedded in paraffin, sectioned at approximately 3- to 5μm thickness, stained with hematoxylin and eosin (H&E), and cover-slipped. Tissues were evaluated by light microscopy by a board-certified veterinary pathologist.

8.3. Tissue Evaluation

H&E-stained glass slides of tissues were examined by a veterinary pathologist certified by the American College of Veterinary Pathologists. The incidence and severity of the lesions were scored using the accepted industry scoring system: normal, minimal, mild, moderate, and severe. Lesions were also assessed for duration (acute, subacute, and chronic) and distribution (focal, multifocal, and diffuse). Occasion small tissues were missing, but this does not impact the outcome of the histopathology interpretation.

8.4. Data

The CBI Histology Accession Number H-11-1016 was assigned to this study (CB10-5065-R-TX). A computer file based on the study protocol was created using StarPath™ (DruQuest, International). Significant macroscopic findings (e.g., as recorded at necropsy or gross trimming) and clinical pathology results were available to the pathologist during the histology phase; relevant data were manually entered into StarPath™ by the pathologist. The pathologist examined all of the submitted tissue sections by light microscopy and recorded the findings by direct entry into the computer file. Tables were generated from the data and used by the pathologist in assessment of the histopathologic findings associated with administration of the test material.

8.5. Regulatory Status

The histopathologic phase of this study was conducted in compliance with the study protocol, with CBI SOPs, and with the GLPs of the US FDA (21 CFR Part 58). There were no circumstances during the histopathology phase that would have affected the quality and/or integrity of the histopathology data.

9. RESULTS

9.1. Mortality

No animals were found dead or were euthanized before the scheduled sacrifice.

9.2. Macroscopic Findings

There were no macroscopic lesions indicative of a treatment-related effect. Intra-abdominal lesions were noted in Animals 107, 253, 261, and 267.

9.3. Microscopic Findings

The histopathologic lesions are presented in detail in the StarPath™ Tables. In general, there were no histopathologic differences between the rats exposed to normal air and the rats exposed to the Boss Hydroxyl Odor Processor®. Special attention was paid to the eyes, eyelids, conjunctiva, larynx, pharynx, trachea, and lungs. There were no changes in these organs and they appeared to be within normal limits in both the control and treated animals.

There was a hepatobiliary carcinoma in a Group-1 male (No. 107), and a renal carcinoma, a hemangiosarcoma and a thymic epithelioma in three females (Nos. 253, 261, and 267) of Group 2. The incidences of 1/20 and 3/40 are statistically indistinguishable. This suggests that the tumors were spontaneously occurring and not related exposure to the Boss Hydroxyl Odor Processor®.

Table 3. Incidence of tumors.

Group	Animal No.	Treatment	Tumor
1	107M	Normal Air	Hepatobiliary carcinoma
2	253F	Boss Hydroxyl Odor Processor® Air Cleansing Unit	Hemangiosarcoma
2	261F	Boss Hydroxyl Odor Processor® Air Cleansing Unit	Thymic epithelioma
2	267F	Boss Hydroxyl Odor Processor® Air Cleansing Unit	Renal Carcinoma

9.4. Nonspecific, Incidental or Background Findings

Nonspecific, incidental or background findings were noted in the adrenal gland (hemorrhage); kidney (chronic progressive nephropathy); lacrimal gland (inflammation); lung (chronic peribronchiolitis); uterus (dilation).

10. CONCLUSIONS AND DISCUSSION

The objective of this study was to evaluate the potential toxicity in rats of exposure to hydroxyl radicals and other compounds that may be released by operation of the Boss Hydroxyl Odor

Processor® air processing machine. A complete tissue list of organs was examined histopathologically.

In general, there were no histopathologic differences between the rats exposed to normal air and those exposed to the Boss Hydroxyl Odor Processor® air processing machine. Special attention was paid to the eyes, eyelids, conjunctiva, tongue, larynx, pharynx, trachea, and lungs. There were no changes in these organs and they appeared to be within normal limits in both the control and treated animals. There were, however, four neoplasms: a hepatobiliary carcinoma in one control male, and a renal carcinoma, a hemangiosarcoma, and a thymic epithelioma in three females in the test group. The incidences are 1/20 and 3/40, which are statistically indistinguishable. This suggests that the tumors were spontaneously occurring and not related exposure to the Boss Hydroxyl Odor Processor® air cleansing machine.

The histopathologic findings from this study indicate that the Boss Hydroxyl Odor Processor® air cleansing machine was well tolerated under the conditions of this study and not associated with effects on the eyes, skin, or respiratory system in particular.

11. REFERENCES

Code of Federal Regulations (CFR). Washington DC: US Government Printing Office 1997; title 9, 1-3.

Prophet EB, Mills B, Arrington JB, Sobin, LH. *Laboratory Methods in Histotechnology*, AFIP, 1994.

Haschek WM, Rousseaux CG (eds.). *Handbook of Toxicologic Pathology*. Academic Press, San Diego, New York, Boston, pp. 829–889, (1991).

12. ABBREVIATIONS

Abbreviations used in this report are defined below.

Abbreviation	Term
CBI	Comparative Biosciences, Inc.
g	gram
IV	intravenous
kg	kilogram
L or l	liter
µm	micrometer
mL	milliliter
m	meter
mm	millimeter
No.	Number
GLP	Good Laboratory Practices
H&E	hematoxylin and eosin
SOP	Standard Operating Procedure
CFR	Code of Federal Regulation
FDA	Food and Drug Administration

13. STARPATH REPORTS

Incidence of Histopathologic Findings for All Study Animals
HGI Industries, Inc.
13-Week GLP Toxicity Study of the Boss Hydroxyl Odor Processor Air Cleansing Machine in Rats

PROJECT NUMBER: CB10-5065-R-TX SPECIES: Sprague Dawley Rat
Printed on 08-26-2011.

Tissue/ Diagnosis/ Modifier(s)	Normal room air M	Normal room air F	Treated room air M	Treated room air F
Adrenal	(10)	(10)	(20)	(20)
Hemorrhage	0	1	0	1
mild	0	1	0	1
Within Normal Limits	10	9	20	19
Aorta	(10)	(10)	(20)	(20)
Within Normal Limits	10	10	20	20
Bone Marrow, Femur	(10)	(10)	(20)	(20)
Within Normal Limits	10	10	20	20
Bone Marrow, Sternum	(10)	(10)	(20)	(20)
Within Normal Limits	10	10	20	20
Bone, Femur	(10)	(10)	(20)	(20)
Within Normal Limits	10	10	20	20
Bone, Sternum	(10)	(10)	(20)	(20)
Within Normal Limits	10	10	20	20
Brain	(10)	(10)	(20)	(20)
Within Normal Limits	10	10	20	20
Cecum	(10)	(10)	(20)	(20)
Within Normal Limits	10	10	20	20
Colon	(10)	(10)	(20)	(20)
Within Normal Limits	10	10	20	20
Duodenum	(10)	(10)	(20)	(20)
Within Normal Limits	10	10	20	20
Epididymis	(10)	(0)	(20)	(0)
Within Normal Limits	10	0	20	0
Esophagus	(10)	(10)	(20)	(20)
Within Normal Limits	10	10	20	20
Eye	(10)	(10)	(20)	(20)
Within Normal Limits	10	10	20	20
Eye, Optic Nerve	(9)	(9)	(20)	(20)
Within Normal Limits	9	9	20	20
Heart	(10)	(10)	(20)	(20)
Within Normal Limits	10	10	20	20
Ileum	(10)	(10)	(20)	(20)
Within Normal Limits	10	10	20	20
Jejunum	(10)	(10)	(20)	(20)
Within Normal Limits	10	10	20	20
Kidney	(10)	(10)	(20)	(20)
Carcinoma	0	0	0	1
Chronic progressive nephropathy	6	2	15	11
trace	0	0	0	1
mild	5	2	12	7
moderate	1	0	3	3

() = Number Of Animals Examined For This Tissue

Only severities are printed. (501-510)

Incidence of Histopathologic Findings for All Study Animals (continued)
HGI Industries, Inc.
13-Week GLP Toxicity Study of the Boss Hydroxyl Odor Processor Air Cleansing Machine in Rats

PROJECT NUMBER: CB10-5065-R-TX SPECIES: Sprague Dawley Rat
Printed on 08-26-2011.

Tissue/ Diagnosis/ Modifier(s)	Normal room air M	Normal room air F	Treated room air M	Treated room air F
Kidney (continued)				
Hydronephrosis	0	1	0	0
Within Normal Limits	4	7	5	8
Lacrimal Gland	(10)	(10)	(20)	(20)
Inflammation	0	0	1	0
mild	0	0	1	0
Within Normal Limits	10	10	19	20
Larynx	(10)	(10)	(20)	(20)
Within Normal Limits	10	10	20	20
Liver	(10)	(10)	(20)	(20)
Carcinoma	1	0	0	0
Within Normal Limits	9	10	20	20
Lung	(10)	(10)	(20)	(20)
Peribronchiolitis, chronic	0	0	0	2
mild	0	0	0	2
Within Normal Limits	10	10	20	18
Lymph Node, Mandibular	(4)	(6)	(12)	(16)
Within Normal Limits	4	6	12	16
Lymph Node, Mesenteric	(10)	(10)	(20)	(20)
Within Normal Limits	10	10	20	20
Mammary Gland	(10)	(10)	(20)	(20)
Within Normal Limits	10	10	20	20
Nasal Tissues, Level 1	(10)	(10)	(20)	(20)
Within Normal Limits	10	10	20	20
Nasal Tissues, Level 2	(10)	(10)	(20)	(20)
Within Normal Limits	10	10	20	20
Nasal Tissues, Level 3	(10)	(10)	(20)	(20)
Within Normal Limits	10	10	20	20
Nerve, Sciatic	(10)	(8)	(18)	(16)
Within Normal Limits	10	8	18	16
Ovary	(0)	(10)	(0)	(20)
Within Normal Limits	0	10	0	20
Oviduct	(0)	(10)	(0)	(20)
Within Normal Limits	0	10	0	20
Pancreas	(10)	(10)	(20)	(20)
Within Normal Limits	10	10	20	20
Parathyroid	(4)	(8)	(14)	(12)
Within Normal Limits	4	8	14	12
Pharynx	(10)	(10)	(20)	(20)
Within Normal Limits	10	10	20	20

() = Number Of Animals Examined For This Tissue

Only severities are printed. (501-510)

Incidence of Histopathologic Findings for All Study Animals (continued)
HGI Industries, Inc.
13-Week GLP Toxicity Study of the Boss Hydroxyl Odor Processor Air Cleansing Machine in Rats

PROJECT NUMBER: CB10-5065-R-TX SPECIES: Sprague Dawley Rat
Printed on 08-26-2011.

Tissue/ Diagnosis/ Modifier(s)	Normal room air M	Normal room air F	Treated room air M	Treated room air F
Pituitary	(9)	(10)	(20)	(20)
Within Normal Limits	9	10	20	20
Prostate	(10)	(0)	(20)	(0)
Within Normal Limits	10	0	20	0
Rectum	(10)	(10)	(20)	(20)
Within Normal Limits	10	10	20	20
Salivary Gland	(10)	(10)	(20)	(20)
Within Normal Limits	10	10	20	20
Seminal Vesicle	(10)	(0)	(20)	(0)
Within Normal Limits	10	0	20	0
Skeletal Muscle	(10)	(10)	(20)	(20)
Within Normal Limits	10	10	20	20
Skin	(10)	(10)	(20)	(20)
Within Normal Limits	10	10	20	20
Skin, Eyelid	(9)	(10)	(14)	(18)
Within Normal Limits	9	10	14	18
Spinal Cord, Cervical	(10)	(10)	(20)	(20)
Within Normal Limits	10	10	20	20
Spinal Cord, Lumbar	(10)	(10)	(20)	(20)
Within Normal Limits	10	10	20	20
Spinal Cord, Thorax	(10)	(10)	(20)	(20)
Within Normal Limits	10	10	20	20
Spleen	(10)	(10)	(20)	(20)
Hemangiosarcoma	0	0	0	1
Within Normal Limits	10	10	20	19
Stomach	(10)	(10)	(20)	(20)
Within Normal Limits	10	10	20	20
Testis	(10)	(0)	(20)	(0)
Within Normal Limits	10	0	20	0
Thymus	(10)	(10)	(20)	(20)
Carcinoma	0	0	0	1
Within Normal Limits	10	10	20	19
Thyroid	(10)	(10)	(20)	(19)
Within Normal Limits	10	10	20	19
Tongue	(10)	(10)	(20)	(20)
Within Normal Limits	10	10	20	20
Trachea	(10)	(10)	(20)	(20)
Within Normal Limits	10	10	20	20
Urinary Bladder	(10)	(10)	(20)	(20)
Within Normal Limits	10	10	20	20

() = Number Of Animals Examined For This Tissue

Only severities are printed. (501-510)

Incidence of Histopathologic Findings for All Study Animals (continued)
HGI Industries, Inc.
13-Week GLP Toxicity Study of the Boss Hydroxyl Odor Processor Air Cleansing Machine in Rats

PROJECT NUMBER: CB10-5065-R-TX SPECIES: Sprague Dawley Rat
Printed on 08-26-2011.

Tissue/ Diagnosis/ Modifier(s)	Normal room air M	Normal room air F	Treated room air M	Treated room air F
Uterus	(0)	(10)	(0)	(20)
Dilatation	0	0	0	1
Within Normal Limits	0	10	0	19
Uterus, Cervix, Vagina	(0)	(10)	(0)	(20)
Within Normal Limits	0	10	0	20

() = Number Of Animals Examined For This Tissue

Only severities are printed. (501-510)

Summarized Single Tabulated Animal Report
Individual Macroscopic and Microscopic Observations
HGI Industries, Inc.
13-Week GLP Toxicity Study of the Boss Hydroxyl Odor Processor Air Cleansing Machine in Rats

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ANIMAL NUMBER: 101 SEX: Male GROUP: (1) Normal room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MACROSCOPIC OBSERVATIONS:
No macroscopic entries are on file.

MICROSCOPIC OBSERVATIONS:

The following tissues were found to be within normal limits:
Adrenal; Aorta; Bone Marrow, Femur; Bone Marrow, Sternum; Bone, Femur; Bone, Sternum; Brain; Cecum; Colon; Duodenum; Epididymis; Esophagus; Eye; Eye, Optic Nerve; Heart; Ileum; Jejunum; Kidney; Lacrimal Gland; Larynx; Liver; Lung; Lymph Node, Mandibular; Lymph Node, Mesenteric; Mammary Gland; Nasal Tissues, Level 1; Nasal Tissues, Level 2; Nasal Tissues, Level 3; Nerve, Sciatic; Pancreas; Parathyroid; Pharynx; Pituitary; Prostate; Rectum; Salivary Gland; Seminal Vesicle; Skeletal Muscle; Skin; Skin, Eyelid; Spinal Cord, Cervical; Spinal Cord, Lumbar; Spinal Cord, Thorax; Spleen; Stomach; Testis; Thymus; Thyroid; Tongue; Trachea; Urinary Bladder.

ANIMAL NUMBER: 102 SEX: Male GROUP: (1) Normal room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MACROSCOPIC OBSERVATIONS:
No macroscopic entries are on file.

MICROSCOPIC OBSERVATIONS:

The following tissues were found to be within normal limits:
Adrenal; Aorta; Bone Marrow, Femur; Bone Marrow, Sternum; Bone, Femur; Bone, Sternum; Brain; Cecum; Colon; Duodenum; Epididymis; Esophagus; Eye; Eye, Optic Nerve; Heart; Ileum; Jejunum; Kidney; Lacrimal Gland; Larynx; Liver; Lung; Lymph Node, Mesenteric; Mammary Gland; Nasal Tissues, Level 1; Nasal Tissues, Level 2; Nasal Tissues, Level 3; Nerve, Sciatic; Pancreas; Pharynx; Pituitary; Prostate; Rectum; Salivary Gland; Seminal Vesicle; Skeletal Muscle; Skin; Skin, Eyelid; Spinal Cord, Cervical; Spinal Cord, Lumbar; Spinal Cord, Thorax; Spleen; Stomach; Testis; Thymus; Thyroid; Tongue; Trachea; Urinary Bladder.

ANIMAL NUMBER: 103 SEX: Male GROUP: (1) Normal room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MACROSCOPIC OBSERVATIONS:
No macroscopic entries are on file.

MICROSCOPIC OBSERVATIONS:
Kidney -Chronic progressive nephropathy, mild

The following tissues were found to be within normal limits:
Adrenal; Aorta; Bone Marrow, Femur; Bone Marrow, Sternum; Bone, Femur; Bone, Sternum; Brain;

SPECIES: Sprague Dawley Rat
PROJECT NUMBER: CB10-5065-R-TX

Summarized Single Tabulated Animal Report (continued)
Individual Macroscopic and Microscopic Observations
HGI Industries, Inc.
13-Week GLP Toxicity Study of the Boss Hydroxyl Odor Processor Air Cleansing Machine in Rats

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ANIMAL NUMBER: 103 SEX: Male GROUP: (1) Normal room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MICROSCOPIC OBSERVATIONS (continued):
The following tissues were found to be within normal limits (continued):
Cecum; Colon; Duodenum; Epididymis; Esophagus; Eye; Eye, Optic Nerve; Heart; Ileum; Jejunum; Lacrimal Gland; Larynx; Liver; Lung; Lymph Node, Mesenteric; Mammary Gland; Nasal Tissues, Level 1; Nasal Tissues, Level 2; Nasal Tissues, Level 3; Nerve, Sciatic; Pancreas; Parathyroid; Pharynx; Pituitary; Prostate; Rectum; Salivary Gland; Seminal Vesicle; Skeletal Muscle; Skin; Spinal Cord, Cervical; Spinal Cord, Lumbar; Spinal Cord, Thorax; Spleen; Stomach; Testis; Thymus; Thyroid; Tongue; Trachea; Urinary Bladder.

ANIMAL NUMBER: 104 SEX: Male GROUP: (1) Normal room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MACROSCOPIC OBSERVATIONS:
No macroscopic entries are on file.

MICROSCOPIC OBSERVATIONS:
Kidney -Chronic progressive nephropathy, moderate

The following tissues were found to be within normal limits:
Adrenal; Aorta; Bone Marrow, Femur; Bone Marrow, Sternum; Bone, Femur; Bone, Sternum; Brain; Cecum; Colon; Duodenum; Epididymis; Esophagus; Eye; Eye, Optic Nerve; Heart; Ileum; Jejunum; Lacrimal Gland; Larynx; Liver; Lung; Lymph Node, Mandibular; Lymph Node, Mesenteric; Mammary Gland; Nasal Tissues, Level 1; Nasal Tissues, Level 2; Nasal Tissues, Level 3; Nerve, Sciatic; Pancreas; Pharynx; Pituitary; Prostate; Rectum; Salivary Gland; Seminal Vesicle; Skeletal Muscle; Skin; Skin, Eyelid; Spinal Cord, Cervical; Spinal Cord, Lumbar; Spinal Cord, Thorax; Spleen; Stomach; Testis; Thymus; Thyroid; Tongue; Trachea; Urinary Bladder.

ANIMAL NUMBER: 105 SEX: Male GROUP: (1) Normal room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MACROSCOPIC OBSERVATIONS:
No macroscopic entries are on file.

MICROSCOPIC OBSERVATIONS:

The following tissues were found to be within normal limits:
Adrenal; Aorta; Bone Marrow, Femur; Bone Marrow, Sternum; Bone, Femur; Bone, Sternum; Brain; Cecum; Colon; Duodenum; Epididymis; Esophagus; Eye; Eye, Optic Nerve; Heart; Ileum; Jejunum; Kidney; Lacrimal Gland; Larynx; Liver; Lung; Lymph Node, Mandibular; Lymph Node, Mesenteric; Mammary Gland; Nasal Tissues, Level 1; Nasal Tissues, Level 2; Nasal Tissues, Level 3; Nerve, Sciatic; Pancreas; Parathyroid; Pharynx; Pituitary; Prostate; Rectum; Salivary Gland;

SPECIES: Sprague Dawley Rat
PROJECT NUMBER: CB10-5065-R-TX

Summarized Single Tabulated Animal Report (continued)
Individual Macroscopic and Microscopic Observations
HGI Industries, Inc.
13-Week GLP Toxicity Study of the Boss Hydroxyl Odor Processor Air Cleansing Machine in Rats

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ANIMAL NUMBER: 105 SEX: Male GROUP: (1) Normal room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MICROSCOPIC OBSERVATIONS (continued):
The following tissues were found to be within normal limits (continued):
Seminal Vesicle; Skeletal Muscle; Skin; Skin, Eyelid; Spinal Cord, Cervical; Spinal Cord, Lumbar; Spinal Cord, Thorax; Spleen; Stomach; Testis; Thymus; Thyroid; Tongue; Trachea; Urinary Bladder.

ANIMAL NUMBER: 106 SEX: Male GROUP: (1) Normal room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MACROSCOPIC OBSERVATIONS:
No macroscopic entries are on file.

MICROSCOPIC OBSERVATIONS:
Kidney -Chronic progressive nephropathy, mild

The following tissues were found to be within normal limits:
Adrenal; Aorta; Bone Marrow, Femur; Bone Marrow, Sternum; Bone, Femur; Bone, Sternum; Brain; Cecum; Colon; Duodenum; Epididymis; Esophagus; Eye; Eye, Optic Nerve; Heart; Ileum; Jejunum; Lacrimal Gland; Larynx; Liver; Lung; Lymph Node, Mandibular; Lymph Node, Mesenteric; Mammary Gland; Nasal Tissues, Level 1; Nasal Tissues, Level 2; Nasal Tissues, Level 3; Nerve, Sciatic; Pancreas; Pharynx; Pituitary; Prostate; Rectum; Salivary Gland; Seminal Vesicle; Skeletal Muscle; Skin; Skin, Eyelid; Spinal Cord, Cervical; Spinal Cord, Lumbar; Spinal Cord, Thorax; Spleen; Stomach; Testis; Thymus; Thyroid; Tongue; Trachea; Urinary Bladder.

ANIMAL NUMBER: 107 SEX: Male GROUP: (1) Normal room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MACROSCOPIC OBSERVATIONS:
Liver -Pea-sized mass on liver lobe.
Testis -Left testes abnormally small.
MICROSCOPIC OBSERVATIONS:
Kidney -Chronic progressive nephropathy, mild
Liver -Carcinoma

The following tissues were found to be within normal limits:
Adrenal; Aorta; Bone Marrow, Femur; Bone Marrow, Sternum; Bone, Femur; Bone, Sternum; Brain; Cecum; Colon; Duodenum; Epididymis; Esophagus; Eye; Heart; Ileum; Jejunum; Lacrimal Gland; Larynx; Lung; Lymph Node, Mesenteric; Mammary Gland; Nasal Tissues, Level 1; Nasal Tissues, Level 2; Nasal Tissues, Level 3; Nerve, Sciatic; Pancreas; Pharynx; Pituitary; Prostate; Rectum; Salivary Gland; Seminal Vesicle; Skeletal Muscle; Skin; Skin, Eyelid; Spinal Cord, Cervical; Spinal Cord, Lumbar; Spinal Cord, Thorax; Spleen; Stomach; Testis;

SPECIES: Sprague Dawley Rat
PROJECT NUMBER: CB10-5065-R-TX

Summarized Single Tabulated Animal Report (continued)
Individual Macroscopic and Microscopic Observations
HGI Industries, Inc.
13-Week GLP Toxicity Study of the Boss Hydroxyl Odor Processor Air Cleansing Machine in Rats

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ANIMAL NUMBER: 107 SEX: Male GROUP: (1) Normal room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MICROSCOPIC OBSERVATIONS (continued):
The following tissues were found to be within normal limits (continued):
Thymus; Thyroid; Tongue; Trachea; Urinary Bladder.

ANIMAL NUMBER: 108 SEX: Male GROUP: (1) Normal room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MACROSCOPIC OBSERVATIONS:
No macroscopic entries are on file.

MICROSCOPIC OBSERVATIONS:

The following tissues were found to be within normal limits:
Adrenal; Aorta; Bone Marrow, Femur; Bone Marrow, Sternum; Bone, Femur; Bone, Sternum; Brain; Cecum; Colon; Duodenum; Epididymis; Esophagus; Eye; Eye, Optic Nerve; Heart; Ileum; Jejunum; Kidney; Lacrimal Gland; Larynx; Liver; Lung; Lymph Node, Mesenteric; Mammary Gland; Nasal Tissues, Level 1; Nasal Tissues, Level 2; Nasal Tissues, Level 3; Nerve, Sciatic; Pancreas; Pharynx; Pituitary; Prostate; Rectum; Salivary Gland; Seminal Vesicle; Skeletal Muscle; Skin; Skin, Eyelid; Spinal Cord, Cervical; Spinal Cord, Lumbar; Spinal Cord, Thorax; Spleen; Stomach; Testis; Thymus; Thyroid; Tongue; Trachea; Urinary Bladder.

ANIMAL NUMBER: 109 SEX: Male GROUP: (1) Normal room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MACROSCOPIC OBSERVATIONS:
No macroscopic entries are on file.

MICROSCOPIC OBSERVATIONS:
Kidney -Chronic progressive nephropathy, mild

The following tissues were found to be within normal limits:
Adrenal; Aorta; Bone Marrow, Femur; Bone Marrow, Sternum; Bone, Femur; Bone, Sternum; Brain; Cecum; Colon; Duodenum; Epididymis; Esophagus; Eye; Eye, Optic Nerve; Heart; Ileum; Jejunum; Lacrimal Gland; Larynx; Liver; Lung; Lymph Node, Mesenteric; Mammary Gland; Nasal Tissues, Level 1; Nasal Tissues, Level 2; Nasal Tissues, Level 3; Nerve, Sciatic; Pancreas; Parathyroid; Pharynx; Prostate; Rectum; Salivary Gland; Seminal Vesicle; Skeletal Muscle; Skin; Skin, Eyelid; Spinal Cord, Cervical; Spinal Cord, Lumbar; Spinal Cord, Thorax; Spleen; Stomach; Testis; Thymus; Thyroid; Tongue; Trachea; Urinary Bladder.

SPECIES: Sprague Dawley Rat
PROJECT NUMBER: CB10-5065-R-TX

Summarized Single Tabulated Animal Report (continued)
Individual Macroscopic and Microscopic Observations
HGI Industries, Inc.
13-Week GLP Toxicity Study of the Boss Hydroxyl Odor Processor Air Cleansing Machine in Rats

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ANIMAL NUMBER: 110 SEX: Male GROUP: (1) Normal room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MACROSCOPIC OBSERVATIONS:
No macroscopic entries are on file.

MICROSCOPIC OBSERVATIONS:
Kidney -Chronic progressive nephropathy, mild

The following tissues were found to be within normal limits:
Adrenal; Aorta; Bone Marrow, Femur; Bone Marrow, Sternum; Bone, Femur; Bone, Sternum; Brain; Cecum; Colon; Duodenum; Epididymis; Esophagus; Eye; Eye, Optic Nerve; Heart; Ileum; Jejunum; Lacrimal Gland; Larynx; Liver; Lung; Lymph Node, Mesenteric; Mammary Gland; Nasal Tissues, Level 1; Nasal Tissues, Level 2; Nasal Tissues, Level 3; Nerve, Sciatic; Pancreas; Pharynx; Pituitary; Prostate; Rectum; Salivary Gland; Seminal Vesicle; Skeletal Muscle; Skin; Skin, Eyelid; Spinal Cord, Cervical; Spinal Cord, Lumbar; Spinal Cord, Thorax; Spleen; Stomach; Testis; Thymus; Thyroid; Tongue; Trachea; Urinary Bladder.

ANIMAL NUMBER: 151 SEX: Female GROUP: (1) Normal room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MACROSCOPIC OBSERVATIONS:
No macroscopic entries are on file.

MICROSCOPIC OBSERVATIONS:
Kidney -Chronic progressive nephropathy, mild

The following tissues were found to be within normal limits:
Adrenal; Aorta; Bone Marrow, Femur; Bone Marrow, Sternum; Bone, Femur; Bone, Sternum; Brain; Cecum; Colon; Duodenum; Esophagus; Eye; Eye, Optic Nerve; Heart; Ileum; Jejunum; Lacrimal Gland; Larynx; Liver; Lung; Lymph Node, Mesenteric; Mammary Gland; Nasal Tissues, Level 1; Nasal Tissues, Level 2; Nasal Tissues, Level 3; Nerve, Sciatic; Ovary; Oviduct; Pancreas; Parathyroid; Pharynx; Pituitary; Rectum; Salivary Gland; Skeletal Muscle; Skin; Skin, Eyelid; Spinal Cord, Cervical; Spinal Cord, Lumbar; Spinal Cord, Thorax; Spleen; Stomach; Thymus; Thyroid; Tongue; Trachea; Urinary Bladder; Uterus; Uterus, Cervix, Vagina.

ANIMAL NUMBER: 152 SEX: Female GROUP: (1) Normal room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MACROSCOPIC OBSERVATIONS:
No macroscopic entries are on file.

MICROSCOPIC OBSERVATIONS:
Kidney -Hydronephrosis, unilateral

SPECIES: Sprague Dawley Rat
PROJECT NUMBER: CB10-5065-R-TX

Summarized Single Tabulated Animal Report (continued)
Individual Macroscopic and Microscopic Observations
HGI Industries, Inc.
13-Week GLP Toxicity Study of the Boss Hydroxyl Odor Processor Air Cleansing Machine in Rats

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ANIMAL NUMBER: 152 SEX: Female GROUP: (1) Normal room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MICROSCOPIC OBSERVATIONS (continued):

The following tissues were found to be within normal limits:
Adrenal; Aorta; Bone Marrow, Femur; Bone Marrow, Sternum; Bone, Femur; Bone, Sternum; Brain; Cecum; Colon; Duodenum; Esophagus; Eye; Eye, Optic Nerve; Heart; Ileum; Jejunum; Lacrimal Gland; Larynx; Liver; Lung; Lymph Node, Mesenteric; Mammary Gland; Nasal Tissues, Level 1; Nasal Tissues, Level 2; Nasal Tissues, Level 3; Ovary; Oviduct; Pancreas; Parathyroid; Pharynx; Pituitary; Rectum; Salivary Gland; Skeletal Muscle; Skin; Skin, Eyelid; Spinal Cord, Cervical; Spinal Cord, Lumbar; Spinal Cord, Thorax; Spleen; Stomach; Thymus; Thyroid; Tongue; Trachea; Urinary Bladder; Uterus; Uterus, Cervix, Vagina.

ANIMAL NUMBER: 153 SEX: Female GROUP: (1) Normal room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MACROSCOPIC OBSERVATIONS:
No macroscopic entries are on file.

MICROSCOPIC OBSERVATIONS:

The following tissues were found to be within normal limits:
Adrenal; Aorta; Bone Marrow, Femur; Bone Marrow, Sternum; Bone, Femur; Bone, Sternum; Brain; Cecum; Colon; Duodenum; Esophagus; Eye; Heart; Ileum; Jejunum; Kidney; Lacrimal Gland; Larynx; Liver; Lung; Lymph Node, Mandibular; Lymph Node, Mesenteric; Mammary Gland; Nasal Tissues, Level 1; Nasal Tissues, Level 2; Nasal Tissues, Level 3; Nerve, Sciatic; Ovary; Oviduct; Pancreas; Pharynx; Pituitary; Rectum; Salivary Gland; Skeletal Muscle; Skin; Skin, Eyelid; Spinal Cord, Cervical; Spinal Cord, Lumbar; Spinal Cord, Thorax; Spleen; Stomach; Thymus; Thyroid; Tongue; Trachea; Urinary Bladder; Uterus; Uterus, Cervix, Vagina.

ANIMAL NUMBER: 154 SEX: Female GROUP: (1) Normal room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MACROSCOPIC OBSERVATIONS:
No macroscopic entries are on file.

MICROSCOPIC OBSERVATIONS:
Kidney -Chronic progressive nephropathy, mild

The following tissues were found to be within normal limits:
Adrenal; Aorta; Bone Marrow, Femur; Bone Marrow, Sternum; Bone, Femur; Bone, Sternum; Brain; Cecum; Colon; Duodenum; Esophagus; Eye; Eye, Optic Nerve; Heart; Ileum; Jejunum; Lacrimal Gland; Larynx; Liver; Lung; Lymph Node, Mandibular; Lymph Node, Mesenteric; Mammary Gland;

SPECIES: Sprague Dawley Rat
PROJECT NUMBER: CB10-5065-R-TX

Summarized Single Tabulated Animal Report (continued)
Individual Macroscopic and Microscopic Observations
HGI Industries, Inc.
13-Week GLP Toxicity Study of the Boss Hydroxyl Odor Processor Air Cleansing Machine in Rats

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ANIMAL NUMBER: 154 SEX: Female GROUP: (1) Normal room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MICROSCOPIC OBSERVATIONS (continued):
The following tissues were found to be within normal limits (continued):
Nasal Tissues, Level 1; Nasal Tissues, Level 2; Nasal Tissues, Level 3; Nerve, Sciatic; Ovary; Oviduct; Pancreas; Parathyroid; Pharynx; Pituitary; Rectum; Salivary Gland; Skeletal Muscle; Skin; Skin, Eyelid; Spinal Cord, Cervical; Spinal Cord, Lumbar; Spinal Cord, Thorax; Spleen; Stomach; Thymus; Thyroid; Tongue; Trachea; Urinary Bladder; Uterus; Uterus, Cervix, Vagina.

ANIMAL NUMBER: 155 SEX: Female GROUP: (1) Normal room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MACROSCOPIC OBSERVATIONS:
No macroscopic entries are on file.

MICROSCOPIC OBSERVATIONS:

The following tissues were found to be within normal limits:
Adrenal; Aorta; Bone Marrow, Femur; Bone Marrow, Sternum; Bone, Femur; Bone, Sternum; Brain; Cecum; Colon; Duodenum; Esophagus; Eye; Eye, Optic Nerve; Heart; Ileum; Jejunum; Kidney; Lacrimal Gland; Larynx; Liver; Lung; Lymph Node, Mandibular; Lymph Node, Mesenteric; Mammary Gland; Nasal Tissues, Level 1; Nasal Tissues, Level 2; Nasal Tissues, Level 3; Nerve, Sciatic; Ovary; Oviduct; Pancreas; Parathyroid; Pharynx; Pituitary; Rectum; Salivary Gland; Skeletal Muscle; Skin; Skin, Eyelid; Spinal Cord, Cervical; Spinal Cord, Lumbar; Spinal Cord, Thorax; Spleen; Stomach; Thymus; Thyroid; Tongue; Trachea; Urinary Bladder; Uterus; Uterus, Cervix, Vagina.

ANIMAL NUMBER: 156 SEX: Female GROUP: (1) Normal room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MACROSCOPIC OBSERVATIONS:
No macroscopic entries are on file.

MICROSCOPIC OBSERVATIONS:

The following tissues were found to be within normal limits:
Adrenal; Aorta; Bone Marrow, Femur; Bone Marrow, Sternum; Bone, Femur; Bone, Sternum; Brain; Cecum; Colon; Duodenum; Esophagus; Eye; Eye, Optic Nerve; Heart; Ileum; Jejunum; Kidney; Lacrimal Gland; Larynx; Liver; Lung; Lymph Node, Mandibular; Lymph Node, Mesenteric; Mammary Gland; Nasal Tissues, Level 1; Nasal Tissues, Level 2; Nasal Tissues, Level 3; Nerve, Sciatic; Ovary; Oviduct; Pancreas; Parathyroid; Pharynx; Pituitary; Rectum; Salivary Gland; Skeletal Muscle; Skin; Skin, Eyelid; Spinal Cord, Cervical; Spinal Cord, Lumbar; Spinal Cord, Thorax; Spleen; Stomach; Thymus; Thyroid; Tongue; Trachea; Urinary Bladder; Uterus;

SPECIES: Sprague Dawley Rat
PROJECT NUMBER: CB10-5065-R-TX

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HGI Industries, Inc.
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ANIMAL NUMBER: 156 SEX: Female GROUP: (1) Normal room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MICROSCOPIC OBSERVATIONS (continued):
The following tissues were found to be within normal limits (continued):
Uterus, Cervix, Vagina.

ANIMAL NUMBER: 157 SEX: Female GROUP: (1) Normal room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MACROSCOPIC OBSERVATIONS:
No macroscopic entries are on file.

MICROSCOPIC OBSERVATIONS:

The following tissues were found to be within normal limits:
Adrenal; Aorta; Bone Marrow, Femur; Bone Marrow, Sternum; Bone, Femur; Bone, Sternum; Brain; Cecum; Colon; Duodenum; Esophagus; Eye; Eye, Optic Nerve; Heart; Ileum; Jejunum; Kidney; Lacrimal Gland; Larynx; Liver; Lung; Lymph Node, Mandibular; Lymph Node, Mesenteric; Mammary Gland; Nasal Tissues, Level 1; Nasal Tissues, Level 2; Nasal Tissues, Level 3; Ovary; Oviduct; Pancreas; Parathyroid; Pharynx; Pituitary; Rectum; Salivary Gland; Skeletal Muscle; Skin; Skin, Eyelid; Spinal Cord, Cervical; Spinal Cord, Lumbar; Spinal Cord, Thorax; Spleen; Stomach; Thymus; Thyroid; Tongue; Trachea; Urinary Bladder; Uterus; Uterus, Cervix, Vagina.

ANIMAL NUMBER: 158 SEX: Female GROUP: (1) Normal room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MACROSCOPIC OBSERVATIONS:
No macroscopic entries are on file.

MICROSCOPIC OBSERVATIONS:
Adrenal -Hemorrhage, multifocal, mild

The following tissues were found to be within normal limits:
Aorta; Bone Marrow, Femur; Bone Marrow, Sternum; Bone, Femur; Bone, Sternum; Brain; Cecum; Colon; Duodenum; Esophagus; Eye; Eye, Optic Nerve; Heart; Ileum; Jejunum; Kidney; Lacrimal Gland; Larynx; Liver; Lung; Lymph Node, Mandibular; Lymph Node, Mesenteric; Mammary Gland; Nasal Tissues, Level 1; Nasal Tissues, Level 2; Nasal Tissues, Level 3; Nerve, Sciatic; Ovary; Oviduct; Pancreas; Parathyroid; Pharynx; Pituitary; Rectum; Salivary Gland; Skeletal Muscle; Skin; Skin, Eyelid; Spinal Cord, Cervical; Spinal Cord, Lumbar; Spinal Cord, Thorax; Spleen; Stomach; Thymus; Thyroid; Tongue; Trachea; Urinary Bladder; Uterus; Uterus, Cervix, Vagina.

SPECIES: Sprague Dawley Rat
PROJECT NUMBER: CB10-5065-R-TX

Summarized Single Tabulated Animal Report (continued)
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HGI Industries, Inc.
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ANIMAL NUMBER: 159 SEX: Female GROUP: (1) Normal room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MACROSCOPIC OBSERVATIONS:
No macroscopic entries are on file.

MICROSCOPIC OBSERVATIONS:

The following tissues were found to be within normal limits:
Adrenal; Aorta; Bone Marrow, Femur; Bone Marrow, Sternum; Bone, Femur; Bone, Sternum; Brain; Cecum; Colon; Duodenum; Esophagus; Eye; Eye, Optic Nerve; Heart; Ileum; Jejunum; Kidney; Lacrimal Gland; Larynx; Liver; Lung; Lymph Node, Mesenteric; Mammary Gland; Nasal Tissues, Level 1; Nasal Tissues, Level 2; Nasal Tissues, Level 3; Nerve, Sciatic; Ovary; Oviduct; Pancreas; Parathyroid; Pharynx; Pituitary; Rectum; Salivary Gland; Skeletal Muscle; Skin; Skin, Eyelid; Spinal Cord, Cervical; Spinal Cord, Lumbar; Spinal Cord, Thorax; Spleen; Stomach; Thymus; Thyroid; Tongue; Trachea; Urinary Bladder; Uterus; Uterus, Cervix, Vagina.

ANIMAL NUMBER: 160 SEX: Female GROUP: (1) Normal room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MACROSCOPIC OBSERVATIONS:
No macroscopic entries are on file.

MICROSCOPIC OBSERVATIONS:

The following tissues were found to be within normal limits:
Adrenal; Aorta; Bone Marrow, Femur; Bone Marrow, Sternum; Bone, Femur; Bone, Sternum; Brain; Cecum; Colon; Duodenum; Esophagus; Eye; Eye, Optic Nerve; Heart; Ileum; Jejunum; Kidney; Lacrimal Gland; Larynx; Liver; Lung; Lymph Node, Mesenteric; Mammary Gland; Nasal Tissues, Level 1; Nasal Tissues, Level 2; Nasal Tissues, Level 3; Nerve, Sciatic; Ovary; Oviduct; Pancreas; Pharynx; Pituitary; Rectum; Salivary Gland; Skeletal Muscle; Skin; Skin, Eyelid; Spinal Cord, Cervical; Spinal Cord, Lumbar; Spinal Cord, Thorax; Spleen; Stomach; Thymus; Thyroid; Tongue; Trachea; Urinary Bladder; Uterus; Uterus, Cervix, Vagina.

ANIMAL NUMBER: 201 SEX: Male GROUP: (2) Treated room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MACROSCOPIC OBSERVATIONS:
No macroscopic entries are on file.

MICROSCOPIC OBSERVATIONS:

The following tissues were found to be within normal limits:
Adrenal; Aorta; Bone Marrow, Femur; Bone Marrow, Sternum; Bone, Femur; Bone, Sternum; Brain;

SPECIES: Sprague Dawley Rat
PROJECT NUMBER: CB10-5065-R-TX

Summarized Single Tabulated Animal Report (continued)
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HGI Industries, Inc.
13-Week GLP Toxicity Study of the Boss Hydroxyl Odor Processor Air Cleansing Machine in Rats

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ANIMAL NUMBER: 201 SEX: Male GROUP: (2) Treated room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MICROSCOPIC OBSERVATIONS (continued):
The following tissues were found to be within normal limits (continued):
Cecum; Colon; Duodenum; Epididymis; Esophagus; Eye; Eye, Optic Nerve; Heart; Ileum; Jejunum; Kidney; Lacrimal Gland; Larynx; Liver; Lung; Lymph Node, Mandibular; Lymph Node, Mesenteric; Mammary Gland; Nasal Tissues, Level 1; Nasal Tissues, Level 2; Nasal Tissues, Level 3; Nerve, Sciatic; Pancreas; Parathyroid; Pharynx; Pituitary; Prostate; Rectum; Salivary Gland; Seminal Vesicle; Skeletal Muscle; Skin; Skin, Eyelid; Spinal Cord, Cervical; Spinal Cord, Lumbar; Spinal Cord, Thorax; Spleen; Stomach; Testis; Thymus; Thyroid; Tongue; Trachea; Urinary Bladder.

ANIMAL NUMBER: 202 SEX: Male GROUP: (2) Treated room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MACROSCOPIC OBSERVATIONS:
No macroscopic entries are on file.

MICROSCOPIC OBSERVATIONS:
Kidney -Chronic progressive nephropathy, mild

The following tissues were found to be within normal limits:
Adrenal; Aorta; Bone Marrow, Femur; Bone Marrow, Sternum; Bone, Femur; Bone, Sternum; Brain; Cecum; Colon; Duodenum; Epididymis; Esophagus; Eye; Eye, Optic Nerve; Heart; Ileum; Jejunum; Lacrimal Gland; Larynx; Liver; Lung; Lymph Node, Mesenteric; Mammary Gland; Nasal Tissues, Level 1; Nasal Tissues, Level 2; Nasal Tissues, Level 3; Nerve, Sciatic; Pancreas; Pharynx; Pituitary; Prostate; Rectum; Salivary Gland; Seminal Vesicle; Skeletal Muscle; Skin; Skin, Eyelid; Spinal Cord, Cervical; Spinal Cord, Lumbar; Spinal Cord, Thorax; Spleen; Stomach; Testis; Thymus; Thyroid; Tongue; Trachea; Urinary Bladder.

ANIMAL NUMBER: 203 SEX: Male GROUP: (2) Treated room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MACROSCOPIC OBSERVATIONS:
No macroscopic entries are on file.

MICROSCOPIC OBSERVATIONS:

The following tissues were found to be within normal limits:
Adrenal; Aorta; Bone Marrow, Femur; Bone Marrow, Sternum; Bone, Femur; Bone, Sternum; Brain; Cecum; Colon; Duodenum; Epididymis; Esophagus; Eye; Eye, Optic Nerve; Heart; Ileum; Jejunum; Kidney; Lacrimal Gland; Larynx; Liver; Lung; Lymph Node, Mandibular; Lymph Node, Mesenteric; Mammary Gland; Nasal Tissues, Level 1; Nasal Tissues, Level 2; Nasal Tissues, Level 3;

SPECIES: Sprague Dawley Rat
PROJECT NUMBER: CB10-5065-R-TX

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ANIMAL NUMBER: 203 SEX: Male GROUP: (2) Treated room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MICROSCOPIC OBSERVATIONS (continued):
The following tissues were found to be within normal limits (continued):
Nerve, Sciatic; Pancreas; Parathyroid; Pharynx; Pituitary; Prostate; Rectum; Salivary Gland; Seminal Vesicle; Skeletal Muscle; Skin; Skin, Eyelid; Spinal Cord, Cervical; Spinal Cord, Lumbar; Spinal Cord, Thorax; Spleen; Stomach; Testis; Thymus; Thyroid; Tongue; Trachea; Urinary Bladder.

ANIMAL NUMBER: 204 SEX: Male GROUP: (2) Treated room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MACROSCOPIC OBSERVATIONS:
No macroscopic entries are on file.

MICROSCOPIC OBSERVATIONS:
Kidney -Chronic progressive nephropathy, mild

The following tissues were found to be within normal limits:
Adrenal; Aorta; Bone Marrow, Femur; Bone Marrow, Sternum; Bone, Femur; Bone, Sternum; Brain; Cecum; Colon; Duodenum; Epididymis; Esophagus; Eye; Eye, Optic Nerve; Heart; Ileum; Jejunum; Lacrimal Gland; Larynx; Liver; Lung; Lymph Node, Mandibular; Lymph Node, Mesenteric; Mammary Gland; Nasal Tissues, Level 1; Nasal Tissues, Level 2; Nasal Tissues, Level 3; Pancreas; Pharynx; Pituitary; Prostate; Rectum; Salivary Gland; Seminal Vesicle; Skeletal Muscle; Skin; Spinal Cord, Cervical; Spinal Cord, Lumbar; Spinal Cord, Thorax; Spleen; Stomach; Testis; Thymus; Thyroid; Tongue; Trachea; Urinary Bladder.

ANIMAL NUMBER: 205 SEX: Male GROUP: (2) Treated room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MACROSCOPIC OBSERVATIONS:
No macroscopic entries are on file.

MICROSCOPIC OBSERVATIONS:

The following tissues were found to be within normal limits:
Adrenal; Aorta; Bone Marrow, Femur; Bone Marrow, Sternum; Bone, Femur; Bone, Sternum; Brain; Cecum; Colon; Duodenum; Epididymis; Esophagus; Eye; Eye, Optic Nerve; Heart; Ileum; Jejunum; Kidney; Lacrimal Gland; Larynx; Liver; Lung; Lymph Node, Mesenteric; Mammary Gland; Nasal Tissues, Level 1; Nasal Tissues, Level 2; Nasal Tissues, Level 3; Pancreas; Parathyroid; Pharynx; Pituitary; Prostate; Rectum; Salivary Gland; Seminal Vesicle; Skeletal Muscle; Skin; Skin, Eyelid; Spinal Cord, Cervical; Spinal Cord, Lumbar; Spinal Cord, Thorax; Spleen; Stomach; Testis; Thymus; Thyroid; Tongue; Trachea; Urinary Bladder.

SPECIES: Sprague Dawley Rat
PROJECT NUMBER: CB10-5065-R-TX

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Individual Macroscopic and Microscopic Observations
HGI Industries, Inc.
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ANIMAL NUMBER: 206 SEX: Male GROUP: (2) Treated room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MACROSCOPIC OBSERVATIONS:
No macroscopic entries are on file.

MICROSCOPIC OBSERVATIONS:
Kidney -Chronic progressive nephropathy, mild

The following tissues were found to be within normal limits:
Adrenal; Aorta; Bone Marrow, Femur; Bone Marrow, Sternum; Bone, Femur; Bone, Sternum; Brain; Cecum; Colon; Duodenum; Epididymis; Esophagus; Eye; Eye, Optic Nerve; Heart; Ileum; Jejunum; Lacrimal Gland; Larynx; Liver; Lung; Lymph Node, Mesenteric; Mammary Gland; Nasal Tissues, Level 1; Nasal Tissues, Level 2; Nasal Tissues, Level 3; Nerve, Sciatic; Pancreas; Parathyroid; Pharynx; Pituitary; Prostate; Rectum; Salivary Gland; Seminal Vesicle; Skeletal Muscle; Skin; Spinal Cord, Cervical; Spinal Cord, Lumbar; Spinal Cord, Thorax; Spleen; Stomach; Testis; Thymus; Thyroid; Tongue; Trachea; Urinary Bladder.

ANIMAL NUMBER: 207 SEX: Male GROUP: (2) Treated room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MACROSCOPIC OBSERVATIONS:
No macroscopic entries are on file.

MICROSCOPIC OBSERVATIONS:
Kidney -Chronic progressive nephropathy, mild

The following tissues were found to be within normal limits:
Adrenal; Aorta; Bone Marrow, Femur; Bone Marrow, Sternum; Bone, Femur; Bone, Sternum; Brain; Cecum; Colon; Duodenum; Epididymis; Esophagus; Eye; Eye, Optic Nerve; Heart; Ileum; Jejunum; Lacrimal Gland; Larynx; Liver; Lung; Lymph Node, Mandibular; Lymph Node, Mesenteric; Mammary Gland; Nasal Tissues, Level 1; Nasal Tissues, Level 2; Nasal Tissues, Level 3; Nerve, Sciatic; Pancreas; Parathyroid; Pharynx; Pituitary; Prostate; Rectum; Salivary Gland; Seminal Vesicle; Skeletal Muscle; Skin; Skin, Eyelid; Spinal Cord, Cervical; Spinal Cord, Lumbar; Spinal Cord, Thorax; Spleen; Stomach; Testis; Thymus; Thyroid; Tongue; Trachea; Urinary Bladder.

ANIMAL NUMBER: 208 SEX: Male GROUP: (2) Treated room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MACROSCOPIC OBSERVATIONS:
Thyroid -Right thyroid and parathyroid smaller than left.

SPECIES: Sprague Dawley Rat
PROJECT NUMBER: CB10-5065-R-TX

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HGI Industries, Inc.
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ANIMAL NUMBER: 208 SEX: Male GROUP: (2) Treated room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MICROSCOPIC OBSERVATIONS (continued):
Kidney -Chronic progressive nephropathy, mild

The following tissues were found to be within normal limits:
Adrenal; Aorta; Bone Marrow, Femur; Bone Marrow, Sternum; Bone, Femur; Bone, Sternum; Brain; Cecum; Colon; Duodenum; Epididymis; Esophagus; Eye; Eye, Optic Nerve; Heart; Ileum; Jejunum; Lacrimal Gland; Larynx; Liver; Lung; Lymph Node, Mandibular; Lymph Node, Mesenteric; Mammary Gland; Nasal Tissues, Level 1; Nasal Tissues, Level 2; Nasal Tissues, Level 3; Nerve, Sciatic; Pancreas; Parathyroid; Pharynx; Pituitary; Prostate; Rectum; Salivary Gland; Seminal Vesicle; Skeletal Muscle; Skin; Spinal Cord, Cervical; Spinal Cord, Lumbar; Spinal Cord, Thorax; Spleen; Stomach; Testis; Thymus; Thyroid; Tongue; Trachea; Urinary Bladder.

ANIMAL NUMBER: 209 SEX: Male GROUP: (2) Treated room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MACROSCOPIC OBSERVATIONS:
No macroscopic entries are on file.

MICROSCOPIC OBSERVATIONS:
Kidney -Chronic progressive nephropathy, moderate

The following tissues were found to be within normal limits:
Adrenal; Aorta; Bone Marrow, Femur; Bone Marrow, Sternum; Bone, Femur; Bone, Sternum; Brain; Cecum; Colon; Duodenum; Epididymis; Esophagus; Eye; Eye, Optic Nerve; Heart; Ileum; Jejunum; Lacrimal Gland; Larynx; Liver; Lung; Lymph Node, Mandibular; Lymph Node, Mesenteric; Mammary Gland; Nasal Tissues, Level 1; Nasal Tissues, Level 2; Nasal Tissues, Level 3; Nerve, Sciatic; Pancreas; Pharynx; Pituitary; Prostate; Rectum; Salivary Gland; Seminal Vesicle; Skeletal Muscle; Skin; Skin, Eyelid; Spinal Cord, Cervical; Spinal Cord, Lumbar; Spinal Cord, Thorax; Spleen; Stomach; Testis; Thymus; Thyroid; Tongue; Trachea; Urinary Bladder.

ANIMAL NUMBER: 210 SEX: Male GROUP: (2) Treated room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MACROSCOPIC OBSERVATIONS:
No macroscopic entries are on file.

MICROSCOPIC OBSERVATIONS:
Kidney -Chronic progressive nephropathy, mild

The following tissues were found to be within normal limits:
Adrenal; Aorta; Bone Marrow, Femur; Bone Marrow, Sternum; Bone, Femur; Bone, Sternum; Brain;

SPECIES: Sprague Dawley Rat
PROJECT NUMBER: CB10-5065-R-TX

Summarized Single Tabulated Animal Report (continued)
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HGI Industries, Inc.
13-Week GLP Toxicity Study of the Boss Hydroxyl Odor Processor Air Cleansing Machine in Rats

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ANIMAL NUMBER: 210 SEX: Male GROUP: (2) Treated room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MICROSCOPIC OBSERVATIONS (continued):
The following tissues were found to be within normal limits (continued):
Cecum; Colon; Duodenum; Epididymis; Esophagus; Eye; Eye, Optic Nerve; Heart; Ileum; Jejunum; Lacrimal Gland; Larynx; Liver; Lung; Lymph Node, Mesenteric; Mammary Gland; Nasal Tissues, Level 1; Nasal Tissues, Level 2; Nasal Tissues, Level 3; Nerve, Sciatic; Pancreas; Pharynx; Pituitary; Prostate; Rectum; Salivary Gland; Seminal Vesicle; Skeletal Muscle; Skin; Skin, Eyelid; Spinal Cord, Cervical; Spinal Cord, Lumbar; Spinal Cord, Thorax; Spleen; Stomach; Testis; Thymus; Thyroid; Tongue; Trachea; Urinary Bladder.

ANIMAL NUMBER: 211 SEX: Male GROUP: (2) Treated room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MACROSCOPIC OBSERVATIONS:
No macroscopic entries are on file.

MICROSCOPIC OBSERVATIONS:
Kidney -Chronic progressive nephropathy, mild

The following tissues were found to be within normal limits:
Adrenal; Aorta; Bone Marrow, Femur; Bone Marrow, Sternum; Bone, Femur; Bone, Sternum; Brain; Cecum; Colon; Duodenum; Epididymis; Esophagus; Eye; Eye, Optic Nerve; Heart; Ileum; Jejunum; Lacrimal Gland; Larynx; Liver; Lung; Lymph Node, Mesenteric; Mammary Gland; Nasal Tissues, Level 1; Nasal Tissues, Level 2; Nasal Tissues, Level 3; Nerve, Sciatic; Pancreas; Parathyroid; Pharynx; Pituitary; Prostate; Rectum; Salivary Gland; Seminal Vesicle; Skeletal Muscle; Skin; Skin, Eyelid; Spinal Cord, Cervical; Spinal Cord, Lumbar; Spinal Cord, Thorax; Spleen; Stomach; Testis; Thymus; Thyroid; Tongue; Trachea; Urinary Bladder.

ANIMAL NUMBER: 212 SEX: Male GROUP: (2) Treated room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MACROSCOPIC OBSERVATIONS:
No macroscopic entries are on file.

MICROSCOPIC OBSERVATIONS:
Kidney -Chronic progressive nephropathy, mild

The following tissues were found to be within normal limits:
Adrenal; Aorta; Bone Marrow, Femur; Bone Marrow, Sternum; Bone, Femur; Bone, Sternum; Brain; Cecum; Colon; Duodenum; Epididymis; Esophagus; Eye; Eye, Optic Nerve; Heart; Ileum; Jejunum; Lacrimal Gland; Larynx; Liver; Lung; Lymph Node, Mandibular; Lymph Node, Mesenteric; Mammary Gland; Nasal Tissues, Level 1; Nasal Tissues, Level 2; Nasal Tissues, Level 3;

SPECIES: Sprague Dawley Rat
PROJECT NUMBER: CB10-5065-R-TX

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ANIMAL NUMBER: 212 SEX: Male GROUP: (2) Treated room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MICROSCOPIC OBSERVATIONS (continued):
The following tissues were found to be within normal limits (continued):
Nerve, Sciatic; Pancreas; Parathyroid; Pharynx; Pituitary; Prostate; Rectum; Salivary Gland; Seminal Vesicle; Skeletal Muscle; Skin; Spinal Cord, Cervical; Spinal Cord, Lumbar; Spinal Cord, Thorax; Spleen; Stomach; Testis; Thymus; Thyroid; Tongue; Trachea; Urinary Bladder.

ANIMAL NUMBER: 213 SEX: Male GROUP: (2) Treated room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MACROSCOPIC OBSERVATIONS:
No macroscopic entries are on file.

MICROSCOPIC OBSERVATIONS:
Kidney -Chronic progressive nephropathy, mild

The following tissues were found to be within normal limits:
Adrenal; Aorta; Bone Marrow, Femur; Bone Marrow, Sternum; Bone, Femur; Bone, Sternum; Brain; Cecum; Colon; Duodenum; Epididymis; Esophagus; Eye; Eye, Optic Nerve; Heart; Ileum; Jejunum; Lacrimal Gland; Larynx; Liver; Lung; Lymph Node, Mandibular; Lymph Node, Mesenteric; Mammary Gland; Nasal Tissues, Level 1; Nasal Tissues, Level 2; Nasal Tissues, Level 3; Nerve, Sciatic; Pancreas; Pharynx; Pituitary; Prostate; Rectum; Salivary Gland; Seminal Vesicle; Skeletal Muscle; Skin; Skin, Eyelid; Spinal Cord, Cervical; Spinal Cord, Lumbar; Spinal Cord, Thorax; Spleen; Stomach; Testis; Thymus; Thyroid; Tongue; Trachea; Urinary Bladder.

ANIMAL NUMBER: 214 SEX: Male GROUP: (2) Treated room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MACROSCOPIC OBSERVATIONS:
No macroscopic entries are on file.

MICROSCOPIC OBSERVATIONS:
Kidney -Chronic progressive nephropathy, moderate

The following tissues were found to be within normal limits:
Adrenal; Aorta; Bone Marrow, Femur; Bone Marrow, Sternum; Bone, Femur; Bone, Sternum; Brain; Cecum; Colon; Duodenum; Epididymis; Esophagus; Eye; Eye, Optic Nerve; Heart; Ileum; Jejunum; Lacrimal Gland; Larynx; Liver; Lung; Lymph Node, Mandibular; Lymph Node, Mesenteric; Mammary Gland; Nasal Tissues, Level 1; Nasal Tissues, Level 2; Nasal Tissues, Level 3; Nerve, Sciatic; Pancreas; Parathyroid; Pharynx; Pituitary; Prostate; Rectum; Salivary Gland; Seminal Vesicle; Skeletal Muscle; Skin; Skin, Eyelid; Spinal Cord, Cervical; Spinal Cord, Lumbar; Spinal Cord, Thorax; Spleen; Stomach; Testis; Thymus; Thyroid; Tongue;

SPECIES: Sprague Dawley Rat
PROJECT NUMBER: CB10-5065-R-TX

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HGI Industries, Inc.
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ANIMAL NUMBER: 214 SEX: Male GROUP: (2) Treated room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MICROSCOPIC OBSERVATIONS (continued):
The following tissues were found to be within normal limits (continued):
Trachea; Urinary Bladder.

ANIMAL NUMBER: 215 SEX: Male GROUP: (2) Treated room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MACROSCOPIC OBSERVATIONS:
No macroscopic entries are on file.

MICROSCOPIC OBSERVATIONS:

The following tissues were found to be within normal limits:
Adrenal; Aorta; Bone Marrow, Femur; Bone Marrow, Sternum; Bone, Femur; Bone, Sternum; Brain; Cecum; Colon; Duodenum; Epididymis; Esophagus; Eye; Eye, Optic Nerve; Heart; Ileum; Jejunum; Kidney; Lacrimal Gland; Larynx; Liver; Lung; Lymph Node, Mandibular; Lymph Node, Mesenteric; Mammary Gland; Nasal Tissues, Level 1; Nasal Tissues, Level 2; Nasal Tissues, Level 3; Nerve, Sciatic; Pancreas; Parathyroid; Pharynx; Pituitary; Prostate; Rectum; Salivary Gland; Seminal Vesicle; Skeletal Muscle; Skin; Skin, Eyelid; Spinal Cord, Cervical; Spinal Cord, Lumbar; Spinal Cord, Thorax; Spleen; Stomach; Testis; Thymus; Thyroid; Tongue; Trachea; Urinary Bladder.

ANIMAL NUMBER: 216 SEX: Male GROUP: (2) Treated room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MACROSCOPIC OBSERVATIONS:
No macroscopic entries are on file.

MICROSCOPIC OBSERVATIONS:
Kidney -Chronic progressive nephropathy, moderate
Lacrimal Gland -Inflammation, chronic, focal, mild

The following tissues were found to be within normal limits:
Adrenal; Aorta; Bone Marrow, Femur; Bone Marrow, Sternum; Bone, Femur; Bone, Sternum; Brain; Cecum; Colon; Duodenum; Epididymis; Esophagus; Eye; Eye, Optic Nerve; Heart; Ileum; Jejunum; Larynx; Liver; Lung; Lymph Node, Mesenteric; Mammary Gland; Nasal Tissues, Level 1; Nasal Tissues, Level 2; Nasal Tissues, Level 3; Nerve, Sciatic; Pancreas; Parathyroid; Pharynx; Pituitary; Prostate; Rectum; Salivary Gland; Seminal Vesicle; Skeletal Muscle; Skin; Spinal Cord, Cervical; Spinal Cord, Lumbar; Spinal Cord, Thorax; Spleen; Stomach; Testis; Thymus; Thyroid; Tongue; Trachea; Urinary Bladder.

SPECIES: Sprague Dawley Rat
PROJECT NUMBER: CB10-5065-R-TX

Summarized Single Tabulated Animal Report (continued)
Individual Macroscopic and Microscopic Observations
HGI Industries, Inc.
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ANIMAL NUMBER: 217 SEX: Male GROUP: (2) Treated room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MACROSCOPIC OBSERVATIONS:
No macroscopic entries are on file.

MICROSCOPIC OBSERVATIONS:

The following tissues were found to be within normal limits:
Adrenal; Aorta; Bone Marrow, Femur; Bone Marrow, Sternum; Bone, Femur; Bone, Sternum; Brain; Cecum; Colon; Duodenum; Epididymis; Esophagus; Eye; Eye, Optic Nerve; Heart; Ileum; Jejunum; Kidney; Lacrimal Gland; Larynx; Liver; Lung; Lymph Node, Mandibular; Lymph Node, Mesenteric; Mammary Gland; Nasal Tissues, Level 1; Nasal Tissues, Level 2; Nasal Tissues, Level 3; Nerve, Sciatic; Pancreas; Parathyroid; Pharynx; Pituitary; Prostate; Rectum; Salivary Gland; Seminal Vesicle; Skeletal Muscle; Skin; Skin, Eyelid; Spinal Cord, Cervical; Spinal Cord, Lumbar; Spinal Cord, Thorax; Spleen; Stomach; Testis; Thymus; Thyroid; Tongue; Trachea; Urinary Bladder.

ANIMAL NUMBER: 218 SEX: Male GROUP: (2) Treated room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MACROSCOPIC OBSERVATIONS:
No macroscopic entries are on file.

MICROSCOPIC OBSERVATIONS:
Kidney -Chronic progressive nephropathy, mild

The following tissues were found to be within normal limits:
Adrenal; Aorta; Bone Marrow, Femur; Bone Marrow, Sternum; Bone, Femur; Bone, Sternum; Brain; Cecum; Colon; Duodenum; Epididymis; Esophagus; Eye; Eye, Optic Nerve; Heart; Ileum; Jejunum; Lacrimal Gland; Larynx; Liver; Lung; Lymph Node, Mesenteric; Mammary Gland; Nasal Tissues, Level 1; Nasal Tissues, Level 2; Nasal Tissues, Level 3; Nerve, Sciatic; Pancreas; Parathyroid; Pharynx; Pituitary; Prostate; Rectum; Salivary Gland; Seminal Vesicle; Skeletal Muscle; Skin; Skin, Eyelid; Spinal Cord, Cervical; Spinal Cord, Lumbar; Spinal Cord, Thorax; Spleen; Stomach; Testis; Thymus; Thyroid; Tongue; Trachea; Urinary Bladder.

ANIMAL NUMBER: 219 SEX: Male GROUP: (2) Treated room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MACROSCOPIC OBSERVATIONS:
No macroscopic entries are on file.

MICROSCOPIC OBSERVATIONS:
Kidney -Chronic progressive nephropathy, mild

SPECIES: Sprague Dawley Rat
PROJECT NUMBER: CB10-5065-R-TX

Summarized Single Tabulated Animal Report (continued)
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HGI Industries, Inc.
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ANIMAL NUMBER: 219 SEX: Male GROUP: (2) Treated room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MICROSCOPIC OBSERVATIONS (continued):

The following tissues were found to be within normal limits:
Adrenal; Aorta; Bone Marrow, Femur; Bone Marrow, Sternum; Bone, Femur; Bone, Sternum; Brain; Cecum; Colon; Duodenum; Epididymis; Esophagus; Eye; Eye, Optic Nerve; Heart; Ileum; Jejunum; Lacrimal Gland; Larynx; Liver; Lung; Lymph Node, Mesenteric; Mammary Gland; Nasal Tissues, Level 1; Nasal Tissues, Level 2; Nasal Tissues, Level 3; Nerve, Sciatic; Pancreas; Parathyroid; Pharynx; Pituitary; Prostate; Rectum; Salivary Gland; Seminal Vesicle; Skeletal Muscle; Skin; Skin, Eyelid; Spinal Cord, Cervical; Spinal Cord, Lumbar; Spinal Cord, Thorax; Spleen; Stomach; Testis; Thymus; Thyroid; Tongue; Trachea; Urinary Bladder.

ANIMAL NUMBER: 220 SEX: Male GROUP: (2) Treated room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MACROSCOPIC OBSERVATIONS:
No macroscopic entries are on file.

MICROSCOPIC OBSERVATIONS:
Kidney -Chronic progressive nephropathy, mild

The following tissues were found to be within normal limits:
Adrenal; Aorta; Bone Marrow, Femur; Bone Marrow, Sternum; Bone, Femur; Bone, Sternum; Brain; Cecum; Colon; Duodenum; Epididymis; Esophagus; Eye; Eye, Optic Nerve; Heart; Ileum; Jejunum; Lacrimal Gland; Larynx; Liver; Lung; Lymph Node, Mandibular; Lymph Node, Mesenteric; Mammary Gland; Nasal Tissues, Level 1; Nasal Tissues, Level 2; Nasal Tissues, Level 3; Nerve, Sciatic; Pancreas; Pharynx; Pituitary; Prostate; Rectum; Salivary Gland; Seminal Vesicle; Skeletal Muscle; Skin; Spinal Cord, Cervical; Spinal Cord, Lumbar; Spinal Cord, Thorax; Spleen; Stomach; Testis; Thymus; Thyroid; Tongue; Trachea; Urinary Bladder.

ANIMAL NUMBER: 251 SEX: Female GROUP: (2) Treated room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MACROSCOPIC OBSERVATIONS:
No macroscopic entries are on file.

MICROSCOPIC OBSERVATIONS:

The following tissues were found to be within normal limits:
Adrenal; Aorta; Bone Marrow, Femur; Bone Marrow, Sternum; Bone, Femur; Bone, Sternum; Brain; Cecum; Colon; Duodenum; Esophagus; Eye; Eye, Optic Nerve; Heart; Ileum; Jejunum; Kidney; Lacrimal Gland; Larynx; Liver; Lung; Lymph Node, Mandibular; Lymph Node, Mesenteric;

SPECIES: Sprague Dawley Rat
PROJECT NUMBER: CB10-5065-R-TX

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ANIMAL NUMBER: 251 SEX: Female GROUP: (2) Treated room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MICROSCOPIC OBSERVATIONS (continued):
The following tissues were found to be within normal limits (continued):
Mammary Gland; Nasal Tissues, Level 1; Nasal Tissues, Level 2; Nasal Tissues, Level 3; Nerve, Sciatic; Ovary; Oviduct; Pancreas; Parathyroid; Pharynx; Pituitary; Rectum; Salivary Gland; Skeletal Muscle; Skin; Skin, Eyelid; Spinal Cord, Cervical; Spinal Cord, Lumbar; Spinal Cord, Thorax; Spleen; Stomach; Thymus; Thyroid; Tongue; Trachea; Urinary Bladder; Uterus; Uterus, Cervix, Vagina.

ANIMAL NUMBER: 252 SEX: Female GROUP: (2) Treated room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MACROSCOPIC OBSERVATIONS:
No macroscopic entries are on file.

MICROSCOPIC OBSERVATIONS:
Kidney -Chronic progressive nephropathy, mild

The following tissues were found to be within normal limits:
Adrenal; Aorta; Bone Marrow, Femur; Bone Marrow, Sternum; Bone, Femur; Bone, Sternum; Brain; Cecum; Colon; Duodenum; Esophagus; Eye; Eye, Optic Nerve; Heart; Ileum; Jejunum; Lacrimal Gland; Larynx; Liver; Lung; Lymph Node, Mesenteric; Mammary Gland; Nasal Tissues, Level 1; Nasal Tissues, Level 2; Nasal Tissues, Level 3; Nerve, Sciatic; Ovary; Oviduct; Pancreas; Parathyroid; Pharynx; Pituitary; Rectum; Salivary Gland; Skeletal Muscle; Skin; Skin, Eyelid; Spinal Cord, Cervical; Spinal Cord, Lumbar; Spinal Cord, Thorax; Spleen; Stomach; Thymus; Thyroid; Tongue; Trachea; Urinary Bladder; Uterus; Uterus, Cervix, Vagina.

ANIMAL NUMBER: 253 SEX: Female GROUP: (2) Treated room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MACROSCOPIC OBSERVATIONS:
Spleen -Spleen fused with pancreas, White nodular spots on spleen. One liver lobe fused with spleen.

MICROSCOPIC OBSERVATIONS:
Spleen -Hemangiosarcoma

The following tissues were found to be within normal limits:
Adrenal; Aorta; Bone Marrow, Femur; Bone Marrow, Sternum; Bone, Femur; Bone, Sternum; Brain; Cecum; Colon; Duodenum; Esophagus; Eye; Eye, Optic Nerve; Heart; Ileum; Jejunum; Kidney; Lacrimal Gland; Larynx; Liver; Lung; Lymph Node, Mandibular; Lymph Node, Mesenteric; Mammary Gland; Nasal Tissues, Level 1; Nasal Tissues, Level 2; Nasal Tissues, Level 3;

SPECIES: Sprague Dawley Rat
PROJECT NUMBER: CB10-5065-R-TX

Summarized Single Tabulated Animal Report (continued)
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ANIMAL NUMBER: 253 SEX: Female GROUP: (2) Treated room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MICROSCOPIC OBSERVATIONS (continued):
The following tissues were found to be within normal limits (continued):
Nerve, Sciatic; Ovary; Oviduct; Pancreas; Pharynx; Pituitary; Rectum; Salivary Gland; Skeletal Muscle; Skin; Skin, Eyelid; Spinal Cord, Cervical; Spinal Cord, Lumbar; Spinal Cord, Thorax; Stomach; Thymus; Thyroid; Tongue; Trachea; Urinary Bladder; Uterus; Uterus, Cervix, Vagina.

ANIMAL NUMBER: 254 SEX: Female GROUP: (2) Treated room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MACROSCOPIC OBSERVATIONS:
No macroscopic entries are on file.

MICROSCOPIC OBSERVATIONS:
Kidney -Chronic progressive nephropathy, moderate

The following tissues were found to be within normal limits:
Adrenal; Aorta; Bone Marrow, Femur; Bone Marrow, Sternum; Bone, Femur; Bone, Sternum; Brain; Cecum; Colon; Duodenum; Esophagus; Eye; Eye, Optic Nerve; Heart; Ileum; Jejunum; Lacrimal Gland; Larynx; Liver; Lung; Lymph Node, Mandibular; Lymph Node, Mesenteric; Mammary Gland; Nasal Tissues, Level 1; Nasal Tissues, Level 2; Nasal Tissues, Level 3; Ovary; Oviduct; Pancreas; Parathyroid; Pharynx; Pituitary; Rectum; Salivary Gland; Skeletal Muscle; Skin; Skin, Eyelid; Spinal Cord, Cervical; Spinal Cord, Lumbar; Spinal Cord, Thorax; Spleen; Stomach; Thymus; Thyroid; Tongue; Trachea; Urinary Bladder; Uterus; Uterus, Cervix, Vagina.

ANIMAL NUMBER: 255 SEX: Female GROUP: (2) Treated room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MACROSCOPIC OBSERVATIONS:
No macroscopic entries are on file.

MICROSCOPIC OBSERVATIONS:
Kidney -Chronic progressive nephropathy, mild

The following tissues were found to be within normal limits:
Adrenal; Aorta; Bone Marrow, Femur; Bone Marrow, Sternum; Bone, Femur; Bone, Sternum; Brain; Cecum; Colon; Duodenum; Esophagus; Eye; Eye, Optic Nerve; Heart; Ileum; Jejunum; Lacrimal Gland; Larynx; Liver; Lung; Lymph Node, Mesenteric; Mammary Gland; Nasal Tissues, Level 1; Nasal Tissues, Level 2; Nasal Tissues, Level 3; Nerve, Sciatic; Ovary; Oviduct; Pancreas; Parathyroid; Pharynx; Pituitary; Rectum; Salivary Gland; Skeletal Muscle; Skin; Skin, Eyelid; Spinal Cord, Cervical; Spinal Cord, Lumbar; Spinal Cord, Thorax; Spleen; Stomach; Thymus;

SPECIES: Sprague Dawley Rat
PROJECT NUMBER: CB10-5065-R-TX

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ANIMAL NUMBER: 255 SEX: Female GROUP: (2) Treated room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MICROSCOPIC OBSERVATIONS (continued):
The following tissues were found to be within normal limits (continued):
Thyroid; Tongue; Trachea; Urinary Bladder; Uterus; Uterus, Cervix, Vagina.

ANIMAL NUMBER: 256 SEX: Female GROUP: (2) Treated room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MACROSCOPIC OBSERVATIONS:
No macroscopic entries are on file.

MICROSCOPIC OBSERVATIONS:

The following tissues were found to be within normal limits:
Adrenal; Aorta; Bone Marrow, Femur; Bone Marrow, Sternum; Bone, Femur; Bone, Sternum; Brain; Cecum; Colon; Duodenum; Esophagus; Eye; Eye, Optic Nerve; Heart; Ileum; Jejunum; Kidney; Lacrimal Gland; Larynx; Liver; Lung; Lymph Node, Mandibular; Lymph Node, Mesenteric; Mammary Gland; Nasal Tissues, Level 1; Nasal Tissues, Level 2; Nasal Tissues, Level 3; Ovary; Oviduct; Pancreas; Pharynx; Pituitary; Rectum; Salivary Gland; Skeletal Muscle; Skin; Skin, Eyelid; Spinal Cord, Cervical; Spinal Cord, Lumbar; Spinal Cord, Thorax; Spleen; Stomach; Thymus; Thyroid; Tongue; Trachea; Urinary Bladder; Uterus; Uterus, Cervix, Vagina.

ANIMAL NUMBER: 257 SEX: Female GROUP: (2) Treated room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MACROSCOPIC OBSERVATIONS:
No macroscopic entries are on file.

MICROSCOPIC OBSERVATIONS:

The following tissues were found to be within normal limits:
Adrenal; Aorta; Bone Marrow, Femur; Bone Marrow, Sternum; Bone, Femur; Bone, Sternum; Brain; Cecum; Colon; Duodenum; Esophagus; Eye; Eye, Optic Nerve; Heart; Ileum; Jejunum; Kidney; Lacrimal Gland; Larynx; Liver; Lung; Lymph Node, Mandibular; Lymph Node, Mesenteric; Mammary Gland; Nasal Tissues, Level 1; Nasal Tissues, Level 2; Nasal Tissues, Level 3; Ovary; Oviduct; Pancreas; Pharynx; Pituitary; Rectum; Salivary Gland; Skeletal Muscle; Skin; Skin, Eyelid; Spinal Cord, Cervical; Spinal Cord, Lumbar; Spinal Cord, Thorax; Spleen; Stomach; Thymus; Thyroid; Tongue; Trachea; Urinary Bladder; Uterus; Uterus, Cervix, Vagina.

SPECIES: Sprague Dawley Rat
PROJECT NUMBER: CB10-5065-R-TX

Summarized Single Tabulated Animal Report (continued)
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HGI Industries, Inc.
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ANIMAL NUMBER: 258 SEX: Female GROUP: (2) Treated room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MACROSCOPIC OBSERVATIONS:
Thyroid -Thyroid lost at necropsy.
MICROSCOPIC OBSERVATIONS:
Kidney -Chronic progressive nephropathy, mild
Thyroid -One of pair present

The following tissues were found to be within normal limits:
Adrenal; Aorta; Bone Marrow, Femur; Bone Marrow, Sternum; Bone, Femur; Bone, Sternum; Brain; Cecum; Colon; Duodenum; Esophagus; Eye; Eye, Optic Nerve; Heart; Ileum; Jejunum; Lacrimal Gland; Larynx; Liver; Lung; Lymph Node, Mandibular; Lymph Node, Mesenteric; Mammary Gland; Nasal Tissues, Level 1; Nasal Tissues, Level 2; Nasal Tissues, Level 3; Nerve, Sciatic; Ovary; Oviduct; Pancreas; Pharynx; Pituitary; Rectum; Salivary Gland; Skeletal Muscle; Skin; Spinal Cord, Cervical; Spinal Cord, Lumbar; Spinal Cord, Thorax; Spleen; Stomach; Thymus; Tongue; Trachea; Urinary Bladder; Uterus; Uterus, Cervix, Vagina.

ANIMAL NUMBER: 259 SEX: Female GROUP: (2) Treated room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MACROSCOPIC OBSERVATIONS:
No macroscopic entries are on file.

MICROSCOPIC OBSERVATIONS:
Kidney -Chronic progressive nephropathy, mild
Lung -Peribronchiolitis, chronic, multifocal, mild

The following tissues were found to be within normal limits:
Adrenal; Aorta; Bone Marrow, Femur; Bone Marrow, Sternum; Bone, Femur; Bone, Sternum; Brain; Cecum; Colon; Duodenum; Esophagus; Eye; Eye, Optic Nerve; Heart; Ileum; Jejunum; Lacrimal Gland; Larynx; Liver; Lymph Node, Mandibular; Lymph Node, Mesenteric; Mammary Gland; Nasal Tissues, Level 1; Nasal Tissues, Level 2; Nasal Tissues, Level 3; Nerve, Sciatic; Ovary; Oviduct; Pancreas; Pharynx; Pituitary; Rectum; Salivary Gland; Skeletal Muscle; Skin; Skin, Eyelid; Spinal Cord, Cervical; Spinal Cord, Lumbar; Spinal Cord, Thorax; Spleen; Stomach; Thymus; Thyroid; Tongue; Trachea; Urinary Bladder; Uterus; Uterus, Cervix, Vagina.

ANIMAL NUMBER: 260 SEX: Female GROUP: (2) Treated room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MACROSCOPIC OBSERVATIONS:
No macroscopic entries are on file.

SPECIES: Sprague Dawley Rat
PROJECT NUMBER: CB10-5065-R-TX

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ANIMAL NUMBER: 260 SEX: Female GROUP: (2) Treated room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MICROSCOPIC OBSERVATIONS (continued):
Kidney -Chronic progressive nephropathy, moderate

The following tissues were found to be within normal limits:
Adrenal; Aorta; Bone Marrow, Femur; Bone Marrow, Sternum; Bone, Femur; Bone, Sternum; Brain; Cecum; Colon; Duodenum; Esophagus; Eye; Eye, Optic Nerve; Heart; Ileum; Jejunum; Lacrimal Gland; Larynx; Liver; Lung; Lymph Node, Mandibular; Lymph Node, Mesenteric; Mammary Gland; Nasal Tissues, Level 1; Nasal Tissues, Level 2; Nasal Tissues, Level 3; Nerve, Sciatic; Ovary; Oviduct; Pancreas; Pharynx; Pituitary; Rectum; Salivary Gland; Skeletal Muscle; Skin; Skin, Eyelid; Spinal Cord, Cervical; Spinal Cord, Lumbar; Spinal Cord, Thorax; Spleen; Stomach; Thymus; Thyroid; Tongue; Trachea; Urinary Bladder; Uterus; Uterus, Cervix, Vagina.

ANIMAL NUMBER: 261 SEX: Female GROUP: (2) Treated room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MACROSCOPIC OBSERVATIONS:
No macroscopic entries are on file.

MICROSCOPIC OBSERVATIONS:
Kidney -Chronic progressive nephropathy, moderate
Lung -Peribronchiolitis, chronic, multifocal, mild
Thymus -Carcinoma

The following tissues were found to be within normal limits:
Adrenal; Aorta; Bone Marrow, Femur; Bone Marrow, Sternum; Bone, Femur; Bone, Sternum; Brain; Cecum; Colon; Duodenum; Esophagus; Eye; Eye, Optic Nerve; Heart; Ileum; Jejunum; Lacrimal Gland; Larynx; Liver; Lymph Node, Mandibular; Lymph Node, Mesenteric; Mammary Gland; Nasal Tissues, Level 1; Nasal Tissues, Level 2; Nasal Tissues, Level 3; Nerve, Sciatic; Ovary; Oviduct; Pancreas; Parathyroid; Pharynx; Pituitary; Rectum; Salivary Gland; Skeletal Muscle; Skin; Skin, Eyelid; Spinal Cord, Cervical; Spinal Cord, Lumbar; Spinal Cord, Thorax; Spleen; Stomach; Thyroid; Tongue; Trachea; Urinary Bladder; Uterus; Uterus, Cervix, Vagina.

ANIMAL NUMBER: 262 SEX: Female GROUP: (2) Treated room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MACROSCOPIC OBSERVATIONS:
No macroscopic entries are on file.

MICROSCOPIC OBSERVATIONS:
Kidney -Chronic progressive nephropathy, mild

The following tissues were found to be within normal limits:
Adrenal; Aorta; Bone Marrow, Femur; Bone Marrow, Sternum; Bone, Femur; Bone, Sternum; Brain;

SPECIES: Sprague Dawley Rat
PROJECT NUMBER: CB10-5065-R-TX

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ANIMAL NUMBER: 262 SEX: Female GROUP: (2) Treated room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MICROSCOPIC OBSERVATIONS (continued):
The following tissues were found to be within normal limits (continued):
Cecum; Colon; Duodenum; Esophagus; Eye; Eye, Optic Nerve; Heart; Ileum; Jejunum; Lacrimal Gland; Larynx; Liver; Lung; Lymph Node, Mesenteric; Mammary Gland; Nasal Tissues, Level 1; Nasal Tissues, Level 2; Nasal Tissues, Level 3; Nerve, Sciatic; Ovary; Oviduct; Pancreas; Pharynx; Pituitary; Rectum; Salivary Gland; Skeletal Muscle; Skin; Spinal Cord, Cervical; Spinal Cord, Lumbar; Spinal Cord, Thorax; Spleen; Stomach; Thymus; Thyroid; Tongue; Trachea; Urinary Bladder; Uterus; Uterus, Cervix, Vagina.

ANIMAL NUMBER: 263 SEX: Female GROUP: (2) Treated room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MACROSCOPIC OBSERVATIONS:
No macroscopic entries are on file.

MICROSCOPIC OBSERVATIONS:
Kidney -Chronic progressive nephropathy, trace

The following tissues were found to be within normal limits:
Adrenal; Aorta; Bone Marrow, Femur; Bone Marrow, Sternum; Bone, Femur; Bone, Sternum; Brain; Cecum; Colon; Duodenum; Esophagus; Eye; Eye, Optic Nerve; Heart; Ileum; Jejunum; Lacrimal Gland; Larynx; Liver; Lung; Lymph Node, Mandibular; Lymph Node, Mesenteric; Mammary Gland; Nasal Tissues, Level 1; Nasal Tissues, Level 2; Nasal Tissues, Level 3; Nerve, Sciatic; Ovary; Oviduct; Pancreas; Parathyroid; Pharynx; Pituitary; Rectum; Salivary Gland; Skeletal Muscle; Skin; Skin, Eyelid; Spinal Cord, Cervical; Spinal Cord, Lumbar; Spinal Cord, Thorax; Spleen; Stomach; Thymus; Thyroid; Tongue; Trachea; Urinary Bladder; Uterus; Uterus, Cervix, Vagina.

ANIMAL NUMBER: 264 SEX: Female GROUP: (2) Treated room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MACROSCOPIC OBSERVATIONS:
No macroscopic entries are on file.

MICROSCOPIC OBSERVATIONS:

The following tissues were found to be within normal limits:
Adrenal; Aorta; Bone Marrow, Femur; Bone Marrow, Sternum; Bone, Femur; Bone, Sternum; Brain; Cecum; Colon; Duodenum; Esophagus; Eye; Eye, Optic Nerve; Heart; Ileum; Jejunum; Kidney; Lacrimal Gland; Larynx; Liver; Lung; Lymph Node, Mandibular; Lymph Node, Mesenteric; Mammary Gland; Nasal Tissues, Level 1; Nasal Tissues, Level 2; Nasal Tissues, Level 3; Nerve, Sciatic; Ovary; Oviduct; Pancreas; Parathyroid; Pharynx; Pituitary; Rectum;

SPECIES: Sprague Dawley Rat
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ANIMAL NUMBER: 264 SEX: Female GROUP: (2) Treated room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MICROSCOPIC OBSERVATIONS (continued):
The following tissues were found to be within normal limits (continued):
Salivary Gland; Skeletal Muscle; Skin; Skin, Eyelid; Spinal Cord, Cervical; Spinal Cord, Lumbar; Spinal Cord, Thorax; Spleen; Stomach; Thymus; Thyroid; Tongue; Trachea; Urinary Bladder; Uterus; Uterus, Cervix, Vagina.

ANIMAL NUMBER: 265 SEX: Female GROUP: (2) Treated room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MACROSCOPIC OBSERVATIONS:
No macroscopic entries are on file.

MICROSCOPIC OBSERVATIONS:

The following tissues were found to be within normal limits:
Adrenal; Aorta; Bone Marrow, Femur; Bone Marrow, Sternum; Bone, Femur; Bone, Sternum; Brain; Cecum; Colon; Duodenum; Esophagus; Eye; Eye, Optic Nerve; Heart; Ileum; Jejunum; Kidney; Lacrimal Gland; Larynx; Liver; Lung; Lymph Node, Mandibular; Lymph Node, Mesenteric; Mammary Gland; Nasal Tissues, Level 1; Nasal Tissues, Level 2; Nasal Tissues, Level 3; Nerve, Sciatic; Ovary; Oviduct; Pancreas; Parathyroid; Pharynx; Pituitary; Rectum; Salivary Gland; Skeletal Muscle; Skin; Skin, Eyelid; Spinal Cord, Cervical; Spinal Cord, Lumbar; Spinal Cord, Thorax; Spleen; Stomach; Thymus; Thyroid; Tongue; Trachea; Urinary Bladder; Uterus; Uterus, Cervix, Vagina.

ANIMAL NUMBER: 266 SEX: Female GROUP: (2) Treated room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MACROSCOPIC OBSERVATIONS:
No macroscopic entries are on file.

MICROSCOPIC OBSERVATIONS:

Adrenal	-Hemorrhage, mild
Kidney	-Chronic progressive nephropathy, mild
Uterus	-Dilatation

The following tissues were found to be within normal limits:
Aorta; Bone Marrow, Femur; Bone Marrow, Sternum; Bone, Femur; Bone, Sternum; Brain; Cecum; Colon; Duodenum; Esophagus; Eye; Eye, Optic Nerve; Heart; Ileum; Jejunum; Lacrimal Gland; Larynx; Liver; Lung; Lymph Node, Mesenteric; Mammary Gland; Nasal Tissues, Level 1; Nasal Tissues, Level 2; Nasal Tissues, Level 3; Nerve, Sciatic; Ovary; Oviduct; Pancreas; Parathyroid; Pharynx; Pituitary; Rectum; Salivary Gland; Skeletal Muscle; Skin; Skin, Eyelid;

SPECIES: Sprague Dawley Rat
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13-Week GLP Toxicity Study of the Boss Hydroxyl Odor Processor Air Cleansing Machine in Rats

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ANIMAL NUMBER: 266 SEX: Female GROUP: (2) Treated room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MICROSCOPIC OBSERVATIONS (continued):
The following tissues were found to be within normal limits (continued):
Spinal Cord, Cervical; Spinal Cord, Lumbar; Spinal Cord, Thorax; Spleen; Stomach; Thymus; Thyroid; Tongue; Trachea; Urinary Bladder; Uterus, Cervix, Vagina.

ANIMAL NUMBER: 267 SEX: Female GROUP: (2) Treated room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MACROSCOPIC OBSERVATIONS:
Kidney -Right kidney, white pea-sized mass.
MICROSCOPIC OBSERVATIONS:
Kidney -Carcinoma

The following tissues were found to be within normal limits:
Adrenal; Aorta; Bone Marrow, Femur; Bone Marrow, Sternum; Bone, Femur; Bone, Sternum; Brain; Cecum; Colon; Duodenum; Esophagus; Eye; Eye, Optic Nerve; Heart; Ileum; Jejunum; Lacrimal Gland; Larynx; Liver; Lung; Lymph Node, Mandibular; Lymph Node, Mesenteric; Mammary Gland; Nasal Tissues, Level 1; Nasal Tissues, Level 2; Nasal Tissues, Level 3; Nerve, Sciatic; Ovary; Oviduct; Pancreas; Pharynx; Pituitary; Rectum; Salivary Gland; Skeletal Muscle; Skin; Skin, Eyelid; Spinal Cord, Cervical; Spinal Cord, Lumbar; Spinal Cord, Thorax; Spleen; Stomach; Thymus; Thyroid; Tongue; Trachea; Urinary Bladder; Uterus; Uterus, Cervix, Vagina.

ANIMAL NUMBER: 268 SEX: Female GROUP: (2) Treated room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MACROSCOPIC OBSERVATIONS:
No macroscopic entries are on file.

MICROSCOPIC OBSERVATIONS:
Kidney -Chronic progressive nephropathy, mild

The following tissues were found to be within normal limits:
Adrenal; Aorta; Bone Marrow, Femur; Bone Marrow, Sternum; Bone, Femur; Bone, Sternum; Brain; Cecum; Colon; Duodenum; Esophagus; Eye; Eye, Optic Nerve; Heart; Ileum; Jejunum; Lacrimal Gland; Larynx; Liver; Lung; Lymph Node, Mandibular; Lymph Node, Mesenteric; Mammary Gland; Nasal Tissues, Level 1; Nasal Tissues, Level 2; Nasal Tissues, Level 3; Nerve, Sciatic; Ovary; Oviduct; Pancreas; Parathyroid; Pharynx; Pituitary; Rectum; Salivary Gland; Skeletal Muscle; Skin; Skin, Eyelid; Spinal Cord, Cervical; Spinal Cord, Lumbar; Spinal Cord, Thorax; Spleen; Stomach; Thymus; Thyroid; Tongue; Trachea; Urinary Bladder; Uterus; Uterus, Cervix, Vagina.

SPECIES: Sprague Dawley Rat
PROJECT NUMBER: CB10-5065-R-TX

Summarized Single Tabulated Animal Report (continued)
Individual Macroscopic and Microscopic Observations
HGI Industries, Inc.
13-Week GLP Toxicity Study of the Boss Hydroxyl Odor Processor Air Cleansing Machine in Rats

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ANIMAL NUMBER: 269 SEX: Female GROUP: (2) Treated room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MACROSCOPIC OBSERVATIONS:
No macroscopic entries are on file.

MICROSCOPIC OBSERVATIONS:

The following tissues were found to be within normal limits:
Adrenal; Aorta; Bone Marrow, Femur; Bone Marrow, Sternum; Bone, Femur; Bone, Sternum; Brain; Cecum; Colon; Duodenum; Esophagus; Eye; Eye, Optic Nerve; Heart; Ileum; Jejunum; Kidney; Lacrimal Gland; Larynx; Liver; Lung; Lymph Node, Mandibular; Lymph Node, Mesenteric; Mammary Gland; Nasal Tissues, Level 1; Nasal Tissues, Level 2; Nasal Tissues, Level 3; Nerve, Sciatic; Ovary; Oviduct; Pancreas; Parathyroid; Pharynx; Pituitary; Rectum; Salivary Gland; Skeletal Muscle; Skin; Skin, Eyelid; Spinal Cord, Cervical; Spinal Cord, Lumbar; Spinal Cord, Thorax; Spleen; Stomach; Thymus; Thyroid; Tongue; Trachea; Urinary Bladder; Uterus; Uterus, Cervix, Vagina.

ANIMAL NUMBER: 270 SEX: Female GROUP: (2) Treated room air
Fate: (Week= 13) Terminal sacrifice Printed on 08-26-2011.

MACROSCOPIC OBSERVATIONS:
No macroscopic entries are on file.

MICROSCOPIC OBSERVATIONS:

The following tissues were found to be within normal limits:
Adrenal; Aorta; Bone Marrow, Femur; Bone Marrow, Sternum; Bone, Femur; Bone, Sternum; Brain; Cecum; Colon; Duodenum; Esophagus; Eye; Eye, Optic Nerve; Heart; Ileum; Jejunum; Kidney; Lacrimal Gland; Larynx; Liver; Lung; Lymph Node, Mandibular; Lymph Node, Mesenteric; Mammary Gland; Nasal Tissues, Level 1; Nasal Tissues, Level 2; Nasal Tissues, Level 3; Ovary; Oviduct; Pancreas; Parathyroid; Pharynx; Pituitary; Rectum; Salivary Gland; Skeletal Muscle; Skin; Skin, Eyelid; Spinal Cord, Cervical; Spinal Cord, Lumbar; Spinal Cord, Thorax; Spleen; Stomach; Thymus; Thyroid; Tongue; Trachea; Urinary Bladder; Uterus; Uterus, Cervix, Vagina.

SPECIES: Sprague Dawley Rat
PROJECT NUMBER: CB10-5065-R-TX