GLP REPORT

TEST FACILITY

NAMSA
6750 Wales Road
Northwood, OH 43619
419.666.9455

SPONSOR

Michel van Schaik
Aquaox Industries, Inc.
16155 Sierra Lakes Pkwy
Suite 160-714
Fontana, CA 92336

CONFIDENTIAL

STUDY TITLE

ISO Ocular Irritation Study in Rabbits

TEST ARTICLE NAME

AX250

TEST ARTICLE IDENTIFICATION

Lot AX-13065-0210

TABLE OF CONTENTS Page

Summary

The test article, AX250, was evaluated for the potential to produce ocular irritation in rabbits based on the requirements of ISO 10993-10, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.

A single 0.1 mL dose of the test article was placed in the right eyes of three male New Zealand White rabbits. The left eyes remained untreated and served as the control condition. Ocular reactions based on a modified Draize classification were evaluated immediately postdose and at 1, 24, 48, and 72 hours after dosing.

There was no irritation or other ocular effects on the cornea, iris, or conjunctiva observed in the treated eyes as compared to the untreated control eyes. The test article was not considered an irritant to the ocular tissue of the rabbit.

Supervisory Personnel:

Lisa A. Severhof, BA
Manager, Toxicology

Colleen M. Stevenson, AA
Supervisor, Toxicology

Study Director Approval:

Laura R. Ott
Laura R. Ott, BS, LAT
Medical Research Manager

13 May 2013
Date Completed

Authorization for duplication of this report, except in whole, is reserved pending NAMSA's written approval.

Statement of GLP Compliance

There were no deviations to the provisions of the FDA Good Laboratory Practice (GLP) Regulations (21 CFR, Part 58) noted during the course of the study.

Study Director: Laura R. Ott — 13 May 2013

Laura R. Ott, BS, LAT — Date

1. Introduction

Purpose
The purpose of this study was to evaluate the potential for the test article to produce ocular irritation following a single instillation in the rabbit eye.

Testing Guidelines
This study was conducted based on the International Organization for Standardization 10993-10, Biological evaluation of medical devices, Part 10: Tests for irritation and skin sensitization.

Dates
Test Article Received: March 14, 2013
Treatment Started: March 25, 2013
Observations Concluded: March 28, 2013

GLP Compliance
The study initiated by protocol signature on March 15, 2013 was conducted in accordance with the provisions of the FDA Good Laboratory Practice (GLP) Regulations, 21 CFR 58. A Statement of Quality Assurance Activities was issued with this report.

Duplication of Experimental Work
By signature on the protocol, the sponsor confirmed that the conduct of this study did not unnecessarily duplicate previous experiments.

2. Materials

The test article provided by the sponsor was identified and handled as follows:

Test Article Name:	AX250
Identification**:**	Lot AX-13065-0210
Certificate of Analysis:	See Appendix 3.
Stability Testing:	The results from both accelerated stability (i.e., 40°C±2°C/75%RH±5%RH) and real time room temperature stability (i.e., 25°C±2°/60%RH±5%RH) programs have demonstrated that the product (AX250) is stable for the duration of the study (per sponsor). See Appendix 4.
Expiration Date:	Additional long term stability testing is in progress (per sponsor).
Strength, Purity and Composition:	Strength: 250 ppm hypochlorous acid; Purity: 100% hypochlorous acid; Composition: Purified water (99.9249%), sodium chloride (0.0500%), hypochlorous acid (0.0240%), hypochlorite ion (0.0010%), and blended phosphate (0.0001%)
Physical Description of the Test Article:	aqueous solution, clear and colorless, slightly chlorinated
Storage Conditions:	Room Temperature
Preparation:	The test article was dosed as received (100% concentration).
pH:	6.22 (per Certificate of Analysis)

3. Test System

Test System

Species:	Rabbit (*Oryctolagus cuniculus*)
Breed:	New Zealand White
Source:	Robinson Services, Inc.
Sex:	Male (naïve)
Body Weight Range:	2.3 kg to 2.4 kg at treatment
Age:	Young adult
Acclimation Period:	Minimum 5 days
Number of Animals:	Three
Identification Method:	Ear tag

Justification of Test System

The ocular tissue of the rabbit (animal) has traditionally been used to predict irritant properties of articles having potential contact with mucosal or ocular tissues during manufacture or use. Because of the lack of pigmentation in the eye, lack of excessive tearing, and ease of handling, the albino rabbit has historically been used for this purpose.

4. Animal Management

Husbandry:	Conditions conformed to NAMSA Standard Operating Procedures that are based on the "*Guide for the Care and Use of Laboratory Animals*."
Food:	A commercially available rabbit feed, PROLAB Hi-Fiber Rabbit - 5P25, was provided daily. A copy of the annual feed analysis report was saved in the study file.
Water:	Potable water was provided *ad libitum* through species appropriate water containers or delivered through an automatic watering system. A copy of the most recent water analysis report was saved in the study file.
Contaminants:	Contaminants reasonably expected in feed or water supplies were not believed to have influenced the outcome of this test.
Housing:	Animals were individually housed in stainless steel or plastic suspended cages identified by a card indicating the lab number, animal number, test code, sex, and date dosed.
Environment:	The animal housing room temperature and relative humidity were monitored daily. The temperature for the room was set to 61-72°F and the relative humidity was set to 30-70%. There were no significant temperature or relative humidity excursions that adversely affected the health of the animals. The light cycle was controlled using an automatic timer (12 hours light, 12 hours dark).
Accreditation:	NAMSA is an AAALAC International accredited facility and is registered with the United States Department of Agriculture. Additionally, NAMSA maintains an approved Animal Welfare Assurance on file with the National Institutes of Health, Office for Laboratory Animal Welfare.
Personnel:	Associates involved were appropriately qualified and trained.
Veterinary Care:	Standard veterinary medical care was provided in this study.
IACUC:	This procedure has been approved by the NAMSA Institutional Animal Care and Use Committee (IACUC), and is reviewed at least annually by the same committee.
Selection:	Only healthy, previously unused animals without significant ocular irritation were selected.

5. Method

Prior to test article instillation, the animals were weighed. All test and control eyes were judged clinically normal by gross examination with an auxiliary light source. To detect any pre-existing corneal injury, the eyes were treated with fluorescein stain, flushed with 0.9% sodium chloride USP solution, and observed with ultraviolet light in a darkened room.

Dosing Procedure

A 0.1 mL dose of the test article was instilled into the lower conjunctival sac of the right eye of each animal and the lid was gently held closed for 1 second. The opposite eye remained untreated and served as the comparative control. The animals were returned to their cages following treatment.

Laboratory Observations
Immediately postdose and at approximately 1, 24, 48, and 72 hours after dosing, the test eye of each animal was examined with an auxiliary light source and appropriate magnification, compared to the untreated control eye, and graded for ocular irritation using a modified Draize scale. Reactions were scored in accordance with the criteria in Appendix 1. At 24 hours, the eyes were treated with fluorescein stain, flushed with 0.9% sodium chloride USP solution, and examined in darkened conditions with an ultraviolet lamp to detect or confirm corneal injury.

All ocular examination times reported herein are approximate and are within ranges established by the external standards described in the References section of this report and/or NAMSA standard operating procedures.

6. Evaluation

No statistical analysis of the data was performed. If the test eye in more than one animal showed a positive irritant response (asterisked grades in Appendix 1), the test article was considered an ocular irritant. A severe reaction in only one animal was considered to be sufficient evidence to label the test article as an ocular irritant.

7. Results

All animals appeared clinically normal throughout the study. Individual results of the ocular scoring appear in Appendix 2. No irritation was observed in the treated eye as compared to the untreated control eye of the animal.

8. Conclusion

The test article was not considered an irritant to the ocular tissue of the rabbit.

Results and conclusions apply only to the test article tested. Any extrapolation of these data to other articles is the sponsor's responsibility.

9. Quality Assurance

Inspections were conducted at intervals adequate to assure the integrity of the study in conformance with 21 CFR 58.35(b)(3). The final report was reviewed for conformance to Section 58.185, Subpart J, of the GLP Regulations. A Statement of Quality Assurance Activities was issued with the report.

10. Records

All raw data pertaining to this study and a copy of the final report are retained in designated NAMSA archive files.

11. ISO Compliance

All procedures were certified to ISO 13485:2003.

12. References

Code of Federal Regulations (CFR), Title 9, Parts 1-4, Animal Welfare Act.

Code of Federal Regulations (CFR), Title 16, Part 1500, Federal Hazardous Substances Act (FHSA) Regulations.

Code of Federal Regulations (CFR), Title 21, Part 58, Good Laboratory Practice for Nonclinical Laboratory Studies.

International Organization for Standardization (ISO) 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (2009).

International Organization for Standardization (ISO) 10993-2, Biological evaluation of medical devices - Part 2: Animal welfare requirements (2006).

International Organization for Standardization (ISO) 10993-10, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization (2010).

International Organization for Standardization (ISO) 10993-12, Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (2012).

International Organization for Standardization (ISO) 13485, Medical devices - Quality management systems - Requirements for regulatory purposes (2003).

National Research Council, *Guide for the Care and Use of Laboratory Animals*, Washington, DC: National Academy Press, 2011.

Office of Laboratory Animal Welfare (OLAW), Public Health Service Policy on Humane Care and Use of Laboratory Animals.

Appendix 1 - Classification System For Grading Ocular Lesions

Reaction		Numerical Grading
1. Cornea	Degree of opacity (most dense area used)	
	No opacity	0
	Scattered or diffuse area, details of iris clearly visible	1*
	Easily discernible translucent areas, details of iris slightly obscured	2*
	Opalescent areas, no details of iris visible, size of pupil barely discernible	3*
	Opaque, iris invisible	4*
	Area of Cornea Involved	
	One-quarter (or less), but not zero	1
	Greater than one-quarter, but less than half	2
	Greater than half, but less than three-quarters	3
	Greater than three-quarters, up to whole area	4
2. Iris	Normal	0
	Folds above normal, congestion swelling, circumcorneal injection (or any or all or combination of these), iris still reacting to light (sluggish reaction is positive)	1*
	No reaction to light, hemorrhage, gross destruction (any or all of these)	2*
3. Conjunctivae	Redness (refers to palpebral and bulbar conjunctiva excluding cornea and iris)	
	Vessels normal	0
	Vessels definitely injected above normal	1
	More diffuse, deeper crimson red, individual vessels not easily discernible	2*
	Diffuse beefy red	3*
	Chemosis	
	No swelling	0
	Any swelling above normal (include nictitating membrane)	1
	Obvious swelling with partial eversion of lids	2*
	Swelling with lids about half-closed	3*
	Swelling with lids about half-closed to completely closed	4*
	Discharge	
	No discharge	0
	Any amount different from normal (does not include small amounts observed in inner canthus of normal animals)	1
	Discharge with moistening of the lids and hairs just adjacent to lids	2
	Discharge with moistening of lids and hairs, and considerable area around the eye	3
*positive result		

Appendix 2 - ISO Ocular Irritation Scores

Animal Number	Sex	Body Weight (kg)	Items Scored	Immediately Postdose		1 hour		24 hours		48 hours		72 hours	
				T	C	T	C	T	C	T	C	T	C
90144	Male	2.4	Cornea - Opacity	0	0	0	0	0	0	0	0	0	0
			Cornea - Area	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
			Iris	0	0	0	0	0	0	0	0	0	0
			Redness*	0	0	0	0	0	0	0	0	0	0
			Chemosis*	0	0	0	0	0	0	0	0	0	0
			Discharge*	0	0	0	0	0	0	0	0	0	0
			Fluorescein Exam	NA	NA	NA	NA	(-)	(-)	NA	NA	NA	NA
90145	Male	2.4	Cornea - Opacity	0	0	0	0	0	0	0	0	0	0
			Cornea - Area	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
			Iris	0	0	0	0	0	0	0	0	0	0
			Redness*	0	0	0	0	0	0	0	0	0	0
			Chemosis*	0	0	0	0	0	0	0	0	0	0
			Discharge*	0	0	0	0	0	0	0	0	0	0
			Fluorescein Exam	NA	NA	NA	NA	(-)	(-)	NA	NA	NA	NA
90147	Male	2.3	Cornea - Opacity	0	0	0	0	0	0	0	0	0	0
			Cornea - Area	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
			Iris	0	0	0	0	0	0	0	0	0	0
			Redness*	0	0	0	0	0	0	0	0	0	0
			Chemosis*	0	0	0	0	0	0	0	0	0	0
			Discharge*	0	0	0	0	0	0	0	0	0	0
			Fluorescein Exam	NA	NA	NA	NA	(-)	(-)	NA	NA	NA	NA

* = Conjunctival tissues
T = Test
C = Control
(-) = Negative
NA = Not applicable

AQUAOX INDUSTRIES INC
16155, Sierra Lakes Parkway,
Suite 160-714, Fontana,
CA 92336, USA.

Certificate of Analysis

Date of Manufacture: 03/06/2013
Product Name: AX250
Batch / Lot #: AX-13065-0210
Production Facility: Innovacyn, Inc.
3546 N. Riverside Ave. Rialto, CA 92377
Testing Facility: Innovacyn, Inc.
3546 N. Riverside Ave. Rialto, CA 92377

TEST	ANALYSIS	UNITS
FAC	233	ppm
pH	6.22	n/a
ORP	964	mV
Osmolarity	17	mOsm/kg

This certification states that the product AX250, bearing the above description and lot number, has been found to conform to the internal specifications established for this product. The above lot was made in accordance with our internal specifications and good manufacturing practices under controlled procedures.

This lot has been appropriately inspected and tested, and, to the best of our knowledge, conforms to all applicable test methods, standards and internal specifications.

This certification does not constitute any written or expressed warranty or guarantee of any kind.

Rebecca Lei _____ Date: 3/12/13
QA Regulatory Specialist

SR: EH 102-207960
(909)-829-1664
(888)-592-7844
www.aquaox.net
info@aquaox.net

EIN: 45-4763694
BANK: Comerica Bank
A/C: 1894563426
ABA: 121137522
EPA #: 085021-CA-001

Issued: March 21, 2013
Last Revised: April 24, 2013

FORM-COA-02

AQUAOX INDUSTRIES INC
16155, Sierra Lakes Parkway,
Suite 160-714,
Fontana. CA 92336. USA.

Certificate of Analysis

Date of Manufacture:	03 / 06 / 2013
Product Name:	AX250
Batch / Lot #:	AX-13065-0210
Production Facility:	Innovacyn, Inc. 3546 N. Riverside Ave. Rialto, CA 92377
Testing Facility:	Innovacyn, Inc. 3546 N. Riverside Ave. Rialto, CA 92377

TEST	ANALYSIS	UNITS
FAC	218	ppm
pH	6.00	n/a
Conductivity	1230	µS/cm
ORP	957	mV
Osmolality	21	mOsm/kg

This certification states that the intermediate product AX250, bearing the above description and lot number, has been found to conform to the internal specifications established for this product. The above lot was made in accordance with our internal specifications and current good manufacturing practices under controlled procedures.

This lot has been appropriately inspected and tested, and, to the best of our knowledge, conforms to all applicable test methods, standards and internal specifications.

This certification does not constitute any written or expressed warranty or guarantee of any kind.

Rebecca Lei _____ Date: 4/24/13

QA Regulatory Specialist

© Aquaox Industries Inc

Statement of Quality Assurance Activities

Phase Inspected	Date Inspected	Date Reported to Study Director	Date Reported to Management
Score	March 25, 2013	March 25, 2013	March 25, 2013
Study Data Review	March 29, 2013	March 29, 2013	March 29, 2013
Final Report Review	April 9, 2013	April 9, 2013	April 9, 2013
Final Report Review	May 9, 2013	May 9, 2013	May 9, 2013

Based on a review of this study, it has been concluded that this report accurately describes the methods and standard operating procedures, and that the reported results accurately reflect the raw data of the study. This study has been reviewed in accordance with the provisions of the FDA Good Laboratory Practice Regulations (21 CFR, Part 58).

QA Representative: Marie Glodowski 5-9-13

Marie A. Glodowski, BS
Auditor, Quality Assurance

Date

GLP REPORT

TEST FACILITY

NAMSA
6750 Wales Road
Northwood, OH 43619
419.666.9455

SPONSOR

Michel van Schaik
Aquaox Industries, Inc.
16155 Sierra Lakes Pkwy
Suite 160-714
Fontana, CA 92336

CONFIDENTIAL

STUDY TITLE

Modified ISO Skin Irritation Study in Rabbits

TEST ARTICLE NAME

AX250

TEST ARTICLE IDENTIFICATION

Lot AX-13065-0210

TABLE OF CONTENTS Page

Summary

The test article, AX250, was evaluated for primary skin irritation in accordance with the guidelines of ISO 10993-10, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization. Two 0.5 mL portions of the test article and control article were topically applied to the skin intact or abraded of each of three rabbits and left in place under occluded conditions for a minimum of 23 and a maximum of 24 hours. The sites were graded for erythema and edema prior to dose and at 1, 24, 48 and 72 hours after removal of the single sample application.

There was no erythema and no edema observed on the intact or abraded skin of the animals treated with the test or control articles. The Primary Irritation Index for the test article was calculated to be 0.0. The response of the test article was categorized as negligible.

Supervisory Personnel:

Lisa A. Severhof, BA
Manager, Toxicology

Colleen M. Stevenson, AA
Supervisor, Toxicology

Study Director Approval:

Laura R. Ott

Laura R. Ott, BS, LAT
Medical Research Manager

13 May 2013
Date Completed

Authorization for duplication of this report, except in whole, is reserved pending NAMSA's written approval.

Statement of GLP Compliance

There were no deviations to the provisions of the FDA Good Laboratory Practice (GLP) Regulations (21 CFR, Part 58) noted during the course of the study.

Study Director: Laura R. Ott — 13 May 2013

Laura R. Ott, BS, LAT — Date

1. Introduction

Purpose
The purpose of this study was to evaluate the test article for the potential to cause skin irritation in the rabbit.

Testing Guidelines
This study was conducted based on the International Organization for Standardization 10993-10, Biological evaluation of medical devices, Part 10: Tests for irritation and skin sensitization.

Dates
Test Article Received: March 14, 2013
Treatment Started: March 20, 2013
Observations Concluded: March 24, 2013

GLP Compliance
The study initiated by protocol signature on March 15, 2013 was conducted in accordance with the provisions of the FDA Good Laboratory Practice (GLP) Regulations, 21 CFR 58. A Statement of Quality Assurance Activities was issued with this report.

Duplication of Experimental Work
By signature on the protocol, the sponsor confirmed that the conduct of this study did not unnecessarily duplicate previous experiments.

2. Materials

The test article provided by the sponsor was identified and handled as follows:

Test Article Name:	AX250
Identification**:**	Lot AX-13065-0210
Certificate of Analysis:	See Appendix 3.
Stability Testing:	The results from both accelerated stability (i.e., 40°C±2°C/75%RH±5%RH) and real time room temperature stability (i.e., 25°C±2°/60%RH±5%RH) programs have demonstrated that the product (AX250) was stable for the duration of the study (per sponsor). See Appendix 4.
Expiration Date:	Additional long term stability testing is in progress (per sponsor).
Strength, Purity and Composition:	Strength: 250 ppm hypochlorous acid; Purity: 100% hypochlorous acid; Composition: Purified water (99.9249%), sodium chloride (0.0500%), hypochlorous acid (0.0240%), hypochlorite ion (0.0010%), and blended phosphate (0.0001%)
Physical Description of the Test Article:	aqueous solution, clear and colorless, slightly chlorinated
Storage Conditions:	Room Temperature
Control Article:	0.9% Sodium Chloride, USP (Baxter Healthcare)
Stability Testing:	Marketed product, stability characterized by its labeling
Expiration Date:	September 2013
Strength, Purity, Composition or Other Characteristics:	Purity: FDA Quality System Requirements (QSR) as stipulated in 21 CFR Part 820; Composition: 20% rayon, 80% polyester blend
Storage Conditions:	Room Temperature
Preparation:	Samples were prepared by placing a 0.5 mL aliquot of the test or control article onto a four-ply gauze pad (25 mm x 25 mm, VWR International, LLC).

3. Test System

Test System

Species:	Rabbit (*Oryctolagus cuniculus*)
Breed:	New Zealand White
Source:	Robinson Services, Inc.
Sex:	Male (naïve)
Body Weight:	2.2 kg at selection
Age:	12 weeks at selection
Acclimation Period:	Minimum 5 days
Number of Animals:	Three
Identification Method:	Ear tag

Justification of Test System

The rabbit is specified as an appropriate animal model for evaluating potential skin irritants by the current ANSI/AAMI/ISO testing standards. The rabbit is widely used for this purpose and relative ranking of irritant scores can be determined.

4. Animal Management

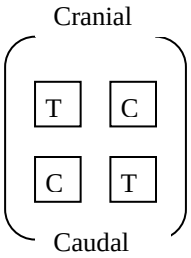
Husbandry:	Conditions conformed to NAMSA Standard Operating Procedures that are based on the "*Guide for the Care and Use of Laboratory Animals*."
Food:	A commercially available rabbit feed, PROLAB Hi-Fiber Rabbit - 5P25, was provided daily. A copy of the annual feed analysis report was saved in the study file.
Water:	Potable water was provided *ad libitum* through species appropriate water containers or delivered through an automatic watering system. A copy of the most recent water analysis report was saved in the study file.
Contaminants:	Contaminants reasonably expected in feed or water supplies were not believed to have influenced the outcome of this test.
Housing:	Animals were individually housed in stainless steel or plastic suspended cages identified by a card indicating the lab number, animal number, test code, sex, and date dosed.
Environment:	The animal housing room temperature and relative humidity were monitored daily. The temperature for the room was set to 61-72°F and the relative humidity was set to 30-70%. There were no significant temperature or relative humidity excursions that adversely affected the health of the animals. The light cycle was controlled using an automatic timer (12 hours light, 12 hours dark).
Accreditation:	NAMSA is an AAALAC International accredited facility and is registered with the United States Department of Agriculture. Additionally, NAMSA maintains an approved Animal Welfare Assurance on file with the National Institutes of Health, Office for Laboratory Animal Welfare.
Personnel:	Associates involved were appropriately qualified and trained.
Veterinary Care:	Standard veterinary medical care was provided in this study.
IACUC:	This procedure has been approved by the NAMSA Institutional Animal Care and Use Committee (IACUC), and is reviewed at least annually by the same committee.
Selection:	Only healthy, previously unused, animals free from irritation or other dermatological lesions that could interfere with the test were selected.

5. Method

The animals were weighed and the fur on the back of each animal was clipped with an electric clipper at least 19 hours prior to treatment. On the day of treatment, four sites, two on each side of the back and positioned cranially and caudally, were designated on each animal. The sites were free of blemishes that could interfere with the interpretation of results. Just prior to test article application, the sites on the right side of the back were abraded. Each rabbit received four, parallel epidermal abrasions with a sterile needle. The sites on the left side of the back remained intact.

A 0.5 mL portion of the test article was applied to one cranial site and one caudal site (two sites per animal) by introduction under a 4 ply gauze layer to an area of skin approximately 25 mm x 25 mm square. The patches were backed with polyethylene plastic and covered with a nonreactive tape. The control was moistened with 0.5 mL of saline and similarly applied to the

opposite cranial and caudal sites. The test (T) and control (C) articles were topically applied as indicated in the diagram below. The trunk of each animal was wrapped with an elastic binder to maintain the test patches in position. Animals were returned to their cages after treatment.



After a minimum of 23 and a maximum of 24 hour exposure, the binders, tape, and patches were removed. The perimeter of each site was marked with nontoxic ink. The sites were gently wiped with a gauze sponge dampened with deionized water in an attempt to remove any remaining residue.

Laboratory Observations

1. Animals were observed daily for general health.
2. Body weights were recorded for each animal at pretreatment.
3. Dermal observations for erythema and edema were recorded prior to dose and at 1, 24, 48 and 72 hours after patch removal in accordance with the criteria in Appendix 1.

All dermal observation times reported herein are approximate and are within ranges established by the external standards described in the References section of this report and/or NAMSA standard operating procedures.

6. Evaluation and Statistical Analysis

The Primary Irritation Index of the test was calculated following test completion for each animal. The erythema and edema scores obtained at the 24, 48 and 72 hour intervals were added together and divided by the total number of observations. The prior to dose and 1 hour post dose scores were not included in the calculation. This calculation was conducted separately for the test and control article for each animal. The score for the control was subtracted from the score for the test article to obtain the Primary Irritation Score. The Primary Irritation Score for each animal was added together and divided by the number of animals to obtain the Primary Irritation Index. The Primary Irritation Index was characterized based on the definitions outlined in Appendix 1.

7. Results

All animals were clinically normal throughout the study. Individual results of dermal scoring appear in Appendix 2. No irritation was observed on the skin of the animals. The Primary Irritation Index of the test article was calculated to be 0.0. The irritation calculations are shown below:

Animal Number	Test Score Average	-	Control Score Average	Individual Primary Irritation Score	Combined Primary Irritation Score (CPIS)	Primary Irritation Index (CPIS ÷ 3)	Response Category
90128	0.0	-	0.0	0.0	0.0	0.0	Negligible
90046	0.0	-	0.0	0.0			
90049	0.0	-	0.0	0.0			

8. Conclusion

There was no erythema and no edema observed on the intact or abraded skin of the animals treated with the test or control articles. The Primary Irritation Index for the test article was calculated to be 0.0. The response of the test article was categorized as negligible.

Results and conclusions apply only to the test article tested. Any extrapolation of these data to other articles is the sponsor's responsibility.

9. Quality Assurance

Inspections were conducted at intervals adequate to assure the integrity of the study in conformance with 21 CFR 58.35(b)(3). The final report was reviewed for conformance to Section 58.185, Subpart J, of the GLP Regulations. A Statement of Quality Assurance Activities was issued with the report.

10. Records

All raw data pertaining to this study and a copy of the final report are retained in designated NAMSA archive files.

11. ISO Compliance

All procedures were certified to ISO 13485:2003 and accredited to ISO 17025:2005.

12. References

Code of Federal Regulations (CFR), Title 9, Parts 1-4, Animal Welfare Act.

Code of Federal Regulations (CFR), Title 16, Part 1500, Federal Hazardous Substances Act (FHSA) Regulations (2008).

Code of Federal Regulations (CFR), Title 21, Part 58, Good Laboratory Practice for Nonclinical Laboratory Studies.

International Organization for Standardization (ISO) 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (2009).

International Organization for Standardization (ISO) 10993-2, Biological evaluation of medical devices - Part 2: Animal welfare requirements (2006).

International Organization for Standardization (ISO) 10993-10, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization (2010).

International Organization for Standardization (ISO) 10993-12, Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (2012).

International Organization for Standardization (ISO) 13485, Medical devices - Quality management systems - Requirements for regulatory purposes (2003).

International Organization for Standardization (ISO) 17025, General requirements for the competence of testing and calibration laboratories (2005).

National Research Council, *Guide for the Care and Use of Laboratory Animals*, Washington, DC: National Academy Press, 2011.

Office of Laboratory Animal Welfare (OLAW), Public Health Service Policy on Humane Care and Use of Laboratory Animals.

Appendix 1 - Classification System For Skin Reaction

Reaction	Numerical Grading
Erythema and Eschar Formation	
No erythema	0
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate erythema	3
Severe erythema (beet redness) to eschar formation preventing grading of erythema	4
Edema Formation	
No edema	0
Very slight edema (barely perceptible)	1
Well-defined edema (edges of area well-defined by definite raising)	2
Moderate edema (raised approximately 1 mm)	3
Severe edema (raised more than 1 mm and extending beyond exposure area)	4
Total possible score for irritation	8

NOTE: Other adverse changes at the skin sites shall be recorded and reported

Irritation Response Categories in the Rabbit

Response Category	Mean Score
Negligible	0.0 to 0.4
Slight	0.5 to 1.9
Moderate	2.0 to 4.9
Severe	5.0 to 8.0

Appendix 2 - Dermal Observations

Animal Number/ Sex	Weight (kg)	Group	Observation	Interval (hours)									
				Predose		1		24		48		72	
				IN	AB	IN	AB	IN	AB	IN	AB	IN	AB
90128 Male	2.2	Test	Erythema	0	0	0	0	0	0	0	0	0	0
			Edema	0	0	0	0	0	0	0	0	0	0
		Control	Erythema	0	0	0	0	0	0	0	0	0	0
			Edema	0	0	0	0	0	0	0	0	0	0
90046 Male	2.2	Test	Erythema	0	0	0	0	0	0	0	0	0	0
			Edema	0	0	0	0	0	0	0	0	0	0
		Control	Erythema	0	0	0	0	0	0	0	0	0	0
			Edema	0	0	0	0	0	0	0	0	0	0
90049 Male	2.2	Test	Erythema	0	0	0	0	0	0	0	0	0	0
			Edema	0	0	0	0	0	0	0	0	0	0
		Control	Erythema	0	0	0	0	0	0	0	0	0	0
			Edema	0	0	0	0	0	0	0	0	0	0

IN = Intact
AB = Abraded

AQUAOX INDUSTRIES INC
16155, Sierra Lakes Parkway,
Suite 160-714, Fontana,
CA 92336, USA.

Certificate of Analysis

Date of Manufacture: 03/06/2013
Product Name: AX250
Batch / Lot #: AX-13065-0210
Production Facility: Innovacyn, Inc.
3546 N. Riverside Ave. Rialto, CA 92377
Testing Facility: Innovacyn, Inc.
3546 N. Riverside Ave. Rialto, CA 92377

TEST	ANALYSIS	UNITS
FAC	233	ppm
pH	6.22	n/a
ORP	964	mV
Osmolarity	17	mOsm/kg

This certification states that the product AX250, bearing the above description and lot number, has been found to conform to the internal specifications established for this product. The above lot was made in accordance with our internal specifications and good manufacturing practices under controlled procedures.

This lot has been appropriately inspected and tested, and, to the best of our knowledge, conforms to all applicable test methods, standards and internal specifications.

This certification does not constitute any written or expressed warranty or guarantee of any kind.

Rebecca Lei _____ Date: 3/12/13
QA Regulatory Specialist

SR: EH 102-207960
(909)-829-1664
(888)-592-7844
www.aquaox.net
info@aquaox.net

EIN: 45-4763694
BANK: Comerica Bank
A/C: 1894563426
ABA: 121137522
EPA #: 085021-CA-001

Issued: March 21, 2013
Last Revised: April 24, 2013

FORM-COA-02

AQUAOX INDUSTRIES INC
16155, Sierra Lakes Parkway,
Suite 160-714,
Fontana. CA 92336. USA.

Certificate of Analysis

Date of Manufacture:	03 / 06 / 2013
Product Name:	AX250
Batch / Lot #:	AX-13065-0210
Production Facility:	Innovacyn, Inc. 3546 N. Riverside Ave. Rialto, CA 92377
Testing Facility:	Innovacyn, Inc. 3546 N. Riverside Ave. Rialto, CA 92377

TEST	ANALYSIS	UNITS
FAC	218	ppm
pH	6.00	n/a
Conductivity	1230	µS/cm
ORP	957	mV
Osmolality	21	mOsm/kg

This certification states that the intermediate product AX250, bearing the above description and lot number, has been found to conform to the internal specifications established for this product. The above lot was made in accordance with our internal specifications and current good manufacturing practices under controlled procedures.

This lot has been appropriately inspected and tested, and, to the best of our knowledge, conforms to all applicable test methods, standards and internal specifications.

This certification does not constitute any written or expressed warranty or guarantee of any kind.

Rebecca Lei _____ Date: 4/24/13

QA Regulatory Specialist

© Aquaox Industries Inc

Statement of Quality Assurance Activities

Phase Inspected	Date Inspected	Date Reported to Study Director	Date Reported to Management
Scoring	March 22, 2013	March 22, 2013	March 22, 2013
Study Data Review	March 28, 2013	March 28, 2013	March 28, 2013
Final Report Review	April 9, 2013	April 9, 2013	April 9, 2013
Final Report Review	May 9, 2013	May 9, 2013	May 9, 2013

Based on a review of this study, it has been concluded that this report accurately describes the methods and standard operating procedures, and that the reported results accurately reflect the raw data of the study. This study has been reviewed in accordance with the provisions of the FDA Good Laboratory Practice Regulations (21 CFR, Part 58).

QA Representative: Heather Baugher 5-9-13

Heather L. Baugher, BS
Auditor, Quality Assurance

Date

GLP REPORT

TEST FACILITY

NAMSA
6750 Wales Road
Northwood, OH 43619
419.666.9455

SPONSOR

Michel van Schaik
Aquaox Industries, Inc.
16155 Sierra Lakes Pkwy
Suite 160-714
Fontana, CA 92336

CONFIDENTIAL

STUDY TITLE

FHSA Oral Toxicity Study in Rats, 14 Day

TEST ARTICLE NAME

AX250

TEST ARTICLE IDENTIFICATION

Lot AX-13065-0210

TABLE OF CONTENTS Page

Summary

The test article, AX250, was evaluated for oral toxicity in accordance with the guidelines of the Code of Federal Regulations (CFR), Title 16, Part 1500, Federal Hazardous Substances Act (FHSA) Regulations. A single oral dose of 20 mL/kg body weight of AX250, the maximum feasible dose, was administered by gavage to fasted Sprague Dawley rats (5 male and 5 female). The animals were then observed for up to 14 days for any signs of toxicity.

Oral (gavage) administration of a single dose of AX250 to fasted 8 week old male and female Sprague Dawley rats did not produce mortality or clinical signs of toxicity at the maximal feasible dose of 20 mL/kg. Therefore, AX250 was considered to be nontoxic at an oral dose of 20 mL/kg in the rat.

Based on the results, the LD50 for AX250 was considered to be greater than 20 mL/kg for 8 week old male and female Sprague Dawley rats. The active ingredient hypochlorous acid (HOCl) comprises 0.0240% of the total AX250 formulation. Therefore, 0.024 g/100 mL of HOCl in 20 mL/kg of AX250 results in 0.0048 g or 4.8 mg per kg body weight. This results in a LD50 of greater than 4.8 mg/kg for the active ingredient HOCl.

Supervisory Personnel:

Colleen M. Stevenson, AA
Supervisor, Toxicology

C. Tyler Long, DVM, DACLAM
Veterinarian

Study Director Approval:

Laura R. Ott
Laura R. Ott, BS, LAT
Medical Research Manager

13 May 2013
Date Completed

Authorization for duplication of this report, except in whole, is reserved pending NAMSA's written approval.

Statement of GLP Compliance

There were no deviations to the provisions of the FDA Good Laboratory Practice (GLP) Regulations (21 CFR, Part 58) noted during the course of the study.

Study Director: Laura R. Ott
Laura R. Ott, BS, LAT

13 May 2013
Date

1. Introduction

Purpose
The purpose of this study was to determine the potential for the test article to cause systemic toxicity following a single dose in the rat.

Testing Guidelines
This study was conducted based on the Code of Federal Regulations (CFR), Title 16, Part 1500, Federal Hazardous Substances Act (FHSA) Regulations.

Dates
Test Article Received: March 14, 2013
Dosed: March 19, 2013
Observations Concluded: April 2, 2013

GLP Compliance
The study initiated by protocol signature on March 15, 2013 was conducted in accordance with the provisions of the FDA Good Laboratory Practice (GLP) Regulations, 21 CFR 58. A Statement of Quality Assurance Activities was issued with this report.

Duplication of Experimental Work
By signature on the protocol, the sponsor confirmed that the conduct of this study did not unnecessarily duplicate previous experiments.

2. Materials

The test article provided by the sponsor was identified and handled as follows:

Test Article Name:	AX250
Identification**:**	Lot AX-13065-0210
Certificate of Analysis:	See Appendix 2.
Stability Testing:	The results from both accelerated stability (i.e., 40°C±2°C/75%RH±5%RH) and real time room temperature stability (i.e., 25°C±2°/60%RH±5%RH) programs have demonstrated that the product (AX250) was stable for the duration of the study (per sponsor). See Appendix 3.
Expiration Date:	Additional long term stability testing is in progress (per sponsor).
Strength, Purity and Composition:	Strength: 250 ppm hypochlorous acid; Purity: 100% hypochlorous acid; Composition: Purified water (99.9249%), sodium chloride (0.0500%), hypochlorous acid (0.0240%), hypochlorite ion (0.0010%), and blended phosphate (0.0001%)
Physical Description of the Test Article:	aqueous solution, clear and colorless, slightly chlorinated
Storage Conditions:	Room Temperature
Preparation:	The test article was dosed as received (100% concentration). For this study, the density of the test article was 1 g /mL (per sponsor).
pH:	6.22 (per Certificate of Analysis)

3. Test System

Test System

Species:	Rat (*Rattus norvegicus*)
Strain:	Hla®:(SD)CVF®
Source:	Hilltop Lab Animals, Inc.
Sex:	Five male, five female
Body Weight Range:	Males: 302 to 314 grams at dosing; Females: 202 grams to 217 grams at dosing
Age:	8 weeks of age at dose administration
Acclimation Period:	Minimum 5 days
Number of Animals:	Ten
Identification Method:	Ear tag

Justification of Test System

The rat has historically been used to establish hazardous substance labeling data. The oral route of dosing was selected as the strongest challenge for materials that could be accidentally ingested.

4. Animal Management

Husbandry:	Conditions conformed to NAMSA Standard Operating Procedures that are based on the "*Guide for the Care and Use of Laboratory Animals*."
Food:	A commercially available rodent feed, PROLAB RMH 1000 - 5P07, was provided daily. Food was withheld 16-20 hours prior to dosing. A copy of the annual feed analysis report was saved in the study file.
Water:	Potable water was provided *ad libitum* through species appropriate water containers or delivered through an automatic watering system. A copy of the most recent water analysis report was saved in the study file.
Contaminants:	Contaminants reasonably expected in feed or water supplies were not believed to have influenced the outcome of this test.
Housing:	Animals were individually housed in stainless steel or plastic suspended cages identified by a card indicating the lab number, animal numbers, test code, sex and date dosed.
Environment:	The animal housing room temperature and relative humidity were monitored daily. The temperature for the room was set to 68-79°F and the relative humidity was set to 30-70%. There were no significant temperature or relative humidity excursions that adversely affected the health of the animals. The light cycle was controlled using an automatic timer (12 hours light, 12 hours dark).
Accreditation:	NAMSA is an AAALAC International accredited facility and is registered with the United States Department of Agriculture. Additionally, NAMSA maintains an approved Animal Welfare Assurance on file with the National Institutes of Health, Office for Laboratory Animal Welfare.
Personnel:	Associates involved were appropriately qualified and trained.
Veterinary Care:	Standard veterinary medical care was provided in this study.
IACUC:	This procedure has been approved by the NAMSA Institutional Animal Care and Use Committee (IACUC), and is reviewed at least annually by the same committee.
Selection:	Only healthy, previously unused animals were selected.

5. Method

The food for each rat was removed from each cage 16-20 hours prior to dosing. Each rat was weighed and gavaged with the test article (undiluted) via a stainless steel blunt-tipped cannula at a maximum dosing volume of 20 mL/kg body weight (Derelanko, 2001). The animals were then returned to their cages and food was returned after treatment.

Animals were observed immediately after dosing, at 1 and 4 hours post dosing, and daily thereafter for 14 days for clinical signs of toxicity and mortality. Body weights were recorded prior to dosing and at 14 days (prior to terminal sacrifice) for survivors. Animals found dead during the study or those euthanized by carbon dioxide inhalation at termination of the study were subjected to a macroscopic examination of the viscera. The necropsy was performed under the supervision of a board certified veterinarian. Based on the FHSA Regulations, a substance is considered "toxic" if it produces death within 14 days in 50% or more of a group of rats.

All clinical observation times reported herein are approximate and are within ranges established by the external standards described in the References section of this report and/or NAMSA standard operating procedures.

6. Results

Individual observations appear in Appendix 1.

Body Weight
All animals gained weight during the study. The body weight gain for the males and females was consistent with the Hilltop Lab Animals, Inc. growth chart for Hla®:(SD)CVF® male and female rats. The test article did not appear to have an effect on growth.

Mortality
No animals died during the 14 day study.

Clinical Observations
All animals appeared clinically normal throughout the study.

Necropsy
There were no macroscopic changes in the viscera at necropsy that could be attributed to the single oral dose.

7. Conclusion

Oral (gavage) administration of a single dose of AX250 to fasted 8 week old male and female Sprague Dawley rats did not produce mortality or clinical signs of toxicity at the maximal feasible dose of 20 mL/kg. Therefore, AX250 was considered to be nontoxic at an oral dose of 20 mL/kg in the rat.

Based on the results, the LD50 for AX250 was considered to be greater than 20 mL/kg for 8 week old male and female Sprague Dawley rats. The active ingredient hypochlorous acid (HOCl) comprises 0.0240% of the total AX250 formulation. Therefore, 0.024 g/100 mL of HOCl in 20 mL/kg of AX250 results in 0.0048 g or 4.8 mg per kg body weight. This results in a LD50 of greater than 4.8 mg/kg for the active ingredient HOCl.

Results and conclusions apply only to the test article tested. Any extrapolation of these data to other articles is the sponsor's responsibility.

8. Quality Assurance

Inspections were conducted at intervals adequate to assure the integrity of the study in conformance with 21 CFR 58.35(b)(3). The final report was reviewed for conformance to Section 58.185, Subpart J, of the GLP Regulations. A Statement of Quality Assurance Activities was issued with the report.

9. Records

All raw data pertaining to this study and a copy of the final report are retained in designated NAMSA archive files.

10. ISO Compliance

All procedures were certified to ISO 13485:2003.

11. References

Code of Federal Regulations (CFR), Title 9, Parts 1-4, Animal Welfare Act.

Code of Federal Regulations (CFR), Title 16, Part 1500, Federal Hazardous Substances Act (FHSA) Regulations.

Code of Federal Regulations (CFR), Title 21, Part 58, Good Laboratory Practice for Nonclinical Laboratory Studies.

Derelanko, M.J. and Hollinger, M.A. *CRC Handbook of Toxicology*, New York: CRC Press, 2nd edition, 2001, p.98.

International Organization for Standardization (ISO) 13485, Medical devices - Quality management systems - Requirements for regulatory purposes (2003).

National Research Council, *Guide for the Care and Use of Laboratory Animals*, Washington, DC: National Academy Press, 2011.

Office of Laboratory Animal Welfare (OLAW), Public Health Service Policy on Humane Care and Use of Laboratory Animals.

Appendix 1 - Individual Observations

Animal Number	Sex	Body Weight (g)		Clinical Observations (Days 0-14)	Necropsy (Day 14)
		Day 0	Day 14		
5738	Male	306	384	No findings	Macroscopically normal.
5739	Male	302	382	No findings	Macroscopically normal.
5742	Male	314	395	No findings	Macroscopically normal.
5741	Male	312	393	No findings	Macroscopically normal.
5740	Male	310	395	No findings	Macroscopically normal.
Mean:		308.8	389.8		
5750	Female	202	269	No findings	Macroscopically normal.
5749	Female	217	261	No findings	Macroscopically normal.
5748	Female	203	265	No findings	Macroscopically normal.
5746	Female	207	253	No findings	Macroscopically normal.
5745	Female	206	257	No findings	Macroscopically normal.
Mean:		207	261		

AQUAOX INDUSTRIES INC
16155, Sierra Lakes Parkway,
Suite 160-714, Fontana,
CA 92336, USA.

Certificate of Analysis

Date of Manufacture: 03/06/2013
Product Name: AX250
Batch / Lot #: AX-13065-0210
Production Facility: Innovacyn, Inc.
3546 N. Riverside Ave. Rialto, CA 92377
Testing Facility: Innovacyn, Inc.
3546 N. Riverside Ave. Rialto, CA 92377

TEST	ANALYSIS	UNITS
FAC	233	ppm
pH	6.22	n/a
ORP	964	mV
Osmolarity	17	mOsm/kg

This certification states that the product AX250, bearing the above description and lot number, has been found to conform to the internal specifications established for this product. The above lot was made in accordance with our internal specifications and good manufacturing practices under controlled procedures.

This lot has been appropriately inspected and tested, and, to the best of our knowledge, conforms to all applicable test methods, standards and internal specifications.

This certification does not constitute any written or expressed warranty or guarantee of any kind.

Rebecca Lei _____ Date: 3/12/13
QA Regulatory Specialist

SR: EH 102-207960
(909)-829-1664
(888)-592-7844
www.aquaox.net
info@aquaox.net

EIN: 45-4763694
BANK: Comerica Bank
A/C: 1894563426
ABA: 121137522
EPA #: 085021-CA-001

Issued: March 21, 2013
Last Revised: April 24, 2013

FORM-COA-02

AQUAOX INDUSTRIES INC
16155, Sierra Lakes Parkway,
Suite 160-714,
Fontana. CA 92336. USA.

Certificate of Analysis

Date of Manufacture:	03 / 06 / 2013
Product Name:	AX250
Batch / Lot #:	AX-13065-0210
Production Facility:	Innovacyn, Inc. 3546 N. Riverside Ave. Rialto, CA 92377
Testing Facility:	Innovacyn, Inc. 3546 N. Riverside Ave. Rialto, CA 92377

TEST	ANALYSIS	UNITS
FAC	218	ppm
pH	6.00	n/a
Conductivity	1230	µS/cm
ORP	957	mV
Osmolality	21	mOsm/kg

This certification states that the intermediate product AX250, bearing the above description and lot number, has been found to conform to the internal specifications established for this product. The above lot was made in accordance with our internal specifications and current good manufacturing practices under controlled procedures.

This lot has been appropriately inspected and tested, and, to the best of our knowledge, conforms to all applicable test methods, standards and internal specifications.

This certification does not constitute any written or expressed warranty or guarantee of any kind.

Rebecca Lei _____ Date: 4/24/13

QA Regulatory Specialist

© Aquaox Industries Inc

Statement of Quality Assurance Activities

Phase Inspected	Date Inspected	Date Reported to Study Director	Date Reported to Management
Termination	April 2, 2013	April 2, 2013	April 2, 2013
Study Data Review	April 2, 2013	April 2, 2013	April 2, 2013
Final Report Review	April 11, 2013	April 11, 2013	April 11, 2013
Final Report Review	April 26, 2013	April 26, 2013	April 26, 2013

Based on a review of this study, it has been concluded that this report accurately describes the methods and standard operating procedures, and that the reported results accurately reflect the raw data of the study. This study has been reviewed in accordance with the provisions of the FDA Good Laboratory Practice Regulations (21 CFR, Part 58).

QA Representative: Susan Pellitieri 5-9-13

Susan Pellitieri, BA
Auditor, Quality Assurance

Date

GLP REPORT

TEST FACILITY

NAMSA
6750 Wales Road
Northwood, OH 43619
419.666.9455

SPONSOR

Michel van Schaik
Aquaox Industries, Inc.
16155 Sierra Lakes Pkwy
Suite 160-714
Fontana, CA 92336

CONFIDENTIAL

STUDY TITLE

ISO Guinea Pig Maximization Sensitization Test

TEST ARTICLE NAME

AX250

TEST ARTICLE IDENTIFICATION

Lot AX-13065-0210

TABLE OF CONTENTS Page

Summary

The test article, AX250, was evaluated for the potential to cause delayed dermal contact sensitization in a guinea pig maximization test. This study was conducted based on the requirements of ISO 10993-10, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization. The test article was intradermally injected undiluted and mixed 1:1 with Freund's Complete Adjuvant:control article (1:1) to ten test guinea pigs for Induction I. For Induction II, the test animals were treated with 10% Sodium Lauryl Sulfate suspension in petrolatum approximately one day prior to the test article being occlusively patched for 48 hours. The control article, 0.9% Sodium Chloride, was similarly injected and occlusively patched to five control guinea pigs. Following a recovery period, the test and control animals received challenge patches of the test article and the control article for 24 hours. All sites were scored for dermal reactions at 24 and 48 hours after patch removal.

The test article showed no evidence of causing delayed dermal contact sensitization in the guinea pig. The test article was not considered a sensitizer in the guinea pig maximization test.

Supervisory Personnel:

Lisa A. Severhof, BA
Manager, Toxicology

Colleen M. Stevenson, AA
Supervisor, Toxicology

Study Director Approval:

Laura R. Ott

Laura R. Ott, BS, LAT
Medical Research Manager

13 May 2013
Date Completed

Authorization for duplication of this report, except in whole, is reserved pending NAMSA's written approval.

Statement of GLP Compliance

There were no deviations to the provisions of the FDA Good Laboratory Practice (GLP) Regulations (21 CFR, Part 58) noted during the course of the study.

Study Director: Laura R. Ott
Laura R. Ott, BS, LAT

13 May 2013
Date

1. Introduction

Purpose
The purpose of this study was to evaluate the potential of the test article to cause delayed dermal contact sensitization in the guinea pig maximization test.

Testing Guidelines
This study was conducted based on the requirements of the International Organization for Standardization 10993-10, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.

Dates
Test Article Received: March 14, 2013
Treatment Started: March 21, 2013
Observations Concluded: April 16, 2013

GLP Compliance
The study initiated by protocol signature on March 15, 2013 was conducted in accordance with the provisions of the FDA Good Laboratory Practice (GLP) Regulations, 21 CFR 58. A Statement of Quality Assurance Activities was issued with this report.

Duplication of Experimental Work
By signature on the protocol for the study, the sponsor confirmed that the conduct of this study did not unnecessarily duplicate previous experiments.

2. Materials

The test article provided by the sponsor was identified and handled as follows:

Test Article Name:	AX250
Identification**:**	Lot AX-13065-0210
Certificate of Analysis:	See Appendix 4.
Stability Testing:	The results from both accelerated stability (i.e., 40°C±2°C/75%RH±5%RH) and real time room temperature stability (i.e., 25°C±2°/60%RH±5%RH) programs have demonstrated that the product (AX250) was stable for the duration of the study (per sponsor). See Appendix 5.
Expiration Date:	Additional long term stability testing is in progress (per sponsor).
Strength, Purity and Composition:	Strength: 250 ppm hypochlorous acid; Purity: 100% hypochlorous acid; Composition: Purified water (99.9249%), sodium chloride (0.0500%), hypochlorous acid (0.0240%), hypochlorite ion (0.0010%), and blended phosphate (0.0001%)
Physical Description of the Test Article:	aqueous solution, clear and colorless, slightly chlorinated
Storage Conditions:	Room Temperature
Test Article Preparation:	The test article was dosed as received (100% concentration). A new unopened bottle of test article was used for each dose.
Control Article:	0.9% Sodium Chloride, USP (SC, Baxter Healthcare)
Stability Testing:	Marketed product, stability characterized by labeling
Expiration Date:	April 2014 and June 2014
Strength, Purity, Composition or Other Characteristics:	Purity: Meets requirements of USP Sodium Chloride for Injection and is certified as USP Grade; Composition: 0.9% NaCl ± 5.0% of label claim, balance is water; sodium chloride CAS #: 7647-14-5/water CAS #: 7732-18-5
Storage Conditions:	Room Temperature

Additional Materials:	These materials were provided by the test facility: Freund's Complete Adjuvant (FCA) and sodium lauryl sulfate (SLS) suspension in petrolatum
Freund's Complete Adjuvant:	FCA (Becton Dickinson and Company) was mixed 50:50 (v/v) with the control article and used at Induction I.
Stability Testing:	Marketed product, stability characterized by labeling
Expiration Date:	August 7, 2015
Storage Conditions:	Room Temperature
Sodium Lauryl Sulfate:	A 10% (w/w) SLS (Sigma-Aldrich) suspension in petrolatum (Covidien) was used prior to Induction II.
Stability Testing:	Marketed product, stability characterized by labeling
Expiration Date:	November 2014 (SLS), December 2017 (petrolatum)
Storage Conditions:	Room Temperature

3. Test System

Test System

Species:	Guinea pig (*Cavia porcellus*)
Strain:	Hartley
Source:	Elm Hill Labs
Sex:	Male (naïve)
Body Weight Range:	301 grams to 441 grams at study initiation
Age:	3 weeks at study initiation
Acclimation Period:	Minimum 5 days
Number of Animals:	Fifteen
Identification Method:	Ear tag

Justification of Test System

The Hartley albino guinea pig (animal) has been used historically for sensitization studies (Magnusson and Kligman, 1970). The guinea pig is believed to be the most sensitive animal model for this type of study. The susceptibility of the Hartley guinea pig strain to a known sensitizing agent, 1-chloro-2,4-dinitrobenzene (DNCB), has been substantiated at NAMSA with a similar method under lab number 12T_56201_01 completed on January 23, 2013 (see Appendix 3).

4. Animal Management

Husbandry:	Conditions conformed to NAMSA Standard Operating Procedures that are based on the "*Guide for the Care and Use of Laboratory Animals*."
Food:	A commercially available guinea pig feed, PROLAB Guinea Pig - 5P18, was provided daily. A copy of the annual feed analysis report was saved in the study file.
Water:	Potable water was provided *ad libitum* through species appropriate water containers or delivered through an automatic watering system. A copy of the most recent water analysis report was saved in the study file.
Contaminants:	Contaminants reasonably expected in feed or water supplies were not believed to have influenced the outcome of this test.
Housing:	Animals were housed in groups in stainless steel or plastic suspended cages identified by a card indicating the lab number, animal numbers, test code, sex, and first treatment date.
Environment:	The animal housing room temperature and relative humidity were monitored daily. The temperature for the room was set to 68-79°F and the relative humidity was set to 30-70%. There were no significant temperature or relative humidity excursions that adversely affected the health of the animals. The light cycle was controlled using an automatic timer (12 hours light, 12 hours dark).

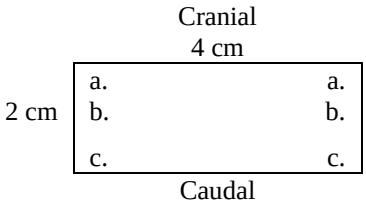
Accreditation:	NAMSA is an AAALAC International accredited facility and is registered with the United States Department of Agriculture. Additionally, NAMSA maintains an approved Animal Welfare Assurance on file with the National Institutes of Health, Office for Laboratory Animal Welfare.
Personnel:	Associates involved in this study were appropriately qualified and trained.
Veterinary Care:	Standard veterinary medical care was provided in this study.
IACUC:	This procedure has been approved by the NAMSA Institutional Animal Care and Use Committee (IACUC), and is reviewed at least annually by the same committee.
Selection:	Only healthy, previously unused animals were selected.

5. Method

Induction I
On the first day of treatment, the animals were weighed and arbitrarily assigned to a treatment group as shown below.

Treatment Group	Number of Animals
Test	10
Control	5

The fur over the dorsoscapular region was removed with an electric clipper. The test animals were injected with the test article (undiluted) and the control animals were injected with the control article. Three rows of intradermal injections (two injections per row) were given to each animal within an approximate 2 cm x 4 cm boundary of the fur clipped area as illustrated below:



Control Animals:
a. 0.1 mL of 50:50 (v/v) mixture of FCA and the control article
b. 0.1 mL of the control article
c. 0.1 mL of a 1:1 mixture of the 50:50 (v/v) control article/FCA mixture and the control article

Test Animals:
a. 0.1 mL of 50:50 (v/v) mixture of FCA and the control article
b. 0.1 mL of test article
c. 0.1 mL of a 1:1 mixture of the 50:50 (v/v) control article/FCA mixture and the test article

Induction II
At 6 days (±1 day) after completion of the Induction I injection, the fur over the dorsoscapular region (same area as used during Induction I) of each animal was removed with an electric clipper. The area was treated with a 10% sodium lauryl sulfate (SLS) suspension in petrolatum sufficient to coat the skin. The SLS suspension, applied to provoke a mild acute inflammation, was massaged into the skin over the injection site. The area was left uncovered.

At 24 hours (± 2 hours) any remaining SLS residue was gently removed with a gauze pad. An approximate 2 cm x 4 cm section of filter paper, saturated with 0.3 mL of test article (undiluted), was then topically applied to the previously injected sites of the test animals. The negative control animals were similarly patched with the control article. Each patch was secured with a nonreactive tape and the trunk of each animal was wrapped with an elastic bandage. At 48 hours, the bandages and patches were removed.

Challenge
At 14 days (±1 day) after completion of Induction II, the fur was removed from the sides and flank areas with an electric clipper. Nonwoven cotton disks contained in a Hill Top Chamber® were saturated with 0.3 mL of the test article (undiluted) or control article. The test article was applied to the right flank of each animal and the control article was applied to the left flank of each animal. The trunk of each animal was wrapped with an elastic bandage to maintain well-occluded sites. At 24 hours, the wraps and Hill Top Chambers were removed. Any residue remaining at the sites was removed.

Laboratory Observations
1. Animals were observed daily for general health.
2. Body weights were recorded at pretreatment.
3. Representative photographs were taken of any irritation or other skin findings. These photographs will not be reported, but are saved in the study file.
4. Observations for dermal reactions were conducted at 24 and 48 hours after challenge patch removal. The sites were wiped with 35% isopropyl alcohol to facilitate scoring. Dermal reactions were scored in accordance with the criteria shown below:

Patch Test Reaction	Grading Scale
No visible change	0
Discrete or patchy erythema	1
Moderate and confluent erythema	2
Intense erythema and swelling	3

All times (dose administration, patch removal, dermal scoring, etc.) reported herein are approximate and are within ranges established by the external standards described in the References section of this report and/or NAMSA standard operating procedures.

6. Evaluation

The responses from the challenge phase were compared within the test animal group and between test and control conditions. In the final analysis of data, consideration was given to the overall pattern, intensity, duration and character of reactions of the test as compared to the control conditions. The control conditions are (1) the control article on the test animals, (2) the test on the negative control animals, and (3) the control article on the negative control animals. Statistical manipulation of data was not applicable to this study. Grades of 1 or greater in the test group generally indicate sensitization, provided that grades of less than 1 were observed on the negative control animals. If grades of 1 or greater were noted on negative control animals, then the reactions of test animals that exceeded the most severe control reaction were considered to be due to sensitization.

7. Results

Clinical Observations and Body Weight Data
All animals were clinically normal throughout the study. The clinical observations and individual body weights at pretreatment are presented in Appendix 1.

Dermal Observations
No evidence of sensitization was observed. Individual results of dermal scoring for the challenge phase appear in Appendix 2.

8. Conclusion

The test article showed no evidence of causing delayed dermal contact sensitization in the guinea pig. The test article was not considered a sensitizer in the guinea pig maximization test.

Results and conclusions apply only to the test article tested. Any extrapolation of these data to other articles is the sponsor's responsibility.

9. Quality Assurance

Inspections were conducted at intervals adequate to assure the integrity of the study in conformance with 21 CFR 58.35(b)(3). The final report was reviewed for conformance to Section 58.185, Subpart J, of the GLP Regulations. A Statement of Quality Assurance Activities was issued with the report.

10. Records

All raw data pertaining to this study and a copy of the final report are retained in designated NAMSA archive files.

11. ISO Compliance

All procedures were certified to ISO 13485:2003 and accredited to ISO 17025:2005.

12. References

Code of Federal Regulations (CFR), Title 9, Parts 1-4, Animal Welfare Act.

Code of Federal Regulations (CFR), Title 21, Part 58, Good Laboratory Practice for Nonclinical Laboratory Studies.

Frankild S, Basketter DA, Andersen ,KE. The value and limitations of rechallenge in the guinea pig maximization test. *Contact Dermatitis*. 1996;35:135-140.

International Organization for Standardization (ISO) 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (2009).

International Organization for Standardization (ISO) 10993-2, Biological evaluation of medical devices - Part 2: Animal welfare requirements (2006).

International Organization for Standardization (ISO) 10993-10, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization (2010).

International Organization for Standardization (ISO) 10993-12, Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (2012).

International Organization for Standardization (ISO) 13485, Medical devices - Quality management systems - Requirements for regulatory purposes (2003).

International Organization for Standardization (ISO) 17025, General requirements for the competence of testing and calibration laboratories (2005).

Klecak G. Identification of Contact Allergens: Predictive Tests in Animals. In: F.N. Marzulli and H.I. Maibach, eds. *Dermatotoxicology, Second Edition*. USA: Hemisphere Publishing Corporation; 1983:193-236.

Kligman AM, Basketter DA. A critical commentary and updating of the guinea pig maximization test. *Contact Dermatitis*. 1995;32:129-134.

Magnusson B, Kligman A. *Allergic Contact Dermatitis in the Guinea Pig*. Springfield: C.H. Thomas, 1970.

National Research Council, *Guide for the Care and Use of Laboratory Animals*, Washington, DC: National Academy Press, 2011.

Office of Laboratory Animal Welfare (OLAW), Public Health Service Policy on Humane Care and Use of Laboratory Animals.

Organisation for Economic Co-operation and Development (OECD), Guideline for Testing of Chemicals, Number 406, Skin Sensitisation (1992).

Appendix 1 - Clinical Observations and Individual Body Weight Data for the Test and Control Article Animals

Treatment Group	Animal Number	Individual Observation	
		Pretreatment Body Weight (g)	Clinical Observations
Test	720	307	No findings
	721	301	No findings
	722	313	No findings
	723	304	No findings
	724	303	No findings
	725	439	No findings
	726	441	No findings
	727	309	No findings
	728	364	No findings
	729	404	No findings
Control	730	334	No findings
	731	343	No findings
	732	345	No findings
	733	362	No findings
	734	308	No findings

Appendix 2 - Dermal Reactions Following Challenge Exposure to the Test and Control Articles

Treatment Group	Animal Number	Dermal Reactions			
		24 Hour Score		48 Hour Score	
		Control Site	Test Article Site	Control Site	Test Article Site
Test	720	0	0	0	0
	721	0	0	0	0
	722	0	0	0	0
	723	0	0	0	0
	724	0	0	0	0
	725	0	0	0	0
	726	0	0	0	0
	727	0	0	0	0
	728	0	0	0	0
	729	0	0	0	0
Control	730	0	0	0	0
	731	0	0	0	0
	732	0	0	0	0
	733	0	0	0	0
	734	0	0	0	0

Appendix 3 - Periodic Positive Control Study for the Guinea Pig Maximization Test

What was tested
1-chloro-2,4-dinitrobenzene (DNCB)

Dates
Treatment Started: December 11, 2012 under NAMSA Lab Number: 12T_56201_01
Observations Concluded: January 6, 2013

Purpose
A periodic positive control study was conducted for the Guinea Pig Maximization Test to meet the following objectives: 1) confirm the methodology in ISO 10993-10, Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization, 2) substantiate the potential of DNCB to cause delayed dermal contact sensitization, 3) verify proper training of the technicians performing these studies, and 4) substantiate the susceptibility of the Hartley guinea pig strain to dermal contact sensitization.

Methods
The test utilized young adult, male Hartley albino guinea pigs supplied by Elm Hill Labs. The weight at study initiation ranged from 362 grams to 463 grams. A 0.1% (w/w) concentration of DNCB in propylene glycol was intradermally injected and occlusively patched to ten test guinea pigs in an attempt to induce sensitization. The propylene glycol vehicle was similarly injected and occlusively patched to five control guinea pigs. Following a recovery period, the test and control animals received a challenge patch of 0.01% (w/w) DNCB in propylene glycol and propylene glycol alone. All sites were scored for dermal reactions at 24 and 48 hours after patch removal. The patch sites were graded using the scale: 0 = no visible change, 1 = discrete or patchy erythema, 2 = moderate and confluent erythema, and 3 = intense erythema and swelling.

Results
All of the ten test animals demonstrated a positive sensitization response to the known sensitizer, DNCB. None of the control animals demonstrated a sensitization response. The results are shown below:

Treatment Group	Animal Number	Dermal Reactions				Results (+) or (-)
		24 Hour Score		48 Hour Score		
		Control Site	Test Article Site	Control Site	Test Article Site	
Test	4545	0	1	0	1	+
	4546	0	1	0	1	+
	4547	0	2	0	1	+
	4548	0	1	0	1	+
	4549	0	1	0	1	+
	4550	0	1	0	1	+
	4551	0	2	0	2	+
	4552	0	1	0	1	+
	4553	0	2	0	1	+
	4554	0	1	0	1	+
Control	4555	0	0	0	0	-
	4556	0	0	0	0	-
	4557	0	0	0	0	-
	4558	0	0	0	0	-
	4559	0	0	0	0	-

Conclusion
The known sensitizer DNCB produced evidence of causing delayed dermal contact sensitization in the Hartley strain of guinea pig. Therefore, the following objectives were met: 1) the methodology in ISO 10993-10, Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Skin Sensitization was confirmed, 2) the potential for DNCB to cause delayed contact sensitization was substantiated, 3) proper training of the technicians performing this study design was verified and 4) the susceptibility of the Hartley guinea pig strain to sensitization was substantiated.

AQUAOX INDUSTRIES INC
16155, Sierra Lakes Parkway,
Suite 160-714, Fontana,
CA 92336, USA.

Certificate of Analysis

Date of Manufacture: 03/06/2013
Product Name: AX250
Batch / Lot #: AX-13065-0210
Production Facility: Innovacyn, Inc.
3546 N. Riverside Ave. Rialto, CA 92377
Testing Facility: Innovacyn, Inc.
3546 N. Riverside Ave. Rialto, CA 92377

TEST	ANALYSIS	UNITS
FAC	233	ppm
pH	6.22	n/a
ORP	964	mV
Osmolarity	17	mOsm/kg

This certification states that the product AX250, bearing the above description and lot number, has been found to conform to the internal specifications established for this product. The above lot was made in accordance with our internal specifications and good manufacturing practices under controlled procedures.

This lot has been appropriately inspected and tested, and, to the best of our knowledge, conforms to all applicable test methods, standards and internal specifications.

This certification does not constitute any written or expressed warranty or guarantee of any kind.

Rebecca Lei _____ Date: 3/12/13
QA Regulatory Specialist

SR: EH 102-207960
(909)-829-1664
(888)-592-7844
www.aquaox.net
info@aquaox.net

EIN: 45-4763694
BANK: Comerica Bank
A/C: 1894563426
ABA: 121137522
EPA #: 085021-CA-001

Issued: March 21, 2013
Last Revised: April 24, 2013

FORM-COA-02

AQUAOX INDUSTRIES INC
16155, Sierra Lakes Parkway,
Suite 160-714,
Fontana. CA 92336. USA.

Certificate of Analysis

Date of Manufacture:	03 / 06 / 2013
Product Name:	AX250
Batch / Lot #:	AX-13065-0210
Production Facility:	Innovacyn, Inc. 3546 N. Riverside Ave. Rialto, CA 92377
Testing Facility:	Innovacyn, Inc. 3546 N. Riverside Ave. Rialto, CA 92377

TEST	ANALYSIS	UNITS
FAC	218	ppm
pH	6.00	n/a
Conductivity	1230	µS/cm
ORP	957	mV
Osmolality	21	mOsm/kg

This certification states that the intermediate product AX250, bearing the above description and lot number, has been found to conform to the internal specifications established for this product. The above lot was made in accordance with our internal specifications and current good manufacturing practices under controlled procedures.

This lot has been appropriately inspected and tested, and, to the best of our knowledge, conforms to all applicable test methods, standards and internal specifications.

This certification does not constitute any written or expressed warranty or guarantee of any kind.

Rebecca Lei _____ Date: 4/24/13

QA Regulatory Specialist

© Aquaox Industries Inc

Phase Inspected	Date Inspected	Date Reported to Study Director	Date Reported to Management
Scoring	April 16, 2013	April 16, 2013	April 16, 2013
Study Data Review	April 17, 2013	April 17, 2013	April 17, 2013
Final Report Review	April 19, 2013	April 19, 2013	April 19, 2013
Final Report Review	May 9, 2013	May 9, 2013	May 9, 2013

Based on a review of this study, it has been concluded that this report accurately describes the methods and standard operating procedures, and that the reported results accurately reflect the raw data of the study. This study has been reviewed in accordance with the provisions of the FDA Good Laboratory Practice Regulations (21 CFR, Part 58).

QA Representative: Elizabeth A. Begle

Elizabeth A. Begle, BS, RLATG
Auditor, Quality Assurance

5-13-13
Date

GLP REPORT

TEST FACILITY

NAMSA
6750 Wales Road
Northwood, OH 43619
419.666.9455

SPONSOR

Michel van Schaik
Aquaox Industries, Inc.
16155 Sierra Lakes Parkway
Suite, 160-714
Fontana, CA 92336

CONFIDENTIAL

STUDY TITLE

28-Day Repeated Dose Dermal Toxicity Study in Male and Female Rats with Intact and Full-Thickness Wounded Skin

TEST ARTICLE NAME

AX250

TEST ARTICLE IDENTIFICATION

Lot: AX-13065-0210

TABLE OF CONTENTS

Page

Summary

The objective of the study was to evaluate the potential local and systemic toxicity of the test article, AX250, following repeated application to intact skin and full-thickness wounded skin in male and female rats. Both local irritation/toxicity and wound healing at the treatment sites were evaluated.

A single full-thickness dermal wound, approximately 2.0 cm x 2.0 cm, was created over the dorsal midline, thoraco-lumbar region of 10 male and 10 female rats. A 6.2 cm x 6.2 cm 2-ply gauze was saturated with test article and applied to the central portion of the full-thickness wound with overlap onto the surrounding intact tissue. To prevent dislodging, the rats were body wrapped with medical tape and application areas were under occluded conditions until the dressing change (approximately every 24 hours). Application of fresh test article occurred at daily dressing changes. Ten male and 10 female rats were similarly treated with saline soaked gauze. Body weight, health observations, food consumption, erythema, edema, and wound size were recorded for evaluation. After an appropriate fast, animals were anesthetized, blood was collected for hematology/clinical chemistry analysis and then euthanized and a necropsy conducted on day 28. The wound sites along with select organs/tissues were collected for histological processing. Local reaction and systemic toxicity was microscopically evaluated by a Board Certified pathologist.

There were no treatment-related clinical signs or effects on body weights, food consumption, wound healing, or local irritation during the study or clinical pathology parameters immediately prior to terminal sacrifice. There were no distinct macroscopic or microscopic effects on wound healing, local cutaneous toxicity/irritation, or systemic toxicity associated with the administration of the test article (AX250). The test article was considered a non-irritant as compared to the negative control, saline.

In conclusion, application of AX250 once daily to full thickness dermal wounds under occluded conditions did not result in local or systemic toxicity and did not adversely effect wound healing.

Study and Supervisory Personnel:	Michelle E. Zdawczyk, MS, ALAT	Supervisor, Toxicology
	C. Tyler Long, DVM, DACLAM	Surgeon
	Colleen M. Stevenson, AA	Supervisor, Toxicology
	Lisa A. Severhof, BA	Manager, Toxicology

Doug Neptun, Principal Investigator
Antech Diagnostics GLP
600 Airport Blvd., Suite 500
Morrisville, NC 27560

Contributing Scientists:

Kelli R. Young, DVM
Clinical Pathology Evaluation

James A. Render, DVM, PhD
Study Pathologist

Approved by:

Elaine M. Daniel, PhD, DABT
Senior Toxicologist

July 5, 2013
Date

Study Director Approval:

Andrew J. Wyen, MS, LAT
Medical Research Manager

7-5-13
Date Completed

Authorization for duplication of this report, except in whole, is reserved pending NAMSA's written approval.

Statement of GLP Compliance

There were no deviations to the provisions of the FDA Good Laboratory Practice (GLP) Regulations (21 CFR, Part 58) noted during the course of the study.

Study Director: _____ 7-5-13

Andrew J. Wyen, MS, LAT — Date

1. Introduction

Purpose
The objective of the study was to evaluate the potential local and systemic toxicity of the test article following repeated application to intact skin and full-thickness wounded skin in male and female rats. Both local irritation/toxicity and wound healing at the treatment sites were evaluated.

Testing Guidelines
This study was based on the International Organization for Standardization 10993: Biological evaluation of medical devices, Part 11: Tests for systemic toxicity and the International Organization for Standardization 10993-6, Biological evaluation of medical devices, Part 6, Tests for local effects after implantation.

Dates

Test Article Received:	March 14, 2013
Surgery:	April 3, 2013
Termination:	May 1, 2013

GLP Compliance
The study was initiated by protocol signature on March 19, 2013 and was conducted in accordance with the provisions of the FDA Good Laboratory Practice (GLP) Regulations, 21 CFR 58. A Statement of Quality Assurance Activities was issued with this report.

Duplication of Experimental Work
By signature on the protocol, the sponsor confirmed that the conduct of this study did not unnecessarily duplicate previous experiments.

2. Materials

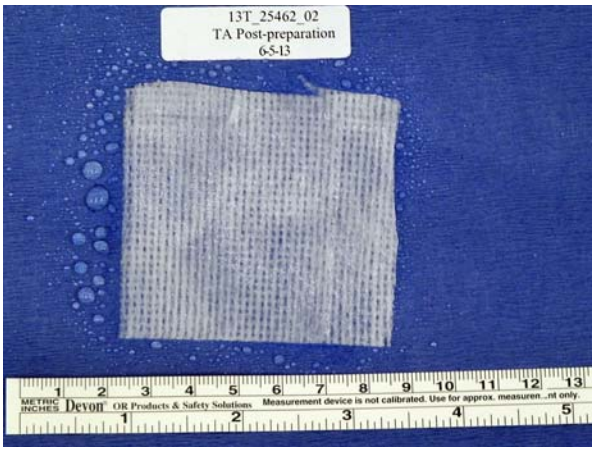
The test article provided by the sponsor was identified and handled as follows:

Test Article Name:	AX250
Manufacturer:	Aquaox Industries, Inc.
Identification:	Lot: AX-13065-0210
Certificate of Analysis:	See Appendix 27
Physical Description:	Aqueous solution, clear and colorless. Solution was contained in plastic bottles with a pump spray applicator. A fresh bottle of test article was used for each day of application.
Intended Clinical Use:	Topical wound cleansing and debridement
Storage Conditions:	Ambient temperature (15-30°C); keep away from sunlight
Stability Testing:	The results from both accelerated stability (i.e., 40°±2°C/75%±5%RH) and real time room temperature stability (i.e., 25°±2°C/60%±5%RH) programs have demonstrated that the product (AX250) was stable for the duration of the study. See Appendix 28 for post experimental Certificate of Analysis.

Strength, Purity, Composition or Other Characteristics:	Strength: 250 ppm hypochlorous acid Purity: 100% hypochlorous acid The test article is composed of the following materials: Purified water (99.9249%), sodium chloride (0.0500%), hypochlorous acid (0.0240%), hypochlorite ion (0.0010%), and blended phosphate (0.0001%). The test solution has a pH of 5.5-6.5 and an osmolality of ≤50 mOsm/kg See Certificate of Analysis in Appendix 27.

Pre-Preparation

Post-Preparation



Negative Control Article:	The testing facility supplied saline as the negative control article.
Manufacturer:	Baxter
Identification:	NAMSA Lot: 13-028-T03, Expiration Date: 1-14 NAMSA Lot: 13-052-T06, Expiration Date: 1-16 NAMSA Lot: 13-063-T15, Expiration Date: 1-16 NAMSA Lot: 13-095-T12, Expiration Date: 1-16 NAMSA Lot: 13-081-T06, Expiration Date: 1-16
Stability Testing:	Marketed product; stability characterized by labeling
Strength, Purity, Composition or Other Characteristics:	Purity: Meets requirements of USP Sodium Chloride for Injection and is certified as USP Grade; Composition: 0.9% NaCl ± 5.0% of label claim, balance is water; sodium chloride CAS #: 7647-14-5/water CAS #: 7732-18-5
Ancillary Materials:	The testing facility supplied 2-ply gauze for the application of the test and control articles, polyethylene plastic for backing the gauze, and the marketed product, Tegaderm™, a semi-permeable, transparent membrane dressing that was placed over the gauze and polyethylene plastic backing after treatment.
2-ply gauze (Name):	Versalon
Manufacturer:	Kendall

Identification:	NAMSA Lot: 13-018-T17, Expiration Date: 1-18-16 NAMSA Lot: 13-059-T09, Expiration Date: 2-28-16
Tegaderm™ (Name):	Tegaderm™ (10 cm x 12 cm)
Manufacturer:	3M
Identification:	Lot: 2015-01TD, Expiration Date: 01-15 Lot: 2015-03TM, Expiration Date: 3-15 Lot: 2014-11PB, Expiration Date: 11-14
Polyethylene plastic (Name):	Polyethylene plastic sterilized by Ethylene Oxide and was allowed to degas for 5 days.

3. Test System

Test System

Species:	Rat (*Rattus norvegicus*)
Strain:	Sprague-Dawley
Source:	Hilltop Lab Animals, Inc.
Sex:	Male and female
Body Weight Range:	Male: 237 grams to 275 grams at pretreatment Female: 167 grams to 197 grams at pretreatment Individual pretreatment body weights were within 20% of the group mean for each sex
Age:	Approximately 7 weeks at first treatment
Acclimation Period:	Minimum 5 days
Number of Animals:	40 (20 male and 20 female)
Identification Method:	Ear tag and skin marker

Justification of Test System

The rat is suggested as an appropriate animal model for evaluating the potential toxicity of materials by various regulatory testing guidelines and standards. In addition the rat is large enough to accommodate surgical creation of full thickness wounds and provide an adequate 10% body surface area for the application of the dermal treatments. The number of animals per treatment group is the minimum necessary to give a sufficient number of treatment sites for each condition and interpretation of the results.

4. Animal Management

Husbandry:	Conditions conformed to NAMSA Standard Operating Procedures that are based on the *Guide for the Care and Use of Laboratory Animals*.
Food:	Purina Mills Prolab® RMH 1000 – 5P07 rodent diet was provided daily.
Water:	Potable water was provided *ad libitum* through species appropriate water containers or delivered through an automatic watering system.
Contaminants:	Contaminants reasonably expected in feed or water supplies were not believed to have influenced the outcome of this test.
Housing:	Animals were individually housed in appropriate caging identified by a card indicating the lab number, animal number, test code, sex, and date of surgery.
Environment:	The animal housing room temperature and relative humidity were monitored daily. The temperature for the room was set to 68-79°F and the relative humidity was set to

	30-70%. There were no temperature or relative humidity excursions that adversely affected the health of the animals. The light cycle was controlled using an automatic timer (12 hours light, 12 hours dark).
Accreditation:	NAMSA is an AAALAC International accredited facility and is registered with the United States Department of Agriculture. Additionally, NAMSA maintains an approved Animal Welfare Assurance on file with the National Institutes of Health, Office for Laboratory Animal Welfare.
Personnel:	Associates involved in this study were appropriately qualified and trained.
Veterinary Care:	Standard veterinary medical care was provided in this study.
IACUC:	Review and approval by the NAMSA Ohio Division Institutional Animal Care and Use Committee (IACUC) were obtained prior to conduct of the study. Any significant changes to this study pertaining to the care and use of animals were approved by the IACUC.
Selection:	Only healthy, previously unused animals were selected.

5. Method

Test Article Dose
Clinically, the test article will be applied once daily to intact and full-thickness wounded skin surfaces. Considering this, the test article was applied daily to the approximate surface area of 10% of the rat, assuming the average weight is 250 grams. The surface area of 10% of a 250 gram rat would be approximately 38 cm^2.

Surface area calculation: $A = KW^{2/3}$, [A= Area (cm^2), K = 9.6, W = weight (grams)]

Test Article Preparation
Sterile 2-ply gauze was aseptically cut into approximate 6.2 cm x 6.2 cm sections (i.e., approximately 38 cm^2) and moistened by spraying the test article onto the gauze until saturated. Each test article moistened gauze pad was backed with a 6.2 cm x 6.2 cm section of sterile polyethylene plastic. A fresh bottle of test article was used for each day of application. The test article was prepared aseptically.

Negative Control Article Preparation
Sterile 2-ply gauze was aseptically cut into approximate 6.2 cm x 6.2 cm sections. Empty spray bottles were supplied by the sponsor and filled with 0.9% sodium chloride USP solution (SC). The prepared gauze was moistened by spraying the SC onto the gauze until saturated. Each control article moistened gauze pad was backed with a 6.2 cm x 6.2 cm section of sterile polyethylene plastic. A fresh bottle of SC was used for each day of application. The control article was prepared aseptically.

Pre-treatment Procedures
Within 2 days prior to the wound procedures, each animal was weighed and randomly assigned (normalizing for body weight) to a treatment group as shown below:

Treatment Group	Number of Animals	
	Male	Female
Test	10	10
Control	10	10

On the day of the procedure, the animals were anesthetized by isoflurane inhalant anesthetic. The hair was clipped from the area over the thoraco-lumbar region. A veterinary ophthalmic ointment was applied to both eyes of each animal as needed to protect the corneas from excessive drying. Each animal was injected subcutaneously with 0.05 mg/kg buprenorphine at a site remote from the intended area of wounding. The shaved area was scrubbed with a germicidal soap and wiped with 70% isopropyl alcohol and the animal was draped.

Wounding Procedure
The four corners of the wound margins were tattooed on the animal prior to surgery and the surgeon used a skin marker to outline the defect location. A scalpel blade and other appropriate sterile instruments were used to surgically induce a single full-thickness wound over the dorsal midline, thoraco-lumbar region of each animal. The wounds were approximately 2.0 cm x 2.0 cm. Hemostasis was achieved by means of sterile gauze and digital pressure.

Treatment
Once hemostasis was achieved, the wounds were treated with the appropriate article. The wounds, with treatments applied, were covered with Tegaderm™ and the dressing was secured with a bandage. To prevent dislodging, the rats were body wrapped with medical tape and application areas were under occluded conditions until the dressing change (approximately every 24 hours). The day of the first treatment was considered day 0.

Post-operative Procedures
Each animal was moved to a recovery area and placed on a heat source. Each animal was monitored for recovery from the anesthetic. Once sternal recumbency was achieved, each animal was returned to its cage.

Laboratory Observations
1. Animals were observed daily for general health.
2. Detailed clinical signs of disease or abnormality were conducted at selection, weekly, and at termination. These detailed observations involved animal handling.
3. Weekly food intake was measured every 7 days to the nearest gram at approximately the same time of day. The last food intake measurement was done on the day the animals were fasted. Food was provided and measured to the nearest gram. Additional feed added during the week was recorded and added to the total amount of food for the week. Daily food consumption was determined by dividing the total amount of feed consumed by the number of days at the determination.
4. Body weights were recorded at pretreatment, weekly, the day prior to termination (pre-fasted weight), and at termination (fasted weight).
5. Article and dressing changes were conducted daily until termination. The animals were placed on inhalant anesthetic for short-term sedation. The bandages, dressings and articles were gently removed from the wound sites. Each site was observed for general condition of the wound and the observations were recorded (erythema and edema). Erythema and edema was recorded as follows:

Scoring	Erythema (ER)	Edema (ED)
0	No erythema	No edema
1	Very Slight erythema (barely perceptible)	Very slight edema (barely perceptible)
2	Well-defined erythema	Well-defined edema (edges of area well-defined by definite raising)
3	Moderate erythema	Moderate edema (raised approximately 1 mm)
4	Severe erythema (beet redness) to eschar formation preventing grading of erythema	Severe Edema (raised more than 1 mm, and extending beyond exposure area)

The unepithelialized wound was measured and recorded to the nearest millimeter. The percent of the wound area healed was determined by using the following calculation:

$$\frac{\text{[Area (length x width) of original wound (day 1) – Area of each day (length x width)]}}{\text{Area (length x width) of original wound (day 1)}} \text{X } 100 = \%\ \text{Healed}$$

Fresh articles were applied as previously described. Animals were recovered and returned to cages.

Terminal Procedures

At 27 days following wound creation, the animals were weighed (prefasted weight) and at the end of the workday food was removed and withheld for a maximum of 20 hours. The following day, the animals were weighed and anesthetized by an intraperitoneal injection of ketamine hydrochloride and xylazine (88 mg/kg + 12 mg/kg) dosed at 3.0 mL/kg. Additional anesthetic was administered at the discretion of a veterinarian to ensure an adequate plane of anesthesia. The abdomen was opened and a blood specimen was collected from the posterior vena cava. The specimens were submitted for complete blood cell count with differential and clinical chemistry analyses at Antech Diagnostics GLP as outlined in Appendix 1. Whole blood and serum samples were sent on ice via next day delivery by Fed-Ex. Animals were euthanized by exsanguination while anesthetized.

Following exsanguination, complete macroscopic examinations of the tissues, viscera, and the wound sites were conducted under the supervision of a NAMSA veterinarian. The tissues and organs listed in Appendix 2 were collected and weighed as indicated. Paired organs were weighed together. Each wound site was excised, allowing about 1-2 cm of intact skin around the circumference of the original wound and laid flat on the cut-out center of a plastic weigh boat to keep the skin sample flat for proper histological preparation. The tissues were preserved in 10% NBF until further processing. The gastrointestinal tract and lungs were infused with 10% NBF. Tissues not being weighed or processed for histopathology were left within the saved carcass and placed into 10% NBF.

Histology

After fixation, the tissues designated in Appendix 2 and the wound sites were trimmed. The wound sites were cross sectioned to obtain 2-3 sections that contain the original wound bed as well as normal tissue surrounding the wound bed. All tissues and skin samples were processed, embedded, sectioned, and stained in hematoxylin and eosin, except the skin (wound) samples were stained with Masson's trichrome,

for microscopic evaluation by a NAMSA board certified veterinary pathologist. The additional tissues that were collected (those tissues not weighed or processed for histopathology including the carcass) will be archived at the completion of the study.

6. Evaluation and Statistical Analysis

Body weight data, weekly food consumption data, unepithelialized measurements (percent wound area healed), erythema, edema, organ weight data, organ/body weight ratios, organ/brain weight ratios, hematology and clinical chemistry data were evaluated statistically. Pre-fasted body weights were used to determine weight gain and the fasted body weights were used to determine anesthetic dosages at termination, and organ/body weight ratios. Descriptive statistics and group comparisons of data were accomplished using a validated statistical program. After screening the data for normality and equal variance, the appropriate parametric or nonparametric tests were performed. Normally distributed data with equal variance were considered parametric and evaluated using an "unpaired t-test" for comparison of two groups. For data that was nonparametric, a two sample t-test unequal variance (Welch Test) was used for two group comparisons. The treatment group was used as variables. Calculations resulting in probability (p) values less than 0.05 were considered statistically significant. Data from male and female rats were analyzed separately.

Clinical signs of systemic illness or death were not analyzed. If the incidence of occurrence of any one or more observations was sufficient to warrant analysis, a chi-square test was employed.

A pathologist conducted a subjective microscopic evaluation of changes in tissues, grading them in a routine fashion. Microscopic findings were subjectively scored as follows: 1 = minimal, 2 = mild, 3 = moderate and 4 = marked. The tissues were evaluated for evidence of toxicity. The incidence and severity of changes were summarized for each treatment group. The wound sites were microscopically evaluated to define any local irritation at the tissue-article interface and to any effect on the healing process (see Appendix 3). In addition, the tissue surrounding the defect (intact) was evaluated for adverse reactions to the test or control article. The findings in the test animals were compared to those in the negative control animals.

7. Results

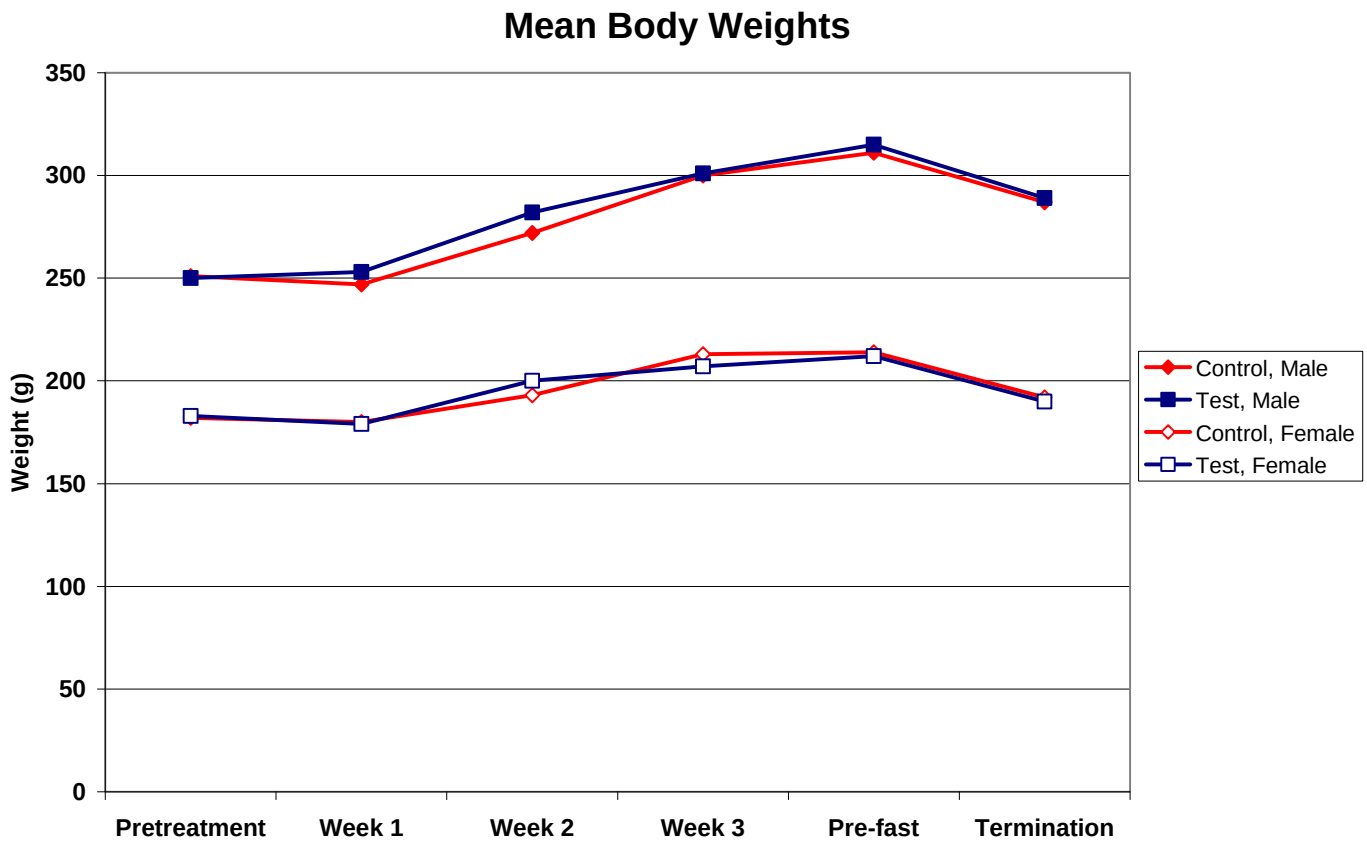
Clinical Observations

Urine staining on the perineum was observed in both the test and control animals and was associated with the bandage altering the animal's motility. Additional observations of alopecia, black substance around eyes, and a lesion at the tip of an animal's tail were considered incidental and unrelated to test article administration. Test female 6056 was found dead on day 7. A necropsy and pathology was performed to determine the cause of the death. Necropsy observations indicated autolysis of various tissues as well as rigor mortis. A board certified pathologist microscopically evaluated the tissues collected during necropsy. A principal finding was marked depletion of lymphocytes in the spleen and thymus, which is consistent with a marked stress response. Another principal finding is acute pulmonary congestion and hemorrhage which is indicative of acute cardiovascular collapse. With an unscheduled death of only one animal occurring after a few days into the study indicates that this particular animal had an issue with the wrapping procedure and the cause of death may be associated with wrapping the animal. There were no microscopic findings of toxicity in animals that completed the study; therefore, the death of this animal does not appear to be the result of a systemic toxicity related to the test article.

Individual observations are presented in Appendix 4.

Body Weight

Weight loss was evident in several animals at week 1 as they became acclimated to their bandages. Overall the individual weight gain and group mean body weights for both male and female animals were considered to be acceptable following treatment. The week 2 male weight was statistically significant between the test (282 ± 8 g) and control (272 ± 12 g) group. Considering the body weight was greater in the test group, the difference was not considered biologically significant. A summary of the body weight data appear in Appendix 5 and individual body weights appear in Appendix 15. A graphical representation of the mean body weights is shown below:



Food Consumption

Individual food consumption and group mean food consumption for both male and female animals were similar between the test and control groups. Statistical analysis indicated differences between test and control male groups at week 3 (24 ± 3 versus 28 ± 4, respectively). There was no correlate to body weight loss or clinical observations. The difference was not biologically significant. A summary of the food consumption data appear in Appendix 6 and average daily food consumption for individual animals appear in Appendix 16.

Wound Observations
Erythema, edema and percent wound area healed parameters were considered to be similar between both control and test article groups and in both sexes. Statistical analysis indicated differences between test and control male groups for erythema on days 3 (2 ± 0 versus 2 ± 1, respectively) and day 17 (0 ± 0 versus 0 ± 1, respectively) and the female groups on days 2 (1 ± 0 versus 1 ± 0) and day 6 (2 ± 1 versus 2 ± 1). There were no statistically significant differences for edema for either the male or female groups. Minimal erythema and edema was similarly noted in test and control groups and it gradually resolved or diminished over the course of the study. Differences between groups for erythema and edema were not considered biologically significant.

Statistical analysis indicated differences for percent wound area healed between test and control male groups for day 3 (3.9 ± 13.9 versus 15.9 ± 9.4, respectively) and the females for days 2 (-30.7 ± 20.3 versus -2.6 ± 10.9, respectively) and day 3 (6.5 ± 16.6 versus 23.0 ± 10.7, respectively). Minimal healing occurred at days 2 and 3 and variations between groups were likely attributed to the subjective measurement techniques. The differences between groups were not considered biologically significant.

A summary of the erythema, edema, and percent wound area healed data appear in Appendices 7 through 9 and individual erythema, edema, and percent healed appear in Appendices 17 through 19.

Clinical Pathology
It was concluded that neither the test nor the control article resulted in any adverse effect on hematology or clinical chemistry parameters. A summary of hematology and clinical chemistry data is shown in Appendix 10 and 11, respectively. Individual values are shown in Appendices 20 through 22. Individual reference ranges, provided by NAMSA, for hematology and clinical chemistry data are shown in Appendix 1.

Evaluation of the clinical pathology data appear in the Clinical Pathology Report (Attachment 1).

Necropsy
There were no macroscopic changes in the viscera at necropsy that could be attributed to the test article. Scattered, raised, red areas around the wound sites were observed in several test and control animals. Microscopic evaluation of these red areas had no microscopic correlate, with the exception of a multifocal dermal hemorrhage in one control animal. The raised red areas were regarded as spontaneous observations and not associated with the test article. Necropsy observations are shown in Appendix 23.

Organ Weights
Absolute organ weights, organ/body weight ratios, and organ/brain weight ratios were similar between test and control groups. There was no difference between the two groups that was considered to be related to treatment. Statistical analysis indicated differences between the test article and control male groups for absolute organ weights of testes (3.63 ± 0.29 g versus 3.31 ± 0.17 g, respectively), organ/body weight ratios for testes (1.26 ± 0.09 versus 1.16 ± 0.06, respectively), organ/brain weight ratios for testes (194.38 ± 15.09 versus 172.58 ± 8.57, respectively), and organ/brain weight ratios for thymus (22.72 ± 4.41 versus 18.73 ± 3.88, respectively). Statistical analysis indicated differences between the test article and control female groups for organ/body weight ratios for the kidneys (0.82 ± 0.05 versus 0.87 ± 0.05, respectively). These differences were considered biologically insignificant as there was no microscopic correlate. A summary of the organ weights appear in Appendices 12 through 14. Individual organ weights appear in Appendices 24 through 26.

Microscopic Evaluation
There were no microscopic findings indicating alterations of normal healing that were associated with administration of the test article. There were no microscopic findings indicating local irritation/toxicity that were the result of administration of the test article. The test article was considered a non-irritant.

Individual results of the pathology findings appear in the microscopic evaluation report (Attachment 2).

8. Conclusion

There were no distinct macroscopic or microscopic effects on wound healing, local cutaneous toxicity/irritation, or systemic toxicity associated with the administration of the test article (AX250). The test article was considered a non-irritant as compared to the negative control, saline.

Results and conclusions apply only to the test article tested. Any extrapolation of these data to other articles is the sponsor's responsibility.

9. Quality Assurance

Inspections were conducted at intervals adequate to assure the integrity of the study in conformance with 21 CFR 58.35(b)(3). The final report was reviewed for conformance to Section 58.185, Subpart J, of the GLP Regulations. A Statement of Quality Assurance Activities was issued with the report.

The hematology and clinical chemistry data were inspected and audited by the Antech Diagnostics GLP Quality Assurance Unit, the results of which were provided to the NAMSA study director and NAMSA management. A Statement of Quality Assurance Activities was provided with the data.

10. Records

All raw data, test and control retention samples, wet tissue, paraffin blocks and tissue slides pertaining to this study and a copy of the final report were retained in designated NAMSA archive files.

11. ISO Compliance

All procedures were certified to ISO 13485:2003.

12. References

Code of Federal Regulations (CFR), Title 21, Part 58, Good Laboratory Practice for Nonclinical Laboratory Studies (2008).

Code of Federal Regulations (CFR), Title 9, Parts 1-199, Animal Welfare Act (2008).

International Organization for Standardization (ISO) 10993-2, Biological evaluation of medical devices - Part 2: Animal welfare requirements (2006).

International Organization for Standardization (ISO) 10993-6, Biological evaluation of medical devices - Part 6: Tests for local effects after implantation (2007).

International Organization for Standardization (ISO) 10993-11, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (2006).

International Organization for Standardization (ISO) 10993-12, Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (2012).

International Organization for Standardization (ISO) 13485, Medical devices - Quality management systems - Requirements for regulatory purposes (2003).

National Research Council, *Guide for the Care and Use of Laboratory Animals*, Washington, DC: National Academy Press, 2011.

Office of Laboratory Animal Welfare (OLAW), Public Health Service Policy on Humane Care and Use of Laboratory Animals.

Appendix 1 - Routine Hematology and Clinical Chemistry Parameters

Routine Hematology
(CBC with differential)

*Basophils (BASO)
*Eosinophils (EOS)
Hematocrit (HCT)
Hemoglobin (HB)
*Lymphocytes (LYMPH)
Mean Corpuscular Hemoglobin (MCH)
Mean Corpuscular Hemoglobin Concentration (MCHC)
Mean Corpuscular Volume (MCV)
*Monocytes (MONO)
*Neutrophils (NEUTRO)
Platelets (PLT)
Red Blood Cell Count (RBC)
White Blood Cell Count (WBC)

Clinical Chemistry

Albumin/Globulin Ratio (A/G)
Albumin (ALB)
Alkaline Phosphatase (ALP)
Bilirubin, total (TBIL)
Blood Urea Nitrogen (BUN)
BUN/Creatinine Ratio (UN/C)
Calcium (Ca)
Chloride (Cl)
Cholesterol (CHOL)
Creatinine, serum (CREA)
γ-Glutamyl transferase (GGT)
Globulin, total (GLOB)
Glucose, serum (GLU)
Phosphorus (PHOS)
Potassium (K)
Aspartate aminotransferase (AST)
Alanine aminotransferase (ALT)
Sodium (Na)
Total protein (TPRO)

*Presented as relative percentages and absolute values

Hematology and clinical chemistry tests were conducted at:

Antech Diagnostics GLP
600 Airport Blvd., Suite 500
Morrisville, NC 27560
Principal Investigator: Doug Neptun, Laboratory Director

NAMSA Reference Ranges

Parameter	Male Reference Range	Female Reference Range
WBC (10^3/µL)	2.6 to 11.6	2.3 to 7.0
RBC (10^6/µL)	7.24 to 9.88	6.74 to 9.01
HGB (g/dL)	13.7 to 17.4	13.1 to 16.4
HCT (%)	40.8 to 54.3	36.3 to 51.8
MCV (fL)	50.7 to 60.6	50.6 to 61.3
MCH (pg)	15.9 to 20.6	17.1 to 20.4
MCHC (g/dL)	29.3 to 36.4	29.8 to 37.3
PLT (10^3/µL)	762 to 1640	901 to 1516
NEUTRO (10^3/µL)	0.3 to 2.4	-0.1 to 1.8
LYMPH (10^3/µL)	1.7 to 9.4	1.7 to 5.6
MONO (10^3/µL)	0.2 to 0.5	0.0 to 0.2
EOS (10^3/µL)	0.0 to 0.1	0.0 to 0.1
BASO (10^3/µL)	0.0 to 0.0	0.0 to 0.0
BUN (mg/dL)	10 to 18	10 to 21
CR (mg/dL)	0.2 to 0.6	0.2 to 0.6
BUN/CR	24.5 to 52.0	24.0 to 58.9
GLU (mg/dL)	87 to 301	98 to 244
Na (mmol/L)	139 to 148	139 to 149
K (mmol/L)	3.6 to 6.2	3.2 to 6.6
Cl (mmol/L)	100 to 110	103 to 113
ALP (U/L)	36 to 157	20 to 96
ALT-SGPT (U/L)	5 to 54	11 to 32
AST-SGOT (U/L)	47 to 98	38 to 102
TOT BIL (mg/dL)	0.1 to 0.1	0.0 to 0.2
GGT (U/L)	-1 to 1	-1 to 1
TOT PRO (g/dL)	4.9 to 6.8	4.9 to 6.7
ALB (g/dL)	2.5 to 3.2	2.6 to 3.6
TOT GLOB (g/dL)	2.2 to 3.8	2.1 to 3.3
ALB/GLOB	0.7 to 1.3	0.9 to 1.3
Ca (mg/dL)	9.3 to 10.6	9.1 to 10.6
P (mg/dL)	6.2 to 9.8	6.2 to 9.7
CHOL (mg/dL)	45 to 106	44 to 94

Appendix 2 - Tissues List

Tissues:	Weighed Tissues[1]	Tissues for Histopathology
Adrenals	X	X
Any abnormal tissue or gross lesion[2]		X
Aorta		
Bone marrow (sternum)		
Brain	X	
Cecum		
Cervix		
Colon		
Duodenum		
Epididymides		
Esophagus		
Eyes		
Heart	X	X
Ileum		
Jejunum		
Kidneys	X	X
Liver	X	X
Lungs and bronchi		X
Lymph nodes (submandibular and mesenteric)		X
Muscle (skeletal)		
Nerve (sciatic)		
Ovaries	X	X
Pancreas		
Parathyroids		
Pituitary		
Prostate		
Rectum		
Salivary glands		
Seminal vesicles		
Skin (non treated)		X
Skin (treated)		X
Spinal cord		
Spleen	X	X
Stomach		
Testes	X	X
Thymus	X	X
Thyroid		
Trachea		
Urinary bladder		
Uterus		
Vagina		

[1] Paired organs were weighed together.
[2] Lesions that are considered incidental were not examined histologically.

Appendix 3 - Microscopic Evaluation

Grading Scheme

Finding	Score	Description
Depressed surface		
	NP	Not present
	P	Present
Serocellular Crusts		
	NP	Not present
	P	Exudate on surface of wound or on surface of epithelium
Re-epitheliazation		
	0	None
	1	Minimal: ≤1/3 of wound surface covered by epithelium
	2	Partial: >1/3 up to ≤ 2/3 of wound surface covered by epithelium
	3	Extensive: >2/3 of wound surface mostly covered by epithelium
	4	Complete: all of wound surface covered by epithelium
Granulation Tissue		
	0	Wound unhealed, devoid of granulation tissue
	1	Wound filled with only immature tissue
	2	Wound filled by immature and mature tissue
	3	Wound mostly filled by mature granulation tissue with some immature tissue
	4	Wound completely filled by mature granulation tissue
Necrotic tissue		
	0	None
	1	Minimal
	2	Slight
	3	Moderate
	4	Severe
Inflammation*		
	0	None
	1	Minimal
	2	Slight
	3	Moderate
	4	Severe
Foreign Debris**		
	0	None
	1	Minimal
	2	Slight
	3	Moderate
	4	Severe
Hemorrhage		
	0	None
	1	Minimal
	2	Slight
	3	Moderate
	4	Severe

*Neutrophilic; Mixed cell (neutrophils, lymphocytes, plasma cells) Mononuclear (lymphocytes and plasma cells); Granulomatous (macrophages with/without multinucleated giant cells).

** Particles of unknown composition, fragments of hair shafts or gauze fibers.

Appendix 4 - Clinical Observations

Group	Sex	Animal Number	Clinical Observations
Control Article	Male	6025	No findings
		6028	No findings
		6029	No findings
		6032	No findings
		6034	No findings
		6036	No findings
		6037	No findings
		6040	Day 8 – Urine staining on perineum (additional body weight was 243 grams on day 9)
		6043	Day 7 – Urine staining on perineum
		6044	No findings
	Female	6049	Days 7 through 17 – Urine staining on perineum
		6051	Days 7 and 8 – Urine staining on perineum
		6052	Days 7 through 18 – Urine staining on perineum
		6053	Days 7 through 18 – Urine staining on perineum; bandage found removed on day 25
		6059	Days 8 through 14, 27, and 28 – Urine staining on perineum (thin body condition on day 7 per veterinarian with body weight 175 grams on day 9)
		6060	Days 7 through 12 – Urine staining on perineum
		6061	Day 6 – Reduced feces Days 7 through 17 – Urine staining on perineum (thin body condition on day 7 per veterinarian with body weight 177 grams on day 9)
		6062	Days 7 through 12 – Urine staining on perineum; bandage found removed on days 11, 12, 19, and 20
		6063	Days 7 through 16 – Urine staining on perineum; bandage found removed on days 19 and 26
		6066	Days 7 through 12 – Urine staining on perineum

Appendix 4 (continued) - Clinical Observations

Group	Sex	Animal Number	Clinical Observations
Test Article	Male	6026	Days 7 through 14 – Urine staining around perineum
		6030	No findings
		6031	Day 0 – Area of alopecia caudal to right ear Day 7 – Urine staining around perineum
		6033	Day 7 – Urine staining around perineum Day 14 – Dry red substance around left eye
		6035	No findings
		6039	Days 4 through 6 – Black substance around both eyes Day 7 – Black substance around both eyes; urine staining around perineum Days 8 through 18 – Urine staining around perineum Day 21 – Alopecia left front arm Days 22 and 24 through 27 – Alopecia left front paw
		6041	Days 7 through 13 – Urine staining around perineum
		6042	Day 7 – Urine staining around perineum
		6045	No findings
		6046	No findings
	Female	6047	Days 7 through 15, 27, and 28 – Urine staining around perineum
		6048	Days 7 through 15 – Urine staining around perineum
		6050	Days 7 through 18, 27, and 28 – Urine staining around perineum
		6054	Days 7 through 19 – Urine staining around perineum; bandage found removed on day 20
		6055	Days 7 and 10 through 17 – Urine staining around perineum
		6056	Day 6 – Reduced feces Day 7 – Found dead
		6058	Day 7 – Urine staining around perineum
		6064	Days 7 and 8 – Urine staining around perineum Days 9 through 21 – Urine staining around perineum; lesion near (at) tip of tail Days 26 through 28 – Tip of tail discolored
		6065	Days 7 through 19 – Urine staining around perineum
		6067	Days 7 through 19 – Urine staining around perineum

Appendix 5 - Summary of Body Weight Data (g)

Sex	Interval	Control Article			Test Article		
		Mean	±	SD	Mean	±	SD
Male	Pretreatment§	251	±	10	250	±	9
	Week 1§	247	±	18	253	±	9
	Week 2‡	**272**	**±**	**12**	**282***	**±**	**8**
	Week 3‡	300	±	17	301	±	7
	Pre-fast‡	311	±	18	315	±	11
	Termination	287	±	16	289	±	9
Female	Pretreatment§	182	±	9	183	±	8
	Week 1§	180	±	16	179	±	6
	Week 2‡	193	±	12	200	±	9
	Week 3‡	213	±	14	207	±	9
	Pre-fast‡	214	±	18	212	±	11
	Termination‡	192	±	14	190	±	12

SD = Standard Deviation
* = Statistically significant difference between control and test groups ($p < 0.05$).
§N = 10 (All groups)
‡N = 10 (test males, control males, control females); N=9 (test females)

Appendix 6 - Summary of Food Consumption (g)

Sex	Interval	Control Article			Test Article		
		Mean	±	SD	Mean	±	SD
Male	Week 1§	35	±	22	24	±	3
	Week 2‡	41	±	26	31	±	3
	Week 3‡	**28**	**±**	**4**	**24***	**±**	**3**
	Week 4‡	29	±	2	31	±	2
Female	Week 1§	43	±	30	43	±	22
	Week 2‡	55	±	48	54	±	38
	Week 3‡	31	±	24	42	±	35
	Week 4‡	31	±	13	25	±	12

SD = Standard Deviation

* = Statistically significant difference between control and test groups ($p < 0.05$).

Note: Chewed food on cage floor or pan was included in weight calculations

Appendix 7 - Summary of Erythema Scores

Sex	Interval	Control Article			Test Article		
		Mean	±	SD	Mean	±	SD
Male	Day 1	2	±	1	2	±	1
	Day 2	1	±	1	2	±	1
	Day 3	**2**	**±**	**1**	**2***	**±**	**0**
	Day 4	1	±	1	1	±	1
	Day 5	2	±	1	2	±	1
	Day 6	2	±	1	2	±	1
	Day 7	0	±	1	0	±	1
	Day 8	1	±	1	0	±	1
	Day 9	2	±	1	2	±	0
	Day 10	1	±	1	1	±	0
	Day 11	1	±	1	1	±	0
	Day 12	1	±	1	1	±	0
	Day 13	1	±	0	1	±	1
	Day 14	1	±	1	1	±	0
	Day 15	1	±	1	1	±	1
	Day 16	1	±	1	1	±	1
	Day 17	**0**	**±**	**1**	**0***	**±**	**0**
	Day 18	0	±	0	0	±	0
	Day 19	0	±	0	0	±	0
	Day 20	0	±	0	0	±	0
	Day 21	0	±	0	0	±	0
	Day 22	0	±	0	0	±	0
	Day 23	0	±	0	0	±	0
	Day 24	0	±	0	0	±	0
	Day 25	0	±	0	0	±	0
	Day 26	0	±	0	0	±	0
	Day 27	0	±	0	0	±	0

SD = Standard Deviation

* = Statistically significant difference between control and test groups ($p < 0.05$).

Appendix 7 (continued) - Summary of Erythema Scores

Sex	Interval	Control Article	Test Article
		Mean ± SD	Mean ± SD
Female	Day 1	2 ± 0	2 ± 1
	Day 2	**1 ± 0**	**1* ± 0**
	Day 3	2 ± 0	2 ± 0
	Day 4	1 ± 1	1 ± 1
	Day 5	2 ± 0	2 ± 0
	Day 6	**2 ± 1**	**2* ± 1**
	Day 7	0 ± 0	0 ± 0
	Day 8	1 ± 1	0 ± 1
	Day 9	2 ± 0	2 ± 1
	Day 10	2 ± 1	2 ± 1
	Day 11	1 ± 1	1 ± 0
	Day 12	1 ± 1	1 ± 1
	Day 13	1 ± 0	1 ± 0
	Day 14	1 ± 0	1 ± 0
	Day 15	1 ± 0	1 ± 0
	Day 16	1 ± 1	1 ± 1
	Day 17	1 ± 1	1 ± 0
	Day 18	1 ± 1	0 ± 1
	Day 19	1 ± 1	1 ± 1
	Day 20	1 ± 1	0 ± 1
	Day 21	0 ± 0	0 ± 0
	Day 22	1 ± 1	0 ± 1
	Day 23	0 ± 0	0 ± 1
	Day 24	1 ± 1	0 ± 1
	Day 25	1 ± 1	0 ± 1
	Day 26	1 ± 1	0 ± 1
	Day 27	1 ± 1	0 ± 1

SD = Standard Deviation

* = Statistically significant difference between control and test groups ($p < 0.05$).

Appendix 8 - Summary of Edema Scores

Sex	Interval	Control Article	Test Article
		Mean ± SD	Mean ± SD
Male	Day 1	0 ± 0	0 ± 0
	Day 2	0 ± 1	0 ± 0
	Day 3	0 ± 0	0 ± 0
	Day 4	0 ± 0	0 ± 0
	Day 5	0 ± 1	0 ± 0
	Day 6	0 ± 0	0 ± 0
	Day 7	0 ± 0	0 ± 0
	Day 8	0 ± 0	0 ± 0
	Day 9	0 ± 0	0 ± 0
	Day 10	0 ± 0	0 ± 0
	Day 11	0 ± 0	0 ± 0
	Day 12	0 ± 0	0 ± 0
	Day 13	0 ± 0	0 ± 0
	Day 14	0 ± 0	0 ± 0
	Day 15	0 ± 0	0 ± 0
	Day 16	0 ± 0	0 ± 0
	Day 17	0 ± 0	0 ± 0
	Day 18	0 ± 0	0 ± 0
	Day 19	0 ± 0	0 ± 0
	Day 20	0 ± 0	0 ± 0
	Day 21	0 ± 0	0 ± 0
	Day 22	0 ± 0	0 ± 0
	Day 23	0 ± 0	0 ± 0
	Day 24	0 ± 0	0 ± 0
	Day 25	0 ± 0	0 ± 0
	Day 26	0 ± 0	0 ± 0
	Day 27	0 ± 0	0 ± 0

SD = Standard Deviation
There were no statistically significant differences between control and test groups.

Appendix 8 (continued) - Summary of Edema Scores

Sex	Interval	Control Article	Test Article
		Mean ± SD	Mean ± SD
Female	Day 1	0 ± 0	0 ± 0
	Day 2	0 ± 0	0 ± 0
	Day 3	0 ± 0	0 ± 0
	Day 4	0 ± 0	0 ± 0
	Day 5	0 ± 1	0 ± 0
	Day 6	0 ± 0	0 ± 0
	Day 7	0 ± 0	0 ± 0
	Day 8	0 ± 0	0 ± 0
	Day 9	0 ± 0	0 ± 0
	Day 10	0 ± 0	0 ± 0
	Day 11	0 ± 0	0 ± 0
	Day 12	0 ± 0	0 ± 0
	Day 13	0 ± 0	0 ± 0
	Day 14	0 ± 0	0 ± 0
	Day 15	0 ± 0	0 ± 0
	Day 16	0 ± 0	0 ± 0
	Day 17	0 ± 0	0 ± 0
	Day 18	0 ± 0	0 ± 0
	Day 19	0 ± 0	0 ± 0
	Day 20	0 ± 0	0 ± 0
	Day 21	0 ± 0	0 ± 0
	Day 22	0 ± 0	0 ± 0
	Day 23	0 ± 0	0 ± 0
	Day 24	0 ± 0	0 ± 0
	Day 25	0 ± 0	0 ± 0
	Day 26	0 ± 0	0 ± 0
	Day 27	0 ± 0	0 ± 0

SD = Standard Deviation
There were no statistically significant differences between control and test groups.

Appendix 9 - Summary of Percent Wound Area Healed

Sex	Interval	Control Article			Test Article		
		Mean	±	SD	Mean	±	SD
Male	Day 2	-7.8	±	12.3	-17.7	±	20.3
	Day 3	**15.9**	**±**	**9.4**	**3.9***	**±**	**13.9**
	Day 4	9.2	±	12.3	6.4	±	16.8
	Day 5	22.4	±	13.9	16.5	±	15.4
	Day 6	27.6	±	13.8	21.1	±	13.3
	Day 7	53.2	±	17.8	55.0	±	21.1
	Day 8	58.1	±	14.8	59.3	±	11.5
	Day 9	62.3	±	16.1	63.8	±	14.7
	Day 10	72.5	±	13.0	73.7	±	11.6
	Day 11	76.3	±	13.1	77.0	±	12.4
	Day 12	88.5	±	8.1	88.9	±	6.0
	Day 13	93.8	±	5.5	94.4	±	5.4
	Day 14	94.2	±	5.2	92.2	±	6.9
	Day 15	95.5	±	4.5	96.0	±	3.6
	Day 16	93.7	±	6.2	95.1	±	4.9
	Day 17	95.4	±	4.7	97.7	±	2.4
	Day 18	94.6	±	5.8	95.0	±	4.7
	Day 19	95.8	±	4.4	94.1	±	9.4
	Day 20	99.3	±	1.3	99.9	±	0.4
	Day 21	100	±	0.0	99.9	±	0.4
	Day 22	100	±	0.0	100	±	0.0
	Day 23	100	±	0.0	100	±	0.0
	Day 24	100	±	0.0	100	±	0.0
	Day 25	100	±	0.0	100	±	0.0
	Day 26	100	±	0.0	100	±	0.0
	Day 27	100	±	0.0	100	±	0.0

SD = Standard Deviation

* = Statistically significant difference between control and test groups ($p < 0.05$).

Appendix 9 (continued) - Summary of Percent Wound Area Healed

Sex	Interval	Control Article			Test Article		
		Mean	±	SD	Mean	±	SD
Female	Day 2	**-2.6**	**±**	**10.9**	**-30.7***	**±**	**20.3**
	Day 3	**23.0**	**±**	**10.7**	**6.5***	**±**	**16.6**
	Day 4	19.7	±	12.2	9.6	±	17.1
	Day 5	24.7	±	11.0	21.1	±	8.7
	Day 6	29.7	±	8.2	23.5	±	9.3
	Day 7	51.1	±	10.2	47.5	±	22.3
	Day 8	59.4	±	7.9	50.3	±	15.5
	Day 9	59.3	±	6.7	56.8	±	16.9
	Day 10	66.8	±	8.8	67.4	±	12.8
	Day 11	69.1	±	10.1	65.5	±	13.1
	Day 12	86.4	±	6.9	84.1	±	7.3
	Day 13	88.2	±	8.2	89.5	±	4.7
	Day 14	88.9	±	7.5	88.2	±	4.8
	Day 15	89.4	±	7.5	89.9	±	4.6
	Day 16	87.0	±	8.3	80.3	±	10.9
	Day 17	90.6	±	6.5	90.9	±	3.3
	Day 18	90.7	±	8.7	90.0	±	7.2
	Day 19	86.3	±	12.9	88.7	±	6.3
	Day 20	92.2	±	7.4	93.5	±	5.7
	Day 21	95.6	±	5.3	94.8	±	6.8
	Day 22	96.8	±	4.9	97.2	±	4.7
	Day 23	96.7	±	4.7	96.6	±	6.2
	Day 24	94.7	±	6.3	96.7	±	5.9
	Day 25	88.6	±	12.6	92.3	±	13.0
	Day 26	90.0	±	10.6	94.2	±	10.6
	Day 27	90.0	±	10.6	94.2	±	10.6

SD = Standard Deviation

* = Statistically significant difference between control and test groups ($p < 0.05$).

Appendix 10 - Summary of Hematology Data

Sex	Parameter	Control Article			Test Article		
		Mean	±	SD	Mean	±	SD
Male	WBC (10^3/µL)	7.76	±	1.56	7.55	±	2.40
	RBC (10^6/µL)	**9.16**	**±**	**0.42**	**8.52***	**±**	**0.41**
	HGB (g/dL)	16.2	±	0.8	15.7	±	0.5
	HCT (%)	**51.2**	**±**	**2.3**	**47.0***	**±**	**2.0**
	MCV (fL)	56.0	±	2.6	55.2	±	1.6
	MCH (pg)	17.7	±	1.0	18.4	±	0.6
	MCHC (g/dL)	**31.7**	**±**	**0.6**	**33.4***	**±**	**0.6**
	PLT (10^3/µL)	1087	±	197	970	±	369
	NEUTRO (10^3/µL)	1.29	±	0.49	1.47	±	0.50
	LYMPH (10^3/µL)	6.17	±	1.08	5.79	±	2.02
	MONO (10^3/µL)	0.12	±	0.04	0.12	±	0.06
	EOS (10^3/µL)	0.10	±	0.06	0.09	±	0.04
	BASO (10^3/µL)	0.05	±	0.01	0.05	±	0.02
Female	WBC (10^3/µL)	4.99	±	1.26	5.18	±	1.23
	RBC (10^6/µL)	8.19	±	0.27	8.30	±	0.34
	HGB (g/dL)	15.1	±	0.5	15.4	±	0.6
	HCT (%)	46.7	±	1.7	45.9	±	1.8
	MCV (fL)	**57.0**	**±**	**1.1**	**55.3***	**±**	**1.4**
	MCH (pg)	18.4	±	0.4	18.5	±	0.5
	MCHC (g/dL)	**32.4**	**±**	**0.5**	**33.5***	**±**	**0.4**
	PLT (10^3/µL)	**1289**	**±**	**186**	**1050***	**±**	**200**
	NEUTRO (10^3/µL)	1.55	±	0.66	1.78	±	0.99
	LYMPH (10^3/µL)	3.24	±	0.90	3.13	±	1.09
	MONO (10^3/µL)	0.09	±	0.04	0.08	±	0.03
	EOS (10^3/µL)	**0.07**	**±**	**0.03**	**0.15***	**±**	**0.08**
	BASO (10^3/µL)	0.02	±	0.01	0.02	±	0.01

SD = Standard Deviation

* = Statistically significant difference between control and test groups ($p < 0.05$).

Appendix 11 - Summary of Clinical Chemistry Data

Parameter	Males						Females					
	Control Article			Test Article			Control Article			Test Article		
	Mean	±	SD	Mean	±	SD	Mean	±	SD	Mean	±	SD
BUN (mg/dL)	21	±	2	19	±	2	26	±	4	26	±	8
CR (mg/dL)	0.3	±	0.1	0.3	±	0.1	0.4	±	0.1	0.3	±	0.0
BUN/CR	61	±	8	64	±	14	75	±	10	81	±	17
GLU (mg/dL)	100	±	18	101	±	15	101	±	14	89	±	11
Na (mmol/L)	143	±	1	144	±	2	144	±	2	144	±	1
K (mmol/L)	5.2	±	0.3	5.6	±	0.8	5.3	±	0.6	5.3	±	0.4
Cl (mmol/L)	104	±	1	104	±	2	**105**	**±**	**2**	**106***	**±**	**1**
ALP (U/L)	125	±	25	103	±	27	105	±	19	94	±	21
ALT-SGPT (U/L)	39	±	6	37	±	20	45	±	22	45	±	15
AST-SGOT (U/L)	125	±	18	124	±	56	**151**	**±**	**38**	**120***	**±**	**21**
TOT BIL (mg/dL)	0.1	±	0.0	0.1	±	0.1	0.1	±	0.0	0.1	±	0.0
GGT (U/L)	0	±	0	0	±	0	0	±	0	0	±	0
TOT PRO (g/dL)	4.9	±	0.2	4.9	±	0.3	4.9	±	0.2	4.8	±	0.2
ALB (g/dL)	2.7	±	0.1	2.7	±	0.1	2.8	±	0.1	2.7	±	0.1
TOT GLOB (g/dL)	2.2	±	0.2	2.1	±	0.2	2.2	±	0.1	2.1	±	0.2
ALB/GLOB	1.25	±	0.08	1.29	±	0.07	1.28	±	0.10	1.26	±	0.08
Ca (mg/dL)	9.3	±	0.2	9.1	±	0.4	9.0	±	0.4	8.8	±	0.3
P (mg/dL)	**10.5**	**±**	**0.6**	**9.7***	**±**	**0.8**	**11.2**	**±**	**0.8**	**9.9***	**±**	**1.0**
CHOL (mg/dL)	68	±	12	65	±	11	56	±	7	54	±	12

SD = Standard Deviation

* = Statistically significant difference between control and test groups ($p < 0.05$).

Appendix 12 - Summary of Organ Weight Data (g)

Sex	Organ	Control Article			Test Article		
		Mean	±	SD	Mean	±	SD
Male	Brain	1.92	±	0.10	1.87	±	0.09
	Heart	1.05	±	0.12	1.10	±	0.09
	Liver	7.72	±	0.70	7.72	±	0.40
	Spleen	0.72	±	0.08	0.76	±	0.09
	Thymus	0.36	±	0.08	0.42	±	0.07
	Kidneys (2)	2.27	±	0.24	2.34	±	0.15
	Adrenal glands (2)	0.07	±	0.02	0.08	±	0.02
	Testes (2)	**3.31**	**±**	**0.17**	**3.63***	**±**	**0.29**
Female	Brain	1.78	±	0.08	1.70	±	0.08
	Heart	0.83	±	0.05	0.81	±	0.05
	Liver	5.65	±	0.48	5.42	±	0.61
	Spleen	0.55	±	0.09	0.53	±	0.09
	Thymus	0.27	±	0.07	0.26	±	0.07
	Kidneys (2)	1.68	±	0.17	1.55	±	0.15
	Adrenal glands (2)	0.09	±	0.01	0.08	±	0.02
	Ovaries (2)	0.10	±	0.02	0.10	±	0.03

SD = Standard Deviation

* = Statistically significant difference between control and test groups ($p < 0.05$).

Appendix 13 - Summary of Organ/Body Weight Ratios (%)

Sex	Organ	Control Article			Test Article		
		Mean	±	SD	Mean	±	SD
Male	Brain	0.67	±	0.04	0.65	±	0.04
	Heart	0.37	±	0.04	0.38	±	0.02
	Liver	2.69	±	0.11	2.67	±	0.08
	Spleen	0.25	±	0.02	0.26	±	0.03
	Thymus	0.13	±	0.03	0.15	±	0.02
	Kidneys (2)	0.79	±	0.06	0.81	±	0.04
	Adrenal glands (2)	0.03	±	0.01	0.03	±	0.01
	Testes (2)	**1.16**	**±**	**0.06**	**1.26***	**±**	**0.09**
Female	Brain	0.93	±	0.08	0.90	±	0.04
	Heart	0.44	±	0.04	0.43	±	0.03
	Liver	2.94	±	0.13	2.84	±	0.20
	Spleen	0.28	±	0.03	0.28	±	0.04
	Thymus	0.14	±	0.03	0.14	±	0.03
	Kidneys (2)	**0.87**	**±**	**0.05**	**0.82***	**±**	**0.05**
	Adrenal glands (2)	0.05	±	0.00	0.04	±	0.01
	Ovaries (2)	0.05	±	0.01	0.05	±	0.01

SD = Standard Deviation

* = Statistically significant difference between control and test groups ($p < 0.05$).

Appendix 14 - Summary of Organ/Brain Weight Ratios (%)

Sex	Organ	Control Article			Test Article		
		Mean	±	SD	Mean	±	SD
Male	Heart	54.83	±	6.54	58.76	±	6.14
	Liver	402.39	±	33.83	413.88	±	32.86
	Spleen	37.35	±	3.66	40.83	±	5.88
	Thymus	**18.73**	**±**	**3.88**	**22.72***	**±**	**4.41**
	Kidneys (2)	118.54	±	14.39	125.77	±	12.42
	Adrenal glands (2)	3.77	±	1.09	4.12	±	0.92
	Testes (2)	**172.58**	**±**	**8.57**	**194.38***	**±**	**15.09**
Female	Heart	47.09	±	4.39	47.66	±	2.43
	Liver	319.03	±	30.81	318.30	±	31.85
	Spleen	30.95	±	5.03	31.07	±	4.62
	Thymus	15.00	±	3.73	15.51	±	3.87
	Kidneys (2)	94.72	±	9.42	91.32	±	8.48
	Adrenal glands (2)	5.01	±	0.42	4.64	±	1.04
	Ovaries (2)	5.70	±	0.96	5.81	±	1.59

SD = Standard Deviation

* = Statistically significant difference between control and test groups ($p < 0.05$).

Appendix 15 - Body Weights for Individual Animals

Group	Sex	Animal Number	Body Weight (g)					
			Pretreatment	Week 1	Week 2	Week 3	Pre-fasted	Termination
Control Article	Male	6025	254	250	269	290	296	274
		6028	248	258	274	299	311	290
		6029	248	233	262	284	288	266
		6032	244	246	268	287	306	284
		6034	251	256	278	306	317	287
		6036	275	272	293	328	341	314
		6037	243	229	259	289	306	281
		6040	259	213	268	318	325	300
		6043	237	241	259	280	286	266
		6044	251	267	289	320	330	306
	Female	6049	183	191	210	231	227	203
		6051	197	197	194	217	218	198
		6052	177	179	194	210	219	194
		6053	184	191	200	211	209	193
		6059	177	156	178	195	179	168
		6060	193	193	208	223	232	208
		6061	176	153	180	209	219	193
		6062	176	178	194	219	219	194
		6063	167	167	175	184	188	167
		6066	192	190	198	226	233	205

Appendix 15 (continued) - Body Weights for Individual Animals

Group	Sex	Animal Number	Body Weight (g)					
			Pretreatment	Week 1	Week 2	Week 3	Pre-fasted	Termination
Test Article	Male	6026	250	238	272	300	324	295
		6030	244	251	276	298	307	282
		6031	252	258	286	301	323	295
		6033	254	258	286	307	327	302
		6035	260	265	290	310	319	295
		6039	237	255	278	306	309	286
		6041	240	253	286	298	320	287
		6042	246	249	284	301	310	282
		6045	250	240	267	286	291	272
		6046	265	262	290	307	315	293
	Female	6047	190	189	206	216	219	196
		6048	194	179	207	211	217	196
		6050	179	180	206	212	217	198
		6054	194	182	200	214	226	202
		6055	185	178	192	207	210	189
		6056	175	*	*	*	*	*
		6058	176	182	209	216	216	199
		6064	176	172	181	195	195	176
		6065	180	184	204	202	215	191
		6067	177	169	197	192	191	167

*Not applicable; animal was found dead on day 7.

Appendix 16 - Average Daily Food Consumption for Individual Animals

Group	Sex	Animal Number	Food Consumption (g)			
			Week 1	Week 2	Week 3	Week 4
Control Article	Male	6025	23	30	30	29
		6028	22	29	35	31
		6029	18	29	29	26
		6032	23	30	31	29
		6034	47	51	30	28
		6036	26	31	27	31
		6037	56	38	27	33
		6040	89	113	27	30
		6043	23	29	19	27
		6044	26	30	26	30
	Female	6049	46	31	27	26
		6051	20	25	21	25
		6052	20	27	17	27
		6053	41	63	59	44
		6059	93	103	90	64
		6060	51	49	23	27
		6061	98	104	18	26
		6062	22	28	22	26
		6063	19	24	16	24
		6066	20	24	18	25

Note: Chewed food on cage floor or pan was included in weight calculations

Appendix 16 (continued) - Average Daily Food Consumption for Individual Animals

Group	Sex	Animal Number	Food Consumption (g)			
			Week 1	Week 2	Week 3	Week 4
Test Article	Male	6026	20	30	25	32
		6030	22	30	24	27
		6031	22	28	24	31
		6033	25	30	23	34
		6035	27	29	26	31
		6039	28	29	20	30
		6041	22	31	23	32
		6042	23	32	25	31
		6045	20	37	21	28
		6046	26	35	30	34
	Female	6047	58	60	41	44
		6048	89	92	48	25
		6050	31	29	22	26
		6054	20	26	25	28
		6055	20	26	19	25
		6056	57	*	*	*
		6058	49	43	22	11
		6064	42	47	54	35
		6065	23	24	21	26
		6067	39	138	129	2

*Not applicable; animal was found dead on day 7.
Note: Chewed food on cage floor or pan was included in weight calculations

Appendix 17 - Erythema Scores for Individual Animals

Group	Sex	Animal Number	Erythema Score						
			Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Control Article	Male	6025	2	2	3	2	1	3	1
		6028	1	1	2	1	2	2	1
		6029	1	2	3	2	1	2	0
		6032	1	2	3	1	3	2	0
		6034	2	2	2	1	2	2	0
		6036	2	1	2	1	1	3	1
		6037	1	1	3	2	2	3	0
		6040	2	1	2	1	2	3	1
		6043	1	1	2	1	1	2	0
		6044	2	1	2	0	1	2	0
	Female	6049	2	2	2	1	2	3	1
		6051	2	1	2	0	2	3	0
		6052	2	1	2	1	2	2	0
		6053	2	1	2	2	2	3	1
		6059	2	1	2	1	1	3	0
		6060	2	1	2	1	2	2	0
		6061	2	1	2	0	2	2	0
		6062	2	1	2	1	2	2	0
		6063	2	2	1	2	2	2	1
		6066	1	2	2	1	2	2	0

Appendix 17 (continued) - Erythema Scores for Individual Animals

Group	Sex	Animal Number	Erythema Score						
			Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14
Control Article	Male	6025	1	2	2	1	1	1	1
		6028	0	2	1	1	1	1	1
		6029	1	2	2	1	0	1	1
		6032	1	2	2	1	2	1	1
		6034	0	1	1	1	0	0	0
		6036	1	3	2	2	1	1	1
		6037	1	2	1	1	0	1	0
		6040	0	2	2	2	2	1	1
		6043	0	1	0	0	0	0	0
		6044	0	2	1	1	0	0	0
	Female	6049	1	3	2	1	1	1	1
		6051	1	2	2	2	1	1	1
		6052	0	2	2	1	1	1	1
		6053	0	2	1	1	1	1	1
		6059	1	2	1	1	2	1	1
		6060	0	2	1	0	1	1	1
		6061	1	3	2	1	0	1	1
		6062	1	3	2	1	0	1	1
		6063	1	2	2	2	1	1	1
		6066	0	2	1	1	1	0	0

Appendix 17 (continued) - Erythema Scores for Individual Animals

Group	Sex	Animal Number	Erythema Score						
			Day 15	Day 16	Day 17	Day 18	Day 19	Day 20	Day 21
Control Article	Male	6025	1	1	1	0	0	0	0
		6028	1	2	1	0	0	0	0
		6029	1	1	0	0	0	0	0
		6032	1	1	1	0	0	0	0
		6034	0	0	0	0	0	0	0
		6036	1	1	0	0	0	0	0
		6037	0	0	0	0	0	0	0
		6040	1	1	1	1	0	0	0
		6043	0	0	0	0	0	0	0
		6044	0	0	0	0	0	0	0
	Female	6049	1	2	2	2	2	2	1
		6051	1	1	1	0	0	0	0
		6052	1	1	0	0	0	0	0
		6053	1	2	0	1	1	1	0
		6059	1	2	1	1	1	0	1
		6060	1	2	2	2	1	1	1
		6061	1	1	1	1	1	0	0
		6062	1	2	2	2	1	1	0
		6063	1	1	0	0	1	0	0
		6066	0	0	0	0	0	0	0

Appendix 17 (continued) - Erythema Scores for Individual Animals

Group	Sex	Animal Number	Erythema Score					
			Day 22	Day 23	Day 24	Day 25	Day 26	Day 27
Control Article	Male	6025	0	0	0	0	0	0
		6028	0	0	0	0	0	0
		6029	0	0	0	0	0	0
		6032	0	0	0	0	0	0
		6034	0	0	0	0	0	0
		6036	0	0	0	0	0	0
		6037	0	0	0	0	0	0
		6040	0	0	0	0	0	0
		6043	0	0	0	0	0	0
		6044	0	0	0	0	0	0
	Female	6049	1	0	0	1	1	1
		6051	0	0	1	1	1	1
		6052	0	0	0	0	0	0
		6053	1	1	1	1	1	1
		6059	1	1	1	1	1	1
		6060	1	1	1	1	1	1
		6061	0	0	0	0	0	0
		6062	1	0	1	1	1	1
		6063	0	0	0	0	0	0
		6066	0	0	0	0	0	0

Appendix 17 (continued) - Erythema Scores for Individual Animals

Group	Sex	Animal Number	Erythema Score						
			Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Test Article	Male	6026	2	2	2	1	2	3	1
		6030	3	1	2	1	3	2	1
		6031	1	1	2	0	2	2	0
		6033	3	2	2	1	1	4	0
		6035	2	1	2	1	3	2	1
		6039	1	2	2	1	3	2	0
		6041	1	2	2	1	2	2	0
		6042	2	2	2	1	3	2	0
		6045	3	3	2	2	2	2	1
		6046	1	2	2	2	1	2	0
	Female	6047	1	1	2	1	2	2	0
		6048	1	0	2	1	2	1	0
		6050	2	1	2	2	2	2	0
		6054	1	1	2	1	2	2	1
		6055	1	1	2	1	1	2	0
		6056	2	1	2	2	1	1	*
		6058	2	1	2	1	2	2	0
		6064	2	1	2	1	2	2	0
		6065	2	1	1	0	2	3	0
		6067	2	1	2	1	2	1	0

*Not applicable; animal was found dead on day 7.

Appendix 17 (continued) - Erythema Scores for Individual Animals

Group	Sex	Animal Number	Erythema Score						
			Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14
Test Article	Male	6026	1	2	1	1	1	1	1
		6030	1	2	1	1	1	1	1
		6031	0	2	1	1	1	1	1
		6033	0	2	1	1	0	0	0
		6035	0	2	1	1	1	1	1
		6039	0	2	2	1	1	1	1
		6041	1	2	1	1	0	0	0
		6042	0	2	1	1	1	1	1
		6045	1	2	1	0	0	0	0
		6046	0	2	2	1	1	0	1
	Female	6047	0	3	2	1	1	1	1
		6048	1	2	1	1	1	1	1
		6050	0	2	3	2	1	1	1
		6054	1	2	2	2	0	0	0
		6055	1	1	1	1	1	0	1
		6056	*	*	*	*	*	*	*
		6058	0	1	1	1	1	1	1
		6064	1	2	2	1	2	1	1
		6065	0	1	1	1	2	1	1
		6067	0	2	2	1	2	1	1

*Not applicable; animal was found dead on day 7.

Appendix 17 (continued) - Erythema Scores for Individual Animals

Group	Sex	Animal Number	Erythema Score						
			Day 15	Day 16	Day 17	Day 18	Day 19	Day 20	Day 21
Test Article	Male	6026	1	1	0	0	0	0	0
		6030	1	1	0	0	1	1	0
		6031	1	1	0	0	0	0	0
		6033	0	0	0	0	0	0	0
		6035	0	0	0	0	0	0	0
		6039	1	1	0	0	0	0	0
		6041	0	0	0	0	0	0	0
		6042	1	1	0	0	0	0	0
		6045	0	0	0	0	0	0	0
		6046	1	1	0	0	0	0	0
	Female	6047	1	2	1	0	1	1	0
		6048	1	1	1	0	1	0	0
		6050	1	1	1	0	1	0	0
		6054	0	1	0	0	0	0	0
		6055	1	1	1	1	1	1	0
		6056	*	*	*	*	*	*	*
		6058	1	2	1	0	0	0	0
		6064	1	2	0	1	1	1	0
		6065	1	2	1	0	0	0	0
		6067	1	1	1	1	1	1	0

*Not applicable; animal was found dead on day 7.

Appendix 17 (continued) - Erythema Scores for Individual Animals

Group	Sex	Animal Number	Erythema Score					
			Day 22	Day 23	Day 24	Day 25	Day 26	Day 27
Test Article	Male	6026	0	0	0	0	0	0
		6030	0	0	0	0	0	0
		6031	0	0	0	0	0	0
		6033	0	0	0	0	0	0
		6035	0	0	0	0	0	0
		6039	0	0	0	0	0	0
		6041	0	0	0	0	0	0
		6042	0	0	0	0	0	0
		6045	0	0	0	0	0	0
		6046	0	0	0	0	0	0
	Female	6047	1	1	1	1	1	1
		6048	0	0	0	0	0	0
		6050	1	1	0	1	1	1
		6054	0	0	0	0	0	0
		6055	1	1	1	1	1	1
		6056	*	*	*	*	*	*
		6058	0	0	0	0	0	0
		6064	0	0	0	0	0	0
		6065	0	0	0	0	0	0
		6067	0	0	1	1	1	1

*Not applicable; animal was found dead on day 7.

Appendix 18 - Edema Scores for Individual Animals

Group	Sex	Animal Number	Edema Score						
			Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Control Article	Male	6025	0	1	0	1	0	0	0
		6028	0	0	0	0	0	0	0
		6029	0	1	0	0	2	0	0
		6032	0	0	0	0	0	0	0
		6034	0	0	0	0	0	0	0
		6036	0	0	0	0	0	0	0
		6037	0	1	0	0	0	0	0
		6040	0	0	0	0	0	0	0
		6043	0	0	0	0	0	0	0
		6044	0	1	0	0	0	0	0
	Female	6049	0	1	0	0	0	0	0
		6051	0	0	0	0	0	0	0
		6052	0	0	0	0	0	0	0
		6053	0	1	0	0	0	0	0
		6059	0	0	0	0	0	0	0
		6060	0	0	0	0	0	0	0
		6061	0	0	0	0	0	0	0
		6062	0	0	0	0	0	0	0
		6063	0	1	0	0	2	0	0
		6066	0	0	0	0	1	0	0

Appendix 18 (continued) - Edema Scores for Individual Animals

Group	Sex	Animal Number	Edema Score						
			Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14
Control Article	Male	6025	0	0	0	0	0	0	0
		6028	0	0	0	0	0	0	0
		6029	0	0	0	0	0	0	0
		6032	0	0	0	0	0	0	0
		6034	0	0	0	0	0	0	0
		6036	0	0	0	0	0	0	0
		6037	0	0	0	0	0	0	0
		6040	0	0	0	0	0	0	0
		6043	0	0	0	0	0	0	0
		6044	0	0	0	0	0	0	0
	Female	6049	0	0	0	0	0	0	0
		6051	0	0	0	0	0	0	0
		6052	0	0	0	0	0	0	0
		6053	0	0	0	0	0	0	0
		6059	0	0	0	0	0	0	0
		6060	0	0	0	0	0	0	0
		6061	0	0	0	0	0	0	0
		6062	0	0	0	0	0	0	0
		6063	0	0	0	0	0	0	0
		6066	0	0	0	0	0	0	0

Appendix 18 (continued) - Edema Scores for Individual Animals

Group	Sex	Animal Number	Edema Score						
			Day 15	Day 16	Day 17	Day 18	Day 19	Day 20	Day 21
Control Article	Male	6025	0	0	0	0	0	0	0
		6028	0	0	0	0	0	0	0
		6029	0	0	0	0	0	0	0
		6032	0	0	0	0	0	0	0
		6034	0	0	0	0	0	0	0
		6036	0	0	0	0	0	0	0
		6037	0	0	0	0	0	0	0
		6040	0	0	0	0	0	0	0
		6043	0	0	0	0	0	0	0
		6044	0	0	0	0	0	0	0
	Female	6049	0	0	0	0	0	0	0
		6051	0	0	0	0	0	0	0
		6052	0	0	0	0	0	0	0
		6053	0	0	0	0	0	0	0
		6059	0	0	0	0	0	0	0
		6060	0	0	0	0	0	0	0
		6061	0	0	0	0	0	0	0
		6062	0	0	0	0	0	0	0
		6063	0	0	0	0	0	0	0
		6066	0	0	0	0	0	0	0

Appendix 18 (continued) - Edema Scores for Individual Animals

Group	Sex	Animal Number	Edema Score					
			Day 22	Day 23	Day 24	Day 25	Day 26	Day 27
Control Article	Male	6025	0	0	0	0	0	0
		6028	0	0	0	0	0	0
		6029	0	0	0	0	0	0
		6032	0	0	0	0	0	0
		6034	0	0	0	0	0	0
		6036	0	0	0	0	0	0
		6037	0	0	0	0	0	0
		6040	0	0	0	0	0	0
		6043	0	0	0	0	0	0
		6044	0	0	0	0	0	0
	Female	6049	0	0	0	0	0	0
		6051	0	0	0	0	0	0
		6052	0	0	0	0	0	0
		6053	0	0	0	0	0	0
		6059	0	0	0	0	0	0
		6060	0	0	0	0	0	0
		6061	0	0	0	0	0	0
		6062	0	0	0	0	0	0
		6063	0	0	0	0	0	0
		6066	0	0	0	0	0	0

Appendix 18 (continued) - Edema Scores for Individual Animals

Group	Sex	Animal Number	Edema Score						
			Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Test Article	Male	6026	0	0	0	0	0	0	0
		6030	0	0	0	0	0	0	0
		6031	0	0	0	0	0	0	0
		6033	0	0	0	0	0	0	0
		6035	0	0	0	1	0	0	0
		6039	0	0	1	1	0	0	0
		6041	0	1	0	0	0	0	0
		6042	0	1	0	0	0	0	0
		6045	0	1	0	0	0	0	0
		6046	0	0	0	0	0	0	0
	Female	6047	0	0	0	0	0	0	0
		6048	0	0	0	0	0	0	0
		6050	0	0	0	1	0	0	0
		6054	0	0	0	1	0	0	0
		6055	0	0	0	0	1	0	0
		6056	0	0	0	1	0	0	*
		6058	0	0	0	0	0	0	0
		6064	0	0	0	0	0	0	0
		6065	0	0	0	0	0	0	0
		6067	0	0	1	0	0	0	0

*Not applicable; animal was found dead on day 7.

Appendix 18 (continued) - Edema Scores for Individual Animals

Group	Sex	Animal Number	Edema Score						
			Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14
Test Article	Male	6026	0	0	0	0	0	0	0
		6030	0	0	0	0	0	0	0
		6031	0	0	0	0	0	0	0
		6033	0	0	0	0	0	0	0
		6035	0	0	0	0	0	0	0
		6039	0	0	0	0	0	0	0
		6041	0	0	0	0	0	0	0
		6042	0	0	0	0	0	0	0
		6045	0	0	0	0	0	0	0
		6046	0	0	0	0	0	0	0
	Female	6047	0	0	0	0	0	0	0
		6048	0	0	0	0	0	0	0
		6050	0	0	0	0	0	0	0
		6054	0	0	0	0	0	0	0
		6055	0	0	0	0	0	0	0
		6056	*	*	*	*	*	*	*
		6058	0	0	0	0	0	0	0
		6064	0	0	0	0	0	0	0
		6065	0	0	0	0	0	0	0
		6067	0	0	0	0	0	0	0

*Not applicable; animal was found dead on day 7.

Appendix 18 (continued) - Edema Scores for Individual Animals

Group	Sex	Animal Number	Edema Score						
			Day 15	Day 16	Day 17	Day 18	Day 19	Day 20	Day 21
Test Article	Male	6026	0	0	0	0	0	0	0
		6030	0	0	0	0	0	0	0
		6031	0	0	0	0	0	0	0
		6033	0	0	0	0	0	0	0
		6035	0	0	0	0	0	0	0
		6039	0	0	0	0	0	0	0
		6041	0	0	0	0	0	0	0
		6042	0	0	0	0	0	0	0
		6045	0	0	0	0	0	0	0
		6046	0	0	0	0	0	0	0
	Female	6047	0	0	0	0	0	0	0
		6048	0	0	0	0	0	0	0
		6050	0	0	0	0	0	0	0
		6054	0	0	0	0	0	0	0
		6055	0	0	0	0	0	0	0
		6056	*	*	*	*	*	*	*
		6058	0	0	0	0	0	0	0
		6064	0	0	0	0	0	0	0
		6065	0	0	0	0	0	0	0
		6067	0	0	0	0	0	0	0

*Not applicable; animal was found dead on day 7.

Appendix 18 (continued) - Edema Scores for Individual Animals

Group	Sex	Animal Number	Edema Score					
			Day 22	Day 23	Day 24	Day 25	Day 26	Day 27
Test Article	Male	6026	0	0	0	0	0	0
		6030	0	0	0	0	0	0
		6031	0	0	0	0	0	0
		6033	0	0	0	0	0	0
		6035	0	0	0	0	0	0
		6039	0	0	0	0	0	0
		6041	0	0	0	0	0	0
		6042	0	0	0	0	0	0
		6045	0	0	0	0	0	0
		6046	0	0	0	0	0	0
	Female	6047	0	0	0	0	0	0
		6048	0	0	0	0	0	0
		6050	0	0	0	0	0	0
		6054	0	0	0	0	0	0
		6055	0	0	0	0	0	0
		6056	*	*	*	*	*	*
		6058	0	0	0	0	0	0
		6064	0	0	0	0	0	0
		6065	0	0	0	0	0	0
		6067	0	0	0	0	0	0

*Not applicable; animal was found dead on day 7.

Appendix 19 - Wound Observations

Day 1

Group	Sex	Animal Number	Length (mm)	Height (mm)	Area (mm^2)	Percent Healed
Control Article	Male	6025*	30	25	750	Not Applicable
		6028*	29	24	696	Not Applicable
		6029*	25	25	625	Not Applicable
		6032*	25	22	550	Not Applicable
		6034*	24	23	552	Not Applicable
		6036*	25	23	575	Not Applicable
		6037*	25	21	525	Not Applicable
		6040*	30	21	630	Not Applicable
		6043*	19	20	380	Not Applicable
		6044*	23	20	460	Not Applicable
	Female	6049*	26	25	650	Not Applicable
		6051*	23	25	575	Not Applicable
		6052*	26	22	572	Not Applicable
		6053*	27	22	594	Not Applicable
		6059*	24	22	528	Not Applicable
		6060*	25	28	700	Not Applicable
		6061*	25	21	525	Not Applicable
		6062*	30	24	720	Not Applicable
		6063*	30	22	660	Not Applicable
		6066*	20	20	400	Not Applicable
Test Article	Male	6026*	31	21	651	Not Applicable
		6030*	30	22	660	Not Applicable
		6031*	30	20	600	Not Applicable
		6033*	29	19	551	Not Applicable
		6035*	29	22	638	Not Applicable
		6039*	27	22	594	Not Applicable
		6041*	23	21	483	Not Applicable
		6042*	24	23	552	Not Applicable
		6045*	24	26	624	Not Applicable
		6046*	21	19	399	Not Applicable
	Female	6047*	25	21	525	Not Applicable
		6048*	24	19	456	Not Applicable
		6050*	24	20	480	Not Applicable
		6054*	24	19	456	Not Applicable
		6055*	21	25	525	Not Applicable
		6056*	22	22	484	Not Applicable
		6058*	25	25	625	Not Applicable
		6064*	25	21	525	Not Applicable
		6065*	25	24	600	Not Applicable
		6067*	27	25	675	Not Applicable

*Minimal bleeding occurred during removal of bandage at wound edges.

Day 2

Group	Sex	Animal Number	Length (mm)	Height (mm)	Area (mm^2)	Percent Healed
Control Article	Male	6025*	35	25	875	-16.7
		6028*	30	25	750	-7.8
		6029*	30	20	600	4.0
		6032*	27	26	702	-27.6
		6034*	27	20	540	2.2
		6036	27	24	648	-12.7
		6037*	28	22	616	-17.3
		6040*	25	28	700	-11.1
		6043*	19	17	323	15.0
		6044	27	18	486	-5.7
	Female	6049*	27	23	621	4.5
		6051	26	22	572	0.5
		6052	26	20	520	9.1
		6053	25	23	575	3.2
		6059	23	22	506	4.2
		6060*	30	28	840	-20.0
		6061	26	19	494	5.9
		6062	33	22	726	-0.8
		6063*	32	23	736	-11.5
		6066*	21	23	483	-20.8
Test Article	Male	6026*	35	22	770	-18.3
		6030*	30	26	780	-18.2
		6031	35	16	560	6.7
		6033	39	18	702	-27.4
		6035*	36	22	792	-24.1
		6039*	30	23	690	-16.2
		6041	30	24	720	-49.1
		6042*	22	21	462	16.3
		6045*	26	25	650	-4.2
		6046*	30	19	570	-42.9
	Female	6047	30	26	780	-48.6
		6048	27	22	594	-30.3
		6050	27	28	756	-57.5
		6054	27	22	594	-30.3
		6055	27	22	594	-13.1
		6056	29	21	609	-25.8
		6058	28	24	672	-7.5
		6064*	30	29	870	-65.7
		6065	28	25	700	-16.7
		6067	30	25	750	-11.1

*Minimal bleeding around wound edges.

Day 3

Group	Sex	Animal Number	Length (mm)	Height (mm)	Area (mm^2)	Percent Healed
Control Article	Male	6025*	29	24	696	7.2
		6028*	26	21	546	21.6
		6029*	27	17	459	26.6
		6032*	28	19	532	3.3
		6034*	22	19	418	24.3
		6036*	26	20	520	9.6
		6037*	24	20	480	8.6
		6040*	29	20	580	7.9
		6043*	20	15	300	21.1
		6044*	22	15	330	28.3
	Female	6049*	25	21	525	19.2
		6051*	24	20	480	16.5
		6052*	19	20	380	33.6
		6053*	22	20	440	25.9
		6059*	20	20	400	24.2
		6060*	25	22	550	21.4
		6061*	22	21	462	12.0
		6062*	18	21	378	47.5
		6063*	28	20	560	15.2
		6066*	19	18	342	14.5
Test Article	Male	6026*	33	19	627	3.7
		6030*	31	21	651	1.4
		6031*	30	17	510	15.0
		6033*	32	15	480	12.9
		6035*	31	18	558	12.5
		6039*	26	20	520	12.5
		6041*	26	19	494	-2.3
		6042*	22	28	616	-11.6
		6045*	25	20	500	19.9
		6046*	25	20	500	-25.3
	Female	6047*	29	21	609	-16.0
		6048*	22	20	440	3.5
		6050*	24	20	480	0.0
		6054*	27	15	405	11.2
		6055*	25	20	500	4.8
		6056*	26	22	572	-18.2
		6058*	20	20	400	36.0
		6064*	24	21	504	4.0
		6065*	26	20	520	13.3
		6067*	25	20	500	25.9

*Minimal bleeding of wound at removal of bandage.

Day 4

Group	Sex	Animal Number	Length (mm)	Height (mm)	Area (mm^2)	Percent Healed
Control Article	Male	6025*	29	28	812	-8.3
		6028*	26	24	624	10.3
		6029*	24	20	480	23.2
		6032*	28	22	616	-12.0
		6034*	22	20	440	20.3
		6036*	24	22	528	8.2
		6037*	25	21	525	0.0
		6040*	25	22	550	12.7
		6043*	16	19	304	20.0
		6044*	21	18	378	17.8
	Female	6049*	21	23	483	25.7
		6051*	19	19	361	37.2
		6052*	20	19	380	33.6
		6053*	20	21	420	29.3
		6059*	20	27	540	-2.3
		6060*	25	25	625	10.7
		6061*	20	21	420	20.0
		6062*	25	23	575	20.1
		6063*	25	23	575	12.9
		6066*	20	18	360	10.0
Test Article	Male	6026*	30	18	540	17.1
		6030*	31	21	651	1.4
		6031*	20	29	580	3.3
		6033*	30	15	450	18.3
		6035*	30	18	540	15.4
		6039*	25	23	575	3.2
		6041*	24	18	432	10.6
		6042*	23	20	460	16.7
		6045*	25	21	525	15.9
		6046*	25	22	550	-37.8
	Female	6047*	20	21	420	20.0
		6048*	24	21	504	-10.5
		6050*	21	21	441	8.1
		6054*	24	18	432	5.3
		6055*	23	22	506	3.6
		6056	24	22	528	-9.1
		6058*	18	20	360	42.4
		6064*	25	21	525	0.0
		6065	25	23	575	4.2
		6067*	19	24	456	32.4

*Bleeding upon removal of bandage.

Day 5

Group	Sex	Animal Number	Length (mm)	Height (mm)	Area (mm^2)	Percent Healed
Control Article	Male	6025*	29	20	580	22.7
		6028*	28	21	588	15.5
		6029*	23	17	391	37.4
		6032*	27	20	540	1.8
		6034*	21	18	378	31.5
		6036*	25	21	525	8.7
		6037*	24	20	480	8.6
		6040*	25	20	500	20.6
		6043*	19	13	247	35.0
		6044*	22	12	264	42.6
	Female	6049*	23	20	460	29.2
		6051*	24	16	384	33.2
		6052*	21	18	378	33.9
		6053*	21	20	420	29.3
		6059*	22	25	550	-4.2
		6060*	22	24	528	24.6
		6061*	23	16	368	29.9
		6062*	25	21	525	27.1
		6063*	24	21	504	23.6
		6066*	20	16	320	20.0
Test Article	Male	6026*	32	18	576	11.5
		6030*	28	20	560	15.2
		6031*	31	16	496	17.3
		6033	29	18	522	5.3
		6035*	26	16	416	34.8
		6039*	25	20	500	15.8
		6041*	24	15	360	25.5
		6042*	24	20	480	13.0
		6045*	23	16	368	41.0
		6046*	24	19	456	-14.3
	Female	6047*	22	18	396	24.6
		6048	21	17	357	21.7
		6050*	23	18	414	13.8
		6054*	24	15	360	21.1
		6055*	21	18	378	28.0
		6056	23	17	391	19.2
		6058*	20	20	400	36.0
		6064*	24	21	504	4.0
		6065*	25	20	500	16.7
		6067*	25	20	500	25.9

*Bleeding upon removal of bandage.

Day 6

Group	Sex	Animal Number	Length (mm)	Height (mm)	Area (mm^2)	Percent Healed
Control Article	Male	6025*†	29	21	609	18.8
		6028*	25	20	500	28.2
		6029*	25	15	375	40.0
		6032*	25	20	500	9.1
		6034*	22	16	352	36.2
		6036*	24	20	480	16.5
		6037*	24	19	456	13.1
		6040*	24	20	480	23.8
		6043*†	18	10	180	52.6
		6044*†	24	12	288	37.4
	Female	6049*	22	19	418	35.7
		6051*†	25	18	450	21.7
		6052*†	22	17	374	34.6
		6053*†	22	20	440	25.9
		6059*	20	22	440	16.7
		6060*†	24	20	480	31.4
		6061	20	15	300	42.9
		6062*†	25	20	500	30.6
		6063*	21	20	420	36.4
		6066*	21	15	315	21.3
Test Article	Male	6026*	30	17	510	21.7
		6030*	30	18	540	18.2
		6031*†	28	15	420	30.0
		6033*†	30	10	300	45.6
		6035*†	29	16	464	27.3
		6039*	26	20	520	12.5
		6041*†‡	24	14	336	30.4
		6042*†	25	18	450	18.5
		6045*†	30	19	570	8.7
		6046*	24	17	408	-2.3
	Female	6047*†	23	19	437	16.8
		6048*†	20	19	380	16.7
		6050*	25	15	375	21.9
		6054*†	25	15	375	17.8
		6055*	22	18	396	24.6
		6056	22	15	330	31.8
		6058*†	18	19	342	45.3
		6064*	22	20	440	16.2
		6065*	25	20	500	16.7
		6067*	26	19	494	26.8

*Bleeding upon removal of bandage.
†Mild re-epithelialization.
‡4 mm^2 superficial ulcer in the middle of the wound.

Day 7

Group	Sex	Animal Number	Length (mm)	Height (mm)	Area (mm^2)	Percent Healed
Control Article	Male	6025*	27	18	486	35.2
		6028*	23	15	345	50.4
		6029*	24	10	240	61.6
		6032*	20	15	300	45.5
		6034*	20	10	200	63.8
		6036*	24	17	408	29.0
		6037*	22	17	374	28.8
		6040*	20	9	180	71.4
		6043*	17	6	102	73.2
		6044*	18	7	126	72.6
	Female	6049*	23	17	391	39.8
		6051*	20	13	260	54.8
		6052*	19	14	266	53.5
		6053*	20	15	300	49.5
		6059*	15	18	270	48.9
		6060*	21	15	315	55.0
		6061*	16	8	128	75.6
		6062*	23	17	391	45.7
		6063*	22	18	396	40.0
		6066*	19	11	209	47.8
Test Article	Male	6026*	28	15	420	35.5
		6030*	29	18	522	20.9
		6031*	29	6	174	71.0
		6033*	17	7	119	78.4
		6035*	28	6	168	73.7
		6039*	23	10	230	61.3
		6041*	17	12	204	57.8
		6042*	23	18	414	25.0
		6045*	23	7	161	74.2
		6046*	21	9	189	52.6
	Female	6047	18	14	252	52.0
		6048*	20	18	360	21.1
		6050	20	11	220	54.2
		6054*	22	9	198	56.6
		6055*	21	9	189	64.0
		6056	†	†	†	Not applicable
		6058*	10	8	80	87.2
		6064*	24	18	432	17.7
		6065*	24	18	432	28.0
		6067*	21	17	357	47.1

*Bleeding upon removal of bandage.
†Not applicable; animal was found dead on day 7.

Day 8

Group	Sex	Animal Number	Length (mm)	Height (mm)	Area (mm^2)	Percent Healed
Control Article	Male	6025*	28	15	420	44.0
		6028*	22	14	308	55.7
		6029*	26	10	260	58.4
		6032*	25	14	350	36.4
		6034*	20	8	160	71.0
		6036*	23	11	253	56.0
		6037*	22	10	220	58.1
		6040*	24	15	360	42.9
		6043	18	4	72	81.1
		6044*	21	5	105	77.2
	Female	6049*	21	12	252	61.2
		6051*	17	10	170	70.4
		6052*	20	11	220	61.5
		6053*	20	15	300	49.5
		6059*	18	15	270	48.9
		6060*	23	15	345	50.7
		6061*	18	10	180	65.7
		6062*	24	13	312	56.7
		6063*	20	10	200	69.7
		6066*	20	8	160	60.0
Test Article	Male	6026*	30	10	300	53.9
		6030*	28	15	420	36.4
		6031*	26	7	182	69.7
		6033*	30	5	150	72.8
		6035*	27	10	270	57.7
		6039*	25	9	225	62.1
		6041*	22	10	220	54.5
		6042*	23	11	253	54.2
		6045*	25	6	150	76.0
		6046*	22	8	176	55.9
	Female	6047*	20	15	300	42.9
		6048*	21	13	273	40.1
		6050*	20	11	220	54.2
		6054*	25	8	200	56.1
		6055*	19	8	152	71.0
		6056	†	†	†	Not applicable
		6058*	19	8	152	75.7
		6064*	25	15	375	28.6
		6065*	25	15	375	37.5
		6067*	24	15	360	46.7

*Bleeding upon removal of gauze.
†Not applicable; animal was found dead on day 7.

Day 9

Group	Sex	Animal Number	Length (mm)	Height (mm)	Area (mm^2)	Percent Healed
Control Article	Male	6025*	30	15	450	40.0
		6028*	21	11	231	66.8
		6029*	24	10	240	61.6
		6032*	25	14	350	36.4
		6034*	20	9	180	67.4
		6036*	20	10	200	65.2
		6037*	20	9	180	65.7
		6040*	22	14	308	51.1
		6043	18	3	54	85.8
		6044*‡	20	4	80	82.6
	Female	6049*	23	11	253	61.1
		6051*	20	10	200	65.2
		6052*	20	11	220	61.5
		6053*	18	14	252	57.6
		6059*	19	13	247	53.2
		6060*	24	15	360	48.6
		6061*	18	14	252	52.0
		6062*	25	12	300	58.3
		6063*	24	9	216	67.3
		6066*	21	6	126	68.5
Test Article	Male	6026*	30	9	270	58.5
		6030*	30	13	390	40.9
		6031*	26	7	182	69.7
		6033*‡	27	3	81	85.3
		6035*‡	29	8	232	63.6
		6039*	26	12	312	47.5
		6041*	19	8	152	68.5
		6042*	23	9	207	62.5
		6045*	21	4	84	86.5
		6046*	20	9	180	54.9
	Female	6047*	22	18	396	24.6
		6048*	21	10	210	53.9
		6050*	22	9	198	58.8
		6054*‡	24	5	120	73.7
		6055*	20	6	120	77.1
		6056	†	†	†	Not applicable
		6058*	20	9	180	71.2
		6064*	23	14	322	38.7
		6065*	22	12	264	56.0
		6067*	24	12	288	57.3

*Bleeding upon removal of gauze.
†Not applicable; animal was found dead on day 7.
‡Re-epitheliazation.

Day 10

Group	Sex	Animal Number	Length (mm)	Height (mm)	Area (mm^2)	Percent Healed
Control Article	Male	6025*	28	12	336	55.2
		6028	19	9	171	75.4
		6029*	23	6	138	77.9
		6032*	24	10	240	56.4
		6034	19	7	133	75.9
		6036*	21	9	189	67.1
		6037	22	6	132	74.9
		6040*	23	11	253	59.8
		6043	10	2	20	94.7
		6044	19	3	57	87.6
	Female	6049*	23	9	207	68.2
		6051*	19	9	171	70.3
		6052*	20	7	140	75.5
		6053*	20	10	200	66.3
		6059	18	10	180	65.9
		6060	22	13	286	59.1
		6061*	19	10	190	63.8
		6062*	27	14	378	47.5
		6063*	24	7	168	74.5
		6066*	23	4	92	77.0
Test Article	Male	6026*	30	9	270	58.5
		6030	29	9	261	60.5
		6031*	25	5	125	79.2
		6033	28	2	56	89.8
		6035*	29	6	174	72.7
		6039*	21	9	189	68.2
		6041*	20	5	100	79.3
		6042	23	8	184	66.7
		6045	21	2	42	93.3
		6046*	21	6	126	68.4
	Female	6047*	20	11	220	58.1
		6048*	19	10	190	58.3
		6050*	20	9	180	62.5
		6054*	24	4	96	78.9
		6055	18	5	90	82.9
		6056	†	†	†	Not applicable
		6058	18	5	90	85.6
		6064*	23	12	276	47.4
		6065*	19	11	209	65.2
		6067*	22	10	220	67.4

*Bleeding upon removal of gauze.
†Not applicable; animal was found dead on day 7.

Day 11

Group	Sex	Animal Number	Length (mm)	Height (mm)	Area (mm^2)	Percent Healed
Control Article	Male	6025	30	12	360	52.0
		6028*	22	5	110	84.2
		6029	25	5	125	80.0
		6032*	25	8	200	63.6
		6034	20	5	100	81.9
		6036	25	5	125	78.3
		6037	24	4	96	81.7
		6040*	25	10	250	60.3
		6043	18	2	36	90.5
		6044	22	2	44	90.4
	Female	6049	24	10	240	63.1
		6051*	20	10	200	65.2
		6052*	22	7	154	73.1
		6053*	24	12	288	51.5
		6059*	17	8	136	74.2
		6060	24	12	288	58.9
		6061*	18	8	144	72.6
		6062*	24	10	240	66.7
		6063	21	5	105	84.1
		6066	24	3	72	82.0
Test Article	Male	6026*	30	10	300	53.9
		6030*	30	7	210	68.2
		6031*	30	5	150	75.0
		6033*	32	1	32	94.2
		6035	30	3	90	85.9
		6039*	24	7	168	71.7
		6041*	25	5	125	74.1
		6042	22	6	132	76.1
		6045	25	1	25	96.0
		6046*	20	5	100	74.9
	Female	6047*	22	12	264	49.7
		6048*	20	10	200	56.1
		6050	24	7	168	65.0
		6054*	28	4	112	75.4
		6055	24	4	96	81.7
		6056	†	†	†	Not applicable
		6058	18	5	90	85.6
		6064	22	12	264	49.7
		6065	22	10	220	63.3
		6067	25	10	250	63.0

*Slight bleeding at bandage removal.
†Not applicable; animal was found dead on day 7.

Day 12

Group	Sex	Animal Number	Length (mm)	Height (mm)	Area (mm^2)	Percent Healed
Control Article	Male	6025*	30	6	180	76.0
		6028	19	5	95	86.4
		6029	23	3	69	89.0
		6032*	25	4	100	81.8
		6034	19	3	57	89.7
		6036*	23	3	69	88.0
		6037	20	1	20	96.2
		6040*	22	6	132	79.0
		6043	0	0	0	100
		6044	5	1	5	98.9
	Female	6049	22	6	132	79.7
		6051	20	5	100	82.6
		6052	20	2	40	93.0
		6053*	20	6	120	79.8
		6059	16	5	80	84.8
		6060	22	6	132	81.1
		6061	16	3	48	90.9
		6062‡	21	7	147	79.6
		6063	17	2	34	94.8
		6066*	11	1	11	97.3
Test Article	Male	6026	31	4	124	81.0
		6030*	31	3	93	85.9
		6031	29	2	58	90.3
		6033	30	1	30	94.6
		6035*	30	2	60	90.6
		6039	26	2	52	91.2
		6041	22	1	22	95.4
		6042*	28	4	112	79.7
		6045	23	1	23	96.3
		6046	22	3	66	83.5
	Female	6047	20	8	160	69.5
		6048*	18	5	90	80.3
		6050	28	3	84	82.5
		6054	26	2	52	88.6
		6055	21	2	42	92.0
		6056	†	†	†	Not applicable
		6058	22	2	44	93.0
		6064	15	7	105	80.0
		6065*	21	5	105	82.5
		6067*	20	4	80	88.1

*Slight bleeding at bandage removal.
†Not applicable; animal was found dead on day 7.
‡Wound bed dry with eschar formation upon bandage removal.

Day 13

Group	Sex	Animal Number	Length (mm)	Height (mm)	Area (mm^2)	Percent Healed
Control Article	Male	6025	29	4	116	84.5
		6028	18	3	54	92.2
		6029	22	2	44	93.0
		6032*	23	2	46	91.6
		6034	0	0	0	100
		6036	21	2	42	92.7
		6037	15	1	15	97.1
		6040*	21	4	84	86.7
		6043	0	0	0	100
		6044	0	0	0	100
	Female	6049*	25	6	150	76.9
		6051	20	4	80	86.1
		6052*	18	2	36	93.7
		6053*	22	6	132	77.8
		6059	17	3	51	90.3
		6060	24	5	120	82.9
		6061	15	2	30	94.3
		6062‡	25	5	125	82.6
		6063	15	1	15	97.7
		6066	0	0	0	100
Test Article	Male	6026*	29	4	116	82.2
		6030*	32	1	32	95.2
		6031	25	1	25	95.8
		6033	0	0	0	100
		6035*	26	1	26	95.9
		6039	24	2	48	91.9
		6041	5	1	5	99.0
		6042	20	2	40	92.8
		6045	0	0	0	100
		6046	18	2	36	91.0
	Female	6047	18	6	108	79.4
		6048*	17	3	51	88.8
		6050*	17	2	34	92.9
		6054*	24	1	24	94.7
		6055	19	2	38	92.8
		6056	†	†	†	Not applicable
		6058	20	2	40	93.6
		6064	16	4	64	87.8
		6065	20	4	80	86.7
		6067*	19	4	76	88.7

*Slight bleeding at bandage removal.
†Not applicable; animal was found dead on day 7.
‡Eschar at cranial aspect of defect.

Day 14

Group	Sex	Animal Number	Length (mm)	Height (mm)	Area (mm^2)	Percent Healed
Control Article	Male	6025	30	4	120	84.0
		6028*	16	3	48	93.1
		6029	20	2	40	93.6
		6032	24	2	48	91.3
		6034	0	0	0	100
		6036	20	2	40	93.0
		6037	15	1	15	97.1
		6040*	21	3	63	90.0
		6043	0	0	0	100
		6044	0	0	0	100
	Female	6049*	21	5	105	83.8
		6051	20	4	80	86.1
		6052	19	2	38	93.4
		6053*	23	6	138	76.8
		6059	16	3	48	90.9
		6060*	24	5	120	82.9
		6061	15	2	30	94.3
		6062*	24	5	120	83.3
		6063	15	1	15	97.7
		6066	0	0	0	100
Test Article	Male	6026	32	4	128	80.3
		6030	30	2	60	90.9
		6031	25	2	50	91.7
		6033	0	0	0	100
		6035	27	1	27	95.8
		6039	25	4	100	83.2
		6041	0	0	0	100
		6042	21	3	63	88.6
		6045	0	0	0	100
		6046	18	2	36	91.0
	Female	6047	17	6	102	80.6
		6048	17	4	68	85.1
		6050	24	2	48	90.0
		6054	25	1	25	94.5
		6055	20	2	40	92.4
		6056	†	†	†	Not applicable
		6058	18	2	36	94.2
		6064	16	5	80	84.8
		6065*	20	4	80	86.7
		6067*	20	5	100	85.2

*Slight bleeding at bandage removal.
†Not applicable; animal was found dead on day 7.

Day 15

Group	Sex	Animal Number	Length (mm)	Height (mm)	Area (mm^2)	Percent Healed
Control Article	Male	6025	30	3	90	88.0
		6028	15	2	30	95.7
		6029	20	2	40	93.6
		6032	22	2	44	92.0
		6034	0	0	0	100
		6036	15	2	30	94.8
		6037	0	0	0	100
		6040	20	3	60	90.5
		6043	0	0	0	100
		6044	0	0	0	100
	Female	6049	21	5	105	83.8
		6051	19	3	57	90.1
		6052	17	2	34	94.1
		6053*	24	6	144	75.8
		6059*	17	3	51	90.3
		6060	22	5	110	84.3
		6061	15	2	30	94.3
		6062*	24	5	120	83.3
		6063	7	2	14	97.9
		6066	0	0	0	100
Test Article	Male	6026	22	2	44	93.2
		6030	24	2	48	92.7
		6031	22	1	22	96.3
		6033	0	0	0	100
		6035	0	0	0	100
		6039	23	2	46	92.3
		6041	0	0	0	100
		6042*	20	2	40	92.8
		6045	0	0	0	100
		6046	15	2	30	92.5
	Female	6047	17	6	102	80.6
		6048	17	4	68	85.1
		6050	20	2	40	91.7
		6054	22	1	22	95.2
		6055	18	2	36	93.1
		6056	†	†	†	Not applicable
		6058	18	2	36	94.2
		6064	15	4	60	88.6
		6065	18	3	54	91.0
		6067	17	4	68	89.9

*Slight bleeding at bandage removal.
†Not applicable; animal was found dead on day 7.

Day 16

Group	Sex	Animal Number	Length (mm)	Height (mm)	Area (mm^2)	Percent Healed
Control Article	Male	6025	35	4	140	81.3
		6028	16	3	48	93.1
		6029	30	2	60	90.4
		6032*	25	2	50	90.9
		6034	0	0	0	100
		6036	26	2	52	91.0
		6037	0	0	0	100
		6040	20	3	60	90.5
		6043	0	0	0	100
		6044	0	0	0	100
	Female	6049	25	5	125	80.8
		6051	24	3	72	87.5
		6052	10	2	20	96.5
		6053	25	6	150	74.7
		6059	22	3	66	87.5
		6060	29	5	145	79.3
		6061	21	2	42	92.0
		6062*	30	5	150	79.2
		6063	25	2	50	92.4
		6066	0	0	0	100
Test Article	Male	6026	25	3	75	88.5
		6030	10	2	20	97.0
		6031	16	2	32	94.7
		6033	0	0	0	100
		6035	0	0	0	100
		6039	24	2	48	91.9
		6041	0	0	0	100
		6042	27	2	54	90.2
		6045	0	0	0	100
		6046	22	2	44	89.0
	Female	6047*	21	4	84	84.0
		6048	25	7	175	61.6
		6050	25	6	150	68.8
		6054	25	1	25	94.5
		6055*	25	5	125	76.2
		6056	†	†	†	Not applicable
		6058*	20	3	60	90.4
		6064	18	5	90	82.9
		6065	20	3	60	90.0
		6067	25	7	175	74.1

*Slight bleeding at bandage removal.
†Not applicable; animal was found dead on day 7.

Day 17

Group	Sex	Animal Number	Length (mm)	Height (mm)	Area (mm^2)	Percent Healed
Control Article	Male	6025	28	2	56	92.5
		6028	23	2	46	93.4
		6029	10	2	20	96.8
		6032	25	3	75	86.4
		6034	0	0	0	100
		6036	25	2	50	91.3
		6037	0	0	0	100
		6040	20	2	40	93.7
		6043	0	0	0	100
		6044	0	0	0	100
	Female	6049	21	4	84	87.1
		6051	23	3	69	88.0
		6052	0	0	0	100
		6053	24	5	120	79.8
		6059	25	3	75	85.8
		6060	25	3	75	89.3
		6061	21	2	42	92.0
		6062	29	3	87	87.9
		6063	23	1	23	96.5
		6066	0	0	0	100
Test Article	Male	6026	11	2	22	96.6
		6030	8	1	8	98.8
		6031	16	1	16	97.3
		6033	0	0	0	100
		6035	0	0	0	100
		6039	19	2	38	93.6
		6041	0	0	0	100
		6042	25	1	25	95.5
		6045	0	0	0	100
		6046	20	1	20	95.0
	Female	6047	20	4	80	84.8
		6048	21	3	63	86.2
		6050	20	2	40	91.7
		6054	23	1	23	95.0
		6055	18	2	36	93.1
		6056	†	†	†	Not applicable
		6058	18	3	54	91.4
		6064	20	2	40	92.4
		6065	21	2	42	93.0
		6067	21	3	63	90.7

†Not applicable; animal was found dead on day 7.

Day 18

Group	Sex	Animal Number	Length (mm)	Height (mm)	Area (mm^2)	Percent Healed
Control Article	Male	6025	27	4	108	85.6
		6028	25	2	50	92.8
		6029	15	1	15	97.6
		6032	30	2	60	89.1
		6034	0	0	0	100
		6036	26	3	78	86.4
		6037	0	0	0	100
		6040	19	2	38	94.0
		6043	0	0	0	100
		6044	0	0	0	100
	Female	6049	21	5	105	83.8
		6051	15	3	45	92.2
		6052	0	0	0	100
		6053	25	7	175	70.5
		6059	17	3	51	90.3
		6060	23	3	69	90.1
		6061	19	2	38	92.8
		6062*	23	3	69	90.4
		6063	10	2	20	97.0
		6066	0	0	0	100
Test Article	Male	6026	16	2	32	95.1
		6030	9	2	18	97.3
		6031	24	2	48	92.0
		6033	0	0	0	100
		6035	29	2	58	90.9
		6039	8	2	16	97.3
		6041	0	0	0	100
		6042	24	3	72	87.0
		6045	0	0	0	100
		6046	20	2	40	90.0
	Female	6047	19	7	133	74.7
		6048	21	4	84	81.6
		6050	20	1	20	95.8
		6054	25	2	50	89.0
		6055	15	2	30	94.3
		6056	†	†	†	Not applicable
		6058	15	2	30	95.2
		6064	12	3	36	93.1
		6065	19	2	38	93.7
		6067	17	3	51	92.4

*Small amount of bleeding at incision when bandage was removed.
†Not applicable; animal was found dead on day 7.

Day 19

Group	Sex	Animal Number	Length (mm)	Height (mm)	Area (mm^2)	Percent Healed
Control Article	Male	6025	25	2	50	93.3
		6028	25	1	25	96.4
		6029	25	3	75	88.0
		6032	25	2	50	90.9
		6034	0	0	0	100
		6036	20	1	20	96.5
		6037	0	0	0	100
		6040	24	2	48	92.4
		6043	0	0	0	100
		6044	0	0	0	100
	Female	6049	22	6	132	79.7
		6051	25	2	50	91.3
		6052	0	0	0	100
		6053	28	9	252	57.6
		6059	19	2	38	92.8
		6060	26	6	156	77.7
		6061	20	2	40	92.4
		6062	30	5	150	79.2
		6063	25	2	50	92.4
		6066	0	0	0	100
Test Article	Male	6026	17	1	17	97.4
		6030	10	1	10	98.5
		6031	20	2	40	93.3
		6033	0	0	0	100
		6035	35	1	35	94.5
		6039	15	2	30	94.9
		6041	0	0	0	100
		6042	35	5	175	68.3
		6045	0	0	0	100
		6046	24	1	24	94.0
	Female	6047	20	5	100	81.0
		6048	22	5	110	75.9
		6050	25	1	25	94.8
		6054	35	1	35	92.3
		6055	25	2	50	90.5
		6056	†	†	†	Not applicable
		6058	17	2	34	94.6
		6064	15	4	60	88.6
		6065	21	3	63	89.5
		6067	20	3	60	91.1

†Not applicable; animal was found dead on day 7.

Day 20

Group	Sex	Animal Number	Length (mm)	Height (mm)	Area (mm^2)	Percent Healed
Control Article	Male	6025	10	1	10	98.7
		6028	11	1	11	98.4
		6029	0	0	0	100
		6032	21	1	21	96.2
		6034	0	0	0	100
		6036	0	0	0	100
		6037	0	0	0	100
		6040	0	0	0	100
		6043	0	0	0	100
		6044	0	0	0	100
	Female	6049	25	3	75	88.5
		6051	21	2	42	92.7
		6052	0	0	0	100
		6053	23	6	138	76.8
		6059	20	3	60	88.6
		6060	23	3	69	90.1
		6061	17	1	17	96.8
		6062	28	3	84	88.3
		6063	0	0	0	100
		6066	0	0	0	100
Test Article	Male	6026	0	0	0	100
		6030	9	1	9	98.6
		6031	0	0	0	100
		6033	0	0	0	100
		6035	0	0	0	100
		6039	0	0	0	100
		6041	0	0	0	100
		6042	0	0	0	100
		6045	0	0	0	100
		6046	0	0	0	100
	Female	6047	22	5	110	79.0
		6048	5	3	15	96.7
		6050	18	1	18	96.3
		6054	15	1	15	96.7
		6055	15	2	30	94.3
		6056	†	†	†	Not applicable
		6058	17	1	17	97.3
		6064	12	2	24	95.4
		6065	23	2	46	92.3
		6067	21	2	42	93.8

†Not applicable; animal was found dead on day 7.

Day 21

Group	Sex	Animal Number	Length (mm)	Height (mm)	Area (mm^2)	Percent Healed
Control Article	Male	6025	0	0	0	100
		6028	0	0	0	100
		6029	0	0	0	100
		6032	0	0	0	100
		6034	0	0	0	100
		6036	0	0	0	100
		6037	0	0	0	100
		6040	0	0	0	100
		6043	0	0	0	100
		6044	0	0	0	100
	Female	6049	21	2	42	93.5
		6051	0	0	0	100
		6052	0	0	0	100
		6053	19	5	95	84.0
		6059	19	2	38	92.8
		6060	25	2	50	92.9
		6061	0	0	0	100
		6062	25	2	50	93.1
		6063	0	0	0	100
		6066	0	0	0	100
Test Article	Male	6026	0	0	0	100
		6030	9	1	9	98.6
		6031	0	0	0	100
		6033	0	0	0	100
		6035	0	0	0	100
		6039	0	0	0	100
		6041	0	0	0	100
		6042	0	0	0	100
		6045	0	0	0	100
		6046	0	0	0	100
	Female	6047	20	6	120	77.1
		6048	5	3	15	96.7
		6050	18	1	18	96.3
		6054	15	1	15	96.7
		6055	15	1	15	97.1
		6056	†	†	†	Not applicable
		6058	0	0	0	100
		6064	10	1	10	98.1
		6065	16	1	16	97.3
		6067	21	2	42	93.8

†Not applicable; animal was found dead on day 7.

Day 22

Group	Sex	Animal Number	Length (mm)	Height (mm)	Area (mm^2)	Percent Healed
Control Article	Male	6025	0	0	0	100
		6028	0	0	0	100
		6029	0	0	0	100
		6032	0	0	0	100
		6034	0	0	0	100
		6036	0	0	0	100
		6037	0	0	0	100
		6040	0	0	0	100
		6043	0	0	0	100
		6044	0	0	0	100
	Female	6049	18	2	36	94.5
		6051	0	0	0	100
		6052	0	0	0	100
		6053	18	5	90	84.8
		6059	17	2	34	93.6
		6060	17	1	17	97.6
		6061	0	0	0	100
		6062*	18	1	18	97.5
		6063	0	0	0	100
		6066	0	0	0	100
Test Article	Male	6026	0	0	0	100
		6030	0	0	0	100
		6031	0	0	0	100
		6033	0	0	0	100
		6035	0	0	0	100
		6039	0	0	0	100
		6041	0	0	0	100
		6042	0	0	0	100
		6045	0	0	0	100
		6046	0	0	0	100
	Female	6047	15	5	75	85.7
		6048	0	0	0	100
		6050	13	1	13	97.3
		6054	0	0	0	100
		6055	15	1	15	97.1
		6056	†	†	†	Not applicable
		6058	0	0	0	100
		6064	0	0	0	100
		6065	0	0	0	100
		6067	18	2	36	94.7

*Slight bleeding at wound upon removal of article.
†Not applicable; animal was found dead on day 7.

Day 23

Group	Sex	Animal Number	Length (mm)	Height (mm)	Area (mm^2)	Percent Healed
Control Article	Male	6025	0	0	0	100
		6028	0	0	0	100
		6029	0	0	0	100
		6032	0	0	0	100
		6034	0	0	0	100
		6036	0	0	0	100
		6037	0	0	0	100
		6040	0	0	0	100
		6043	0	0	0	100
		6044	0	0	0	100
	Female	6049	20	2	40	93.8
		6051	0	0	0	100
		6052	0	0	0	100
		6053	22	4	88	85.2
		6059	15	2	30	94.3
		6060	20	1	20	97.1
		6061	0	0	0	100
		6062	25	1	25	96.5
		6063	0	0	0	100
		6066	0	0	0	100
Test Article	Male	6026	0	0	0	100
		6030	0	0	0	100
		6031	0	0	0	100
		6033	0	0	0	100
		6035	0	0	0	100
		6039	0	0	0	100
		6041	0	0	0	100
		6042	0	0	0	100
		6045	0	0	0	100
		6046	0	0	0	100
	Female	6047	20	5	100	81.0
		6048	0	0	0	100
		6050	13	1	13	97.3
		6054	0	0	0	100
		6055	16	1	16	97.0
		6056	†	†	†	Not applicable
		6058	0	0	0	100
		6064	0	0	0	100
		6065	0	0	0	100
		6067	20	2	40	94.1

†Not applicable; animal was found dead on day 7.

Day 24

Group	Sex	Animal Number	Length (mm)	Height (mm)	Area (mm^2)	Percent Healed
Control Article	Male	6025	0	0	0	100
		6028	0	0	0	100
		6029	0	0	0	100
		6032	0	0	0	100
		6034	0	0	0	100
		6036	0	0	0	100
		6037	0	0	0	100
		6040	0	0	0	100
		6043	0	0	0	100
		6044	0	0	0	100
	Female	6049	20	2	40	93.8
		6051	22	2	44	92.3
		6052	0	0	0	100
		6053	24	5	120	79.8
		6059	18	2	36	93.2
		6060	29	2	58	91.7
		6061	0	0	0	100
		6062	28	1	28	96.1
		6063	0	0	0	100
		6066	0	0	0	100
Test Article	Male	6026	0	0	0	100
		6030	0	0	0	100
		6031	0	0	0	100
		6033	0	0	0	100
		6035	0	0	0	100
		6039	0	0	0	100
		6041	0	0	0	100
		6042	0	0	0	100
		6045	0	0	0	100
		6046	0	0	0	100
	Female	6047	19	5	95	81.9
		6048	0	0	0	100
		6050	11	1	11	97.7
		6054	0	0	0	100
		6055	16	1	16	97.0
		6056	†	†	†	Not applicable
		6058	0	0	0	100
		6064	0	0	0	100
		6065	0	0	0	100
		6067	20	2	40	94.1

†Not applicable; animal was found dead on day 7.

Day 25

Group	Sex	Animal Number	Length (mm)	Height (mm)	Area (mm^2)	Percent Healed
Control Article	Male	6025	0	0	0	100
		6028	0	0	0	100
		6029	0	0	0	100
		6032	0	0	0	100
		6034	0	0	0	100
		6036	0	0	0	100
		6037	0	0	0	100
		6040	0	0	0	100
		6043	0	0	0	100
		6044	0	0	0	100
	Female	6049	25	5	125	80.8
		6051	25	2	50	91.3
		6052	0	0	0	100
		6053	25	9	225	62.1
		6059	18	3	54	89.8
		6060	30	5	150	78.6
		6061	0	0	0	100
		6062	30	4	120	83.3
		6063	0	0	0	100
		6066	0	0	0	100
Test Article	Male	6026	0	0	0	100
		6030	0	0	0	100
		6031	0	0	0	100
		6033	0	0	0	100
		6035	0	0	0	100
		6039	0	0	0	100
		6041	0	0	0	100
		6042	0	0	0	100
		6045	0	0	0	100
		6046	0	0	0	100
	Female	6047	20	10	200	61.9
		6048	0	0	0	100
		6050	25	1	25	94.8
		6054	0	0	0	100
		6055	20	2	40	92.4
		6056	†	†	†	Not applicable
		6058	0	0	0	100
		6064	0	0	0	100
		6065	0	0	0	100
		6067	25	5	125	81.5

†Not applicable; animal was found dead on day 7.

Day 26

Group	Sex	Animal Number	Length (mm)	Height (mm)	Area (mm^2)	Percent Healed
Control Article	Male	6025	0	0	0	100
		6028	0	0	0	100
		6029	0	0	0	100
		6032	0	0	0	100
		6034	0	0	0	100
		6036	0	0	0	100
		6037	0	0	0	100
		6040	0	0	0	100
		6043	0	0	0	100
		6044	0	0	0	100
	Female	6049	24	5	120	81.5
		6051	25	2	50	91.3
		6052	0	0	0	100.0
		6053	25	7	175	70.5
		6059	17	2	34	93.6
		6060	28	5	140	80.0
		6061	0	0	0	100
		6062*	30	4	120	83.3
		6063	0	0	0	100
		6066	0	0	0	100
Test Article	Male	6026	0	0	0	100
		6030	0	0	0	100
		6031	0	0	0	100
		6033	0	0	0	100
		6035	0	0	0	100
		6039	0	0	0	100
		6041	0	0	0	100
		6042	0	0	0	100
		6045	0	0	0	100
		6046	0	0	0	100
	Female	6047	19	9	171	67.4
		6048	0	0	0	100
		6050	20	1	20	95.8
		6054	0	0	0	100
		6055	18	2	36	93.1
		6056	†	†	†	Not applicable
		6058	0	0	0	100
		6064	0	0	0	100
		6065	0	0	0	100
		6067	20	3	60	91.1

*Approximate 2 mm x 1 mm portion of cranial wound appeared moist.
†Not applicable; animal was found dead on day 7.

Day 27

Group	Sex	Animal Number	Length (mm)	Height (mm)	Area (mm^2)	Percent Healed
Control Article	Male	6025	0	0	0	100
		6028	0	0	0	100
		6029	0	0	0	100
		6032	0	0	0	100
		6034	0	0	0	100
		6036	0	0	0	100
		6037	0	0	0	100
		6040	0	0	0	100
		6043	0	0	0	100
		6044	0	0	0	100
	Female	6049	24	5	120	81.5
		6051	25	2	50	91.3
		6052	0	0	0	100
		6053	25	7	175	70.5
		6059	17	2	34	93.6
		6060	28	5	140	80.0
		6061	0	0	0	100
		6062	30	4	120	83.3
		6063	0	0	0	100
		6066	0	0	0	100
Test Article	Male	6026	0	0	0	100
		6030	0	0	0	100
		6031	0	0	0	100
		6033	0	0	0	100
		6035	0	0	0	100
		6039	0	0	0	100
		6041	0	0	0	100
		6042	0	0	0	100
		6045	0	0	0	100
		6046	0	0	0	100
	Female	6047	19	9	171	67.4
		6048	0	0	0	100.0
		6050	19	1	19	96.0
		6054	0	0	0	100
		6055	18	2	36	93.1
		6056	†	†	†	Not applicable
		6058	0	0	0	100
		6064	0	0	0	100
		6065	0	0	0	100
		6067	20	3	60	91.1

†Not applicable; animal was found dead on day 7.

Appendix 20 - Hematology Values for Individual Animals

Group	Sex	Animal Number	WBC (10^3/µL)	RBC (10^6/µL)	HGB (g/dL)	HCT (%)	MCV (fL)	MCH (pg)
Control Article	Male	6025	9.64	9.49	16.2	51.6	54.3	17.0
		6028	6.98	8.79	15.9	50.4	57.3	18.1
		6029	7.98	8.98	16.2	49.5	55.1	18.1
		6032	5.47	9.67	15.0	48.8	50.5	15.5
		6034	5.57	9.26	16.6	52.1	56.3	18.0
		6036	8.56	9.36	16.0	51.4	54.9	17.1
		6037	7.95	8.70	16.5	52.7	60.6	19.0
		6040	7.70	8.92	16.4	51.3	57.5	18.3
		6043	7.38	8.60	15.6	47.9	55.7	18.1
		6044	10.40	9.82	17.9	56.2	57.3	18.2
	Female	6049	5.86	8.30	15.3	47.9	57.6	18.4
		6051	5.97	8.17	14.8	45.9	56.2	18.1
		6052	4.79	8.72	15.6	49.2	56.4	17.8
		6053	5.92	7.79	14.4	44.8	57.6	18.5
		6059	2.85	8.46	15.3	47.6	56.2	18.1
		6060	5.30	8.22	15.6	47.6	57.9	19.0
		6061	6.76	8.19	15.7	47.6	58.1	19.1
		6062	3.71	8.01	15.1	47.0	58.7	18.9
		6063	3.53	8.12	14.8	45.7	56.3	18.2
		6066	5.20	7.93	14.5	43.6	55.0	18.2

Appendix 20 (continued) - Hematology Values for Individual Animals

Group	Sex	Animal Number	MCHC (g/dL)	PLT (10^3/µL)	NEUTRO (%)	LYMPH (%)	MONO (%)	EOS (%)	BASO (%)
Control Article	Male	6025	31.4	1532	18.5	78.1	1.4	0.9	0.7
		6028	31.6	1133	16.3	80.0	2.1	0.4	0.6
		6029	32.8	927	14.7	80.5	2.0	1.3	0.7
		6032	30.8	1109	12.8	83.8	1.6	0.7	0.5
		6034	31.9	1000	16.2	81.1	0.9	0.9	0.4
		6036	31.2	1019	13.4	83.0	1.5	0.9	0.5
		6037	31.4	1028	11.8	84.8	1.0	1.3	0.5
		6040	31.9	1290	20.0	76.4	1.1	1.5	0.6
		6043	32.5	857	16.5	79.4	1.9	1.3	0.5
		6044	31.8	979	22.8	71.9	1.9	2.3	0.6
	Female	6049	32.0	1035	27.2	69.6	1.6	0.9	0.5
		6051	32.2	1262	28.6	68.1	1.7	0.6	0.6
		6052	31.7	1202	18.9	78.3	1.1	0.7	0.5
		6053	32.2	1566	42.9	52.5	2.4	1.2	0.5
		6059	32.2	1205	37.8	58.2	1.4	2.0	0.4
		6060	32.8	1549	41.3	54.4	1.6	1.6	0.5
		6061	32.9	1312	36.9	58.9	1.7	1.6	0.6
		6062	32.2	1274	27.5	67.2	3.7	0.9	0.3
		6063	32.4	1040	32.8	62.7	0.8	3.3	0.3
		6066	33.2	1444	15.5	80.3	1.7	1.8	0.4

Appendix 20 (continued) - Hematology Values for Individual Animals

Group	Sex	Animal Number	WBC (10^3/µL)	RBC (10^6/µL)	HGB (g/dL)	HCT (%)	MCV (fL)	MCH (pg)
Test Article	Male	6026	7.67	8.94	15.6	48.2	53.9	17.5
		6030	7.59	9.10	16.3	49.2	54.1	18.0
		6031	9.69	7.83	15.2	46.1	58.9	19.5
		6033	2.32	8.03	15.2	43.8	54.6	18.9
		6035	10.22	8.82	16.2	48.8	55.3	18.4
		6039	6.30	8.75	16.5	49.6	56.8	18.9
		6041	6.99	8.65	15.7	47.9	55.4	18.2
		6042	7.05	8.43	15.2	45.2	53.6	18.1
		6045	10.76	8.45	15.2	45.5	53.8	17.9
		6046	6.95	8.16	15.5	45.4	55.7	19.0
	Female	6047	6.85	7.65	14.2	42.9	56.0	18.6
		6048	4.72	8.32	15.7	46.1	55.4	18.9
		6050	5.24	8.65	15.6	46.8	54.2	18.1
		6054	3.60	8.01	15.2	45.1	56.3	19.0
		6055	6.82	8.67	15.4	45.6	52.6	17.7
		6056	*	*	*	*	*	*
		6058	5.81	8.06	14.8	44.3	55.0	18.4
		6064	5.51	8.47	16.4	48.9	57.7	19.3
		6065	4.61	8.26	15.4	45.5	55.1	18.6
		6067	3.45	8.57	15.6	47.7	55.6	18.2

*Not applicable; animal was found dead on day 7.

Appendix 20 (continued) - Hematology Values for Individual Animals

Group	Sex	Animal Number	MCHC (g/dL)	PLT (10^3/µL)	NEUTRO (%)	LYMPH (%)	MONO (%)	EOS (%)	BASO (%)
Test Article	Male	6026	32.5	1215	18.8	76.5	2.2	1.4	0.7
		6030	33.2	854	16.7	78.6	1.4	1.9	0.7
		6031	33.0	910	24.1	71.8	1.8	1.1	0.7
		6033	34.7	57	21.4	75.8	1.5	0.9	0.2
		6035	33.2	1240	18.0	78.0	1.2	1.2	0.7
		6039	33.2	782	21.8	73.7	1.5	2.1	0.5
		6041	32.8	1202	24.1	72.8	1.4	0.8	0.6
		6042	33.7	1176	18.3	78.9	1.0	0.9	0.6
		6045	33.4	1299	10.1	85.5	2.1	0.9	0.6
		6046	34.1	961	26.3	70.8	1.2	1.1	0.3
	Female	6047	33.1	994	62.4	31.0	1.7	4.2	0.4
		6048	34.1	949	38.6	55.4	1.9	3.5	0.4
		6050	33.4	1067	30.5	65.3	2.4	1.1	0.4
		6054	33.7	1464	39.5	53.4	1.2	5.2	0.4
		6055	33.7	960	24.8	70.7	1.3	2.3	0.4
		6056	*	*	*	*	*	*	*
		6058	33.4	810	19.8	76.6	1.3	1.7	0.5
		6064	33.5	861	33.5	60.5	1.4	3.8	0.5
		6065	33.8	1136	18.2	79.3	0.9	0.5	0.5
		6067	32.8	1209	39.9	53.3	1.1	4.9	0.6

*Not applicable; animal was found dead on day 7.

Appendix 21 - Absolute Differential Values for Individual Animals (10^3/µL)

Group	Sex	Animal Number	NEUTRO	LYMPH	MONO	EOS	BASO
Control Article	Male	6025	1.79	7.52	0.14	0.08	0.06
		6028	1.14	5.59	0.14	0.03	0.04
		6029	1.17	6.42	0.16	0.11	0.06
		6032	0.70	4.58	0.09	0.04	0.03
		6034	0.90	4.52	0.05	0.05	0.02
		6036	1.15	7.10	0.12	0.08	0.05
		6037	0.94	6.74	0.08	0.10	0.04
		6040	1.54	5.88	0.09	0.12	0.05
		6043	1.22	5.86	0.14	0.10	0.04
		6044	2.37	7.48	0.20	0.24	0.06
	Female	6049	1.60	4.08	0.09	0.05	0.03
		6051	1.71	4.07	0.10	0.04	0.04
		6052	0.90	3.75	0.05	0.03	0.02
		6053	2.54	3.11	0.14	0.07	0.03
		6059	1.08	1.66	0.04	0.06	0.01
		6060	2.19	2.89	0.09	0.09	0.02
		6061	2.49	3.98	0.12	0.11	0.04
		6062	1.02	2.49	0.14	0.03	0.01
		6063	1.16	2.21	0.03	0.12	0.01
		6066	0.81	4.17	0.09	0.09	0.02

Appendix 21 (continued) - Absolute Differential Values for Individual Animals (10^3/µL)

Group	Sex	Animal Number	NEUTRO	LYMPH	MONO	EOS	BASO
Test Article	Male	6026	1.44	5.87	0.17	0.11	0.06
		6030	1.27	5.97	0.11	0.15	0.05
		6031	2.34	6.96	0.17	0.10	0.07
		6033	0.50	1.76	0.03	0.02	0.01
		6035	1.84	7.97	0.13	0.12	0.08
		6039	1.37	4.64	0.10	0.13	0.03
		6041	1.68	5.09	0.10	0.05	0.04
		6042	1.29	5.56	0.07	0.06	0.04
		6045	1.09	9.20	0.22	0.10	0.06
		6046	1.83	4.92	0.08	0.07	0.02
	Female	6047	4.28	2.12	0.12	0.29	0.03
		6048	1.82	2.61	0.09	0.17	0.02
		6050	1.60	3.42	0.13	0.06	0.02
		6054	1.42	1.92	0.04	0.19	0.02
		6055	1.69	4.82	0.09	0.16	0.03
		6056	*	*	*	*	*
		6058	1.15	4.45	0.07	0.10	0.03
		6064	1.84	3.33	0.07	0.21	0.03
		6065	0.84	3.66	0.04	0.02	0.02
		6067	1.37	1.84	0.04	0.17	0.02

*Not applicable; animal was found dead on day 7.

Appendix 22 - Clinical Chemistry Values for Individual Animals

Group	Sex	Animal Number	BUN (mg/dL)	CR (mg/dL)	BUN/CR	GLU (mg/dL)	Na (mmol/L)	K (mmol/L)	Cl (mmol/L)
Control Article	Male	6025	23	0.3	77	111	144	5.2	104
		6028	19	0.3	63	86	144	5.4	102
		6029	23	0.4	58	91	143	4.8	103
		6032	24	0.4	60	88	144	5.5	105
		6034	21	0.4	53	95	144	5.1	104
		6036	21	0.4	53	120	142	5.2	102
		6037	18	0.3	60	87	142	5.9	102
		6040	16	0.3	53	137	143	5.4	105
		6043	20	0.3	67	103	143	4.7	105
		6044	20	0.3	67	83	145	5.2	104
	Female	6049	22	0.3	73	99	143	5.8	105
		6051	23	0.4	58	102	141	5.5	102
		6052	25	0.4	63	67	143	6.0	104
		6053	27	0.4	68	97	142	6.1	104
		6059	25	0.3	83	112	145	4.5	106
		6060	33	0.4	83	112	144	5.4	103
		6061	23	0.3	77	93	148	4.9	108
		6062	34	0.4	85	116	144	4.8	103
		6063	26	0.3	87	112	143	5.3	106
		6066	23	0.3	77	97	144	4.6	106

Appendix 22 (continued) - Clinical Chemistry Values for Individual Animals

Group	Sex	Animal Number	ALP (U/L)	ALT-SGPT (U/L)	AST-SGOT (U/L)	TOT BIL (mg/dL)	GGT (U/L)	TOT PRO (g/dL)	ALB (g/dL)
Control Article	Male	6025	145	52	137	0.1	1	4.8	2.7
		6028	115	38	122	0.2	0	5.1	2.9
		6029	113	32	131	0.1	0	5.1	2.7
		6032	166	38	135	0.1	0	4.8	2.7
		6034	160	39	125	0.1	0	5.2	2.8
		6036	121	34	95	0.1	0	4.5	2.6
		6037	108	37	119	0.2	0	4.9	2.7
		6040	126	35	101	0.1	0	4.7	2.6
		6043	107	37	124	0.1	0	4.6	2.6
		6044	86	49	160	0.1	0	4.9	2.6
	Female	6049	88	34	107	0.1	0	5.2	2.9
		6051	85	32	144	0.1	0	5.2	2.9
		6052	109	30	144	0.1	0	4.8	2.7
		6053	117	84	171	0.1	1	4.8	2.5
		6059	81	26	129	0.1	0	4.6	2.6
		6060	116	76	219	0.1	0	5.1	2.8
		6061	107	66	175	0.1	0	5.1	3.0
		6062	144	41	195	0.1	1	5.1	2.8
		6063	97	28	112	0.1	0	4.8	2.8
		6066	101	36	117	0.1	1	4.7	2.7

Appendix 22 (continued) - Clinical Chemistry Values for Individual Animals

Group	Sex	Animal Number	TOT GLOB (g/dL)	ALB/GLOB	Ca (mg/dL)	P (mg/dL)	CHOL (mg/dL)
Control Article	Male	6025	2.1	1.29	9.3	10.7	75
		6028	2.2	1.32	9.3	11.0	60
		6029	2.4	1.13	9.1	9.9	78
		6032	2.1	1.29	9.2	10.3	79
		6034	2.4	1.17	9.1	10.5	75
		6036	1.9	1.37	9.5	11.5	53
		6037	2.2	1.23	9.4	10.9	64
		6040	2.1	1.24	9.2	9.7	48
		6043	2.0	1.30	9.0	9.7	63
		6044	2.3	1.13	9.7	10.6	81
	Female	6049	2.3	1.26	9.3	10.8	55
		6051	2.3	1.26	9.6	10.5	66
		6052	2.1	1.29	9.3	13.1	56
		6053	2.3	1.09	8.9	10.9	50
		6059	2.0	1.30	8.4	10.5	45
		6060	2.3	1.22	8.7	12.1	59
		6061	2.1	1.43	9.6	10.9	65
		6062	2.3	1.22	8.7	11.4	49
		6063	2.0	1.40	8.9	11.1	65
		6066	2.0	1.35	8.6	10.4	53

Appendix 22 (continued) - Clinical Chemistry Values for Individual Animals

Group	Sex	Animal Number	BUN (mg/dL)	CR (mg/dL)	BUN/CR	GLU (mg/dL)	Na (mmol/L)	K (mmol/L)	Cl (mmol/L)
Test Article	Male	6026	19	0.4	48	129	143	5.3	101
		6030	19	0.3	63	107	145	5.1	104
		6031	18	0.3	60	92	146	4.7	107
		6033	16	0.4	40	92	138	7.8	105
		6035	19	0.3	63	106	145	5.2	106
		6039	18	0.2	90	79	145	5.3	106
		6041	23	0.3	77	118	145	5.4	104
		6042	19	0.3	63	94	144	5.4	104
		6045	19	0.3	63	102	143	5.8	102
		6046	15	0.2	75	91	144	5.7	105
	Female	6047	23	0.4	58	74	142	5.7	106
		6048	23	0.3	77	91	145	5.1	106
		6050	23	0.3	77	91	142	5.0	106
		6054	24	0.3	80	103	143	5.4	106
		6055	21	0.3	70	85	144	5.4	107
		6056	*	*	*	*	*	*	*
		6058	22	0.3	73	87	145	5.0	106
		6064	23	0.3	77	104	144	4.8	105
		6065	30	0.3	100	98	144	5.9	107
		6067	46	0.4	115	72	145	5.6	109

*Not applicable; animal was found dead on day 7.

Appendix 22 (continued) - Clinical Chemistry Values for Individual Animals

Group	Sex	Animal Number	ALP (U/L)	ALT-SGPT (U/L)	AST-SGOT (U/L)	TOT BIL (mg/dL)	GGT (U/L)	TOT PRO (g/dL)	ALB (g/dL)
Test Article	Male	6026	113	38	125	0.2	0	5.5	3.0
		6030	111	29	111	0.2	0	4.9	2.7
		6031	132	31	104	0.1	0	5.0	2.8
		6033	71	91	273	0.3	0	4.7	2.7
		6035	109	25	76	0.1	0	4.8	2.8
		6039	95	24	99	0.1	0	4.6	2.6
		6041	148	35	146	0.1	0	5.2	2.9
		6042	98	31	98	0.1	0	4.5	2.6
		6045	91	42	120	0.1	0	4.8	2.7
		6046	58	23	86	0.1	0	4.6	2.5
	Female	6047	115	31	95	0.1	0	4.9	2.7
		6048	103	36	112	0.1	0	5.2	2.9
		6050	100	54	127	0.1	0	4.4	2.5
		6054	69	29	109	0.1	0	4.7	2.7
		6055	72	63	108	0.1	0	4.6	2.6
		6056	*	*	*	*	*	*	*
		6058	63	70	123	0.1	0	4.7	2.7
		6064	104	33	103	0.1	0	4.9	2.6
		6065	121	40	163	0.1	1	4.9	2.7
		6067	101	50	138	0.1	1	4.9	2.6

*Not applicable; animal was found dead on day 7.

Group	Sex	Animal Number	TOT GLOB (g/dL)	ALB/GLOB	Ca (mg/dL)	P (mg/dL)	CHOL (mg/dL)
Test Article	Male	6026	2.5	1.20	9.5	9.0	77
		6030	2.2	1.23	9.2	9.5	58
		6031	2.2	1.27	8.9	9.4	74
		6033	2.0	1.35	8.3	11.1	80
		6035	2.0	1.40	9.3	10.2	61
		6039	2.0	1.30	9.1	9.9	60
		6041	2.3	1.26	9.5	11.0	74
		6042	1.9	1.37	8.8	9.3	52
		6045	2.1	1.29	8.9	9.2	50
		6046	2.1	1.19	9.1	8.7	59
	Female	6047	2.2	1.23	8.8	10.2	66
		6048	2.3	1.26	9.1	10.1	56
		6050	1.9	1.32	8.4	8.2	36
		6054	2.0	1.35	9.1	10.5	51
		6055	2.0	1.30	9.0	9.0	56
		6056	*	*	*	*	*
		6058	2.0	1.35	8.9	9.2	51
		6064	2.3	1.13	8.9	9.7	77
		6065	2.2	1.23	8.6	10.4	45
		6067	2.3	1.13	8.5	11.7	45

*Not applicable; animal was found dead on day 7.

Appendix 23 - Necropsy Observations for Individual Animals

Group	Sex	Animal Number	Macroscopic Observations
Control Article	Male	6025	Wound healed. Superficial abrasions on skin at edge of bandage (incidental finding), otherwise macroscopically normal.
		6028	Wound healed. Macroscopically normal.
		6029	Wound healed. Superficial abrasions on ventral abdomen at edge of bandage (incidental finding), otherwise macroscopically normal.
		6032	Wound healed. Macroscopically normal.
		6034	Wound healed. Superficial abrasions on ventral abdomen at edge of bandage (incidental finding). Right testicle small (20 mm x 14 m x 10 mm).
		6036	Wound healed. Diaphragmatic hernia of cranial liver lobe 5 mm in diameter.
		6037	Wound healed. Macroscopically normal.
		6040	Wound healed. Superficial abrasions on ventral abdomen at edge of bandage (incidental finding), otherwise macroscopically normal.
		6043	Wound healed. Macroscopically normal.
		6044	Wound healed. Macroscopically normal.
	Female	6049	Wound healing (3 mm x 25 mm with no erythema or edema). Macroscopically normal.
		6051	Wound healing (3 mm x 21 mm with no erythema or edema). Macroscopically normal.
		6052	Wound healed. Superficial abrasions on ventral abdomen at edge of bandage (incidental finding), otherwise macroscopically normal.
		6053	Wound healing (6 mm x 24 mm with no erythema or edema). Left kidney and adrenal in contact with one another. Cranial pole of left kidney conforming to shape of adrenal, consistent with long term bandage application.
		6059	Wound healing (2 mm x 18 mm with no erythema or edema). Macroscopically normal.
		6060	Wound healing (3 mm x 28 mm with no erythema or edema). Macroscopically normal.
		6061	Wound healing (1 mm x 24 mm with no erythema or edema). Macroscopically normal.
		6062	Wound healing (2 mm x 33 mm with no erythema or edema). Macroscopically normal.
		6063	Wound healed. Superficial abrasions on ventral abdomen at edge of bandage (incidental finding), otherwise macroscopically normal.
		6066	Wound healed. Scattered superficial raised, red areas of the skin adjacent to the healed wound.

Group	Sex	Animal Number	Macroscopic Observations
Test Article	Male	6026	Wound healed. Superficial abrasions on ventral abdomen next to bandage (incidental finding), otherwise macroscopically normal.
		6030	Wound healing (2 mm x 10 mm with no erythema or edema); previous observations indicated wound healed but after shaving, it was revealed a small wound was still observed. Superficial abrasions on ventral abdomen at edge of bandage (incidental finding), otherwise macroscopically normal.
		6031	Wound healed. Superficial raised, red, scattered areas to the left of the wound site and adjacent to the bandage.
		6033	Wound healed. Superficial scattered raised, red areas of the skin on either side of the healed wound. Fat caudal to the left kidney, raised with fresh hemorrhage consistent with injection site trauma from anesthesia.
		6035	Wound healed. Slight, scattered, raised red areas adjacent to wound site.
		6039	Wound healed. Scattered raised, red areas adjacent to the wound site.
		6041	Wound healed. Macroscopically normal.
		6042	Wound healed. Slight, raised, red areas on the sides of the thoracic/abdominal wall. Raised, red areas are at least 2 cm away from wound site.
		6045	Wound healed. Slight, scattered red, raised areas adjacent to the wound site.
		6046	Wound healed. Raised, red areas adjacent to the wound.
	Female	6047	Wound healing (7 mm x 24 mm with no erythema, slight erythema at central wound). Macroscopically normal.
		6048	Wound healing (2 mm x 24 mm with no erythema or edema). Macroscopically normal.
		6050	Wound healing (1 mm x 20 mm). Macroscopically normal.
		6054	Wound healed. Macroscopically normal.
		6055	Wound healing (2 mm x 20 mm). Macroscopically normal.
		6056	Animal found dead on day 7 with rigor mortis. Wound dimensions were 22 mm length x 19 mm width. Autolysis was present on the following organs: stomach, small and large intestines, liver, spleen, pancreas, kidneys, reproductive organs, heart, and lungs. In addition, the lungs were multi-focal dark red with lesions along the lung lobes consistent with autolysis.
		6058	Wound healing (1 mm x 24 mm). Macroscopically normal.
		6064	Wound healing (1 mm x 10 mm). Macroscopically normal.
		6065	Wound healed. Macroscopically normal.
		6067	Wound healing (3 mm x 23 mm). Macroscopically normal.

Appendix 24 - Organ Weight Data for Individual Animals (g)

Group	Sex	Animal Number	Brain	Heart	Liver	Spleen	Thymus	Kidneys	Adrenal Glands	Testes/ Ovaries
Control Article	Male	6025	1.94	1.00	6.95	0.67	0.47	2.13	0.10	3.35
		6028	1.74	1.21	7.57	0.62	0.29	2.30	0.10	3.06
		6029	1.83	0.88	7.01	0.73	0.33	2.14	0.05	3.14
		6032	2.04	1.17	7.21	0.66	0.34	1.85	0.07	3.25
		6034	1.93	1.04	7.85	0.69	0.25	2.33	0.04	3.17
		6036	1.95	0.98	8.72	0.81	0.33	2.77	0.07	3.68
		6037	2.00	1.06	7.66	0.76	0.45	2.16	0.08	3.43
		6040	1.99	1.00	8.44	0.69	0.44	2.24	0.08	3.34
		6043	1.80	0.94	7.05	0.66	0.26	2.28	0.07	3.30
		6044	1.98	1.23	8.74	0.88	0.45	2.49	0.06	3.38
	Female	6049	1.83	0.85	5.98	0.60	0.38	1.94	0.08	0.11
		6051	1.78	0.85	5.81	0.67	0.23	1.91	0.09	0.10
		6052	1.77	0.85	5.76	0.57	0.32	1.62	0.09	0.13
		6053	1.72	0.82	5.83	0.46	0.16	1.66	0.09	0.09
		6059	1.72	0.89	4.51	0.40	0.18	1.38	0.08	0.09
		6060	1.88	0.80	5.89	0.61	0.29	1.77	0.10	0.12
		6061	1.60	0.89	5.90	0.57	0.25	1.66	0.08	0.10
		6062	1.85	0.82	5.48	0.48	0.25	1.66	0.10	0.09
		6063	1.82	0.73	5.22	0.48	0.26	1.48	0.08	0.07
		6066	1.78	0.83	6.15	0.65	0.35	1.72	0.10	0.11

Appendix 24 (continued) - Organ Weight Data for Individual Animals (g)

Group	Sex	Animal Number	Brain	Heart	Liver	Spleen	Thymus	Kidneys	Adrenal Glands	Testes/ Ovaries
Test Article	Male	6026	1.74	1.11	7.84	0.77	0.51	2.33	0.06	3.46
		6030	1.92	1.08	7.21	0.72	0.31	2.29	0.06	3.51
		6031	1.85	1.12	7.52	0.66	0.42	2.35	0.05	3.47
		6033	1.88	1.20	8.43	0.91	0.52	2.51	0.09	3.95
		6035	1.95	1.13	7.98	0.81	0.47	2.18	0.07	4.25
		6039	1.86	1.00	7.72	0.81	0.40	2.24	0.07	3.38
		6041	1.88	1.16	7.74	0.76	0.40	2.43	0.09	3.48
		6042	2.03	1.02	7.42	0.60	0.32	2.29	0.09	3.74
		6045	1.84	0.93	7.18	0.71	0.42	2.15	0.10	3.30
		6046	1.74	1.20	8.11	0.85	0.45	2.66	0.09	3.76
	Female	6047	1.74	0.79	5.33	0.53	0.18	1.38	0.06	0.06
		6048	1.73	0.85	5.54	0.50	0.24	1.56	0.09	0.14
		6050	1.70	0.77	5.60	0.60	0.41	1.73	0.10	0.09
		6054	1.71	0.90	6.25	0.61	0.24	1.70	0.09	0.11
		6055	1.80	0.84	5.55	0.50	0.33	1.50	0.05	0.07
		6056	*	*	*	*	*	*	*	*
		6058	1.81	0.86	5.89	0.69	0.29	1.70	0.09	0.14
		6064	1.56	0.75	5.27	0.49	0.22	1.45	0.06	0.08
		6065	1.64	0.74	5.32	0.47	0.25	1.64	0.08	0.09
		6067	1.63	0.80	4.03	0.38	0.22	1.32	0.09	0.11

*Not applicable; animal was found dead on day 7.

Appendix 25 - Organ/Body Weight Ratios for Individual Animals (%)

Group	Sex	Animal Number	Brain	Heart	Liver	Spleen	Thymus	Kidneys	Adrenal Glands	Testes/ Ovaries
Control Article	Male	6025	0.71	0.36	2.54	0.24	0.17	0.78	0.04	1.22
		6028	0.60	0.42	2.61	0.21	0.10	0.79	0.03	1.06
		6029	0.69	0.33	2.64	0.27	0.12	0.80	0.02	1.18
		6032	0.72	0.41	2.54	0.23	0.12	0.65	0.02	1.14
		6034	0.67	0.36	2.74	0.24	0.09	0.81	0.01	1.10
		6036	0.62	0.31	2.78	0.26	0.11	0.88	0.02	1.17
		6037	0.71	0.38	2.73	0.27	0.16	0.77	0.03	1.22
		6040	0.66	0.33	2.81	0.23	0.15	0.75	0.03	1.11
		6043	0.68	0.35	2.65	0.25	0.10	0.86	0.03	1.24
		6044	0.65	0.40	2.86	0.29	0.15	0.81	0.02	1.10
	Female	6049	0.90	0.42	2.95	0.30	0.19	0.96	0.04	0.05
		6051	0.90	0.43	2.93	0.34	0.12	0.96	0.05	0.05
		6052	0.91	0.44	2.97	0.29	0.16	0.84	0.05	0.07
		6053	0.89	0.42	3.02	0.24	0.08	0.86	0.05	0.05
		6059	1.02	0.53	2.68	0.24	0.11	0.82	0.05	0.05
		6060	0.90	0.38	2.83	0.29	0.14	0.85	0.05	0.06
		6061	0.83	0.46	3.06	0.30	0.13	0.86	0.04	0.05
		6062	0.95	0.42	2.82	0.25	0.13	0.86	0.05	0.05
		6063	1.09	0.44	3.13	0.29	0.16	0.89	0.05	0.04
		6066	0.87	0.40	3.00	0.32	0.17	0.84	0.05	0.05

Appendix 25 (continued) - Organ/Body Weight Ratios for Individual Animals (%)

Group	Sex	Animal Number	Brain	Heart	Liver	Spleen	Thymus	Kidneys	Adrenal Glands	Testes/ Ovaries
Test Article	Male	6026	0.59	0.38	2.66	0.26	0.17	0.79	0.02	1.17
		6030	0.68	0.38	2.56	0.26	0.11	0.81	0.02	1.24
		6031	0.63	0.38	2.55	0.22	0.14	0.80	0.02	1.18
		6033	0.62	0.40	2.79	0.30	0.17	0.83	0.03	1.31
		6035	0.66	0.38	2.71	0.27	0.16	0.74	0.02	1.44
		6039	0.65	0.35	2.70	0.28	0.14	0.78	0.02	1.18
		6041	0.66	0.40	2.70	0.26	0.14	0.85	0.03	1.21
		6042	0.72	0.36	2.63	0.21	0.11	0.81	0.03	1.33
		6045	0.68	0.34	2.64	0.26	0.15	0.79	0.04	1.21
		6046	0.59	0.41	2.77	0.29	0.15	0.91	0.03	1.28
	Female	6047	0.89	0.40	2.72	0.27	0.09	0.70	0.03	0.03
		6048	0.88	0.43	2.83	0.26	0.12	0.80	0.05	0.07
		6050	0.86	0.39	2.83	0.30	0.21	0.87	0.05	0.05
		6054	0.85	0.45	3.09	0.30	0.12	0.84	0.04	0.05
		6055	0.95	0.44	2.94	0.26	0.17	0.79	0.03	0.04
		6056	*	*	*	*	*	*	*	*
		6058	0.91	0.43	2.96	0.35	0.15	0.85	0.05	0.07
		6064	0.89	0.43	2.99	0.28	0.13	0.82	0.03	0.05
		6065	0.86	0.39	2.79	0.25	0.13	0.86	0.04	0.05
		6067	0.98	0.48	2.41	0.23	0.13	0.79	0.05	0.07

*Not applicable; animal was found dead on day 7.

Appendix 26 - Organ/Brain Weight Ratios for Individual Animals (%)

Group	Sex	Animal Number	Heart	Liver	Spleen	Thymus	Kidneys	Adrenal Glands	Testes/ Ovaries
Control Article	Male	6025	51.55	358.25	34.54	24.23	109.79	5.15	172.68
		6028	69.54	435.06	35.63	16.67	132.18	5.75	175.86
		6029	48.09	383.06	39.89	18.03	116.94	2.73	171.58
		6032	57.35	353.43	32.35	16.67	90.69	3.43	159.31
		6034	53.89	406.74	35.75	12.95	120.73	2.07	164.25
		6036	50.26	447.18	41.54	16.92	142.05	3.59	188.72
		6037	53.00	383.00	38.00	22.50	108.00	4.00	171.50
		6040	50.25	424.12	34.67	22.11	112.56	4.02	167.84
		6043	52.22	391.67	36.67	14.44	126.67	3.89	183.33
		6044	62.12	441.41	44.44	22.73	125.76	3.03	170.71
	Female	6049	46.45	326.78	32.79	20.77	106.01	4.37	6.01
		6051	47.75	326.40	37.64	12.92	107.30	5.06	5.62
		6052	48.02	325.42	32.20	18.08	91.53	5.08	7.34
		6053	47.67	338.95	26.74	9.30	96.51	5.23	5.23
		6059	51.74	262.21	23.26	10.47	80.23	4.65	5.23
		6060	42.55	313.30	32.45	15.43	94.15	5.32	6.38
		6061	55.63	368.75	35.63	15.63	103.75	5.00	6.25
		6062	44.32	296.22	25.95	13.51	89.73	5.41	4.86
		6063	40.11	286.81	26.37	14.29	81.32	4.40	3.85
		6066	46.63	345.51	36.52	19.66	96.63	5.62	6.18

Appendix 26 (continued) - Organ/Brain Weight Ratios for Individual Animals (%)

Group	Sex	Animal Number	Heart	Liver	Spleen	Thymus	Kidneys	Adrenal Glands	Testes/ Ovaries
Test Article	Male	6026	63.79	450.57	44.25	29.31	133.91	3.45	198.85
		6030	56.25	375.52	37.50	16.15	119.27	3.13	182.81
		6031	60.54	406.49	35.68	22.70	127.03	2.70	187.57
		6033	63.83	448.40	48.40	27.66	133.51	4.79	210.11
		6035	57.95	409.23	41.54	24.10	111.79	3.59	217.95
		6039	53.76	415.05	43.55	21.51	120.43	3.76	181.72
		6041	61.70	411.70	40.43	21.28	129.26	4.79	185.11
		6042	50.25	365.52	29.56	15.76	112.81	4.43	184.24
		6045	50.54	390.22	38.59	22.83	116.85	5.43	179.35
		6046	68.97	466.09	48.85	25.86	152.87	5.17	216.09
	Female	6047	45.40	306.32	30.46	10.34	79.31	3.45	3.45
		6048	49.13	320.23	28.90	13.87	90.17	5.20	8.09
		6050	45.29	329.41	35.29	24.12	101.76	5.88	5.29
		6054	52.63	365.50	35.67	14.04	99.42	5.26	6.43
		6055	46.67	308.33	27.78	18.33	83.33	2.78	3.89
		6056	*	*	*	*	*	*	*
		6058	47.51	325.41	38.12	16.02	93.92	4.97	7.73
		6064	48.08	337.82	31.41	14.10	92.95	3.85	5.13
		6065	45.12	324.39	28.66	15.24	100.00	4.88	5.49
		6067	49.08	247.24	23.31	13.50	80.98	5.52	6.75

*Not applicable; animal was found dead on day 7.

AQUAOX INDUSTRIES INC
16155, Sierra Lakes Parkway,
Suite 160-714, Fontana,
CA 92336, USA.

Certificate of Analysis

Date of Manufacture:	03/06/2013
Product Name:	AX250
Batch / Lot #:	AX-13065-0210
Production Facility:	Innovacyn, Inc. 3546 N. Riverside Ave. Rialto, CA 92377
Testing Facility:	Innovacyn, Inc. 3546 N. Riverside Ave. Rialto, CA 92377

TEST	ANALYSIS	UNITS
FAC	233	ppm
pH	6.22	n/a
ORP	964	mV
Osmolarity	17	mOsm/kg

This certification states that the product AX250, bearing the above description and lot number, has been found to conform to the internal specifications established for this product. The above lot was made in accordance with our internal specifications and good manufacturing practices under controlled procedures.

This lot has been appropriately inspected and tested, and, to the best of our knowledge, conforms to all applicable test methods, standards and internal specifications.

This certification does not constitute any written or expressed warranty or guarantee of any kind.

Rebecca Lei _____ Date: 3/12/13

QA Regulatory Specialist

SR: EH 102-207960
(909)-829-1654
(888)-592-7844
www.aquaox.net
info@aquaox.net

EIN: 45-4763694
BANK: Comerica Bank
A/C: 1894563426
ABA: 121137522
EPA #: 085021-CA-001

Issued: March 21, 2013
Last Revised: May 3, 2013

FORM-COA-02

AQUAOX INDUSTRIES INC
16155, Sierra Lakes Parkway,
Suite 160-714,
Fontana. CA 92336. USA.

Certificate of Analysis

Date of Manufacture:	03 / 06 / 2013
Product Name:	AX250
Batch / Lot #:	AX-13065-0210
Production Facility:	Innovacyn, Inc. 3546 N. Riverside Ave. Rialto, CA 92377
Testing Facility:	Innovacyn, Inc. 3546 N. Riverside Ave. Rialto, CA 92377

TEST	ANALYSIS	UNITS
FAC	214	ppm
pH	6.03	n/a
Conductivity	1233	µS/cm
ORP	956	mV
Osmolality	21	mOsm/kg

This certification states that the intermediate product AX250, bearing the above description and lot number, has been found to conform to the internal specifications established for this product. The above lot was made in accordance with our internal specifications and current good manufacturing practices under controlled procedures.

This lot has been appropriately inspected and tested, and, to the best of our knowledge, conforms to all applicable test methods, standards and internal specifications.

This certification does not constitute any written or expressed warranty or guarantee of any kind.

Rebecca Lei _____ Date: 5 / 3 / 13

QA Regulatory Specialist

© Aquaox Industries Inc

Statement of Quality Assurance Activities

Phase Inspected*	Date Inspected	Date Reported to Study Director**	Date Reported to Management**
Implant	April 3, 2013	April 3, 2013	April 3, 2013
Study Data Review	May 22, 2013	May 22, 2013	May 22, 2013
Final Report Review	July 3, 2013	July 3, 2013	July 3, 2013

* The following phase of the study conducted at Antech Diagnostics was audited by their Quality Assurance Unit as documented on the quality assurance statement: Term, Study Data-Inspected May 17, 2013.
** Antech Diagnostics audit reported to Study Director and Management: May 20, 2013.

Based on a review of this study, it has been concluded that this report accurately describes the methods and standard operating procedures, and that the reported results accurately reflect the raw data of the study. This study has been reviewed in accordance with the provisions of the FDA Good Laboratory Practice Regulations (21 CFR, Part 58).

QA Representative: Susan Pellitieri 7-5-13

Susan Pellitieri, BA
Auditor, Quality Assurance

Date