TEST FACILITY

NAMSA
6750 Wales Road
Northwood, OH 43619
419.666.9455

SPONSOR

Huh Sung Yeu1
Arirang Ion
Room #302, Ace Techno S Cha Guro 3-dong
Guro-gu. Seoul,
Korea, Republic of

STUDY TITLE

FHSA Modified Oral Toxicity Study - 5 Rat, 7 Day (FASTOX)

TEST ARTICLE NAME

Arirang Multi-Ionizer

Note: Any test results under the name 'Arirangion' refer to ELIM Sterilizer products.

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Note: Any test results under the name 'Arirangion' refer to ELIM Sterilizer products.

Summary

The test article, Arirang Multi-lonizer, was screened for oral toxicity. The test was conducted in accordance with the guidelines of the Federal Hazardous Substances Act (FHSA) Regulations, 16 CFR 1500, but was modified by NAMSA to reduce the num ber of animals from ten to five and the number of observation days from 14 to 7.

A single dose of 5 g/kg of body weight was gavaged to five rats. The animals were then observed for up to 7 days for any signs of toxicity.

There was no mortality or significant evidence of toxicity observed in the rats. The test article would not be considered toxic at a dose of 5 g/kg by the oral route in the rat.

Study and Supervisory Personnel:

Colleen M. Stevenson, A.A.
Supervisor, Toxicology

Approved by:

Colleen M. Stévenson, A.A.
Supervisor, Toxicology

4-30-10
Date Completed

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Note: Any test results under the name 'Arirangion' refer to ELIM Sterilizer products.

1. Introduction

Purpose

The test article identified below was screened for oral toxicity to determine the potential for systemic toxicity of the article following a single dose in the rat.

Testing Guidelines

The study was conducted based on the Federal Hazardous Substances Act Regulations, 16 CFR 1500,, but was modified by NAMSA to reduce the number of animals from ten to five and the number of observation days from 14 to 7.

Dates
Test Article Receipt: April 16, 2010
Dosed: April 22, 2010
Observations Concluded: April 29, 2010

2. Materials

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

Test Article Naeie:	Aréang Multi-Ionizer
Test Article Identification:	None
Physical Description of the Test AHicle:	liquid
Storage Conditions:	Room Temperature
Preparation:	The test article was dosed as received. For this study, the density of ihe test article was determined to be 1.0 g/mL.

3. Test System

Test System Species:	Rat *(Rattus narvegicus)*
Strain:	Hla&:(SD)CVFB
Source:	Hilltop Lab Animals, Inc.
Sex:	Female
Body Weight Range:	258 grams to 282 grams at dosing
Age:	No particular age was prescribed for this test
AcGlimation Period:	Minimum 5 days
Number of Animals: I	Five
dentification Method:	Ear tag

Justification of **Test System**

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

Note: Any test results under the name 'Arirangion' refer to ELIM Sterilizer products.

4. Animal Management

Husbandry:	Conditionsconformed toNAMSAStandard OperatingProceduresthatarebasedonthe *"Guideforthe Care and Use ofLaboratory Animals."*
Food:	Acommercially availablerodentfeed, PROLAB **RMH** 1000-5P07, wasprovideddaily. Foodwas withheld 16-20 hours prior to dosing.
Water:	Potable water was provided *ad libilum* 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:	Animalswereindividually housed in stainlesssteelsuspended cages identified byacardindicatingthelab number, animal numbers, test code, sex and date dosed.
Environment:	Theanimalhousingroomtemperature and relativehumidity weremonitored daily. Thetemperaturefor the room was 64-79'F and therelative humidity was 30-70%. Therewere no significant temperature or relative humidity excursions that adversely affected the health of the animals.
	The light cycle was controlled using an automatlK tlmRfi (12 hours light, 12 hours dark). NAMS
Accreditation:	A 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.
Selection:	Only healthy, previously unused animals were **selected.**
Veterinary Care:	Standard veterinary **medical care** was provided in this study.
IACUC:	This procedure has been approved by NAMSA Institutional Animal Care and Use Committees (IACUC), and is reviewed at lcast annually by the same committees.

5. Method

The food for each rat was removed from each cage 16-20 hours prior to dosing. Each ratwas weighed and gavaged with the test article via astainless steel blunt-tipped cannula at adose of 5 g/kg ofbody weight. The animals were then returned to their cages and food was returned after treatment.

Animals were observed immediately after dosing, at 4 hours, and daily for up to 7 days for signs of illness or mortality. Body w eights were recorded at dosing and at 7 daysforsurvivors. Animals found dead duringthestudy or thoseeuthanized by carbon d ioxide inhalation at termination of thestudy were subjected to a macroscopic examination oftheviscera. Thesubstance was co nsidered "toxic" if it produced death within 7 days in 50% or more of the rats gavaged with a single 5 g/kg dose.

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

6. Results

Individual observations appear in Appendix 1.

Body Weight
Body weight data were acceptable.

Mortality
No animals died during the 7 day study.

Clinical Observations
All animals were 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.

Note: Any test results under the name 'Arirangion' refer to ELIM Sterilizer products.

7. Conclusion

The test article would not be considered toxic at a dose of 5 g/kg by the oral route in the rat.

Results and conclusions apply only to the test article tested. Any extrapolation of these data to other articles is the sponsor's responsibility. All procedures were conducted in conformance with good manufacturing practices and certified to lSO 13485:2003.

8. Records

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

9. References

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

National Research Council, *Guide for the Care and Use ofLaboratory Animals*, Washington, DC: National Academy Press, 1996.

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

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

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Appendix 1 - Individual Observations

Animal Number	Sex	Body Weight (g)		Clinical Observations (Days 0-7)	Necropsy (Day 7)
		Day 0	Day 7		
5038	Female	282	310	Normal	Macroscopically normal.
5039	Female	270	290	Normal	Macroscopically normal.
5040	Female	269	295	Normal	Macroscopically normal.
5041	Female	279	301	Normal	Macroscopically normal.
5042	Female	258	277	Normal	Macroscopically normal.
Mean:		272	295		

M = Male
F = Female

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SPONSOR

Huh Sung Yeul
Arirang Ion
Room #302, Ace Techno S Cha Guro 3-dong
Guro-gu, Seoul,
Korea, Republic of

STUDY TITLE

ISO Skin Irritation Study in Rabbits

TEST ARTICLE NAME

Arirang Multi-lonizer

Note: Any test results under the name 'Arirangion' refer to ELIM Sterilizer products.

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Note: Any test results under the name 'Arirangion' refer to ELIM Sterilizer products.

Summary

The test article, Arirang Multi-Ionizer, was evaluated for primary skin irritation in accordance with the guidelines of ISO 10993, Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Delayed-Type Hypersensitivity. Two 0.5 mL portions of the test article and control article were topically applied to the skin of each of three rabbits and left in **place** for 24 hours. The sites were graded for erythema and edema at 1, 24, 48 and 72 hours after removal of the single sample application.

There was very slight erythema and no edema observed on the skin of the animals. The Primary Irritation Index for the test article was calculated to be 0.0. The response of the test article was categorized as negligible.

Study and Supervisory Personnel:

Don R. Pohl, B.S.
Manager, Technical Sales and Services

Colleen M. Stevenson, A.A.
Supervisor, Toxicology

Approved by:

Colleen M. Stevenson, A.A.
Supervisor, Toxicology

Date Completed

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Note: Any test results under the name 'Arirangion' refer to ELIM Sterilizer products.

1. Introduction

Purpose

The test article identified below was evaluated the potential of a s Ble topical application to irritate skin of the rabbit.

Testing Guideliaes

This study was conducted based on the International Organization for Standardization l099o, Biological Evaluation of Medical Devices, *P*art 10: Tests for Irritation and Delayed-Type Hypersensitivity.

Dates

Test Article Receipt: April 16,2010
Treatment Started: April 22, 2010
Observations Concluded: April 26, 2010

2. Materials

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

Test Article Name:	Arirang Multi-lonizer
Test Article Identification:	None
_Physical Description of the **Test Article:**	liquid
Storage *Conditions:*	Room Temperature
Control A rticle:	Four-ply gauze supplied by the test facility, was cut into 25 mm x 25 mm sections, moistened with 0.5 mL of saline per section and backed with polyethylene plastic.
Control Article **Stability Testing:**	Marketed product, stability characterized by its labeling.
Control Article Strength, Purity **and Composition:**	Gauze: Strength: Not applicable, no active components in the formulation; **Purity:** FDA Quality System Requirements (QSR) as stipulated in 21 CFR Part 820; Composition: 20 % rayon, 80% polyester blend.
Preparatioa:	The test article was divided into 0.5 mL portions.

3. Test System

Test System

Species:	Rabbit *(Oryctolagus cuniculus)*
Breed:	New Zealand White
Source:	Myrtle's Rabbitry, Inc.
Sex:	Male
Body Weight:	2.5 kg at selection
Age:	Young adult Mini
Acclimation Period:	mum 5 days Thre
Number of Animals: I	e
dentification Method:	Ear tag

Justification of Test System

The rabbit (animal) is specified as an appropriate animal model for evaluating potential skin irritants by the **current** ANSI/ AAJ'vtI/ISO testing standards. The rabbit is widely used for this purpose and **relative** ranking of irritant scores can be deter mined.

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4. Animal Management

Husbandry:	Conditionsconformed toNAMSA Standard Operating Proceduresthatarebased on the *"Guideforthe Core and Use ofLaboratory Animals."*
Food:	A commercially available rabbit feed, PROLAB Hi-Fiber Rabbit - 5P25, was provided daily.
Water:	Potable water was provided *ad libitum* through species appropriate water containers or delivered through an automatic watering system.
Contaminants:	Contaminants reasonablyexpected in feedorwatersupplieswerenotbelieved to haveinfluencedthe outcome of this test.
Housing:	Animalswereindividually housed in stainlesssteelsuspended cages identified byacardindicatingthelab number, animal number, test code, sex, and date dosed.
Environment:	Theanimal housing roomtemperature and relativehumidity weremonitored daily. Thetemperature for the room was 61-72°F and the relative humidity was 30-70%. There were no significant temperature or relative humidity excursions that adversely affected the health of theanimals.
	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 D epartment of Agriculture. Additionally, NAMSA maintains an approved Animal Welfare **Assurance on** fi le with the National Institutes of Health, Office for Laboratory Animal Welfare.
Personnel:	Associates involved were appropriately qualified and trained.
Selection:	Only healthy, previously unused, animals free from irritation or other dermatological lesions that could i nterfere with the test were selected.
Veterinary **Care:**	Standard veterinary medical care was provided in this study.
IACUC:	This procedure has been approved by NAMSA Institutional Animal Care and Use Committees (IACUC), and is reviewed at least annually by the same committees.

5. Method

The animals wereweighed and the furon the **back of** each animal was clipped with an electricclipper 4 to 24 **hours** prior to treatment. On the day of treatment, four sites, two on each side of the back and positioned cranially and caudally, were de signated on each animal. The sites were free of blemishes that could interfere with the interpretation of results.

A 0.5 mL portion of the test article was applied to one cranial site and one caudal site tw o sites per animal) by introduction un der a 4 ply gauze layer to an area ofskin approximately 25 mm x 25 mm square. The patches were backed with plastic and cov ered with a nonreaclive tape. Thecontrol wasmoistened with 0.5 mL ofsaline and similarly applied to theopposite cranial and caudal sites. Thetrunk of each animal was wrapped with an elastic binder to maintain thetest patches in position. Animals wer e returned to their cages after treatment.

Aflerthe 24 hourexposure, the binders, tape, and patches were removed. Thesites weregentlywiped with agauzesponge 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. Dermalobservations forerythema and edemawere recorded at 1, 24, 48 and 72 hoursafterpatch removal in accordance with the criteria in Appendix 1.

Alltimesandtemperaturesreportedhereinareapproximate and arewithinrangesestablished by theexternalstandardsdescribed in the References section of this report and/or NAMSA standard operating procedures.

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6. Evaluation and Statisticai Analysis

The Primary Irritation Indexof the test was calculated following test completion for each animal. The erythema and edema sc ores obtained at the 24, 48 and 72 hour intervals were added together and divided by the total number of observations. This ca lculation wasconducted separately for the test and control article for each animal. Thescorefor the control wassubtracted fro m thescore for the test articleto obtain the Primary Irritation Score. The Primary Irritation Score foreach animal was added to gether and divided by the number of animals to obtain the Primary Irritation Index. The Primary Irritation Index was char acterized based on the definitions outlined in Appendix l.

7. Results

Allanimals appearedclinically normalthroughout thestudy. Individual results ofdermalscoringappear in Appendix 2. Very slight erythema and no edema reactions resulted in an overall evaluation ofnegligible irritation to the skin of the animals. The time of onset of the Maximum Irritation Response was at 1 hour and the time to Maximum response was 1 hour. The Primary Irritation Index of the test article was calculated to be 0.0. The irritation calculations are shownbelow:

Anima l Nuriiñe r	Test Score **Average**	Control Score **Average**	Individual Primary **Irritation Score**	**Cozabined Primary Irritation Score** (CPIS)	Iriitafion **Index** (CPIS 3)	**Response Category**
67555	0.0	- ____0.0	O.O	0.0	0.0	Negligible
67556	0.0	0.0	O.O			
67560	0.0	0.0	O.O			

8. Conclusion

There wasveryslight erythema and noedema observed on theskin oftheanimals. 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 thetestarticle tested. Any extrapolation ofthesedata to other articles is thesponsor's responsibility. All procedures were conducted in conformance with good manufacturing practices and certified to ISO 13485:2003.

9. Records

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

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

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

International Organization for Standardization (ISO) 10993, Biological Evaluation of Medical Devices - Pan 2: Animal Welfare Requirements (2006).

International Organization for Standardization (ISO) 10993, Biological Evaluation of Medical Devices - Part 10: Tests for I rritation and Delayed-Type Hypersensitivity (2002).

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Appendix 1 - Classification System For Skin Reaction

Reaction	Numerical Gmding
Erythema and Eschar Formation	
No erythema	0
Very slight erythema (barely perceptible)	I
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 I mm)	3
Severe edema (raised more than 1 mm anal extending beyond exposure area)	4
Total possible score for irritation	8

NOTE: Gther 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

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Animal Number/ Sex	Weight (kg)	Group	Observation	Itttery8l {hotlrs)							
				1		24		48		72	
				Laft	Ri@t	Aft	Ri$bt	Aft	Rigbt	Aft	might
67555 Male	2.5	Test	Erythema	0	0	0	0	0	0	0	0
			Edema	0	0	0	0	0	0	0	0
		Control	Erythema	0	0	0	0	0	0	0	0
			Edema	0	0	0	0	0	0	0	0
67556 Male	2.5	Test	Erythema	0	1	0	0	0	0	0	0
			Edema	0	0	0	0	0	0	0	0
		Control	Erythema	0	0	0	0	0	0	0	0
			Edema	0	0	0	0	0	0	0	0
67560 Male	2.5	Test	Erythema	0	0	0	0	0	0	0	0
			Edema	0	0	0	0	0	0	0	0
		Control	Erythema	0	0	0	0	0	0	0	0
			Edema	0	0	0	0	0	0	0	0

Note: Any test results under the name 'Arirangion' refer to ELIM Sterilizer products.