

GLP REPORT

TEST FACILITY

NAMSA
6750 Wales Road
Northwood, OH 43619
419.666.9455

SPONSOR

Hamid Lamoudan
CTT Group
3000, Avenue Boullé
St-Hyacinthe, Quebec J2S 1H9
Canada

CONFIDENTIAL

STUDY TITLE

ISO Skin Irritation Study in Rabbits

TEST ARTICLE NAME

CTT-Halo 1

TEST ARTICLE IDENTIFICATION

Antibacterial CADPAT



TABLE OF CONTENTS	Page
Summary	3
1. Introduction.....	4
2. Identification of Test and Control Articles	4
3. Test System.....	5
4. Animal Management	5
5. Method	6
6. Evaluation and Statistical Analysis	7
7. Results.....	7
8. Conclusion	7
9. Quality Assurance	7
10. Records	8
11. References.....	8
Appendix 1 - Classification System For Skin Reaction	9
Appendix 2 - Dermal Observations	10
Appendix 3 - Periodic Positive Control Study for Skin Irritation Study in Rabbits	11
Statement of Quality Assurance Activities	14

Summary

The test article, CTT-Halo 1, was evaluated for primary skin irritation in rabbits. This study was conducted in accordance with the guidelines of ISO 10993-23, Biological evaluation of medical devices - Part 23: Tests for irritation. Two 25 mm x 25 mm sections of the test article and control article were topically applied to the skin of each of three rabbits and left in place for a minimum of 23 hours and a maximum of 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 no erythema and no edema observed on the skin of the animals treated with the test article. 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: Michelle E. Zdawczyk, MS, ALAT
Associate Director, In Life Services

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 Approval:

Signed by:
Jennifer Johnson



Signer Name: Jennifer Johnson
Signing Reason: I approve this document
Signing Time: 28-Apr-2026 | 13:07 EDT
7E4D71A969E748DFA9B3B151541BAF7B

Jennifer M. Johnson, BS, LAT
Study Director

1. Introduction

1.1 Purpose

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

1.2 Testing Guidelines

This study was conducted based on the ISO 10993-23, Biological evaluation of medical devices - Part 23: Tests for irritation.

This test was performed in compliance with the ISO 13485 standard, with the test method accredited to the ISO 17025 standard.

1.3 Dates

Test Article Received:	March 26, 2026
Treatment Started:	April 16, 2026
Observations Concluded:	April 20, 2026

1.4 GLP Compliance

The study initiated by protocol signature on April 7, 2026 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.

1.5 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. Identification of Test and Control Articles

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

Table 1: Test Article

Name:	CTT-Halo 1
Identification:	Antibacterial CADPAT
Stability Testing:	In progress (per sponsor)
Expiration Date:	Stable for duration of intended testing (per sponsor)
Strength, Purity and Composition:	Strength: not applicable because no active ingredients are used to formulate a concentration; Purity: not applicable because the test article does not contain an active ingredient; Composition: The fabric is made of 50% nylon and 50% cotton.
Storage Conditions:	Ambient Temperature

Table 2: Control Article

Name:	Four-ply gauze, supplied by the test facility, was cut into 25 mm x 25 mm sections.
Stability Testing:	Marketed product, stable for intended use
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

3. Test System

3.1 Test System

Species:	Rabbit (<i>Oryctolagus cuniculus</i>)
Breed:	New Zealand White
Source:	Palladium Farms, Inc.
Sex:	Male
Body Weight Range:	3.2 kg to 3.3 kg at selection
Age:	Young adult
Acclimation Period:	Minimum 5 days
Number of Animals:	Three
Identification Method:	Ear tag or marking

3.2 Justification of Test System

The rabbit (animal) is specified as an appropriate animal model for evaluating potential skin irritants by the current ISO testing standards. The rabbit is widely used for this purpose and relative ranking of irritant scores can be determined. The susceptibility of the New Zealand White Rabbit to a known irritant, sodium lauryl sulfate (SLS), has been substantiated at NAMSA with this method under lab No. 25T_54924_02. Testing was completed on October 31, 2025 (see Appendix 3).

4. Animal Management

4.1 Husbandry, Housing and Environment

Conditions conformed to NAMSA Standard Operating Procedures that are based on the “*Guide for the Care and Use of Laboratory Animals*.” 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.

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 environmental excursions that adversely affected the health of the animals.

The light cycle was controlled using an automatic timer (12 hours light, 12 hours dark).

4.2 Food, Water and Contaminants

A commercially available rabbit feed, Laboratory Rabbit Diet - 5L6N, was provided daily. Potable water was provided *ad libitum* through species appropriate water containers or delivered through an automatic watering system.

No contaminants present in the feed and water impacted the results of this study.

4.3 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.

4.4 Personnel

Associates involved were appropriately qualified and trained.

4.5 Veterinary Care

Standard veterinary medical care was provided in this study.

4.6 IACUC

The procedures for this study were approved by the NAMSA Institutional Animal Care and Use Committee (IACUC) prior to conduct.

4.7 Selection

Only healthy, previously unused, animals free from irritation or other dermatological lesions that could interfere with the test were selected.

5. Method

5.1 Test Article Preparation

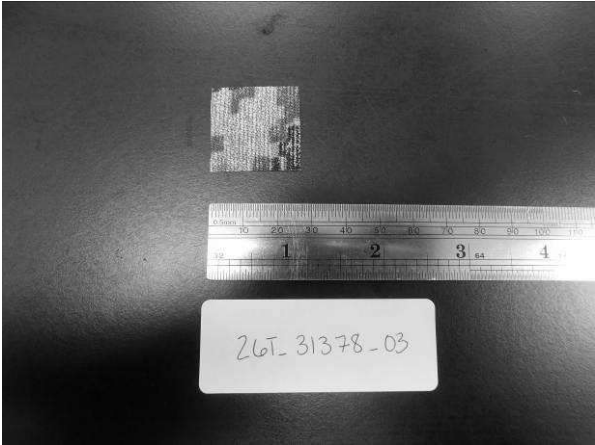
The test article was cut into 25 mm x 25 mm sections. The internal side (the side not labeled “face side”) was tested.

Figure 1: Representative Photographs of the Test Article

Test Article



Test Article Post-Preparation



5.2 Test Procedure

Prior to treatment, each animal was identified and weighed. Within a 4 to 24 hour period before treatment, each animal was clipped free of fur from the back and both sides of the spinal column to yield a sufficient area for application. 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.

The test article was applied to one cranial site on the left side and one caudal site on the right side (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 covered with a nonreactive tape. The control was similarly applied to the opposite cranial and caudal sites. 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 hours and a maximum of 24 hours 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.

5.2.1 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 at 1, 24, 48 and 72 hours after patch removal in accordance with the criteria in Appendix 1.

All times and temperatures 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 1 hour score was 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

7.1 Clinical Observations

All animals were clinically normal throughout the study.

7.2 Dermal Observations

Individual results of dermal scoring are presented 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:

Table 3: Irritation Calculations

Animal Number	Test Score Average	-	Control Score Average	Individual Primary Irritation Score	Summed Primary Irritation Score	Primary Irritation Index (Summed PI ÷ 3)	Response Category
87462	0.0	-	0.0	0.0	0.0	0.0	Negligible
87468	0.0	-	0.0	0.0			
87469	0.0	-	0.0	0.0			

8. Conclusion

There was no erythema and no edema observed on the skin of the animals treated with the test article. 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 in accordance with NAMSA SOPs.

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 (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 (2018).

International Organization for Standardization (ISO) 10993-2, Biological evaluation of medical devices - Part 2: Animal welfare requirements (2022).

International Organization for Standardization (ISO) 10993-12, Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (2021).

International Organization for Standardization (ISO) 10993-23, Biological evaluation of medical devices - Part 23: Tests for irritation (2021/Amendment 1 2025).

International Organization for Standardization (ISO) 13485, Medical devices - Quality management systems - Requirements for regulatory purposes (2016).

International Organization for Standardization (ISO) 17025, General requirements for the competence of testing and calibration laboratories (2017).

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)							
				1		24		48		72	
				Left	Right	Left	Right	Left	Right	Left	Right
87462 Male	3.2	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
87468 Male	3.3	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
87469 Male	3.3	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

Appendix 3 - Periodic Positive Control Study for Skin Irritation Study in Rabbits

Article

Sodium Lauryl Sulfate (SLS)

Dates

Treatment Started: October 27, 2025 under NAMSALab Number: 25T_54924_02
Observations Concluded: October 31, 2025
Report Finalized: December 31, 2025

Purpose

The purpose of this study was to demonstrate that the rabbit skin irritation reactivity model and test system could detect a positive response from an approximate 1% and 2.5% concentration of SLS with deionized water previously shown to elicit an irritant response. This study was conducted based on the guidelines of ISO 10993-23, Biological evaluation of medical devices - Part 23: Tests for irritation.

Materials and Methods

An approximate 1% and 2.5% SLS concentration was prepared by mixing SLS with deionized water. The test utilized young adult, male New Zealand White Rabbits Supplied by Palladium Farms, Inc. The weight at study initiation ranged from 2.9 kg to 3.7 kg. Two test article application patches were prepared per animal by applying 0.5 mL of the appropriate concentration of the SLS solution on a 4 ply, 25 mm x 25 mm gauze patch. Two control article application patches were similarly prepared. The test article patches were applied to one cranial and one caudal site on the back of each animal and the control patches were similarly applied to the opposite cranial and caudal sites. The patches were secured with nonreactive tape and 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 hours and a maximum of 24 hours of exposure, the binders, tape, and patches were removed. The sites were gently wiped with a gauze sponge dampened with deionized water in an attempt to remove any remaining residue. Dermal observations for erythema and edema were recorded at 1, 24, 48, and 72 hours after patch removal. Reactions were scored on a 0 to 4 basis. Any reactions at the application sites were also noted. The reactions were evaluated according to the following subjective rating scale.

Score	Erythema (ER) and Eschar	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)

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 3 (continued) - Periodic Positive Control Study for Skin Irritation Study in Rabbits**Results - Approximate 1%**

Animal Number/ Sex	Weight (kg)	Group	Observation	Interval (hours)							
				1		24		48		72	
				Left	Right	Left	Right	Left	Right	Left	Right
84235 Male	3.1	Test	Erythema	1	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
84237 Male	3.7	Test	Erythema	1	1	1	1	1	1	1	1
			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
84241 Male	2.9	Test	Erythema	1	1	1	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

Irritation Calculation

Animal Number	Test Score Average	-	Control Score Average	Individual Primary Irritation Score	Summed Primary Irritation Score	Primary Irritation Index (Summed PI ÷ 3)	Response Category
84235	0.0	-	0.0	0.0	1.2	0.4	Negligible‡
84237	1.0	-	0.0	1.0			
84241	0.2	-	0.0	0.2			

‡See Discussion section in 25T_54924_02

Conclusion

The approximate 1% SLS concentration demonstrated a positive response since the primary irritation index was slight or greater. The response of the approximate 1% SLS concentration was negligible.

Appendix 3 (continued) - Periodic Positive Control Study for Skin Irritation Study in Rabbits**Results - Approximate 2.5%**

Animal Number/ Sex	Weight (kg)	Group	Observation	Interval (hours)							
				1		24		48		72	
				Left	Right	Left	Right	Left	Right	Left	Right
84243 Male	3.1	Test	Erythema	2	2*	2	2*	2	2	3	2
			Edema	1	1	1	1	1	1	1	1
		Control	Erythema	0	0	0	0	0	0	0	0
			Edema	0	0	0	0	0	0	0	0
84244 Male	3.1	Test	Erythema	1	2*	1	3*	1	2	1	2
			Edema	0	1	0	1	0	1	0	1
		Control	Erythema	0	0	0	0	0	0	0	0
			Edema	0	0	0	0	0	0	0	0
84245 Male	3.1	Test	Erythema	2	2	2*	2	2	1	3	2
			Edema	1	1	1	0	1	0	1	0
		Control	Erythema	0	0	0	0	0	0	0	0
			Edema	0	0	0	0	0	0	0	0

*Slight tan discoloration present at site; did not interfere with scoring.

Irritation Calculation

Animal Number	Test Score Average	-	Control Score Average	Individual Primary Irritation Score	Summed Primary Irritation Score	Primary Irritation Index (Summed PI ÷ 3)	Response Category
84243	3.2	-	0.0	3.2	7.9	2.6	Moderate
84244	2.2	-	0.0	2.2			
84245	2.5	-	0.0	2.5			

Conclusion

The approximate 2.5% SLS concentration demonstrated a positive response since the primary irritation index was moderate or greater. The response of the approximate 2.5% SLS concentration was moderate.

Statement of Quality Assurance Activities

Phase Inspected	Date Inspected	Study Director Notification Date	Management Notification Date
Test Article Application	April 16, 2026	April 16, 2026	April 16, 2026
Final Report Review	April 28, 2026	April 28, 2026	April 28, 2026

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).

Signed by:





Signer Name: Lisa Byrd

Signing Reason: I have reviewed this document

Signing Time: 28-Apr-2026 | 12:41 EDT

77933E3E3BD649AFA58FAF00150CACDC

QA Representative:

Lisa M. Byrd RQAP-GLP, CQA, ALAT

Auditor, Quality Assurance

Taylor Irwin

From: OH Order Processing
Sent: Thursday, March 26, 2026 3:53 PM
To: Jenny Johnson
Cc: Taylor Irwin
Subject: FW: Electronic Sample Submission 488552-1

Categories: JMH

26T_31378

From: connect@namsa.com <connect@namsa.com>
Sent: Wednesday, March 25, 2026 12:10 PM
To: hlamoudan@gcttg.com
Subject: Electronic Sample Submission 488552-1

Overview

Submission ID: 488552
Revision #: 1
Date Created: 25 Mar 2026
Testing Location: Northwood
Control Article: No
Proposal Number: 1_Q-124259
Quantity Submitted: 1

Billing and Shipping

Bill To: CTT Group (50072)
3000, Avenue Boullé
St-Hyacinthe, Quebec J2S 1H9
Canada
Ship To: CTT Group (50072)
3000, Avenue Boullé
St-Hyacinthe, Quebec J2S 1H9
Canada
Contact: Hamid Lamoudan (50072_008)
CTT Group (50072)
hlamoudan@gcttg.com
450-501-4959

Test Article Information

Name: CTT-Halo 1
Test Article ID: Antibacterial CADPAT
Physical Description: Fabric treated with an antibacterial treatment
Type: Other
Type Other: Treated textile
Clinical Use: The treated fabric is intended for use in military applications as a functional antimicrobial textile for personnel equipment and field use
Sterility: Aseptically Prepared
Can Be Cut: Yes
Is An Absorbent: No
Reported Client Specific Number:
Special Instructions:

Contains Elastomer: No
Storage Conditions: Ambient (15-30 °C)
Shipping Conditions: Ambient
Shipping Receipt Date: Already Shipped
Disposition: Discard used and unused test article

GLP Information

Stability: Stability testing is in progress and sponsor affirms that test article is stable for duration of intended testing.

Analysis is not necessary due to test article being a solid, powder, gel, or
Analysis: liquid being extracted or tested as received (mixture with a carrier not needed).

26T-31378

Has Active Ingredient: No

Composition: The fabric is made of 50% nylon and 50% cotton.

Fabrication Method Documented: Yes

Testing Services

Test Code	Qty	Proposal	Grouping	STAT	Regulatory Scope	Draft Report	Comments	Purchase Order	Test Spec	Extracts
V0705-001	1	1_Q-124259		No	GLP	No	The sample I submitted is treated CADPAT fabric. I have specified the face side in the textile.	T26-0243 HL		
TI262-809	1	1_Q-124259		No	GLP	No	The sample I submitted is treated CADPAT fabric. I have specified the face side in the textile.	T26-0243 HL		

Attachments

File Name	Comment
T26-0243 HL-NAMSA.pdf	P.O

Authorization

Electronically Signed By: hlamoudan@gcttg.com

Date: 25 Mar 2026

Reviewed By (NAMSA Associate Signature): _____ Date: _____

Due to the current volume of chemical characterization and GLP biocompatibility testing, NAMSA has made process improvements to better serve you. Sponsors will not receive an assigned GLP study director until test articles arrive at the NAMSA laboratory. Following test article arrival, a study director will be assigned to begin work on study protocols. By making this process improvement, we can reduce the time required to initiate testing in our NAMSA laboratories. This does not apply to pre-clinical/surgical studies and does not modify any process in place for Non GLP studies. Thank you.

GLP PROTOCOL

TEST FACILITY

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STUDY TITLE

ISO Skin Irritation Study in Rabbits



TABLE OF CONTENTS		Page
Approvals.....		3
1.	Introduction	4
2.	Identification of Test and Control Articles	4
3.	Test System	4
4.	Animal Management.....	5
5.	Method	6
6.	Evaluation and Statistical Analysis.....	7
7.	Protocol Changes	7
8.	Report.....	7
9.	Quality Assurance	7
10.	Records.....	7
11.	References	8
Appendix 1 - Classification System For Skin Reaction		9

Approvals

Sponsor Representative:

Signé par :
Hamid Lamoudan

Nom du signataire : Hamid Lamoudan
Motif de la signature : J'approuve ce document
Heure de signature : 07-avr.-2026 | 09:08 EDT
EC4A188154CB4468832D5CE69D78D4E4

Study Director (NAMSA):

Signed by:
Jennifer Johnson

Signer Name: Jennifer Johnson
Signing Reason: I approve this document
Signing Time: 07-Apr-2026 | 09:36 EDT
7E4D71A969E748DFA9B3B151541BAF7B

Jennifer M. Johnson, BS, LAT
Study Director

1. Introduction

1.1 Purpose

The purpose of this study is to determine whether a single topical application of a designated test article is irritating to the skin of the rabbit.

1.2 Testing Guidelines

This study will be conducted based on the ISO 10993-23, Biological evaluation of medical devices - Part 23: Tests for irritation.

1.3 GLP Compliance

Good Laboratory Practice - This nonclinical laboratory study will be conducted in accordance with the United States Food and Drug Administration Good Laboratory Practice Regulations, 21 CFR Part 58.

1.4 Duplication of Experimental Work

By signature on this protocol, the sponsor confirms that the conduct of this study does not unnecessarily duplicate previous experiments.

2. Identification of Test and Control Articles

2.1 Test Article

The sponsor will submit the test article, CTT-Halo 1, to be evaluated. The sponsor provided detailed information about the test article to NAMSA on the sample submission form.

2.2 Control Article

4 ply, 25 mm x 25 mm sections of gauze will be used as the control article.

3. Test System

3.1 Test System

Species:	Rabbit (<i>Oryctolagus cuniculus</i>)
Breed:	New Zealand White
Source:	Single USDA licensed supplier
Sex:	No particular sex is prescribed for this test; females will be nulliparous and nonpregnant
Body Weight Range:	Not less than 2.0 kg at selection
Age:	Young adults
Acclimation Period:	Minimum 5 days
Number of Animals:	Three
Identification Method:	Ear tag or marking

3.2 Justification of Test System

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

4. Animal Management

4.1 Husbandry, Housing and Environment

Conditions will conform to NAMSA Standard Operating Procedures that are based on the “*Guide for the Care and Use of Laboratory Animals*.” Animals will be 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.

The animal housing room temperature and relative humidity will be monitored daily. The recommended temperature range for the room is 61-72°F. The recommended humidity range for the room is 30-70%.

The light cycle will be controlled using an automatic timer (12 hours light, 12 hours dark).

4.2 Food, Water and Contaminants

A commercially available rabbit feed will be provided daily. Potable water will be provided *ad libitum* through species appropriate water containers or delivered through an automatic watering system.

No contaminants present in the feed and water are expected to impact the results of this study.

4.3 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.

4.4 Personnel

Associates involved in this study will be appropriately qualified and trained.

4.5 Sedation, Analgesia or Anesthesia

It has been determined that the use of sedation, analgesia or anesthesia will not be necessary during the routine course of this procedure.

4.6 Veterinary Care

All anesthetics, analgesics, and other medications may be given or altered at the discretion of the attending veterinarian in accordance with standard veterinary practice and the study objectives. This applies to specific medication, dose, and dosing intervals. In the unlikely event that an animal should become injured, ill, or moribund, care will be conducted in accordance with current veterinary medical practice. If warranted for humane reasons, euthanasia will be conducted in accordance with the current report of the American Veterinary Medical Association's Guidelines on Euthanasia. The objective of the study will be given due consideration in any decision and the study sponsor will be advised.

4.7 IACUC

This test method has been approved by the NAMSA Institutional Animal Care and Use Committee (IACUC) and is reviewed by the same committee as required. Any changes to the test method that are incorporated into this protocol that pertain to the care and use of animals must be approved by the IACUC prior to conduct.

4.8 Selection

Only healthy animals with intact skin that is free from irritation or other dermatological lesions that could interfere with the test will be selected. To reduce the number of animals used for testing, and to comply with the directives of the NAMSA IACUC, animals on this study may have been used previously in an unrelated test model. Any previously evaluated test or control articles did not cause a response in the animals. Complete history of animal usage is traceable in laboratory records. Animals used for previous evaluations will be identified in the report.

5. Method

5.1 Test Article Preparation

The following information was completed based on the sponsor providing the information to NAMSA. The units of measure are per test site. Further instructions may be attached to the protocol.

The sample will be prepared as follows:

The test article will be cut into 25 mm x 25 mm sections, backed with a 4 ply, 25 mm x 25 mm gauze pad. The internal side (side not labeled face side) will be applied against the test system.

5.2 Control Article Preparation

4 ply, 25 mm x 25 mm sections of gauze will be used as the control article.

5.3 Test Procedure

Prior to treatment, each animal will be identified and weighed. Within a 4 to 24 hour period before treatment, each animal will be clipped free of fur from the back and both sides of the spinal column to yield a sufficient area for application. On the day of treatment, the test sample, prepared as previously specified, will be topically applied to one cranial site and one caudal site on the back of each animal.

The samples will be secured with a nonreactive tape. The control sample will be similarly applied to the opposite cranial and caudal sites. The entire trunk of each animal will be wrapped with an elastic binder to maintain the patches in position.

After a minimum of 23 hours and a maximum of 24 hours of exposure, the binder, tape, and patches will be removed. Material residue will be gently removed with a gauze sponge, saturated with deionized water.

5.4 Laboratory Observations

1. Animals will be observed daily for general health.
2. Body weights will be recorded for each animal at pretreatment.
3. Dermal observations for erythema and edema will be conducted at 1, 24, 48, and 72 hours after patch removal. Skin reactions will be graded in accordance with the criteria outlined in Appendix 1. Other adverse changes at the skin sites will also be recorded.

After the test is completed, all animals will be handled in accordance with IACUC approved NAMSA procedures.

6. Evaluation and Statistical Analysis

For each animal, the erythema and edema scores obtained at the 24, 48, and 72 hour intervals will be added together and divided by the total number of observations (six, two at each time specified). The 1 hour score is not included in the calculation. This calculation will be conducted separately for the test and control article for each animal. The score for the control will be subtracted from the score for the test article to obtain the Primary Irritation Score. The Primary Irritation Score of each animal will be added together and divided by the total number of animals to determine the Primary Irritation Index (PII). The Primary Irritation Index will be categorized based on the definitions outlined in Appendix 1. If scores are present, the Maximum Irritation Response will be determined.

7. Protocol Changes

Any necessary changes to the protocol after sponsor approval or study initiation will be documented and approved by the study director as protocol amendments. Copies will be distributed to the sponsor, the raw data file, and the NAMSA Quality Assurance department.

8. Report

The final report will contain a description of the methods employed, a table of individual erythema and edema scores, the Primary Irritation Index, the Maximum Irritation Response, and a summary of findings.

9. Quality Assurance

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

10. Records

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

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.

International Organization for Standardization (ISO) 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (2018).

International Organization for Standardization (ISO) 10993-2, Biological evaluation of medical devices - Part 2: Animal welfare requirements (2022).

International Organization for Standardization (ISO) 10993-12, Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (2021).

International Organization for Standardization (ISO) 10993-23, Biological evaluation of medical devices - Part 23: Tests for irritation (2021/Amendment 1 2025).

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



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