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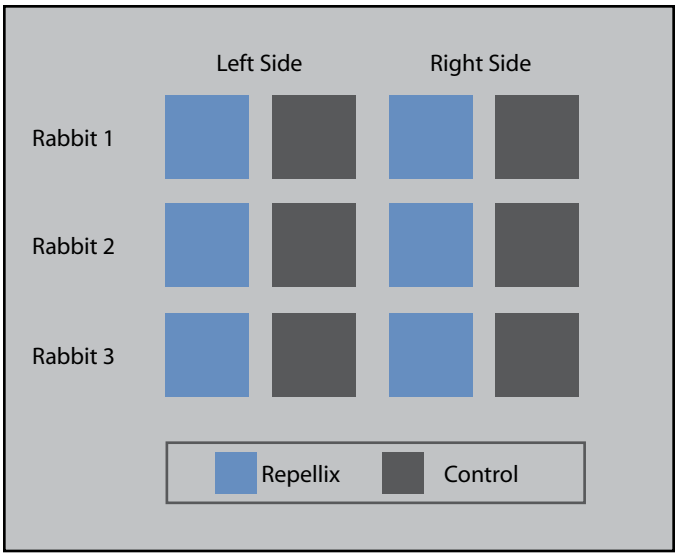
Repellix™ Skin Irritation Test

An evaluation of Repellix™ Coating from IST™ was conducted for primary skin irritation in accordance with the guidelines of the International Organization for Standardization 10993, Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Delayed-Type Hypersensitivity. The purpose of this study was to determine the potential for a single topical application of the test article to irritate the skin of a rabbit. Under the conditions of this study, no erythema and no edema were observed on the skin of the rabbits. 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 24 hours. The sites were graded for erythema and edema at 1, 24, 48 and 72 hours after removal of the single sample application. The control artical was a four-ply gauze supplied by the test facility, cut into 25 mm x 25 mm sections, moistened with 0.5 ml of saline per section and backed with polyethylene plastic.

Test Description



Repellix Lab Test - 2 Swatches per 3 Test Subjects

Test Results

Test Article		Observation	Interval (hours) 1 L	1 R	24 L	24 R	48 L	48 R	72 L	72 R
1		Erythema	0	0	0	0	0	0	0	0
		Edema	0	0	0	0	0	0	0	0
		Erythema	0	0	0	0	0	0	0	0
		Edema	0	0	0	0	0	0	0	0
2		Erythema	0	0	0	0	0	0	0	0
		Edema	0	0	0	0	0	0	0	0
		Erythema	0	0	0	0	0	0	0	0
		Edema	0	0	0	0	0	0	0	0
3		Erythema	0	0	0	0	0	0	0	0
		Edema	0	0	0	0	0	0	0	0
		Erythema	0	0	0	0	0	0	0	0
		Edema	0	0	0	0	0	0	0	0

Repellix Test Results:

Erythema is redness of the skin caused by capillary congestion. It can be caused by infection, massage, electrical treatments, acne medication, allergies, exercise, solar radiation (sunburn).

Edema is the increase of interstitial fluid in any organ, i.e., swelling.

No Erythema or Edema Observed

Biocompatability Test Details

Test System

Test System Management
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.

Animal Management
Conditions conformed to Standard Operating Procedures that are based on the "Guide for the Care and Use of Laboratory Animals."

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

Test Procedure

On the day prior to treatment, the animals were weighed and the fur on the back of each rabbit was clipped with an electric clipper. On the day of treatment, four sites, two on each side of the back and positioned cranially and caudally, were designated on each rabbit. The sites were free of blemishes that could interfere with the interpretation of results. A 25 mm x 25 mm section of the test article was moistened with 0.5 ml of saline, and applied to each cranial site (two sites per rabbit) 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 plastic and covered with a nonreactive tape. The control sample was similarly applied to the caudal sites. The trunk of each animal was wrapped with an elastic hinder to maintain the test patches in position. Animals were returned to their cages after treatment. After the 24 hour exposure, the hinders, 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.

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.

Results

Rabbit Number	Test Score Average	Control Score Average	Individual Primary Irritation Score	Combined Primary Irritation Score	Combined Primary Irritation Index	Response Category
90112	0.0	0.0	0.0	0.0	0.0	Negligible
89992	0.0	0.0	0.0			
89994	0.0	0.0	0.0			

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. 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 rabbit was added together and divided by the number of rabbits to obtain the Primary Irritation Index. All animals appeared clinically normal throughout the study. No irritation was observed on the skin of the rabbits. The Maximum Irritation Response was not applicable. The Primary Irritation Index of the test article was calculated to be 0.0. The irritation calculations are shown above.

Under the conditions of this study, no erythema and no edema were observed on the skin of the rabbits. The Primary Irritation Index for the test article was calculated to be 0.0. The response of the test article was categorized as negligible.

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