



Repellix™ Delayed Skin Sensitivity Study

An evaluation of Repellix™ Coating from IST™ was conducted by NAMSA to evaluate the potential for delayed dermal contact sensitization, 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 test spanned a three week period, consisting of nine treatments of six to eight hours each, three times per week, to each of 10 subjects. Following a recovery period, a challenge patch was applied and observations made for evidence of dermal reactions at 24 and 48 hour intervals after patch removal. Repellix showed no evidence of causing delayed dermal contact sensitization.

Test Method

After shaving the area, a 25 mm X 25 mm section of Repellix was applied and secured with hypoallergenic tape to the skin. At 6 to 8 hours, the patches were removed and the site cleaned of residue. This procedure was repeated three times each week for three consecutive weeks until nine applications were made to the left flank. 14 days after the final patch, a challenge patch was applied to the right flank of each test and control subject. At 24 hours after patch removal the challenge sites were shaved and dermal observations for erythema recorded 2-4 hours later, followed by observations at 48 hours after patch removal. No evidence of sensitization was observed.

Patch Test Reaction	Grading Scale
No Visible Change	0
Discrete or Patchy Erythema	1
Moderate and Confluent Erythema	2
Intense Erythema and Swelling	3

Dermal Reaction Scoring

Test Results

Test Group	Subject Number	Hours Following Patch Removal			
		24 Hour Score		48 Hour Score	
		Control	Test Article	Control	Test Article
Test	1	0	0	0	0
	2	0	0	0	0
	3	0	0	0	0
	4	0	0	0	0
	5	0	0	0	0
	6	0	0	0	0
	7	0	0	0	0
	8	0	0	0	0
	9	0	0	0	0
	10	0	0	0	0
Control	1	0	0	0	0
	2	0	0	0	0
	3	0	0	0	0
	4	0	0	0	0
	5	0	0	0	0

24 and 48 Hour Scores

Repellix Test Results:

No Evidence of Sensitization