



Number: B.30.2.HAC.0.03.00.00/

13-19

## SKIN IRRITATION TEST REPORT

### GENERAL INFORMATION

**Test Name** Skin irritation

**Guidelines**

This study followed the procedures indicated by the following internationally accepted guidelines:

ISO 10993: Biological evaluation of medical devices

ISO 10993-1: Evaluation and testing

ISO 10993-10: Test for irritation and skin sensitization

**Testing Facility** : Hacettepe University  
Faculty of Pharmacy  
Department of Pharmacology 06100 ANKARA

**Supplier of the Sample** : Kurt Kumaş San. ve Tic. A.Ş.  
2. O. S. B. 83228 No'lu Cd. No: 16 P. K. 6  
Başpınar / Gaziantep

**Test Sample** : 45 g/ sqm non-woven SMS web (polypropylen)  
**Intended use area** : Fabric for laboratory coat  
**Lot No** : 1767717  
**Quantity** : 75 mm x 50 mm

**Arrival of the test sample** : 15.03.2013

**Start of Experiment** : 09.04.2013

**End of Experiment** : 12.04.2013

**Date of Report** : 18.04.2013



Number: B.30.2.HAC.0.03.00.00/

13-19

### EXPERIMENTAL PROCEDURE

**Negative control:** 25 x 25 mm four-ply gauze patch

**Test procedure:**

Three healthy adult albino rabbits (either sex, 2-3 kg) was used.

On the day before the test, the fur on the back of the animals was clipped. A sufficient distance was kept on both sides of the spine for the application and observation of all test sites. The test material and a sample of negative control were applied directly to the skin on both sides in two different areas of the rabbit. The application sites were covered with a 25 x 25 mm gauze patch and were wrapped with a semi-occlusive bandage for 4 h. At the end of the contact time the patches and dressings were removed and the position of the sites were marked by permanent ink.



Number: B.30.2.HAC.0.03.00.00/

13-19

## OBSERVATION

Application sites are observed for erythema and oedema at 1<sup>st</sup>, 24<sup>th</sup>, 48<sup>th</sup>, and 72<sup>nd</sup> hours following the removal of the patches. Irritation was scored by using ISO 10993-10, "Scoring system for skin reaction". Irritation grades are presented mean of two application sites of either test or negative control. The primary irritation score for each animal is calculated by dividing the sum of all the irritation scores by three observation time points (24<sup>th</sup>, 48<sup>th</sup>, 72<sup>nd</sup> hours). Primary irritation index is calculated by dividing the all primary irritation scores by the number of animals. According to the primary irritation index numbers the results are presented as the appropriate response category which is given below.

### Scoring system for skin reaction

Reaction	Irritation score
<b>Erythema and eschar formation</b>	
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
<b>Oedema formation</b>	
No oedema	0
Very slight oedema (barely perceptible)	1
Well-defined oedema (edges of area well-defined by definite raising)	2
Moderate oedema (raised approximately 1 mm)	3
Severe oedema (raised more than 1 mm and extending beyond exposure area)	4
<b>Maximal possible score for irritation</b>	<b>8</b>
Other adverse changes at the skin sites shall be recorded and reported.	

3/4



Number: B.30.2.HAC.0.03.00.00/

13-19

## RESULT

One hour after removing the test and control patches, no erythema reaction was appeared on the application areas of the test material for each rabbit. No skin reaction appeared following the 24, 48 and 72 hours observations of the sites where test sample and negative control were applied. The primary irritation score for each rabbit was calculated using irritation grades shown below.

### Irritation scores for each rabbit at observation time points

Observation time points (hours)	1 <sup>st</sup> rabbit		2 <sup>nd</sup> rabbit		3 <sup>rd</sup> rabbit	
	Control site	Test site	Control site	Test site	Control site	Test site
24 <sup>th</sup>	0	0	0	0	0	0
48 <sup>th</sup>	0	0	0	0	0	0
72 <sup>nd</sup>	0	0	0	0	0	0
Primary irritation score	0	0	0	0	0	0

Primary irritation index: 0

Primary irritation index	Response category
0 to 0.4	Negligible
0.5 to 1.9	Slight
2 to 4.9	Moderate
5 to 8	Severe

Response category: Negligible

## CONCLUSION

This indicates that the test sample 45 g/sqm non-woven SMS web (polypropylen), (Lot1767717) **does not cause skin irritation.**

Study Director

Prof. Dr. Serdar UMA

4/4

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