HACETTEPE UNIVERSITY
Faculty of Pharmacy

Department of Pharmacology

SKIN IRRITATION TEST REPORT

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SKIN IRRITATION TEST REPORT FORM

Contract Number: **BU-2020/49B**

Customer Name/Address: Narkonteks Tekstil İhr. İth. San. ve Tic. A.Ş.
Doğuş Cad. 3/19 Sok. No: 12 Begos Buca İZMİR

Test Sample Name: SMS Blue Gown Fabric

Test Sample Description: Disposable surgical gown fabric

Test Sample Lot Number: 9060

Testing Facility: Hacettepe University Faculty of Pharmacy
Pharmacology Department
06100, Sıhhiye Ankara, Turkey

Arrival of the Test Sample: 15.09.2020

Date of Report: 02.10.2020

Attachment: Technical Information

RESULT

The test material "SMS Blue Gown Fabric (Lot 9060)" **does not cause skin irritation.**

ACTING COORDINATOR
ADMINISTRATIVE DIRECTOR

Professor Serdar Uma

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TECHNICAL INFORMATION

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GUIDELINES

TS EN ISO 10993:	Biological evaluation of medical devices
TS EN ISO 10993-1:2014	Evaluation and testing within a risk management process
TS EN ISO 10993-2:2006	Animal welfare requirements
TS EN ISO 10993-10:2014	Tests for irritation and skin sensitization
TS EN ISO 10993-12:2013	Sample preparation and reference materials

DESIGN OF STUDYING

Test Sample Quantity: 37.5 cm^2

Start of Test: 29.09.2020

End of Test: 02.10.2020

Practice*:

The test was performed on the samplings that were provided by the customer.

DIRECT CONTACT METHOD	X	EXTRACTION METHOD	-	OTHER/INSTRUCTIONS	-
Solid Samples: Test sample is used directly in accordance with TS EN ISO 10993-10 "Tests for irritation and skin sensitization" standart. Test samples was cut to size of 25x25 mm. Blank Sample: • 25 x 25 mm four-ply gauze patch		Test sample extract is prepared according to table of "Standart surface areas and extract liquid volumes" in TS EN ISO 10993-12 "Sample preparation and reference materials" standart. Extract is obtained by incubation of sample with physiological saline (% 0.9 (m/v) NaCl) and in non-polar solvent (sunflower oil) at 37 °C for 72 hours. At the end of the period, polar and nonpolar extracts were applied to the skin by 25 x 25 mm four layered gauze. All of the sample was extracted. **Blank Sample:** • 25 x 25 mm four-ply gauze patch with physiological saline (0.9 % (m/v) NaCl) (water-based sample) 25 x 25 mm four-ply gauze patch with sunflower oil (oil-based sample)			

*SIGN THE SUITABLE CHOICE WITH "X", UNSUITABLE CHOICE WITH "-".

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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 shaved. A sufficient distance was kept on both sides of the spine for the application and observation of all test sites. Test material and blank sample that prepared in accordance with practice method were applied to the skin on both sides in two different areas of the rabbit. The application sites 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.

OBSERVATION AND CALCULATION

Application sites are observed for erythema and oedema at 1st, 24th, 48th, and 72nd hours following the removal of the patches. Only 24th, 48th, and 72nd hours observations are used for calculations. Irritation was scored by using ISO 10993-10, "Scoring system for skin reaction". Irritation grades are presented as mean of two application sites of either test or blank sample. The primary irritation score for each animal is calculated by dividing the sum of all the irritation scores by six (two test/observation sites, three time points). Primary irritation index is calculated by subtracting the sum of primary irritation scores for the blank sample from the sum of primary irritation scores for the test samples and then dividing this difference by the total number of animals (three). According to the calculated primary irritation index values, the results are presented as the appropriate response category which is given below.

TABLE 1: SCORING SYSTEM FOR SKIN REACTION

Reaction	Irritation score
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
Oedema formation	
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
Maximal possible score for irritation	8
Other adverse changes at the skin sites shall be recorded and reported.	

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TABLE 2: MEAN IRRITATION SCORES OF TWO APPLICATION SITES AT 24 th, 48th,72th HOURS

OBSERVATION TIME POINTS (HOURS)	1ST RABBIT		2ND RABBIT		3RD RABBIT	
	CONTROL SITE	TEST SITE	CONTROL SITE	TEST SITE	CONTROL SITE	TEST SITE
24th	0	0	0	0	0	0
48th	0	0	0	0	0	0
72nd	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

The test sample with **BU-2020/49B** code **does not cause skin irritation.**

CHIEF OF TEST DEPARTMENT

Professor Pelin Kelicen Uğur