HACETTEPE UNIVERSITY
Faculty of Pharmacy

Department of Pharmacology

SENSITIZATION TEST REPORT

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SENSITIZATION 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: 19.11.2020

Attachment: Technical Information

RESULT

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

ACTING COORDINATOR
ADMINISTRATIVE DIRECTOR

Professor Serdar Uma

SENSITIZATION TEST REPORT FORM

TECHNICAL INFORMATION

Contract Number: BU-2020/49B

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: 660 cm^2

Start of Test: 13.10.2020

End of Test: 14.11.2020

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.			

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

Test Procedure:

Healthy adult albino guinea pigs of either sex from single strain, weighing 300-500 g were used. Ten animals for test material and five animals for control group were used.
Prior to all steps in the test procedure, the fur on the back of the animals were clipped. Induction phase: Test material and blank sample that prepared in accordance with practice method were applied directly to the clipped sites for 6 hours and then removed. This procedure was repeated on three days a week for three weeks. Challenge phase: At fourteen days after the last induction of application, all test and control group of animals were challenged with only the test sample by single

topical application to a clipped untested area for 6 hours and then removed.

OBSERVATION

At 24 h and 48 h after the removal of the challenge patches, the test sites were graded according to Magnusson and Kligman Scale (ISO 10993-10; Test for irritation and skin sensitization).

Magnusson and Kligman Scale

PATCH TEST REACTION	GRADING SCALE
No visible change	0
Discrete or patchy erythema	1
Moderate and confluent erythema	2
Well-defined erythema	3
Intense erythema and/or swelling	4

RESULT

Sensitive skin reactions occurred on challenged skin sites of two test animals, while no reaction appeared on the rest of the test animals or the control group, both at 24th and 48th hours. The lesions were graded according to the Magnusson and Kligman Scale and were shown in the below.

ERYTHEMA GRADE	NUMBER OF GUINEA PIGS			
	24TH HOUR		48TH HOUR	
	CONTROL GROUP	TEST GROUP	CONTROL GROUP	TEST GROUP
0	5	10	5	10
1	0	0	0	0
2	0	0	0	0
3	0	0	0	0
4	0	0	0	0

CONCLUSION

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

CHIEF OF TEST DEPARTMENT

Professor Pelin Kelicen Uğur