SMP Fabric won't make sensitive skin, redness and swelling

Test Report

TEST RESULT:
Test request: Dermal Irritation Test*
Test method: with reference to ISO 10993-10:2010, Biological evaluation of medical devices-Part 10: Tests for irritation and skin sensitization.

Test environment: Rabbit room of conventional condition. The license number of using laboratory animals is No. SYXK(粤) 2018-0086; Room temperature 22~24℃,Relative humidity 41~49%.

Test animal: New Zealand white albino rabbits, weighing between 2.2kg and 2.4kg at the start of the test,were used. They were supplied by Guangdong Medical Laboratory Animal Center (Sanshui Base). The production license number of laboratory animals is No. SCXK(粤)2019-0035. The animal certificate number is No. 44411600006665.
No. of animals/sex: 3/♀:♂=2:1

Preparation of Sample: The sample was cut to 2.5 cm×2.5 cm /piece and moistened with deionized water as test substance.

Observation period: 1±0.1h, 24±2h, 48±2h and 72±2h hours following removal of the test substance, use only 24±2h, 48±2h and 72±2h observations for calculations.

Test procedures: (1) Preparation of test animals. Selected three healthy young adult New Zealand white albino rabbits. Fur was shaved 24h before the test (approximately 10cm×15cm). (2) Procedures for testing. The test substance was applied to the test sides as shown in Figure 1 of test method with a gauze patch respectively. Applied the control patch of gauze (was moistened with deionized water) on the control site indicated in Figure 1 of test method. And then the application sites were wrapped with a non-irritation tape and bandage for 4 hours. At the end of the contact time, removed the dressings and marked the sites, removed and wiped the residual test substance using warm water. Examined for signs of erythema and edema, recorded the dermal reactions at each observation period according to "Table 1" and "Table 2" in test method.

Result(s):
The Primary Irritation Index (PII) of the test substance is 0.

The scores of the test substance

Observation period	(1±0.1)h								(24±2) h							
Skin reaction	Erythema-eschar				Edema				Erythema-eschar				Edema			
Skin application site / Rabbit Number	Test Site		Control Site		Test Site		Control Site		Test Site		Control Site		Test Site		Control Site	
	L	R	L	R	L	R	L	R	L	R	L	R	L	R	L	R
1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Observation period	(48±2) h								(72±2) h							
Skin reaction	Erythema-eschar				Edema				Erythema-eschar				Edema			
Skin application site / Rabbit Number	Test Site		Control Site		Test Site		Control Site		Test Site		Control Site		Test Site		Control Site	
	L	R	L	R	L	R	L	R	L	R	L	R	L	R	L	R
1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Note: 1. L= Left, R = Right
2. *Test was carried out by external laboratory assessed as competent.

Reference information:

ISO 10993-10:2010 Table2- Primary or cumulative irritation index categories in a rabbit

Mean score	Response category
0~0.4	Negligible
0.5~1.9	Slight
2~4.9	Moderate
5~8	Severe

Silver ions will not be released, harmless to human health and has a powerful and long-lasting sterilizing effect

Test Report

TEST METHOD:
As provided by client. sample was washed by running distilled water for 5~10 seconds before migration procedure. 1g of sample was put in 200mL of simulant at 45℃ for 10 hours, then analysis Ag in simulant by ICP-OES.

TEST RESULT(S):

Simulant Used	Time	Temperature	MDL	Test result
Distilled water	10hr	45℃	1.0mg/L	<1.0mg/L
3% Acetic Acid (W/V) Aqueous Solution	10hr	45℃	1.0mg/L	<1.0mg/L

SAMPLE DESCRIPTION: Beige sheet

Photo Appendix

*** End of Report***

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