

Textile Laboratory

Test Report

No: TXA2416C /2020 /LI

Date: Dec. 25, 2020

Page 1 of 4

Magical Film Enterprise Co Ltd
No. 36, Lane 378, Sec.2, Youngsing Rd.,
Wuqi Dist., Taichung City 435, Taiwan

The following sample was submitted and identified by applicant as:

Sample Description	:	Hydrophilic Nonwovens
Color	:	White
Fiber Content	:	PP
Fabric Weight	:	23g/m ² +H54
End Use	:	Mask
Applicant	:	Magical Film Enterprise Co Ltd
Sample Receiving Date	:	Oct. 30, 2020
Test Performance Period	:	Oct. 30, 2020 to Dec. 18, 2020
Test Performed	:	Selected test(s) as requested by applicant.
Test Results	:	For further details, please refer to the following page(s).

Remark: Test results have been taken from report number No: TXA2416 /2020 /LI, Date: Dec. 18, 2020

Signed for and on behalf of
SGS Taiwan Ltd.

Ronnie Chang

Chang Chia Hao, Ronnie
Asst. Manager



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Test results:

TEST METHOD(S):

Test Standard	ISO 10993-10:2010											
Test Item	Animal irritation test: Single-exposure test											
Test Environment	Rabbit room of conventional condition. Certificate No. SYXK (Zhe) 2018-0003, Room temperature 20.2°C ~22.6°C; Relative humidity 53.4% ~66.7%.											
Test Animals	New Zealand Albino Rabbit, supplied by Yin Hai rabbit specialty cooperative organization of Tongxiang Zhejiang Province, Certificate No. SCXK (Zhe) 2018-0002.											
Number of Animals/sex	6, female animals are nulliparous and non-pregnant											
Sample Preparation	<p>According to ISO 10993-12:2012 Biological evaluation of medical devices — Part 12: Sample preparation and reference materials, Based on the ratio of 6cm²/mL, the test sample was taken and covered with extraction vehicle for preparing the test extraction at condition, (37±1) °C for 72h. Freshly prepared extracts are preferred. The sampling mass and extraction vehicle volume are as follows :</p> <table border="1" data-bbox="584 1088 1311 1261"> <thead> <tr> <th>Extraction vehicle</th> <th>Quantity of samples(cm²)</th> <th>Extraction vehicle volume(mL)</th> </tr> </thead> <tbody> <tr> <td>NS</td> <td>150</td> <td>25</td> </tr> <tr> <td>SO</td> <td>150</td> <td>25</td> </tr> </tbody> </table>			Extraction vehicle	Quantity of samples(cm ²)	Extraction vehicle volume(mL)	NS	150	25	SO	150	25
Extraction vehicle	Quantity of samples(cm ²)	Extraction vehicle volume(mL)										
NS	150	25										
SO	150	25										
Test Method	Animals were individually housed, and had been acclimatized to the test environment for 3 days before test. Closely clip the fur on both sides of the animal spine 24h prior to test, the scope is about 10cm×15cm. The 0.5mL of the extract was applied separately to the 2.5cm×2.5cm absorbent gauze patches, which were applied on each test site of the animal clipped area. The patches moistened with the extraction vehicle were applied on each control site of the clipped area. The application sites were covered with a bandage for 4h. At the end of the contact time, the dressing was removed, and the contact sites were wiped clean with lukewarm water.											
Observation Period	Record the appearances of the application site at 1h, 24h, 48h and 72h following removal of the patches.											
Results	Both the primary irritation index (PII) were 0.											
Conclusions	According to Primary irritation index categories in a rabbit, the test sample is negligible to the skin.											

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Attached Table 1 Score of skin reaction-Extraction of normal saline

Animal No.	skin application sites	1h		24h		48h		72h		Primary irritation score
		Erythema and eschar formation	Oedema formation	Erythema and eschar formation	Oedema formation	Erythema and eschar formation	Oedema formation	Erythema and eschar formation	Oedema formation	
1	Front of Left (Test sample)	0	0	0	0	0	0	0	0	0
	Front of Right (control)	0	0	0	0	0	0	0	0	
	Behind Left (control)	0	0	0	0	0	0	0	0	
	Behind Right (Test sample)	0	0	0	0	0	0	0	0	
2	Front of Left (Test sample)	0	0	0	0	0	0	0	0	0
	Front of Right (control)	0	0	0	0	0	0	0	0	
	Behind Left (control)	0	0	0	0	0	0	0	0	
	Behind Right (Test sample)	0	0	0	0	0	0	0	0	
3	Front of Left (Test sample)	0	0	0	0	0	0	0	0	0
	Front of Right (control)	0	0	0	0	0	0	0	0	
	Behind Left (control)	0	0	0	0	0	0	0	0	
	Behind Right (Test sample)	0	0	0	0	0	0	0	0	
Primary irritation index (PII)										0

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Attached Table 2 Score of skin reaction-Extraction of sesame oil

Animal No.	skin application sites	1h		24h		48h		72h		Primary irritation score
		Erythema and eschar formation	Oedema formation	Erythema and eschar formation	Oedema formation	Erythema and eschar formation	Oedema formation	Erythema and eschar formation	Oedema formation	
1	Front of Left (Test sample)	0	0	0	0	0	0	0	0	0
	Front of Right (control)	0	0	0	0	0	0	0	0	
	Behind Left (control)	0	0	0	0	0	0	0	0	
	Behind Right (Test sample)	0	0	0	0	0	0	0	0	
2	Front of Left (Test sample)	0	0	0	0	0	0	0	0	0
	Front of Right (control)	0	0	0	0	0	0	0	0	
	Behind Left (control)	0	0	0	0	0	0	0	0	
	Behind Right (Test sample)	0	0	0	0	0	0	0	0	
3	Front of Left (Test sample)	0	0	0	0	0	0	0	0	0
	Front of Right (control)	0	0	0	0	0	0	0	0	
	Behind Left (control)	0	0	0	0	0	0	0	0	
	Behind Right (Test sample)	0	0	0	0	0	0	0	0	
Primary irritation index (PII)										0

Tested by relevant SGS laboratory.

*** End of Report ***