

## 紡織實驗室

**Test Report** 報告號碼: TXA2416B /2020 /LI 日期: 2020 年 12 月 25 日 頁數: 四 之 一 頁

彩麗薄膜股份有限公司  
臺中市梧棲區草湳里永興路 2 段 378 巷 36 號

我們依照客戶的要求, 根據申請者送交的樣品進行測試如下:

樣品敘述 : 親水不織布

顏色 : 白色

成份 : PP

布重 : 23g/m<sup>2</sup>+H54

最終產品 : 口罩

申請者 : 彩麗薄膜股份有限公司

收件日期 : 2020 年 10 月 30 日

測試週期 : 2020 年 10 月 30 日至 2020 年 12 月 18 日

測試項目&測試方法 : 依申請者要求進行下列測試

測試結果 : 請參照下一頁結果

備註: 此份報告的測試結果摘錄自報告號碼 TXA2416/2020/LI, 日期: 2020 年 12 月 18 日。

台灣檢驗科技股份有限公司

張家豪

張家豪  
副理



"Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, and such sample(s) are retained for 1 months only." This test report cannot be reproduced, except in full, without prior written permission of the Company.

"This document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com.tw/Terms-and-Conditions> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com.tw/Terms-and-Conditions>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law."

測試結果:

檢測方法:

檢測依據	ISO 10993-10:2010									
*檢測項目	動物皮膚刺激試驗-單次接觸試驗									
檢測環境	普通環境兔房，使用許可證號：SYXK（浙）2018-0003， 室溫 20.2℃~22.6℃；相對濕度 53.4%~66.7%。									
試驗動物	紐西蘭白兔，由桐鄉市銀海牧業專業合作社提供，生產許可證號： SCXK（浙）2018-0002。									
動物數/性別	6 隻（雌性動物為未孕和未曾產仔）									
樣品處理	<p>根據《ISO 10993-12:2012 醫療器械生物學評價 第 12 部分：樣品製備與參照材料》，將樣品分別用生理鹽水和芝麻油在(37±1) °C 的條件下浸提 72h，製成浸提液待測。浸提液新鮮製備，取樣量及浸提介質體積如下表：</p> <table border="1" data-bbox="584 1111 1311 1245"> <thead> <tr> <th>浸提介質</th> <th>取樣量(cm<sup>2</sup>)</th> <th>浸提體積(mL)</th> </tr> </thead> <tbody> <tr> <td>生理鹽水</td> <td>150</td> <td>25</td> </tr> <tr> <td>芝麻油</td> <td>150</td> <td>25</td> </tr> </tbody> </table>	浸提介質	取樣量(cm <sup>2</sup> )	浸提體積(mL)	生理鹽水	150	25	芝麻油	150	25
浸提介質	取樣量(cm <sup>2</sup> )	浸提體積(mL)								
生理鹽水	150	25								
芝麻油	150	25								
試驗方法	實驗動物單籠飼養，試驗前已在實驗動物房環境中適應 3 天。試驗前 24h，將實驗動物背部脊柱兩側被毛(約 10cm×15cm)去除。分別取 0.5mL 樣品浸提液滴到 2.5cm×2.5cm 大小的紗布上，然後敷貼于動物去毛區試驗部位，將滴有浸提介質的紗布塊敷貼于動物去毛區對照部位，4 小時後去除敷貼片，用溫水清洗接觸部位。									
觀察時間	除去敷貼片後 1h、24、48h 和 72h 記錄各接觸部位情況。									
結果	該受試物的生理鹽水浸提液和芝麻油浸提液對兔皮膚的原發性刺激指數均為 0。									
結論	按兔原發性刺激指數類型，該樣品對家兔皮膚的刺激反應類型屬極輕微。									

"Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, and such sample(s) are retained for 1 months only." This test report cannot be reproduced, except in full, without prior written permission of the Company.

"This document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com.tw/Terms-and-Conditions> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com.tw/Terms-and-Conditions>.

Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law."

附表 1 皮膚刺激反應評分表-生理鹽水浸提液

動物編號	試驗貼部位	1h		24h		48h		72h		原發性刺激計分
		紅斑	水腫	紅斑	水腫	紅斑	水腫	紅斑	水腫	
1	左前 (試驗)	0	0	0	0	0	0	0	0	0
	右前 (對照)	0	0	0	0	0	0	0	0	
	左後 (對照)	0	0	0	0	0	0	0	0	
	右後 (試驗)	0	0	0	0	0	0	0	0	
2	左前 (試驗)	0	0	0	0	0	0	0	0	0
	右前 (對照)	0	0	0	0	0	0	0	0	
	左後 (對照)	0	0	0	0	0	0	0	0	
	右後 (試驗)	0	0	0	0	0	0	0	0	
3	左前 (試驗)	0	0	0	0	0	0	0	0	0
	右前 (對照)	0	0	0	0	0	0	0	0	
	左後 (對照)	0	0	0	0	0	0	0	0	
	右後 (試驗)	0	0	0	0	0	0	0	0	
原發性刺激指數(PII)										0

"Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, and such sample(s) are retained for 1 months only." This test report cannot be reproduced, except in full, without prior written permission of the Company.

"This document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com.tw/Terms-and-Conditions> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com.tw/Terms-and-Conditions>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law."

附表 2 皮膚刺激反應評分表-芝麻油浸提液

動物編號	試驗貼部位	1h		24h		48h		72h		原發性刺激計分
		紅斑	水腫	紅斑	水腫	紅斑	水腫	紅斑	水腫	
1	左前 (試驗)	0	0	0	0	0	0	0	0	0
	右前 (對照)	0	0	0	0	0	0	0	0	
	左後 (對照)	0	0	0	0	0	0	0	0	
	右後 (試驗)	0	0	0	0	0	0	0	0	
2	左前 (試驗)	0	0	0	0	0	0	0	0	0
	右前 (對照)	0	0	0	0	0	0	0	0	
	左後 (對照)	0	0	0	0	0	0	0	0	
	右後 (試驗)	0	0	0	0	0	0	0	0	
3	左前 (試驗)	0	0	0	0	0	0	0	0	0
	右前 (對照)	0	0	0	0	0	0	0	0	
	左後 (對照)	0	0	0	0	0	0	0	0	
	右後 (試驗)	0	0	0	0	0	0	0	0	
原發性刺激指數(PII)										0

測試由 SGS 相關實驗室執行

\*\*\* 結 束 \*\*\*