SUBJECT	**Skin Irritation Test**
TEST LOCATION	**TÜV SÜD China** TÜV SÜD Products Testing (Shanghai) Co., Ltd. B-3/4,No.1999 Du Hui Road, Minhang District Shanghai 201108, P.R. China
CLIENT NAME	**Jiangyin Xinni Textile Co., Ltd**
CLIENT ADDRESS	10 Huanxi Road,Zhutang Town,Jiangyin City,Jiangsu Province
TEST PERIOD	20-Oct-2021~26-Oct-2021

Prepared By

Shao Xiaomin

(Shao Xiaomin)
Report Drafter

Authorized By

(Steven Zhang)
Authorized Signatory

Note: (1) General Terms & Conditions as mentioned overleaf. (2) The results relate only to the items tested.(3) The test report shall not be reproduced except in full without the written approval of the laboratory.(4) Without the agreement of the laboratory , the client is not authorized to use the test results for unapproved propaganda.

Chemical/Microbiology Laboratory:
TÜV SÜD Products Testing (Shanghai) Co., Ltd.
B-3/4,No.1999 Du Hui Road, Minhang District
Shanghai
201108
P.R. China

Phone : +86 (21) 6037 6375
Fax : +86 (21) 6037 6345
Email: food.chem@tuv-sud.cn
Webpage: www.tuv-sud.cn

Regional Head Office:
TÜV SÜD Certification and Testing (China) Co., Ltd.
No.151 Heng Tong Road Shanghai
200 070 P.R.China

RECEIPT DATE/ TEST DATE

29-Sep-2021/ 20-Oct-2021

THE FOLLOWING SAMPLE(S) WAS/WERE SUBMITTED

BY/ ON BEHALF OF THE CLIENTS AS:

Sample Name: Reusable Particle Filtering Cloth Mask

Sample Specification: RY-CR1

Batch No/ Date: XN01111B

Manufacturer: Jiangyin Xinn Textile Co., Ltd

SAMPLE NO.	DESCRIPTION	PHOTOGRAPH
721667378	Black Mask	

SUMMARY

1. Purpose

To evaluate the potential skin irritation caused by the extraction of the test article extract contacting with the skin surface of rabbits.

2. Process Description

The specified test article was sampled by 6 cm^2/mL extraction condition was 37℃, 72 h. Extraction solvent was 0.9% sodium chloride (SC).

The rabbits used to conduct experiments were healthy and with intact skin. The fur on the back of the rabbit was clipped within 24 h before the test started, a sufficient area on both sides of the spine for application and observation of all test sites (approximately 10 cm×15 cm). The 2.5 cm×2.5 cm absorbent gauze patches were soaked with 0.5 mL extraction of test article or control and put the patches on the skin on each side of each rabbit directly, then wrapped the test sites with bandage (occlusive) for at least 4 h. At the end of the contact time, removed residual test materials by washing with warm water and made it dry carefully.

Described and scored the skin reactions for erythema and oedema according to the scoring system for each application site at each time interval. Recorded the reaction of each application site at (1±0.1) h, (24±2) h, (48±2) h and (72±2) h after removal of the patches.

3. Result

Based on what observed:

The primary irritation index for the test article were calculated to be 0.

No abnormal clinical symptoms except skin reactions was found for all animals.

4. Conclusion

Under the conditions of this study, the test result showed that the response category of test article polar extract in rabbit skin irritation: Negligible.

Chemical/Microbiology Laboratory:
TÜV SÜD Products Testing (Shanghai) Co., Ltd.
B-3/4,No.1999 Du Hui Road, Minhang District
Shanghai
201108
P.R. China

Phone : +86 (21) 6037 6375
Fax : +86 (21) 6037 6345
Email: food.chem@tuv-sud.cn
Webpage: www.tuv-sud.cn

Regional Head Office:
TÜV SÜD Certification and Testing (China) Co., Ltd.
No.151 Heng Tong Road Shanghai
200 070 P.R.China

1. STUDY SUMMARIES

1.1. Purpose

To evaluate the potential skin irritation caused by the extraction of the test article extract contacting with the skin surface of rabbits.

1.2. Referred Standard

➢ ISO 10993-10: 2010
Biological evaluation of medical devices—Part 10: Tests for irritation and skin sensitization

1.3. Deviation(s) and Incident(s) Treatment

If any deviation or incident occurred during the test, the related information would be recorded timely and a deviation report should be submitted with the final report to interpretate the specific effect(s) on the final result caused by the deviation or incident.

1.4. Schedule of The Study

Test Start Date:	2021-10-20
Test Completion Date:	2021-10-26

2. TEST MATERIAL

2.1. Test Article

2.1.1. General information [1)]

Name:	Reusable Particle Filtering Cloth Mask
Initial state:	Not applicable
Size:	RY-CR1
Model:	/
Lot/ Batch#:	/
Physical State:	Solid
Color:	Black
Density:	/
Stability:	/
Solubility:	/
Storage Condition:	Room temperature
Test Article Material:	/
Packaging Material:	/

2.1.2. Retention of test article(s)

Reserve Sample Volume: 5 pcs
Storage Location: Sample reserve room

2.1.3. Handling of residual test article(s)

Remaining after the Test Complete: Destroy and waste
Remaining after the Study Complete: Destroy and waste

2.2. Negative Control

Name:	0.9% Sodium Chloride (SC)
Size:	500mL
Lot/ Batch#:	L221052008

Physical State:	Liquid
Color:	Colorless
Storage Condition:	Room Temperature
Manufacturer:	Sichuan Kelun

2.3. Positive Control

Name:	Sodium Dodecyl Sulfate (SDS)
Size:	500g
Lot/ Batch#	C11609662
Physical State:	White powder
Storage Condition:	Room temperature
Manufacturer:	Macklin

2.4. Animal

2.4.1. Animal Information

Species:	New Zealand White Rabbit
Microbial levels:	Conventional
Number/Sex:	3/Female
Weight:	More than 2 kg at the beginning of the test
Manufacturer:	Shanghai Jiagan Biotechnology Co., LTD.
Production License#:	SCXK(Su)2020-0007
Quality Certificate#:	No.202132902

2.4.2. Animal feeding conditions

Breeding density:	One animals per cage
Cages:	Suspended stainless steel
Animal identification:	Marked the ID in animal's right ear and identified by a card
Acclimation period:	At least 7 days under the same conditions as for the actual test
Fodder:	Name:Rabbit maintain feed
	Manufacturer: Jiangsu Xietong
	Daily 75g quantitative uptake per animal
Water:	Barreled pure water
	Free intake

2.4.3. Animal room environmental conditions

Temperature:	16°C~26°C
Relative humidity:	40%~70%RH
Ventilation rate:	≥8/h
Lights:	12 hours light/dark cycle, full spectrum fluorescent light

2.5. Main instruments

Name	No.	Calibration Due Date
Electronic Balance	EPB-302	2022-09-16

Shaking Bath	EPB-311	2022-09-16
Clean Bench	EPB-314	2022-09-16

2.6. Justification of the Test System

The rabbit is specified as an appropriate animal model for evaluating potential skin irritants by the current testing standards. 20% Sodium Dodecyl Sulfate (SDS) is recommended as the positive substance by guiding principle.

3. TEST DESIGN

3.1. Test Article Preparation

3.1.1. Extraction process[1)]

Sampling Manner	Actual Sampling	Ratio	Solvent	Amount	Conditions
Specified (inner side of mask contact)	60 cm^2	6 cm^2/mL	SC	10.0 mL	37°C,72h

1) The vehicle (without the test article) was similarly prepared to serve as the negative control.

3.1.2. Final extract[1)]

Final extract	Additional processing prior to the testing or Not	Presence of particles or Not	Color and Clear or Not
SC	Not	Not	Colorless and Clear

1) Used the final extracts immediately.

3.2. Grouping

Took 3 rabbits into one group.

Group No.	Group Name	Amount	Sex	Numbered list
1	Test group (SC)	3	♀	1201~1203

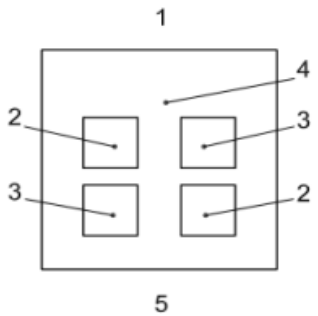
3.3. Experimental Process

3.3.1. Dosing process

Rabbits with healthy and intact skin were used. The fur on the back of the rabbit was clipped within 24 h before the test started, a sufficient area on both sides of the spine for application and observation of all test sites (approximately 10 cm×15 cm).

The 2.5 cm×2.5 cm absorbent gauze patches were soaked with 0.5 mL extract (s) of test article or control and put the patches on the skin on each side of each rabbit directly (See Figure1), and then wrapped the application sites with an occlusive bandage for a minimum of 4 h.

At the end of the contact time, removed the dressings and marked the positions of the sites with permanent ink. Removed residual test material by lukewarm water and careful drying



1. Cranial end 2. Test site 3. Negative control site 4. Clipped dorsal region 5. Caudal end

Figure 1 Location of skin application sites

3.3.2. Observation of animal

Described and scored the skin reaction for erythema and oedema according to the scoring system given in Table 1 for each application site at each time interval. Recorded the appearance of each application site at (1±0.1) h, (24±2) h, (48±2) h and (72±2) h following removal of the patches.

Table 1 Classification System for Skin Reaction

Erythema and Eschar Formation:	score
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 1mm)	3
Severe oedema (raised more than 1mm and extending beyond exposure area)	4
Maximal possible score for irritation	**8**

3.3.3. Other observed endpoints

Clinical symptoms except dermal reactions should be observed every day.

4. EVALUATION CRITERION

Determined the primary irritation index (PII) as follows.
1) Only the data that observed at (24±2) h, (48±2) h and (72±2) h is used for calculation.
2) The erythema grade of every animal at every time point added the oedema grade of every animal at every time point, then the primary irritation score for an animal was calculated by dividing the sum of all the scores by 6 (two test/observation sites, three time points).
3) The sum of average grade of all the animals divided by the number of animals.
4) When blank or negative control is used, the primary irritation score was calculated by the average score of test material subtracted the average score of control.

Table 2 Irritation Response Categories in the Rabbit

Response Category	Mean score
Negligible	0 to 0.4
Slight	0.5 to 1.9
Moderate	2 to 4.9
Severe	5 to 8

5. ALTERATION AND DEVIATION

Alteration and deviation did not happen in this test.

6. RESULTS

Based on what observed:
The primary irritation index for the test article were calculated to be 0.
No abnormal clinical symptoms except skin reactions was found for all animals.
See **Attached Table 1~2.**

7. CONCLUSION

Under the conditions of this study, the test result showed that the response category of test article polar extract in rabbit skin irritation: **Negligible.**

8. ATTACHED TABLE

8.1. Attached Table 1 Dermal Observations of Test Group (SC)

Animal No.	Dosing zone	Skin Reaction	Interval (Hours)				Average score
			1±0.1	24±2	48±2	72±2	
1201	Test Site(Left)	Erythema	0	0	0	0	0
		Oedema	0	0	0	0	
	Test Site(Right)	Erythema	0	0	0	0	
		Oedema	0	0	0	0	
	Negative Site(Left)	Erythema	0	0	0	0	0
		Oedema	0	0	0	0	
	Negative Site(Right)	Erythema	0	0	0	0	
		Oedema	0	0	0	0	
1202	Test Site(Left)	Erythema	0	0	0	0	0
		Oedema	0	0	0	0	
	Test Site(Right)	Erythema	0	0	0	0	
		Oedema	0	0	0	0	
	Negative Site(Left)	Erythema	0	0	0	0	0
		Oedema	0	0	0	0	
	Negative Site(Right)	Erythema	0	0	0	0	
		Oedema	0	0	0	0	
1203	Test Site(Left)	Erythema	0	0	0	0	0
		Oedema	0	0	0	0	
	Test Site(Right)	Erythema	0	0	0	0	
		Oedema	0	0	0	0	
	Negative Site(Left)	Erythema	0	0	0	0	0
		Oedema	0	0	0	0	
	Negative Site(Right)	Erythema	0	0	0	0	
		Oedema	0	0	0	0	
The primary irritation index (PII): 0							
Irritation Response Categories: Negligible							

8.2 Attached Table 2 Body Weight and Clinical Observation

Animal Number	Body Weight (g)		Clinical Observation
	Initiation	End	
1201	2631	2699	Normal
1202	2776	2854	Normal
1203	2945	2994	Normal

8.3. Attached Table 3 Dermal Observations of Positive Group (Polar)

Animal No.	Dosing zone	Skin Reaction	Interval (Hours)				Average score
			1±0.1	24±2	48±2	72±2	
5207	Positive Site (Left)	Erythema	1	2	2	2	4.0
		Oedema	1	2	1	1	
	Positive Site (Right)	Erythema	1	2	2	2	
		Oedema	1	2	1	1	
	Negative Site(Left)	Erythema	0	0	0	0	0
		Oedema	0	0	0	0	
	Negative Site(Right)	Erythema	0	0	0	0	
		Oedema	0	0	0	0	
5208	Positive Site (Left)	Erythema	1	2	2	2	4.7
		Oedema	1	2	2	2	
	Positive Site (Right)	Erythema	1	2	2	2	
		Oedema	1	2	2	2	
	Negative Site(Left)	Erythema	0	0	0	0	0
		Oedema	0	0	0	0	
	Negative Site(Right)	Erythema	0	0	0	0	
		Oedema	0	0	0	0	
5209	Positive Site (Left)	Erythema	1	2	1	1	4.3
		Oedema	1	2	2	2	
	Positive Site (Right)	Erythema	1	2	2	2	
		Oedema	1	2	2	2	
	Negative Site(Left)	Erythema	0	0	0	0	0
		Oedema	0	0	0	0	
	Negative Site(Right)	Erythema	0	0	0	0	
		Oedema	0	0	0	0	
The primary irritation index (PII): 4.3 Irritation Response Categories: Moderate							

8.4. Attached Table 4 Body Weight and Clinical Observation of Positive Group

Animal Number	Body Weight (g)		Clinical Observation
	Initiation	End	
5207	2402	2482	Normal
5208	2431	2514	Normal
5209	2404	2470	Normal

Note:
1.This test was carried out by external laboratory assessed as competent.
2.This report is for internal use only such as internal scientific research ,education, quality control, product R&D.

-END OF THE TEST REPORT-