



中国认可
国际互认
检测
TESTING
CNAS L10463

Test Report

Report Number: 26020328-04-R01EN

Sponsor: Shenzhen Esun Industrial Co., Ltd.

Factory: Xiaogan Esun New Material Co., Ltd.

Sample Name: TPU-95A filament, TPU-90A filament,

TPU-85A filament, TPU-64D filament,

PEBA-90A filament, PEBA-85A filament

Model/ Specification: TPU-95A, TPU-90A, TPU-85A,

TPU-64D, PEBA-90A, PEBA-85A

Test Category: Commission Test

EPINTEK Suzhou Ltd.



Declaration

1. The report is invalid without the special stamp for test report of the test facility.
2. Partial copy is invalid without written approval of the test facility.
3. Any copy is invalid without the special stamp of the test facility for test report.
4. The report is invalid without the signature of the authorized signatory.
5. The report is invalid once altered.
6. Any comment to the report should be submitted in writing to the test facility, otherwise it may not be accepted.
7. The results in this report are relevant only to the articles tested.
8. The sponsor is responsible for the authenticity of the sample and its information.

Institution name: EPINTEK Suzhou Ltd.

Address: Floors 1-3, West side of Building A2;

Floors 1-4, Building 4; Floor 5, Building 3.

No. 558, Fenhu Avenue, Lili Town, Wujiang District, Suzhou, China

Web site: www.epintek.com

Telephone: 0512-63228100

Postal Code: 215211

EPINTEK Suzhou Ltd.

Test Report

Report Number: 26020328-04-R01EN

Sample Name	TPU-95A filament, TPU-90A filament, TPU-85A filament, TPU-64D filament, PEBA-90A filament, PEBA-85A filament	Sample ID	26020328
Model/Specification	TPU-95A, TPU-90A, TPU-85A, TPU-64D, PEBA-90A, PEBA-85A		
Sponsor	Shenzhen Esun Industrial Co., Ltd.		
Address	15A, Microsoft Ketong Building, No. 55 Gaoxinnan 9th Road, High tech Community, Yuehai Street, Nanshan District, Shenzhen.		
Factory	Xiaogan Esun New Material Co., Ltd. / Xinhua Road, Economic Development Zone, Xiaonan District, Xiaogan City, Hubei, P.R.China (432100)		
Test Facility	EPINTEK Suzhou Ltd.		
Test Category	Commission Test	Lot/Batch#	/
Produced Date	/	Sample Quantity	1 set
Received Date	2026-02-28	Test Date(s)	2026-03-09 to 2026-03-15
Test Item(s)	Skin Irritation Test		
Test Method(s)	ISO 10993-23:2021 Biological evaluation of medical devices - Part 23: Tests for irritation		
Conclusion	The test result showed that the response category of test article (During sampling, cut off the residual area on the tape, avoid testing this area, and conduct a 1:1 mixed test for each sample.) extracts in rabbit skin irritation: Negligible. (Stamp for Test Report) Issued Date: 2026-04-17		
Note	Upon the request of the sponsor, a mixed testing was performed. “NA” means “not applicable”, “/” means “blank”		

Approved By: Evelyn Yuan
Evelyn Yuan

Position: Authorized Signatory

EPINTEK Suzhou Ltd.

Test Report

Report Number: 26020328-04-R01EN

No.	Item	Standard Method	Acceptance Criteria	Test Result	Conclusion	Note
1	Skin Irritation Test	ISO 10993-23:2021	The primary irritation index (PII) was 0~0.4, the irritation was Negligible. the primary irritation index (PII) was 0.5~1.9, the irritation was slight. the primary irritation index (PII) was 2 to 4.9, the irritation was moderate. the primary irritation index (PII) was 5~8, the irritation was severe.	The primary irritation index of testing was 0.	Negligible	Shown in Annex.
Following Blank						



EPINTEK Suzhou Ltd.

Test Report

Report Number: 26020328-04-R01EN

Picture & Introduction

Description for Sample, Model/Specification
Initial State: Unsterilized Intended Clinical Use: / (The information regarding the sample is hereby provided by the sponsor.)
Misc
/

Test Report

Animal Test- Skin Irritation Test

Sponsor: Shenzhen Esun Industrial Co., Ltd.

Sample Name: TPU-95A filament, TPU-90A filament, TPU-85A filament, TPU-64D filament, PEBA-90A filament, PEBA-85A filament

Model/ Specification: TPU-95A, TPU-90A, TPU-85A, TPU-64D, PEBA-90A, PEBA-85A

Sample Amount for this test: 6.00 g

Lot/Batch#: /

EPINTEK Suzhou Ltd.

SUMMARY

1. Purpose

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

2. Process Description

The test article was random sampled (During sampling, cut off the residual area on the tape, avoid testing this area, and conduct a 1:1 mixed test for each sample.) and extracted by 0.2 g/mL, extraction condition was 37°C 72h. Extraction solvents were 0.9% Sodium Chloride (SC) and Sesame Oil (SO).

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 dermal 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. Results

Based on what observed:

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

No abnormal clinical symptoms except dermal reactions were found for all animals.

4. Conclusion

Under the conditions of this study, the test result showed that the response category of the test article (During sampling, cut off the residual area on the tape, avoid testing this area, and conduct a 1:1 mixed test for each sample.) extract in rabbit skin irritation: **Negligible**.

Edited by: Colin Lu
Colin Lu

Checked by: Patryk Chen
Patryk Chen

1. STUDY SUMMARIES

1.1. Study Name (Study No.)

TPU-95A filament, TPU-90A filament, TPU-85A filament, TPU-64D filament, PEBA-90A filament, PEBA-85A filament - Skin Irritation Test (26020328-000018).

1.2. Purpose

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

1.3. Testing Facility

Name: EPINTEK Suzhou Ltd.

Address: Floors 1-3, West side of Building A2; Floors 1-4, Building 4; Floor 5, Building 3.
No. 558, Fenhu Avenue, Lili Town, Wujiang District, Suzhou, China

1.4. Sponsor

Name: Shenzhen Esun Industrial Co., Ltd.

Address: 15A, Microsoft Ketong Building, No. 55 Gaoxinnan 9th Road, High tech
Community, Yuehai Street, Nanshan District, Shenzhen.

ATTN: Zhixiang He

Contact Information: +86 199 0729 8768 / hzx@brightcn.net

1.5. Study Alteration Treatment

Before the study start, the study protocol was approved by Study Director and Sponsor. Any study alteration should be approved by Study Director.

1.6. 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.

1.7. Major Laboratory Personnel

Study Director: Patryk Chen

Main Operation Personnel: Pineapple Chen, Aro Yang

1.8. Schedule of the Study

Protocol Effective Date:	2026-03-04
Test Start Date:	2026-03-09
Test Completion Date:	2026-03-15
Report Completion Date:	2026-04-14

2. CONTROL AND TEST SYSTEM CONFIRMATION

2.1. Negative Control

2.1.1. Polar control information

Name:	0.9% Sodium Chloride (SC)
Lot/ Batch#:	2508114A
Physical State:	Colorless Liquid
Manufacturer:	Double-Crane Pharmaceutical

2.1.2. Non-polar control information

Name:	Sesame Oil (SO)
Lot/ Batch#:	20240802M3
Physical State:	Light yellow oily liquid
Manufacturer:	Shanxi Jinyang

2.2. Positive control

Name:	Sodium Dodecyl Sulfate
Lot/ Batch#:	C16887901
Physical State:	White powder
Manufacturer:	Macklin

2.3. Animal

2.3.1. Animal use license

Application scope:	Barrier Environment (SPF grade: Mouse, Rat, Hamster, Guinea pig, Rabbit)
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Animal Use License#: SYXK(Su)2024-0063
Application scope: General Environment (General grade: Hamster, Guinea pig, Rabbit)
Animal Use License#: SYXK(Su)2021-0084

2.3.2. Animal information

Species: New Zealand White Rabbit
Microbial Levels: Conventional
Number/Sex: 6/Female (nulliparous and non-pregnant)
Weight: More than 2 kg at the beginning of the test
Manufacturer: JIAGANSHENGWU
Production License#: SCXK(Hu)2025-0007
Quality Certificate#: 20250007000160

2.3.3. Animal feeding conditions

Rearing Density: One animal 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: Rabbits maintain feed
Manufacturer: KEAO XIELI FEED CO., LTD
Feed: Continuous supply, free intake
Water: Water bottles supply water
Free intake

2.3.4. Animal room environmental conditions

Temperature: 16°C-26°C
Relative Humidity: 30%-70%RH
Ventilation Rate: ≥ 8 times/h
Lights: 12 hours light/dark cycle, full spectrum fluorescent lights

2.4. Main Instruments

Name	No.	Calibration Due Date
Electronic Balance	EPB-691	2026-06-10
Electronic Balance	EPB-627	2027-02-01
Constant temperature vibrator	EPB-284	2026-05-13
Clean Bench	EPB-598	2026-06-10

2.5. 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. The recent data of positive control came from 25072121-000018 (Completed Date: 2025-10-01), See Attached Table 4~6.

3. TEST DESIGN

3.1. Extract Preparation

3.1.1. Extraction process¹⁾

Samples were taken under sterile conditions and prepared as follows.

Sampling Manner	Actual Sampling	Ratio	Solvent	Amount	Conditions
Random (During sampling, cut off the residual area on the tape, avoid testing this area, and conduct a 1:1 mixed test for each sample.)	3.00 g	0.2 g/mL	SC	15.0 mL	37°C 72h 60 rpm
	3.00 g	0.2 g/mL	SO	15.0 mL	37°C 72h 60 rpm

- 1) The vehicle (without the test article) was similarly prepared to serve as the negative control, the extraction process was dynamic conditions.

3.1.2. Final extract treatment¹⁾

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
SO	Not	Not	Light yellow and Clear

- 1) Used the final extracts immediately.

3.2. Grouping

Took 6 rabbits into 2 groups.

Group No.	Group Name	Amount	Sex	Numbered list	Animal Temporary Number
1	Test group (SC)	3	♀	1201-1203	♀: C 59~C 64
2	Test group (SO)	3	♀	2204-2206	

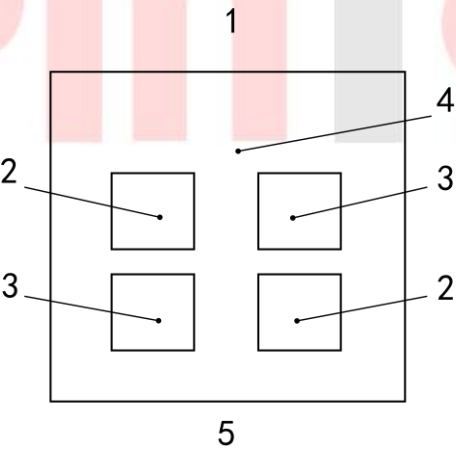
3.3. Experimental Process

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 Figure 1), 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 animals

Described and scored the dermal 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 Dermal 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 1 mm)	3
Severe oedema (raised more than 1 mm 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. Weighting all the test animals at the beginning and end of the test.

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.

Skin irritation intensity was graded according to the value of primary irritation index (PII) according to Table 2.

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

There were no changes and deviations of technical parameters that affect the experimental results.

6. RESULTS

Based on what observed:

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

No abnormal clinical symptoms except dermal reactions were found for all animals.

See Attached Table 1~3.

7. CONCLUSION

Under the conditions of this study, the test result showed that the response category of test article (During sampling, cut off the residual area on the tape, avoid testing this area, and conduct a 1:1 mixed test for each sample.) extract in rabbit skin irritation: **Negligible.**

8. ARCHIVING

All correspondence, including original copy of the protocol, original copy of the test report, and all raw data generated during the study (i.e., documentation forms as well as any other notes of raw data, printouts of instruments and computers) are stored in the archives room of the EPINTEK Suzhou Ltd.

9. ATTACHED TABLE

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

Animal No.	Dosing Zone	Dermal 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							

9.2. Attached Table 2 Dermal Observations of Test Group (SO)

Animal No.	Dosing Zone	Dermal reaction	Interval (Hours)				Average Score
			1±0.1	24±2	48±2	72±2	
2204	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	
2205	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	
2206	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							

9.3. Attached Table 3 Body Weight and Clinical Observation

Animal No.	Body Weight (g)		Clinical Observation Except Dermal Reactions
	Test Begin	Test End	
1201	2194.7	2288.9	Normal
1202	2358.6	2427.3	Normal
1203	2348.1	2435.6	Normal
2204	2281.3	2340.5	Normal
2205	2330.4	2407.2	Normal
2206	2332.5	2422.5	Normal

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9.4. Attached Table 4 Dermal Observations of Positive Group (SC)

Animal No.	Dosing zone	Dermal reaction	Interval (hours)				Average score	
			1±0.1	24±2	48±2	72±2		
5207	Positive Site (Left)	Erythema	3	3	4	4	7.33	
		Oedema	2	3	4	4		
	Positive Site (Right)	Erythema	3	3	4	4		
		Oedema	2	3	4	4		
	Negative Site (Left)	Erythema	0	0	0	0	0.00	
		Oedema	0	0	0	0		
		Negative Site (Right)	Erythema	0	0	0		0
			Oedema	0	0	0		0
5208	Positive Site (Left)	Erythema	3	4	4	4	8.00	
		Oedema	3	4	4	4		
	Positive Site (Right)	Erythema	3	4	4	4		
		Oedema	3	4	4	4		
	Negative Site (Left)	Erythema	0	0	0	0	0.00	
		Oedema	0	0	0	0		
		Negative Site (Right)	Erythema	0	0	0		0
			Oedema	0	0	0		0
5209	Positive Site (Left)	Erythema	4	4	4	4	8.00	
		Oedema	4	4	4	4		
	Positive Site (Right)	Erythema	4	4	4	4		
		Oedema	4	4	4	4		
	Negative Site (Left)	Erythema	0	0	0	0	0.00	
		Oedema	0	0	0	0		
		Negative Site (Right)	Erythema	0	0	0		0
			Oedema	0	0	0		0
The primary irritation index (PII): 7.78								
Irritation Response Categories: Severe								

Note: The recent data of positive control came from 25072121-000018 (Completed Date: 2025-10-01).

9.5. Attached Table 5 Dermal Observations of Positive Group (SO)

Animal No.	Dosing zone	Dermal reaction	Interval (hours)				Average score	
			1±0.1	24±2	48±2	72±2		
6210	Positive Site (Left)	Erythema	4	4	4	4	8.00	
		Oedema	3	4	4	4		
	Positive Site (Right)	Erythema	4	4	4	4		
		Oedema	3	4	4	4		
	Negative Site (Left)	Erythema	0	0	0	0	0.00	
		Oedema	0	0	0	0		
		Negative Site (Right)	Erythema	0	0	0		0
			Oedema	0	0	0		0
6211	Positive Site (Left)	Erythema	4	4	4	4	7.67	
		Oedema	2	3	4	4		
	Positive Site (Right)	Erythema	4	4	4	4		
		Oedema	2	3	4	4		
	Negative Site (Left)	Erythema	0	0	0	0	0.00	
		Oedema	0	0	0	0		
		Negative Site (Right)	Erythema	0	0	0		0
			Oedema	0	0	0		0
6212	Positive Site (Left)	Erythema	3	4	4	4	8.00	
		Oedema	3	4	4	4		
	Positive Site (Right)	Erythema	3	4	4	4		
		Oedema	3	4	4	4		
	Negative Site (Left)	Erythema	0	0	0	0	0.00	
		Oedema	0	0	0	0		
		Negative Site (Right)	Erythema	0	0	0		0
			Oedema	0	0	0		0
The primary irritation index (PII): 7.89								
Irritation Response Categories: Severe								

Note: The recent data of positive control came from 25072121-000018 (Completed Date: 2025-10-01).

9.6. Attached Table 6 Body Weight and Clinical Observation of Positive Group

Animal No.	Body Weight (g)		Clinical Observation Except Dermal Reactions
	Test Begin	Test End	
5207	2208	2265	Normal
5208	2396	2466	Normal
5209	2270	2358	Normal
6210	2332	2424	Normal
6211	2150	2215	Normal
6212	2295	2395	Normal

Note: The recent data of positive control came from 25072121-000018 (Completed Date: 2025-10-01) .

..... End of Report

