



中国认可
国际互认
检测
TESTING
CNAS L10463

Test Report

Report Number: 26020328-05-R02EN

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.

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检验检测专用章

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.

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EPINTEK Suzhou Ltd.

Test Report

Report Number: 26020328-05-R02EN

Sample Name	TPU-95A filament、TPU-90A filament、TPU-85A filament、TPU-64D filament、PEBA-90A filament、PEBA-85A filament		Sample ID	26020328-S001
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	Batch#	/	
Produced Date	/	Sample Quantity	1 set	
Received Date	2026-02-28	Test Date(s)	2026-03-09 to 2026-03-11	
Test Item(s)	Cytotoxicity Test			
Test Method(s)	ISO 10993-5:2009 Biological evaluation of medical devices—Part 5: Tests for in vitro cytotoxicity			
Conclusions	Under the conditions of this study, the mixed test article (Mixed testing of six models) extract did not show a cytotoxic potential to L-929 cells. (Stamp for Test Report) Issued Date: 2026-03-26			
Note	“NA” means “not applicable”, “/” means “blank”.			

Approved By:

Jade Xu

Jade Xu

Position: Authorized Signatory

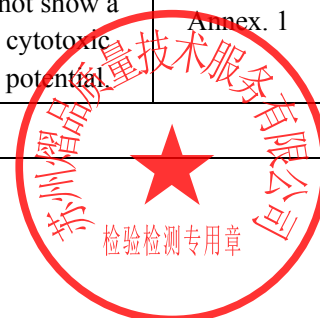


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Test Report

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No.	Item	Standard Method	Acceptance Criteria	Test Results	Conclusion	Note
1	Cytotoxicity Test	ISO 10993-5:2009	If cell viability less than 70%, the sample extract has a cytotoxic potential.	The 100% extracts of the test sample Viab.% was 71.9%.	The mixed test article extract did not show a cytotoxic potential.	Details Shown in Annex. 1
Following Blank						



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Test Report

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Picture of Sample	
	
Description for Sample, Model/Specification	
Sample Status: Unsterilized (The information of sample hereby are provided by the sponsor.)	
Misc	
The laboratory random sampled according to the requirements of the sponsor. (Each sample was tested in a 1:1 ratio)	

Test Report

Cytotoxicity Test - MTT 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: 3.36 g

Batch#: /

EPINTEK Suzhou Ltd.

SUMMARY

1. Purpose

The purpose of the test is to determine the cytotoxicity of the test article TPU-95A filament、TPU-90A filament、TPU-85A filament、TPU-64D filament、PEBA-90A filament、PEBA-85A filament extract to L929 cells.

2. Process Description

Sample (Random sampled: Each sample was tested in a 1:1 ratio) was extracted in complete MEM medium with 10% FBS at 0.2 g /mL at 37°C for 24 h, and the negative control and positive control were extracted at 3 cm² /mL and 6 cm²/mL, respectively, under the same conditions. The media control was extracted under the same conditions.

The suspended cells were dispensed in 96-well plate, and incubated in cell incubator (5% CO₂, 37°C) on the first day.

On the second day, the test article extract (100%, 75%, 50% and 25% in growth medium) was added to L929 cells in 96-well plates and then incubated at 37°C in 5% CO₂ for another 24 h.

After 24 h incubation, observed the cell morphology first and 50 µL aliquot of MTT (1 mg/mL) was added. 2 h incubation later, the OD value was determined.

3. Results

The MTT test results showed that the relative cell viability of the 100% test article extract was 71.9%. The results of control groups showed the test was valid.

4. Conclusion

Under the conditions of this study, the mixed test article extract did not show a cytotoxic potential to L-929 cells.

Edited by: Youhan Fu
Youhan Fu

Checked by: Hulda Tan
Hulda Tan

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 - In Vitro Cytotoxicity Test (26020328-003506)

1.2. Purpose

The purpose of the test is to determine cytotoxic potential of the test article extract on L-929 cells.

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 interpretative the specific effect(s) on the final result caused by the deviation or incident.

1.7. Major Laboratory Personnel(s)

Study Director: Hulda Tan

Main Operation Personnel: Caya Chao, Positive Xu

1.8. Schedule of the Study

Protocol Effective Date:	2026-03-04
Test Start Date:	2026-03-09
Test Completion Date:	2026-03-11
Report Completion Date:	2026-03-19

2. TEST INFORMATION

2.1. Blank Control

Name:	MEM medium with 10% FBS
Manufacturer:	Servicebio
Lot/ Batch#:	GP2510036
Size:	500 mL
Physical State:	Liquid
Color:	Pink
Storage Condition:	(2-8) °C
Extract Condition:	37°C, 24 h, 60 rpm

2.2. Negative Control

Name:	High Density Polyethylene Film
Manufacturer:	Hatano Research Institute, FDSC
Lot/Batch#:	C-212
Size:	c.a.3 cm × 10 cm (5 sheets)
Physical State:	Solid
Color:	White
Storage Condition:	Room temperature
Extract Ratio:	3 cm ² : 1 mL
Extract Condition:	37°C, 24 h, 60 rpm

2.3. Positive Control

Name:	No powder latex gloves
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Manufacturer:	TitanCare
Lot/Batch#:	P3711326
Size:	S
Physical State:	Solid
Color:	Ivory
Storage Condition:	Room temperature
Extract Ratio:	6 cm ² : 1 mL
Extract Condition:	37°C, 24 h, 60 rpm

2.4. Main Instruments and Reagents

2.4.1. Main instruments

Name	No.	Calibration Due Date
CO ₂ Incubator	EPB-122	2026-06-10
Shaking Incubator	EPB-232	2026-06-10
Micro-plate Reader	EPB-362	2026-06-10
Inverted Microscope	EPB-003	2026-06-10

2.4.2. Main reagents

Name	Lot/ Batch#	Manufacturer
3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazoliumbromide (MTT)	P24MZ522C	PERFEMIKER
Fetal bovine serum (FBS)	NZJ6291	HyClone
Trypsin	J240019	HyClone
Penicillin streptomycin	J240017	HyClone
Minimum essential medium (MEM)	GP2510036	Servicebio
Isopropanol	C16200780	MACKLIN

3. JUSTIFICATION OF THE TEST SYSTEM

Historically, L929 cells have been used for cytotoxicity studies because they demonstrate sensitivity to extractable cytotoxic articles.

4. IDENTIFICATION OF TEST SYSTEM

L929 cells obtained from Shanghai Cell Line Resources, CAS.

5. ROUTE OF ADMINISTRATION

The test article was extracted and administrated in vitro to L929 cells through a solvent compatible with the test system. This was the optimal route of administration available in this test system as recommended in the guidelines.

6. TEST DESIGN

6.1. Sample Extraction

The samples were handled aseptically throughout the test sample preparation:

Table 1 Extraction process

Aseptically Sampling			Media	Sterilization Method	Extract Condition ³⁾
Ratio	Sampling Method ¹⁾	Actually Sampling ²⁾			
0.2 g / mL	Random	3.36 g	MEM with 10% FBS	Soaked in 75% alcohol for 30 min	37°C 24 h 60 rpm

Table 2 Final extract⁴⁾

Extract	pH	Clear or Not	Color changed or not	Presence of particles or not	Diluted/ filtered/pH adjusted or not
16.80 mL	7.0	Clear	Not	Not	Not

1) Each sample was tested in a 1:1 ratio.

2) Six models, each model weighing 0.56 g.

3) Extraction process was dynamic.

4) The final extract was used immediately.

6.2. Preparation of MTT solution

MTT was dissolved in MEM without phenol red at a concentration of 1 mg/mL, this solution was sterilized by filtering with 0.22 µm membrane. The MTT solution can only be used on the same day.

6.3. Testing Procedure

L929 cells were cultured in MEM medium (10% FBS, Penicillin 100 IU/mL, Streptomycin 100 µg/mL) at 37°C in a humidified atmosphere of 5% CO₂, then digest cells with 0.25% trypsin (containing EDTA) to prepare a single-cell suspension. And obtained a 1×10⁵ cells/mL suspension by centrifuging (200 g, 3 min) and re-suspended in MEM medium finally.

The suspended cells were dispensed at 100 µL per well in 96-well plate (marginal holes were excluded), and

cultured it in cell incubator (5% CO₂, 37°C), Cell morphology was evaluated to verify that the monolayer was satisfactory.

After the cells grew to form a monolayer, original culture medium was discarded. The 96-well plates were then treated with 100 µL extract of test article (100%, 75%, 50%, 25%), blank control, negative control (100%) and positive control (100%) respectively. Incubated the 96-well plate incubator (37°C, 5%CO₂) for another 24 h. Six parallel wells of each test were tested.

After 24 h incubation, firstly observed the cell morphology and then discarded the culture medium. 50 µL aliquot of MTT (1 mg/mL) was added to each well and then incubated at 37°C in a humidified atmosphere of 5% CO₂ for 2 h. The liquid in each well was tipped out and 100 µL isopropanol was added to each well.

Evaluated the OD Value with a dual-wavelength Micro-plate Reader with the measurement wavelength at 570 nm and reference wavelength at 650 nm.

7. DATA ANALYSIS AND CALCULATION

Mean ± standard deviation ($\bar{X} \pm SD$)

$$\text{Viab.\%} = \frac{100 \times OD_{570e}}{OD_{570b}}$$

OD_{570e}—is the mean value of the measured optical density of the extracts of the test article;

OD_{570b}—is the mean value of the measured optical density of the blanks.

8. EVALUATION CRITERION

- The lower the Viab.% value, the higher the cytotoxic potential of the test article is.
- If Viab.% is reduced to <70% of the blank, it has a cytotoxic potential.
- The survival rate of 50% extract of the test article should be at least the same or higher than that of 100% extract, otherwise the test should be repeated.

9. ALTERATION AND DEVIATION

No deviation affecting the validity of the test data occurred.

10. RESULTS

10.1. Results of Cell Morphology

Table 3 Observation of cell morphology

Group	Before treated with extract	24 h after treatment
Blank control		Discrete intracytoplasmatic granules, no cell lysis, no reduction of cell growth.
Negative control		Not more than 20% of the cells are round, loosely attached and without intracytoplasmatic granules, or show changes in morphology; occasional lysed cells are present; only slight growth inhibition observable.
Positive control		Nearly complete or complete destruction of the cell layers.
100% Test article extract	Discrete intracytoplasmatic granules, no cell lysis,	Not more than 50% of the cells are round, devoid of intracytoplasmatic granules, no extensive cell lysis; not more than 50% growth inhibition observable.
75% Test article extract	no reduction of cell growth.	Not more than 50% of the cells are round, devoid of intracytoplasmatic granules, no extensive cell lysis; not more than 50% growth inhibition observable.
50% Test article extract		Not more than 20% of the cells are round, loosely attached and without intracytoplasmatic granules, or show changes in morphology; occasional lysed cells are present; only slight growth inhibition observable.
25% Test article extract		Not more than 20% of the cells are round, loosely attached and without intracytoplasmatic granules, or show changes in morphology; occasional lysed cells are present; only slight growth inhibition observable.

10.2. Results of Cell Viability

Table 4 Results of cell viability

Group	$\bar{X} \pm SD$	Viability
Blank control	0.626±0.010	100.0%
Negative control	0.589±0.024	94.1%
Positive control	0.019±0.003	3.0%
100% test article extract	0.450±0.010	71.9%
75% test article extract	0.479±0.016	76.5%
50% test article extract	0.507±0.020	81.0%
25% test article extract	0.535±0.019	85.5%

11. CONCLUSION

Under the conditions of this study, the mixed test article extract did not show a cytotoxic potential to L-929 cells.

12. 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.

..... End of the Report

