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CNAS L1446



Shenzhen Testing Center of Medical Devices

# Test Report



Report No.: WY20232383  
Test Article: PCL (Polycaprolactone)  
Sponsor: Shenzhen Esun Industrial Co., Ltd.  
Manufacturer: Shenzhen Jusing Biotechnology Co., Ltd.  
Test Type: Commission Test  
Date of Issue: Nov. 13, 2023

扫码验证报告



提取码: 825613

## **Shenzhen Testing Center of Medical Devices**

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## Test Report

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Test Article	PCL (Polycaprolactone)		
Test Type	Commission Test	Identification No./ Lot No.	/
Trade Mark	esun	Model / Type	Viscosity-average Molecular Weight 60000 - 80000 g/mol
Date of Manufacturing	Aug. 11, 2023	Accepting Date	Aug. 29, 2023
Sponsor	Shenzhen Esun Industrial Co., Ltd.		
Applicant Address	Wuhan University Building A403-I and A901, No. 6 Yuexing 2 Road, Nanshan District, Shenzhen 518057		
Manufacturer	Shenzhen Jusing Biotechnology Co., Ltd.		
Production Address	Floor 3, No. 9, Yifenghua Innovation Industrial Park, Xinshi Community, Dalang Street, Longhua district, Shenzhen City		
Test Items	Skin sensitization tests		
Test in Accordance with	ISO 10993-10:2021 <i>Biological evaluation of medical devices - Part 10: Tests for skin sensitization</i>		
Summary	<p>The test article, PCL (Polycaprolactone), was extracted in 0.9% sodium chloride injection and sesame oil respectively at 37°C for 72h. The resulting extract was evaluated the potential for skin sensitization tests in accordance with the guinea pig maximization test requirements of ISO 10993-10:2021 <i>Biological evaluation of medical devices - Part 10: Tests for skin sensitization</i>.</p> <p>The test article extract was intradermally injected and occlusively patched to ten test guinea pigs in an attempt to induce sensitization. The solvent control were similarly injected and occlusively patched to ten control guinea pigs respectively. Following a recovery period, the test and control animals received a challenge patch of the appropriate test article extract and solvent control. All sites were scored at 24h and 48h after patch removal.</p> <p>Under the conditions of this study, the 0.9% sodium chloride injection and sesame oil test article extracts showed no evidence of causing skin sensitization in the guinea pig.</p>		
Comments	/		
Authorized Signatory	刘亮	Date Completed	Nov.13,2023 检验检测专用章

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## INTRODUCTION

A guinea pig maximization test of the test article identified below was conducted to evaluate the potential to cause skin sensitization. This study was conducted based on the guinea pig maximization test requirements of the ISO 10993-10:2021 *Biological evaluation of medical devices - Part 10: Tests for skin sensitization*. The test article was accepted on Aug. 29, 2023. The extraction was applied from Sept. 16, 2023 to Sept. 19, 2023. The treatment began on Sept. 19, 2023, and the observations were concluded on Oct. 16, 2023.

## MATERIALS

The sample provided by the sponsor was identified and handled as follows:

Test Article:	PCL (Polycaprolactone)
Identification No.:	/
Storage Conditions:	Room temperature
Extract Vehicle:	Polar solvent: 0.9% sodium chloride injection ChP (SC) Non-polar solvent: Sesame oil
Freund's Complete Adjuvant:	FCA, SIGMA
Preparation:	Prior to use, according to the requirements, a quantity of the test article was covered with SC based on a ratio of 0.2g/mL, a quantity of other test article was covered with sesame oil in the same way. They were extracted at 37°C for 72h. The extract vehicle without test article was similarly prepared to serve as the solvent control. The extract was used immediately.

## METHODS

### Test System:

Species:	Conventional guinea pig
Breed	Albino
Source:	Guangdong Animal Center of Medical Experimental
Sex:	Males and nonpregnant nulliparous Females
Body Weight Range:	300g to 400g
Age:	Young adult
Acclimation:	3 days
Number of Animals:	40

### Animal Management:

Husbandry:	Conditions conformed to ISO 10993-2 Animal welfare requirements.
Food:	General Guinea pig diet was provided daily.
Water:	Urban domestic water was provided.
Contamination:	Reasonably expected contaminants in food or water supplies did not have the potential to influence the outcome of this test.
Environmental:	The room temperature and humidity were daily monitored. The temperature range for the room was controlled within 20°C ~ 26°C. The humidity range for the room was controlled within 40% ~ 70%.
Facility:	Shenzhen Testing Center of Medical Devices is a CNAS accredited facility.
Personnel:	Associates involved were appropriately qualified and trained.
Selection:	Only healthy and previously unused animals were selected.

# Test Report

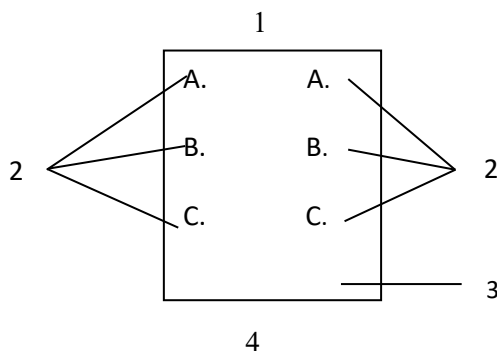
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SZIDC/F-7.8-001-15-10Experimental Procedure:

4h prior to treatment, each animal was weighed, identified and clipped free of fur over the dorsoscapular region.

Intradermal Induction:

The test animals were injected with the test article extract and the control animals were injected with the control. Intradermal injections were given to each animal within an approximate 4cm×6cm boundary of the fur clipped area as illustrated below:



- 1- Cranial end
- 2- 0.1mL intradermal injections
- 3- Clipped intrascapular region
- 4- Caudal end
- A, B, C injection sites

Fig.1 Location of intradermal injection sites

Solvent Control Animal:

- A. 0.1 mL of 50:50 (v/v) mixture of FCA and the solvent
- B. 0.1 mL of the solvent
- C. 0.1 mL of an emulsion of the blank liquid with adjuvant

Test Animal:

- A. 0.1 mL of 50:50 (v/v) mixture of FCA and the solvent
- B. 0.1 mL of test extract
- C. 0.1 mL of a 1:1 mixture of the 50:50 (v/v) solvent / FCA mixture and the test extract

Topical Induction:

6 days after the intradermal injections phase, the same area used during intradermal induction was clipped free of fur and treated with 10 % sodium dodecyl sulfate suspension in petrolatum. The suspension was massaged into the skin over the injection site to provoke a mild acute inflammation. The area was left uncovered for 24h. Then 8cm<sup>2</sup> section of medical gauze, saturated with the test article extract, was applied to the previously injected sites of the test animals. The control animals were similarly patched with the appropriate control. Secure the patches with an occlusive dressing. Remove the dressings and patches after 48h.

Challenge:

At 15 days after the removal of the topical induction patch, 8cm<sup>2</sup> section of medical gauze, saturated with the test article extract or control. All patches were applied to upper flank areas. Secure with an occlusive dressing. Remove the dressings and patches after 24h.

Observation:

Observe the appearance of the challenge skin sites of the test and control animals at 24h and 48h after removal of the dressings. Describe and grade the skin reactions for erythema and oedema according to the Magnusson and Kligman grading given in Table 1 for each challenge site and at each time interval.

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Table 1-Magnusson and Kligman scale

Patch test reaction	Grading scale
No visible change	0
Discrete or patchy erythema	1
Moderate and confluent erythema	2
Intense erythema and/or swelling	3

Magnusson and Kligman grades of 1 or greater in the test group generally indicate sensitization, provided grades of less than 1 are seen in solvent control animals. If grades of 1 or greater are noted in the solvent control animals, then the reactions of test animals which exceed the most severe reaction in solvent control animals are presumed to be due to sensitization.

## RESULTS

Individual body observations are presented in Table 2.

The solvent control group and the test article group was a grade 0 during observation period.

Table 2-Individual observations

Polar solvent control	Animal No.	1	2	3	4	5	6	7	8	9	10
	weight(g)	351	323	342	333	372	358	372	374	372	362
	24h	0	0	0	0	0	0	0	0	0	0
	48h	0	0	0	0	0	0	0	0	0	0
Polar extracts	Animal No.	11	12	13	14	15	16	17	18	19	20
	weight(g)	363	370	357	360	318	332	367	319	339	343
	24h	0	0	0	0	0	0	0	0	0	0
	48h	0	0	0	0	0	0	0	0	0	0
Non-polar solvent control	Animal No.	21	22	23	24	25	26	27	28	29	30
	weight(g)	317	314	331	366	376	327	366	338	349	338
	24h	0	0	0	0	0	0	0	0	0	0
	48h	0	0	0	0	0	0	0	0	0	0
Non-polar extracts	Animal No.	31	32	33	34	35	36	37	38	39	40
	weight(g)	353	374	344	362	320	317	314	323	334	350
	24h	0	0	0	0	0	0	0	0	0	0
	48h	0	0	0	0	0	0	0	0	0	0

Note: 0.1% 1-chloro-2,4-dinitrobenzene was the sensitizer for guinea pigs. A positive control test with the sensitizer was carried out on Aug. 18, 2023. The positive control group was a grade 1~3 during observation period.

## CONCLUSION

Under the conditions of this study, the 0.9% sodium chloride injection and sesame oil test article extracts showed no evidence of causing skin sensitization in the guinea pig.

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Results and conclusions apply only to the test article tested. No further evaluation of these results is made by our testing center. Any extrapolation of these data to other samples is the responsibility of the sponsor. All procedures were conducted in conformance with ISO 17025.

## **RECORD STORAGE**

All raw data pertaining to this study and a copy of the final report are to be retained in designated archive files in our testing center.

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## Test Article

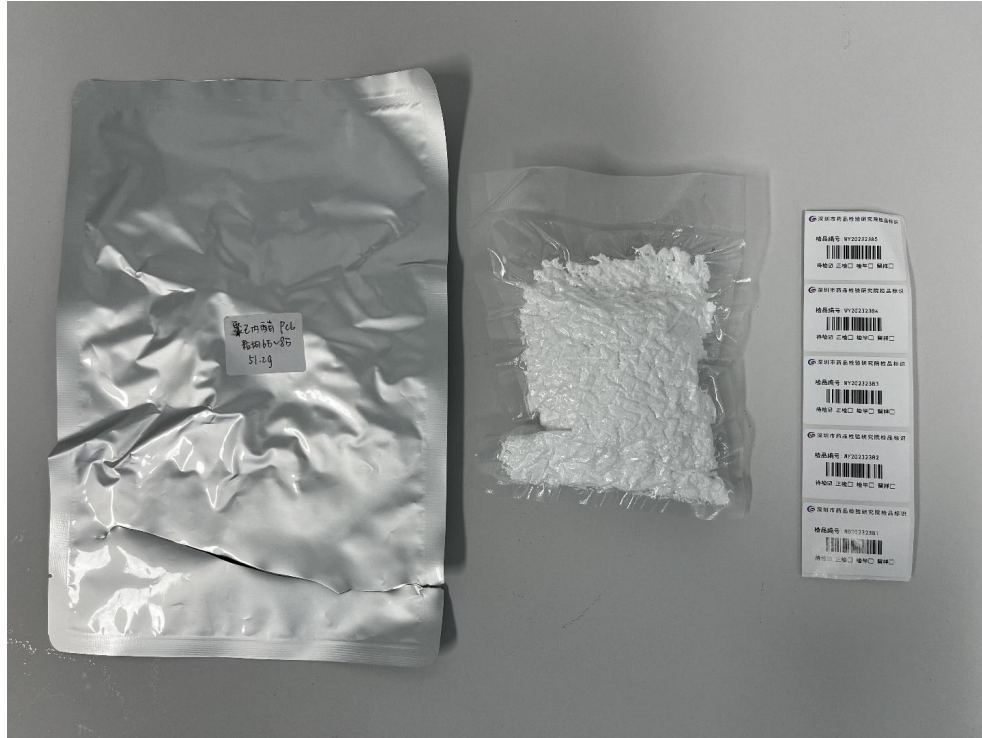


Fig. 2 Test Article

## Sample Specification

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## Model / Type

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