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BIOLOGICAL EVALUATION AT A GLANCE

Cytotoxicity	ISO 10993-5	No potential cytotoxic effect on L929 cells (MTT assay)
Skin sensitisation	ISO 10993-10	No evidence of sensitisation — 0 % positive challenge (guinea pig test)
Skin irritation	ISO 10993-23	No evidence of irritation — response category “very slight” (rabbit test)

1 · SAMPLE TESTED

Sample name	WESTRU® PDMS film (微思创®PDMS 薄膜)	Material	PDMS film — solid
Manufacturer	Hangzhou Westru Technology Co., Ltd. — Room 501, Building 9, No.68 Dakang Road, Qingshanhu Street, Lin'an District, Hangzhou, Zhejiang 310000, China		
State as received	Non-sterile solid, stored at room temperature	Batch / model	Not specified by applicant

2 · RESULTS SUMMARY

Endpoint	Standard	Method	Report No.	Outcome as reported
Cytotoxicity	ISO 10993-5:2009	MTT assay, L929 mouse fibroblasts, MEM + 10 % FBS extract	SDWH-M202400989-1	No potential cytotoxic effect
Skin sensitisation	ISO 10993-10:2021	Guinea pig maximisation test (Magnusson–Kligman), 15 Hartley guinea pigs	M26C0323-01N / -02N	No evidence of sensitisation (0 % positive challenge)
Skin irritation	ISO 10993-23:2021	Skin contact test, New Zealand White rabbits	M26C0323-03N / -04N	No evidence of irritation (category: very slight)

Each endpoint was tested on both a polar extract (0.9 % sodium chloride injection) and a non-polar extract (cottonseed oil). Both vehicles gave the same outcome in every case.

3 · TEST CONDITIONS AND DATES

Extraction vehicles	0.9 % sodium chloride (polar) · cottonseed oil (non-polar)	Extraction ratio	60 cm ² at 6 cm ² /mL → 10 mL
Extraction conditions	121 ± 2 °C for 1 ± 0.1 h; extract pH 6.0	Extract handling	Used within 24 h; no pH adjustment, filtration or dilution
Cytotoxicity report issued	2024-04-03	Sensitisation / irritation issued	2026-05-18

4 · TESTING LABORATORY AND ACCREDITATION

Issuing laboratory	Suzhou Sodatest — Suzhou Suda Health & Environment Technology Research Institute Co., Ltd. (苏州苏大卫生与环境技术研究所有限公司)		
Address	No.88 Zhenbei Road, Suzhou New District, Jiangsu 215153, China	Contact	www.sodatest.com · med@sodatest.com
Quality systems	Cytotoxicity study performed to FDA GLP (21 CFR Part 58); laboratory accredited to ISO/IEC 17025 (CNAS L2954) and CMA-certified (No. 230015349795)		

Note. The English text on this page is a summary prepared by Hangzhou Westru Technology Co., Ltd. for the convenience of overseas customers. The complete original test reports in Chinese — including the laboratory's seals, signatures and raw data — are available on request at info@westrufilm.com. In case of any discrepancy, the original reports prevail.