MedGaea Life Sciences Institute

Report NO.
RE26058LL01

Skin Sensitization Study (Local Lymph Node Assay) TPU / 70D Nylon Fabric

Study Report

GLP Compliance
Registered No. 0010

MedGaea Life Sciences Institute

Report NO.
RE26058LL01

Skin Sensitization Study (Local Lymph Node Assay)
TPU / 70D Nylon Fabric

The study complied with the Taiwan FDA GLP (2019), OECD-GLP (ENV/MC/CHEM (98) 17, 1997) and U.S. FDA (21 CFR Part 58, 2025) on principles of Good Laboratory Practice for Nonclinical Laboratory Studies. The study was performed in accordance with the agreed protocol and described in this report providing a true and accurate record of the results. The test article characteristics and its related properties in vehicle including purity, concentration, stability and homogeneity are provided and confirmed by the sponsor, and are excluded from GLP.

Yi-Hsuan Hsieh, Ph.D.
Study Director

04/13/2026
Date

MedGaea Life Sciences Institute

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QUALITY ASSURANCE STATEMENT

In compliance with the Taiwan FDA, OECD and U.S. FDA (21 CFR Part 58) "Good Laboratory Practice for Nonclinical Laboratory Studies", the Quality Assurance Unit conducted study-based type of audits on facility, equipment, personnel, test methods, raw data, and records regularly.

The study report had been reviewed and presented for internal approval. All parts of the experimentation involved were conducted according to the protocol. All original records, raw data, and documentations were truthfully transferred and addressed in the results of this report.

Inspection record:

Inspection Date	Inspection Phase	Date of Reports to	
		Study Director	Management
02/23/2026	Protocol	02/23/2026	02/23/2026
03/16/2026	Test article extraction	03/16/2026	03/16/2026
03/18/2026	Administration	03/18/2026	03/18/2026
03/23/2026	Lymph node isolation	03/23/2026	03/23/2026
04/01/2026	Raw data	04/01/2026	04/01/2026
04/01/2026	Study report	04/01/2026	04/01/2026

Yi-Jie Liao
Quality Assurance Unit in Charge

04/13/2026
Date

Test Facility: MedGaea Life Sciences Institute
Address: 7F., No.45, Lane 3, Sec.1, Zhongzheng E. Rd., Tamsui Dist., New Taipei City, Taiwan

Study Director: Yi-Hsuan Hsieh
Address: 7F., No.45, Lane 3, Sec.1, Zhongzheng E. Rd., Tamsui Dist., New Taipei City, Taiwan

Sponsor: JIUNDAR INDUSTRIAL CO., LTD.
Address: No. 9, Aly. 2, Ln. 252, Sanjun St., Shulin Dist., New Taipei City 238024, TAIWAN

Study Announcement

The study report is valid for the test article used only.
The study report could not be recopied or extracted without the permission from MedGaea Life Sciences Ltd.
The study report is invalid without the endorsement of MedGaea Life Sciences Ltd.

Protocol Number: PE26058LL01

Experimentation Staff

Test article extraction: Chia-Wei Lin, Zhi-Ling Hong, Yuan-Ling Hsiung
Administration: Yuan-Ling Hsiung, Ya-Ting Lee, Cheng-Chia Chen
Body weight measurement: Mei-Chu Lin, Yuan-Ling Hsiung
Lymph node cell isolation: Tzu-Ying Cheng, Pei-Yu Chiou
BrdU ELISA: Pei-Yu Chiou, Tzu-Ying Cheng
Quality assurance unit in charge: Yi-Jie Liao, Syuan-Yu Chang

Study Period

Animal acclimation: 03/09/2026~03/17/2026
Experimental starting: 03/15/2026
Extraction of the test article: 03/15/2026~03/18/2026, 03/16/2026~03/19/2026, 03/17/2026~03/20/2026
Animal grouping: 03/17/2026
Administration: 03/18/2026~03/20/2026
BrdU injection: 03/22/2026
Lymph node collection: 03/23/2026
BrdU ELISA: 03/23/2026
Experimental completion: 03/26/2026

CONTENTS

SUMMARY

This study was conducted to evaluate the potential of the test article extracts to induce hypersensitivity using the murine local lymph node assay (LLNA). The experiment was performed in accordance with ISO 10993-10 (2021): Biological Evaluation of Medical Devices – Tests for Skin Sensitization. Thirty mice were divided into six groups, including the test article saline extract group, the test article oil extract group, the positive control group (25% hexyl cinnamic aldehyde), and three solvent control groups (normal saline, cottonseed oil, and AOO [acetone/olive oil = 4:1]), with five female mice in each group. The test article extracts or control solvents were applied to the dorsum of both ears of the mice for three consecutive days. All mice received an intraperitoneal injection of BrdU on Day 5. On the day of sacrifice (Day 6), the ear punch weight and auricular lymph node weight were measured for each mouse. BrdU-ELISA was performed on the lymph nodes to calculate the stimulation index (SI).

The results are summarized below:

1. Clinical observations: The test article saline and oil extracts produced no adverse effects or clinical signs during the study.
2. Body weight: There were no significant differences in body weights between the test article groups and their concurrent control groups at both the beginning and the end of the study.
3. Local irritation: No observable irritation was noted in the treated areas of all mice in the negative control and test article groups. However, slight erythema was observed in some animals in the positive control group on Day 3.
4. Ear punch weight and lymph node weight: A significant increase in lymph node weight was observed in the positive control group compared to the AOO control group. Ear punch weight and lymph node weight in the test article groups were comparable to their concurrent controls.
5. Stimulation index: The stimulation index (SI) value of the positive control exceeded the threshold of 1.6, confirming a positive response in the BrdU LLNA. In contrast, the SI values of the negative controls and the test article groups were all less than 1.6.

Based on the results of this study, the test article extracts did not induce skin sensitization in the murine Local Lymph Node Assay (LLNA: BrdU-ELISA) under the conditions of this study.

INTRODUCTION

This study follows the test guidelines of ISO 10993-10 (2021): Biological Evaluation of Medical Devices – Tests for Skin Sensitization to evaluate the skin sensitization potential of the test article saline and oil extracts using the local lymph node assay (LLNA) with 5-bromo-2'-deoxyuridine (BrdU).

The skin sensitization potential of the “TPU / 70D Nylon Fabric” was evaluated using the Local Lymph Node Assay (LLNA) in accordance with ISO 10993-10 (2021). Polar and non-polar extracts prepared in normal saline and cottonseed oil (6 cm^2/mL, 50 °C, 72 h) represent a worst-case assessment of potential leachable substances from the device. LLNA was selected over the Guinea Pig Maximization Test (GPMT) because it evaluates sensitization following topical dermal exposure, which is more relevant to the clinical use of this skin-contacting device, and provides a quantitative, sensitive, and reproducible endpoint for assessing extractable mixtures. In addition, LLNA is considered a refinement consistent with 3R principles, requiring fewer animals and avoiding intradermal injections and adjuvant use associated with GPMT. Measures were implemented to monitor local irritation and minimize the risk of irritation-related false positive responses, ensuring appropriate interpretation of sensitization potential.

MATERIALS AND METHODS

1 Test Article Information
- 1.1 Name: TPU / 70D Nylon Fabric
- 1.2 Batch/Lot No.: J685-10-58-F / 70D
- 1.3 Package: Bag
- 1.4 External features: Flat
- 1.5 Color: Black
- 1.6 Major components: TPU / 70D Nylon Fabric
- 1.7 Storage condition: Room temperature
- 1.8 Receiving date: 02/12/2026
- 1.9 Expiration date: (Labeled expiry date) 02/09/2028

The above information was enclosed in Appendix 7.

2 Positive Control Article: 25% hexyl cinnamic aldehyde (HCA，Sigma-Aldrich，Lot No. RQ7MN).

3 Animals
- 3.1 Species/Strain: mouse/BALB/c
- 3.2 Source: BioLASCO Taiwan Co., Ltd.
- 3.3 Age (sex): 8 weeks old (female, nulliparous and non-pregnant)
- 3.4 Reasons for choosing the animals: The Local Lymph Node Assay (LLNA) was originally developed using BALB/c mice, and extensive reference databases are

available for skin sensitization testing with this strain. Besides, BALB/c mice are commonly used due to their well-characterized immune responses, reproducibility in LLNA studies, and sensitivity to potential sensitizers, making them the preferred choice for evaluating skin sensitization potential.

4 Feeding and Care (SOP: MG-QP-1702)
- 4.1 Housing: Animal Center Room 6, MedGaea Life Sciences Institute
- 4.2 Environment
  - 4.2.1 Temperature: 22 ± 3°C
  - 4.2.2 Humidity: 50 ± 20%
  - 4.2.3 Lighting: 12 hours (06:00 on, 18:00 off)
- 4.3 Monitoring
  - 4.3.1 Temperature, humidity: Daily
- 4.4 Cage and animal number
  - 4.4.1 Acclimation period: five mice per cage.
  - 4.4.2 Study period: five mice per cage.
- 4.5 Feeding
  - 4.5.1 Name: Laboratory Autoclavable Rodent Diet 5010
  - 4.5.2 Brand : LabDiet, USA
  - 4.5.3 Source: PMI Nutrition International, USA
  - 4.5.4 Access to feed: *ad libitum*
- 4.6 Drinking water
  - 4.6.1 Source: Reverse osmosis-treated tap water from Tamsui District was filled into sterilized water bottles before use.
  - 4.6.2 Access to water: *ad libitum*
- 4.7 Equipment
  - 4.7.1 Cages and bottles: Cages and bottles were sterilized using a high-pressure steam autoclave.
  - 4.7.2 Experimental equipment: All equipment was sterilized using a high- pressure steam autoclave, while heat-sensitive items were disinfected with 70% alcohol before use.

5 Acclimation

All mice were weighed and assigned provisional identification numbers upon arrival. The animals underwent a 9-day acclimation period in the housing facility before the experiment began, and only healthy animals were selected for use in the study.

6 Individual and Group Identifications (SOP: MG-ARS-016, MG-ARS-017 & MG-ARS-018)
- 6.1 Grouping: Each animal was assigned a provisional identification number, weighed, and arranged by body weight for S-type group allocation.
- 6.2 Individual identification: The animals are identified using cage card or colored markings on their tails.
- 6.3 Group identification: The cages are properly labeled for identifications for at least including by the room number, cage number, species/strain, sex, age, study number, study title, study period, in-housing date, and animal I.D. number, etc.

7 Group Designation (Guideline: ISO 10993-10, 2021)

Group	Sample	Applied area	Dose volume (μL/day)	Dose frequency (study days)	No. of animal
Polar extraction group	Normal saline with 0.5% HEC	dorsum of each ear	25	Day 1~Day 3	5
	Test article saline extract with 0.5% HEC[1]	dorsum of each ear	25	Day 1~Day 3	5
Nonpolar extraction group	Cottonseed oil	dorsum of each ear	25	Day 1~Day 3	5
	Test article oil extract	dorsum of each ear	25	Day 1~Day 3	5
Positive control group	AOO[2]	dorsum of each ear	25	Day 1~Day 3	5
	25% HCA[3]	dorsum of each ear	25	Day 1~Day 3	5

[1] HEC (hydroxyethyl cellulose) is used to thicken the solution, thereby increasing the duration that the solution adheres to the application sites.

[2] AOO: acetone: olive oil (4:1), vehicle control for the positive control

[3] HCA: hexyl cinnamic aldehyde

8 Preparation and Administration of the Test Article and Control Solvent (SOP MG-QP-1803)

8.1 Test article and control solvent preparations

In this study, normal saline (Tai-Yu Chemical & phamraceutical Co., Ltd., Lot No. AK1306) and cottonseed oil (Sigma-Aldrich, Lot No. MKCT7708) were used as extraction vehicles for polar and non-polar solvents, respectively. The test article thickness was 0.18 mm, as specified by the sponsor. Extraction was performed in accordance with ISO 10993-12:2021/Amd 1:2025 using a surface area-to-volume ratio of 6 cm^2/mL. For each extraction, 60 cm^2 of the test article was immersed in 10 mL of the respective extraction vehicle and incubated for 72 ± 2 hours at 50 ± 2°C with continuous agitation. The resulting saline extracts were colorless and clear, while the oil extracts were yellow and clear. The extracts were applied directly to the animals without centrifugation, filtration, pH adjustment, or any additional processing or storage.

To increase viscosity, hydroxyethyl cellulose (HEC; Tokyo Chemical Industry Co., Ltd., Lot No. UGDBA-VR) was added to both the normal saline (vehicle control) and the test article saline extract to achieve a final concentration of 0.5%

(w/v) prior to dermal application to the test mice.

Acetone:olive oil (AOO, 4:1, v/v) was used as the vehicle for the positive control. Acetone (Macron Fine Chemicals, Lot No. 21I0961020) and olive oil (Sigma-Aldrich, Lot No. 102828103) were used for preparation of the AOO vehicle. Hexyl cinnamic aldehyde (HCA) was prepared at 25% (w/v) in AOO and served as the positive control.

8.2 Method of administration

Treatment was applied to the dorsum of both ears once daily for three consecutive days. Control mice received 25 μL of the solvent control (either 0.5% hydroxyethyl cellulose solution, cottonseed oil or AOO).

8.3 Reasons for selecting the method of administration

The method of administration was chosen based on the recommendations provided in the test guidelines of ISO 10993-10 (2021) and OECD TG 442B (2025).

8.4 The time of administration and the calculation of dosing volume

Dosing was completed in the morning, with a dosing volume of 25 μL/day.

9 Procedures (SOP: MG-QP-1815)

9.1 On the treatment day, 25 μL/ear of the test article saline extract, oil extract, control solvent, or positive control solution was applied to the dorsum of both ears of each animal, ensuring even distribution across the ear surface. This treatment is performed once daily for three consecutive days (Day 1 to Day 3).

9.2 On Day 5, a single intraperitoneal injection of 5 mg/mouse of 5-bromo-2'-deoxyuridine (BrdU, Sigma-Aldrich, Lot No. HMBH2316) was administered (SOP: MG-ADS-001).

9.3 On Day 6, all mice were sacrificed. The central portions of both ears are isolated and weighed. Additionally, the auricular lymph nodes (right and left) were removed and weighed.

9.4 The lymph nodes were crushed and suspended in approximately 15 mL of physiological saline for analysis using an enzyme-linked immunosorbent assay (ELISA) to determine BrdU incorporation (Roche Diagnostics GmbH, Roche Applied Science, Mannheim, Germany; Lot No. 79287800). Briefly, 100 μL aliquots of the lymph node cell (LNC) suspension were dispensed into microplate wells in triplicate. Following fixation and denaturation of the LNCs, 100 μL of anti-BrdU antibody was added to each well. After washing, 100 μL of substrate solution containing tetramethylbenzidine (TMB) was added to allow chromogen development.

10 Clinical Observations and Examinations

10.1 Clinical observations (SOP: MG-ARS-019)

All animals were observed daily for general health conditions and clinical signs of illness or discomfort. Any abnormalities or deaths were recorded.

Erythema at the treated skin sites was scored in accordance with the Draize scoring system (Appendix 6). Scoring was performed daily prior to test article application on Days 1 to 3 and prior to sacrifice on Day 6.

10.2 Body weight monitoring

Each animal was weighed on the first day prior to administration (Day 1), and again at the end of the study (Day 6).

10.3 Stimulation index (SI) calculation

$$SI = \frac{\text{Mean BrdU labeling index of test article or positive control group}}{\text{Mean BrdU labeling index of the concurrent vehicle control group}}$$

11. Criteria for the valid test

The test is considered valid if the stimulation index (SI) of the positive control is greater than 1.6.

DATA MANAGEMENT

For statistical analysis, data including body weight, ear punch weight, and lymph node weight were analyzed using the Student's t-test to compare differences between groups. A probability value of less than 0.05 ($p < 0.05$) indicates a statistically significant difference between groups.

The mean BrdU labeling index for each animal was calculated based on the results of the BrdU ELISA. The stimulation index (SI) for each animal was calculated by dividing the mean BrdU labeling index of each treated animal by the mean BrdU labeling index of the concurrent vehicle control group. A positive response was defined as a SI ≥ 1.6 in the test article group.

AMENDMENTS / DEVIATIONS

This study was completed in accordance with the approved protocol without deviations.

ARCHIVING

All the study-related raw data, documents, records, test article, study protocol, study report and specimens are kept at MedGaea Life Sciences Institute archives D-4 and 106 for a defined period. During this period, agents authorized by the sponsor can apply to review the records.

RESULTS

This study was conducted to assess the potential of the test article to cause contact sensitization by measuring lymphocyte proliferative responses in the auricular lymph nodes. The results are described below:

1 Clinical observations (Table 1 & Appendix 1)

No clinical signs of toxicity or abnormal behavior were observed during the observation period in animals exposed to the “TPU / 70D Nylon Fabric” saline and oil extracts.

2 Skin erythema (Table 2 & Appendix 2)

No erythema was observed at the application sites of animals in the negative control or test article groups throughout the study period. In contrast, slight erythema (grade 1) was observed in animals in the positive control group on Days 3.

3 Body weight (Table 3 & Appendix 3)

During the study period, no significant differences in body weight were observed between the control and test article groups.

4 Ear punch weight and lymph node weight (Table 4 & Appendix 4)

A significant increase in both ear punch weight and lymph node weight was observed in the positive control group. In contrast, the test article groups showed no significant differences in ear punch weight or lymph node weight compared to the concurrent control groups.

5 Sensitization and stimulation index (Table 5 & Appendix 5)

The stimulation index (SI) values for the test article saline extract, oil extract, and 25% HCA (positive control) were 1.04, 0.98, and 2.72, respectively. Both the saline and oil extracts of the test article produced negative responses for skin sensitization (SI < 1.6). In contrast, 25% HCA in AOO (4:1) induced a clearly positive response (SI > 1.6), confirming the sensitivity of the assay.

CONCLUSION

This study was conducted in accordance with the test guidelines of ISO 10993-10 (2021) to evaluate the skin sensitization potential of the test article saline and oil extracts using the local lymph node assay (LLNA) with 5-bromo-2'-deoxyuridine (BrdU).

The test article extracts, control solvents, or positive control solution were applied to the dorsum of both ears of each animal once daily for three consecutive days. All mice received an intraperitoneal injection of BrdU approximately 24 hours prior to sacrifice.

The results revealed that the stimulation index (SI) value of the positive control was greater than 1.6, thereby fulfilling the validity criteria of the test. Under the conditions of this study, no local irritation was observed at the treatment sites. The SI values for both the saline and oil extracts of the test article were below 1.6, indicating that “TPU / 70D Nylon Fabric” extracts did not induce dermal sensitization.

REFERENCES

1. Animal welfare requirements. In: Biological evaluation of medical devices-Part 2, ISO 10993-2 (2022) International Standards Organization.

2. Good laboratory practice for nonclinical laboratory studies. (2019) Taiwan Food and Drug Administration.

3. Good laboratory practice for nonclinical laboratory studies. In: Title 21 of the United States Code of Federal Regulations - Food and Drugs (21 CFR), Part 58 (2025) United States Food and Drug Administration.

4. Principles on good laboratory practice. (1997) Organization for Economic Cooperation and Development.

5. Sample preparation and reference materials. In: Biological evaluation of medical devices-Part 12, ISO 10993-12 (2021)/Amd 1 (2025) International Standards Organization.

6. Skin sensitization: Local lymph node assay: BrdU-ELISA or FCM. In: OECD Guideline for the Testing of Chemicals. Section 4: Health Effects, Test No: 442B (2025) Organization for Economic Cooperation and Development.

7. Tests for skin sensitization. In: Biological evaluation of medical devices - Part 10, ISO 10993-10 (2021) International Standards Organization.

8. Tests for skin sensitization. In: Biological evaluation of medical devices - Part 10, GB/T 16886.10 (2024).

Table 1. Incidence of Clinical Observations

Group	Polar extraction Group [1]		Nonpolar extraction group		Positive control Group	
Test sample	Normal saline with 0.5% HEC	Test article saline extract with 0.5% HEC	cottonseed oil	Test article oil extract	AOO	25% HCA
Abnormality[1]	0/5	0/5	0/5	0/5	0/5	0/5

n/n: Number of rats with abnormalities / Number of rats in the group

[1] Skin reaction data are presented in Table 2 and are not included in this table.

HEC, hydroxyethyl cellulose; AOO, acetone: olive oil (4:1); HCA, hexyl cinnamic aldehyde.

Table 2. Incidence of Skin Erythema

Group	Polar extraction group		Nonpolar extraction group		Positive control group	
Test sample	Normal saline with 0.5% HEC	Test article saline extract with 0.5% HEC	Cottonseed oil	Test article oil extract	AOO	25% HCA
Erythema Scores						
Day 1						
0	5/5	5/5	5/5	5/5	5/5	5/5
1	0/5	0/5	0/5	0/5	0/5	0/5
2	0/5	0/5	0/5	0/5	0/5	0/5
3	0/5	0/5	0/5	0/5	0/5	0/5
4	0/5	0/5	0/5	0/5	0/5	0/5
Day 2						
0	5/5	5/5	5/5	5/5	5/5	5/5
1	0/5	0/5	0/5	0/5	0/5	0/5
2	0/5	0/5	0/5	0/5	0/5	0/5
3	0/5	0/5	0/5	0/5	0/5	0/5
4	0/5	0/5	0/5	0/5	0/5	0/5
Day 3						
0	5/5	5/5	5/5	5/5	5/5	0/5
1	0/5	0/5	0/5	0/5	0/5	5/5
2	0/5	0/5	0/5	0/5	0/5	0/5
3	0/5	0/5	0/5	0/5	0/5	0/5
4	0/5	0/5	0/5	0/5	0/5	0/5
Day 6						
0	5/5	5/5	5/5	5/5	5/5	5/5
1	0/5	0/5	0/5	0/5	0/5	0/5
2	0/5	0/5	0/5	0/5	0/5	0/5
3	0/5	0/5	0/5	0/5	0/5	0/5
4	0/5	0/5	0/5	0/5	0/5	0/5

n/n: Number of rats with abnormalities / Number of rats in the group
Test sites were evaluated and scored by the method of Draize for signs of dermal irritation (Appendix 6).
HEC, hydroxyethyl cellulose; AOO, acetone: olive oil (4:1); HCA, hexyl cinnamic aldehyde.

Table 3. Body Weight Monitoring

Group		Body weight (g)	
		Day 1 [1]	Day 6 [2]
Polar extraction group	Normal saline with 0.5% HEC	16.96 ± 1.42	17.48 ± 1.13
	Test article saline extract with 0.5% HEC	16.90 ± 0.94	17.76 ± 0.93
Nonpolar extraction group	Cottonseed oil	17.00 ± 1.06	17.66 ± 1.06
	Test article oil extract	17.32 ± 1.04	17.78 ± 0.91
Positive control group	AOO	17.34 ± 1.03	18.20 ± 0.71
	25% HCA	17.26 ± 0.94	17.20 ± 0.98

Data were presented as mean ± S.D. of 5 animals per group
[1] Day 1, before administration
[2] Day 6, before sacrificed
HEC, hydroxyethyl cellulose; AOO, acetone: olive oil (4:1); HCA, hexyl cinnamic aldehyde.

Table 4. Ear Punch Weight and Auricle Draining Lymph Node Weight

Group		Weight (g)	
		Ear punch	Auricular lymph node
Polar extraction group	Normal saline with 0.5% HEC	0.01154 ± 0.00061	0.00392 ± 0.00070
	Test article saline extract with 0.5% HEC	0.01100 ± 0.00035	0.00370 ± 0.00052
Nonpolar extraction group	Cottonseed oil	0.01144 ± 0.00063	0.00530 ± 0.00064
	Test article oil extract	0.01172 ± 0.00068	0.00554 ± 0.00063
Positive control group	AOO	0.01092 ± 0.00038	0.00462 ± 0.00117
	25% HCA	0.01224 ± 0.00096*	0.00780 ± 0.00034*

Data were presented as mean ± S.D. of 5 animals per group.
* Significant difference compared to the control group ($p < 0.05$)
HEC, hydroxyethyl cellulose; AOO, acetone: olive oil (4:1); HCA, hexyl cinnamic aldehyde

Table 5. Stimulation Index

Group		Mean BrdU labeling index	SI value [1]
Polar extraction group	Normal saline with 0.5% HEC)	0.1283 ± 0.0078	1.00
	Test article saline extract with 0.5% HEC	0.1333 ± 0.0120	1.04
Nonpolar extraction group	Cottonseed oil	0.1361 ± 0.0052	1.00
	Test article oil extract	0.1337 ± 0.0185	0.98
Positive control group	AOO	0.1435 ± 0.0093	1.00
	25% HCA	0.3904 ± 0.0796	2.72

Data were presented as mean ± S.D. of 5 animals per group
[1] The SI is derived by dividing the mean BrdU labelling index/mouse within each test article group and the PC group by the mean BrdU labelling index for the solvent group
HEC, hydroxyethyl cellulose; AOO, acetone: olive oil (4:1); HCA, hexyl cinnamic aldehyde.

Appendix 1. Clinical Observations of Each Individual Mouse

Group		Animal I.D.	Clinical observations
Polar extraction	Normal saline with 0.5% HEC	260581201	—
		260581202	—
		260581203	—
		260581204	—
		260581205	—
	Test article saline extract with 0.5% HEC	260581206	—
		260581207	—
		260581208	—
		260581209	—
		260581210	—
Non-Polar extraction	Cottonseed oil	260581211	—
		260581212	—
		260581213	—
		260581214	—
		260581215	—
	Test article oil extract	260581216	—
		260581217	—
		260581218	—
		260581219	—
		260581220	—
Positive control group	AOO	260581221	—
		260581222	—
		260581223	—
		260581224	—
		260581225	—
	25% HCA	260581226	— [a]
		260581227	— [a]
		260581228	— [a]
		260581229	— [a]
		260581230	— [a]

—: No abnormal clinical signs; HEC, hydroxyethyl cellulose; AOO, acetone: olive oil (4:1); HCA, hexyl cinnamic aldehyde.

[a] Skin reaction refer to Appendix 2.

Appendix 2. Skin Reaction Observation of Each Individual Mouse

Group		Animal I.D.	Erythema scores[1]			
			Day 1	Day 2	Day 3	Day 6
Polar extraction	Normal saline with 0.5% HEC	260581201	0	0	0	0
		260581202	0	0	0	0
		260581203	0	0	0	0
		260581204	0	0	0	0
		260581205	0	0	0	0
	Test article saline extract with 0.5% HEC	260581206	0	0	0	0
		260581207	0	0	0	0
		260581208	0	0	0	0
		260581209	0	0	0	0
		260581210	0	0	0	0
Non-Polar extraction	Cottonseed oil	260581211	0	0	0	0
		260581212	0	0	0	0
		260581213	0	0	0	0
		260581214	0	0	0	0
		260581215	0	0	0	0
	Test article oil extract	260581216	0	0	0	0
		260581217	0	0	0	0
		260581218	0	0	0	0
		260581219	0	0	0	0
		260581220	0	0	0	0
Positive control group	AOO	260581221	0	0	0	0
		260581222	0	0	0	0
		260581223	0	0	0	0
		260581224	0	0	0	0
		260581225	0	0	0	0
	25% HCA	260581226	0	0	1	0
		260581227	0	0	1	0
		260581228	0	0	1	0
		260581229	0	0	1	0
		260581230	0	0	1	0

[1] Erythema in the treated portions of the skin was scored in accordance with the Draize test method (Appendix 6)

HEC, hydroxyethyl cellulose; AOO, acetone: olive oil (4:1); HCA, hexyl cinnamic aldehyde.

Appendix 3. Body Weight of Each Individual Mouse

Group		Animal I.D.	Body weight (g) [1]	
			Day 1	Day 6
Polar extraction	Normal saline with 0.5% HEC	260581201	15.1	16.1
		260581202	16.8	18.0
		260581203	16.3	16.6
		260581204	17.8	17.8
		260581205	18.8	18.9
	Test article saline extract with 0.5% HEC	260581206	15.5	16.5
		260581207	16.6	17.2
		260581208	17.0	18.0
		260581209	17.4	18.2
		260581210	18.0	18.9
Non-Polar extraction	Cottonseed oil	260581211	15.6	17.2
		260581212	16.6	16.6
		260581213	17.0	17.3
		260581214	17.3	17.8
		260581215	18.5	19.4
	Test article oil extract	260581216	16.6	16.9
		260581217	16.4	17.1
		260581218	17.0	17.5
		260581219	17.6	18.3
		260581220	19.0	19.1
Positive control group	AOO	260581221	16.3	17.8
		260581222	16.8	17.7
		260581223	17.1	18.3
		260581224	17.5	17.8
		260581225	19.0	19.4
	25% HCA	260581226	16.2	16.3
		260581227	16.7	16.2
		260581228	17.3	17.2
		260581229	17.4	17.8
		260581230	18.7	18.5

[1] Day 1: the first day of the study prior to administration; Day 6: before sacrifice.
HEC, hydroxyethyl cellulose; AOO, acetone: olive oil (4:1); HCA, hexyl cinnamic aldehyde.

Appendix 4. Ear Punch Weight and Lymph Node Weight of Each Individual Mouse

Group		Animal I.D.	Weight (g)	
			Ear punch	Auricular lymph node
Polar extraction	Control (Normal saline with 0.5% HEC)	260581201	0.0112	0.0039
		260581202	0.0118	0.0034
		260581203	0.0110	0.0038
		260581204	0.0112	0.0034
		260581205	0.0125	0.0051
	Test article saline extract with 0.5% HEC	260581206	0.0104	0.0034
		260581207	0.0110	0.0035
		260581208	0.0111	0.0043
		260581209	0.0112	0.0042
		260581210	0.0113	0.0031
Non-Polar extraction	Control (cottonseed oil)	260581211	0.0124	0.0048
		260581212	0.0111	0.0053
		260581213	0.0112	0.0064
		260581214	0.0108	0.0051
		260581215	0.0117	0.0049
	Test article oil extract	260581216	0.0110	0.0055
		260581217	0.0120	0.0066
		260581218	0.0110	0.0054
		260581219	0.0121	0.0049
		260581220	0.0125	0.0053
Positive control group	AOO	260581221	0.0110	0.0046
		260581222	0.0109	0.0055
		260581223	0.0107	0.0039
		260581224	0.0105	0.0031
		260581225	0.0115	0.0060
	25% HCA	260581226	0.0127	0.0077
		260581227	0.0137	0.0080
		260581228	0.0118	0.0082
		260581229	0.0116	0.0073
		260581230	0.0114	0.0078

HEC, hydroxyethyl cellulose; AOO, acetone: olive oil (4:1); HCA, hexyl cinnamic aldehyde.

Appendix 5. BrdU Labeling Index and Stimulation Index of Each Individual Mouse

Group		Animal I.D.	BrdU labelling index			
			1	2	3	Mean BrdU labeling index
Polar extraction	Control (Normal saline with 0.5% HEC)	260581201	0.133	0.120	0.122	0.1250
		260581202	0.114	0.121	0.117	0.1173
		260581203	0.140	0.127	0.143	0.1367
		260581204	0.121	0.133	0.130	0.1280
		260581205	0.144	0.126	0.134	0.1347
	Test article saline extract with 0.5% HEC	260581206	0.144	0.152	0.141	0.1457
		260581207	0.141	0.139	0.142	0.1407
		260581208	0.136	0.143	0.137	0.1387
		260581209	0.122	0.115	0.115	0.1173
		260581210	0.123	0.127	0.122	0.1240
Non-Polar extraction	Control (cottonseed oil)	260581211	0.140	0.138	0.136	0.1380
		260581212	0.135	0.119	0.135	0.1297
		260581213	0.130	0.141	0.129	0.1333
		260581214	0.122	0.146	0.140	0.1360
		260581215	0.143	0.141	0.147	0.1437
	Test article oil extract	260581216	0.158	0.163	0.158	0.1597
		260581217	0.117	0.108	0.104	0.1097
		260581218	0.141	0.129	0.127	0.1323
		260581219	0.121	0.124	0.132	0.1257
		260581220	0.142	0.152	0.130	0.1413
Positive control group	AOO	260581221	0.141	0.129	0.131	0.1337
		260581222	0.144	0.129	0.135	0.1360
		260581223	0.139	0.158	0.132	0.1430
		260581224	0.159	0.158	0.152	0.1563
		260581225	0.144	0.153	0.149	0.1487
	25% HCA	260581226	0.259	0.264	0.280	0.2677
		260581227	0.400	0.359	0.387	0.3820
		260581228	0.459	0.433	0.440	0.4440
		260581229	0.367	0.398	0.383	0.3827
		260581230	0.504	0.447	0.476	0.4757

HEC, hydroxyethyl cellulose; AOO, acetone: olive oil (4:1); HCA, hexyl cinnamic aldehyde.

Appendix 6. Evaluation Criteria for the Treated Skin Area

Draize Scoring System

Erythema Scores Observation	Score
No erythema	0
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate to severe erythema	3
Severe erythema (beet redness) to eschar formation preventing grading of erythema	4

Appendix 7. Test Article Information Sheet

Medgaea Life Sciences Ltd.

INFORMATION FOR
■TEST ARTICLE/□SAMPLE/SPECIMEN
□CONTROL ARTICLE SHEET

管制文件章
品保室(麥)

Medical device

Sponsor's company name	JIUNDAR INDUSTRIAL CO., LTD.
Sponsor's address	No. 9, Aly. 2, Ln. 252, Sanjun St., Shulin Dist., New Taipei City 238024, TAIWAN
Test article name	TPU / 70D Nylon Fabric
Package	■Bag □Tube □Box □Bottle □Other:
External features	□Irregular □Liquid □Powder ■Flat □Membrane □Tube □Other:
Color	Black
Major components	TPU / 70D Nylon Fabric
Storage condition	■Room temperature □Refrigerated □Frozen
Expiration date	■Labeled expiry date: 02/09/2028 □Minimum validity for testing: MM/DD/YYYY
Batch/Lot No.	J685-10-58-F / 70D
Surface area of test article	**Surface area per test article___-___cm²** **Thickness: 0.18 mm (Thickness < 0.5mm or ≧ 0.5mm)** *Please provide the surface area if applicable. (This area includes the combined area of all tissue contacting surfaces of the test article.)
Remark/Requirement	
Sponsor Signature	

Note:

1. Please indicate" - "where not applicable.
2. MDG is not responsible and liable for any test article properties. The test article information listed above is provided and confirmed by the sponsor. Sponsor is take fully responsibility on the test article chemical and physical characteristics, and it's related analyses information.
3. Target Regulatory Authority(ies) (multiple selections allowed):
   ■TFDA ■US FDA ■ CE Marking ■NMPA □Others:

MG-QR-2201 10

Appendix 7. Test Article Information Sheet (cont'd)