



# STC



中国认可  
国际互认  
检测  
TESTING  
CNAS L3428

## Test Report

Date: 2020-04-21  
No.: DE20030094

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### TEST FACILITY

STC (Dongguan)  
68 Fumin Nan Road, Dalang,  
Dongguan, Guangdong,  
China. (Zip code 523770)

### SPONSOR

Yulan Yang  
Foshan Ruixin Non Woven Co., Ltd  
Hongxingcun Industrial Zone, Guanyao Nanhai,  
Foshan City, Guangdong,  
P.R. China

### CONFIDENTIAL

### STUDY TITLE

Primary skin irritation Study in Rabbits

### TEST ARTICLE NAME

PP Non Woven Fabric

### TEST ARTICLE IDENTIFICATION

CP-MD-1952  
CSD NO.: CL20200301970

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### Summary

The test article, PP Non Woven Fabric, was evaluated for primary skin irritation in rabbits. This study was conducted based on the requirements of ISO 10993-10:2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization. The test articles were extracted in 0.9% sodium chloride injection and Soybean oil. Two 25 mm x 25 mm sections of absorbent gauze patches with 0.5ml test extracts/ control extracts were topically applied to the skin of each of three rabbits and left in place for 4 hours. The sites were graded for erythema and edema at 1, 24, 48 and 72 hours after removal of the single application.

There was no erythema and no edema observed on the skin of the animals treated with the test extracts. The Primary Irritation Index for the test extracts was calculated to be 0.0. The response of the test article was categorized as negligible.

Authorized Signatory Approval: \_\_\_\_\_

*Tang*

Jonathan Tang



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### 1. Introduction

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#### 1.1 Purpose

The purpose of this study was to evaluate the test article for the potential to cause skin irritation in the rabbit.

#### 1.2 Testing Guidelines

This study was based on the requirements of the International Organization for Standardization 10993-10:2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.

#### 1.3 Dates

|                         |            |
|-------------------------|------------|
| Test Article Received:  | 2020.03.17 |
| Treatment Started:      | 2020.03.23 |
| Observations Concluded: | 2020.03.29 |

### 2. Identification of Test and Control Articles

---

The test article provided by the sponsor was identified and handled as described below:

**Table 1: Test Article**

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|   |                     |
|---|---------------------|
| Name:                                     | PP Non Woven Fabric |
| Size:                                     | 130cm*100cm         |
| CAS Code:                                 | N.A                 |
| Model:                                    | Sy-rs               |
| Lot:                                      | SY-200314           |
| Initial State:                            | Not Sterilized      |
| Strength, Purity and Composition:         | Polypropylene       |
| Color:                                    | White               |
| Physical Description of the Test Article: | Others              |
| Manufacture date:                         | N.A                 |
| Expiration Date:                          | N.A                 |

**Table 2: Negative Control Article**

|   |  |
|---|--|
| Name:   | 0.9% Sodium chloride injection (SC)<br>Soybean oil (SO)  |
| Purity, Composition, and Other Characteristics: | SC: Composition: 0.9% NaCl $\pm$ 5.0% of label claim, balance is water; sodium chloride CAS No.: 7647-14-5/water CAS No.: 7732-18-5<br>SO: Composition: CAS No.: 8001-22-7 |

**Table 3: Reagents**

| Name | Brand      | Lot       |
|------|------------|-----------|
| SC   | Yuyuan     | L19090507 |
| SO   | Tianyushan | 20190701  |

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### 3. Test System

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#### 3.1 Test System

|                     |  |
|---------------------|--|
| Species:            | Rabbit ( <i>Oryctolagus cuniculus</i> )                                |
| Strain:             | New Zealand White  |
| Source:             | Guangzhou baiyun district longgui xingke animal farm (广州市白云区龙归兴科动物养殖场) |
| Sex:                | Male   |
| Age:                | Young adult  |
| Acclimation Period: | Minimum 5 days   |
| Number of Animals:  | 6  |

#### 3.2 Test System Management

The rabbit (animal) is specified as an appropriate animal model for evaluating potential skin irritants by the current ISO testing standards. The rabbit is widely used for this purpose and relative ranking of irritant scores can be determined.

### 4. Animal Management

---

#### 4.1 Husbandry, Housing and Environment

Conditions conformed to STC Standard Operating Procedures. Animals were housed in groups in stainless steel or plastic suspended cages identified by a card indicating the animal numbers, test code, sex, animal code and date dosed.

The animal housing room is conventional system lab. The lab animal use permit No. SYXK(粤)2019-0159. The animal housing room temperature and relative humidity were monitored daily. The temperature for the room was set to 19-26°C and the relative humidity was set to 40-70%. There were no significant temperature or relative humidity excursions that adversely affected the health of the animals.

The light cycle was controlled (12 hours light, 12 hours dark).

#### 4.2 Food, Water and Contaminants

Food: Laboratory animal formula feed (rabbit), Shenyang maohua biotechnology co. LTD(沈阳茂华生物科技有限公司), was provided daily.

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Water: The water quality met the "Sanitary standard for drinking water" (GB5749-2006)

Food and water meet animal welfare requirements. No contaminants present in the feed and water impacted the results of this study.

### **4.3 Personnel**

Associates involved in this study were appropriately qualified and trained.

### **4.4 Veterinary Care**

Standard veterinary medical care was provided in this study.

### **4.5 IACUC**

This procedure has been approved by the STC Institutional Animal Care and Use Committee (IACUC), and is reviewed at least annually by the same committee.

### **4.6 Selection**

Only healthy, animals free from irritation or other dermatological lesions that could interfere with the test were selected.

## **5. Method**

---

### **5.1 Test and Control Article Preparation**

The test articles were measured and calculated. The preparations of the test article and the negative control were subjected to the extraction conditions as described below. The extracts were continuously agitated during extraction.

**Table 4: Extraction**

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| Vehicle | Treatment Group | Extraction Ratio       | Article Amount    | Volume of Vehicle | Extraction Condition     |
|---------|-----------------|------------------------|-------------------|-------------------|--------------------------|
| SC      | Test            | 6cm <sup>2</sup> :1 mL | 70cm <sup>2</sup> | 11.7 mL           | 50±2°C for<br>72±2 hours |
|         | Control         | N. A                   | N. A              | 20.0mL            |                          |
| SO      | Test            | 6cm <sup>2</sup> :1 mL | 70cm <sup>2</sup> | 11.7 mL           |                          |
|         | Control         | N. A                   | N. A              | 20.0mL            |                          |

The following table contains a description of the test and control article extracts before and after extraction.

**Table 5: Condition of Extracts**

| Vehicle | Time Observed     | Extract | Condition of Extracts |         |              |
|---------|-------------------|---------|-----------------------|---------|--------------|
|         |                   |         | Color                 | Clarity | Particulates |
| SC      | Before Extraction | Test    | Colorless             | Clear   | None         |
|         |                   | Control | Colorless             | Clear   | None         |
|         | After Extraction  | Test    | Colorless             | Clear   | None         |
|         |                   | Control | Colorless             | Clear   | None         |
|         | Prior to Use      | Test    | Colorless             | Clear   | None         |
|         |                   | Control | Colorless             | Clear   | None         |
| SO      | Before Extraction | Test    | Colorless             | Oily    | None         |
|         |                   | Control | Colorless             | Oily    | None         |
|         | After Extraction  | Test    | Colorless             | Oily    | None         |
|         |                   | Control | Colorless             | Oily    | None         |
|         | Prior to Use      | Test    | Colorless             | Oily    | None         |
|         |                   | Control | Colorless             | Oily    | None         |

The test article extracted in SC and SO remained unchanged during the extraction process. The extracts were maintained at ambient temperature <24 hours before use for all phases. The extracts were not centrifuged, filtered, or otherwise altered prior to dosing.

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### 5.2 Test Procedure

The animals were weighed and the fur on the back of each animal was clipped with an electric clipper 24 hours prior to treatment. On the day of treatment, four sites, two on each side of the back and positioned cranially and caudally, were designated on each animal. The sites were free of blemishes that could interfere with the interpretation of results. The appropriate extracts were applied to the 2.5 cm × 2.5 cm absorbent gauze patches. 0.5 ml extract was used to saturate the gauze. A control patch of gauze moistened with the extract vehicle was applied as well. And then all the application sites were covered with a bandage (semi-occlusive or occlusive) for a minimum of 4 h. Animals were returned to their cages after treatment. After the 4-hour exposure, the binders, tape, and patches were removed. The sites were gently wiped with a gauze sponge dampened with deionized water in an attempt to remove any remaining residue.

#### 5.2.1 Laboratory Observations

1. Animals were observed daily for general health.
2. Body weights were recorded for each animal at pretreatment.
3. Dermal observations for erythema and edema were recorded at 1, 24, 48 and 72 hours after patch removal in accordance with the criteria in Appendix 1.

**Table 6 Classification System for Skin Reaction**

| Erythema and Eschar Formation   | Numerical Grading | Edema Formation   | Numerical Grading |
|---|-------------------|---|-------------------|
| No erythema   | 0                 | No edema  | 0                 |
| Very slight erythema (barely perceptible)   | 1                 | Very slight edema (barely perceptible)                                  | 1                 |
| Well-defined erythema   | 2                 | Well-defined edema (edges of area well-defined by definite raising)     | 2                 |
| Moderate erythema   | 3                 | Moderate edema (raised approximately 1 mm)                              | 3                 |
| Severe erythema (beet redness) to eschar formation preventing grading of erythema | 4                 | Severe edema (raised more than 1 mm and extending beyond exposure area) | 4                 |
| Total possible score for irritation   |                   |   | 8                 |

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**Table 7 Irritation Response Categories in the Rabbit**

| Irritation Response Categories in the Rabbit |            |
|--|------------|
| Response Category                            | Mean Score |
| Negligible                                   | 0-0.4      |
| Slight                                       | 0.5-1.9    |
| Moderate                                     | 2.0-4.9    |
| Severe                                       | 5-8        |

All times and temperatures reported herein are approximate and are within ranges established by the external standards described in the References section of this report and/or STC standard operating procedures.

### **6. Evaluation**

The Primary Irritation Index of the test was calculated following test completion for each animal. The erythema and edema scores obtained at the 24, 48 and 72-hour intervals were added together and divided by the total number of observations. This calculation was conducted separately for the test and control article for each animal. The score for the control was subtracted from the score for the test article to obtain the Primary Irritation Score. The Primary Irritation Score for each animal was added together and divided by the number of animals to obtain the Primary Irritation Index. The Primary Irritation Index was characterized based on the definitions.

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### 7. Results

All the animals were clinically normal throughout the study. Individual results of dermal scoring are presented in Appendix 1. No irritation was observed on the skin of the animals. The Primary Irritation Index of the test article was calculated to be 0.0. The irritation calculations are shown below:

**Table 8 Irritation Calculations of SC group**

| Animal Number  | Test Score Average | - | Control Score Average | Individual Primary Irritation Score | Combined Primary Irritation Score (CPIS) | Primary Irritation Index (CPIS/3) | Response Category |
|----------------|--------------------|---|-----------------------|-------------------------------------|--|-----------------------------------|-------------------|
| 20200<br>21101 | 0                  | - | 0                     | 0                                   | 0  | 0                                 | Negligible        |
| 20200<br>21102 | 0                  | - | 0                     | 0                                   |  |                                   |                   |
| 20200<br>21103 | 0                  | - | 0                     | 0                                   |  |                                   |                   |

**Table 9 Irritation Calculations of SO group**

| Animal Number  | Test Score Average | - | Control Score Average | Individual Primary Irritation Score | Combined Primary Irritation Score (CPIS) | Primary Irritation Index (CPIS/3) | Response Category |
|----------------|--------------------|---|-----------------------|-------------------------------------|--|-----------------------------------|-------------------|
| 20200<br>21104 | 0                  | - | 0                     | 0                                   | 0  | 0                                 | Negligible        |
| 20200<br>21105 | 0                  | - | 0                     | 0                                   |  |                                   |                   |
| 20200<br>21110 | 0                  | - | 0                     | 0                                   |  |                                   |                   |

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### 8. Conclusion

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There was no erythema and no edema observed on the skin of the animals treated with the test article. The Primary Irritation Indexes for the test article extracts were both calculated to be 0.0. The response of the test article extracts was categorized as negligible.

Results and conclusions apply only to the test article tested. Any extrapolation of these data to other articles is the sponsor's responsibility.

### 9. Records

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All raw data pertaining to this study and a copy of the final report are retained in designated STC archive files in accordance with STC SOPs.

### 10. ISO Compliance

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All procedures were compliance to ISO 17025.

### 11. References

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Code of Federal Regulations (CFR), Title 21, Part 58, Good Laboratory Practice for Nonclinical Laboratory Studies  
International Organization for Standardization (ISO) 10993-1, Biological evaluation of medical devices -Part 1: Evaluation and testing within a risk management process (2018).  
International Organization for Standardization (ISO) 10993-2, Biological evaluation of medical devices -Part 2: Animal welfare requirements (2006).  
International Organization for Standardization (ISO) 10993-10, Biological evaluation of medical devices -Part 10: Tests for irritation and skin sensitization (2010).  
International Organization for Standardization (ISO) 10993-12, Biological evaluation of medical devices -Part 12: Sample preparation and reference materials (2012).  
International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025, General requirements for the competence of testing and calibration laboratories (2017).

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### Appendix 1 – Dermal Observations

**Table 10 Dermal Observations of SC group**

| Animal number  | Weight (g) | Group   | Observation | Interval (hours) |    |    |    |
|----------------|------------|---------|-------------|------------------|----|----|----|
|                |            |         |             | 1                | 24 | 48 | 72 |
| 20200<br>21101 | 3826.2     | Test    | Erythema    | 0                | 0  | 0  | 0  |
|                |            |         | Edema       | 0                | 0  | 0  | 0  |
|                |            | Control | Erythema    | 0                | 0  | 0  | 0  |
|                |            |         | Edema       | 0                | 0  | 0  | 0  |
| 20200<br>21102 | 2924.3     | Test    | Erythema    | 0                | 0  | 0  | 0  |
|                |            |         | Edema       | 0                | 0  | 0  | 0  |
|                |            | Control | Erythema    | 0                | 0  | 0  | 0  |
|                |            |         | Edema       | 0                | 0  | 0  | 0  |
| 20200<br>21103 | 3697.6     | Test    | Erythema    | 0                | 0  | 0  | 0  |
|                |            |         | Edema       | 0                | 0  | 0  | 0  |
|                |            | Control | Erythema    | 0                | 0  | 0  | 0  |
|                |            |         | Edema       | 0                | 0  | 0  | 0  |

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**Table 11 Dermal Observations of SO group**

| Animal number  | Weight (g) | Group   | Observation | Interval (hours) |    |    |    |
|----------------|------------|---------|-------------|------------------|----|----|----|
|                |            |         |             | 1                | 24 | 48 | 72 |
| 20200<br>21104 | 3564.5     | Test    | Erythema    | 0                | 0  | 0  | 0  |
|                |            |         | Edema       | 0                | 0  | 0  | 0  |
|                |            | Control | Erythema    | 0                | 0  | 0  | 0  |
|                |            |         | Edema       | 0                | 0  | 0  | 0  |
| 20200<br>21105 | 3758.3     | Test    | Erythema    | 0                | 0  | 0  | 0  |
|                |            |         | Edema       | 0                | 0  | 0  | 0  |
|                |            | Control | Erythema    | 0                | 0  | 0  | 0  |
|                |            |         | Edema       | 0                | 0  | 0  | 0  |
| 20200<br>21110 | 3352.6     | Test    | Erythema    | 0                | 0  | 0  | 0  |
|                |            |         | Edema       | 0                | 0  | 0  | 0  |
|                |            | Control | Erythema    | 0                | 0  | 0  | 0  |
|                |            |         | Edema       | 0                | 0  | 0  | 0  |

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### Appendix 2 - Periodic Positive Control Study for Primary Skin Irritation Test

**What was tested**  
sodium dodecyl sulfate (SDS)

**Dates**  
Treatment Started: 2020.02.07  
Observations Concluded: 2020.03.05

**Purpose**  
A periodic positive control study was conducted for the Primary Skin Irritation Test to meet the following objectives: 1) confirm the methodology in ISO 10993-10:2010, Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization, 2) substantiate the potential of SDS to cause irritant effects, 3) verify proper training of the technicians performing these studies, and 4) substantiate the susceptibility of the rabbit strain to primary skin irritation test.

**Methods**  
The test utilized young adult, nulliparous and not pregnant, female rabbit supplied by Guangzhou baiyun district longgui xingke animal farm (广州市白云区龙归兴科动物养殖场). The weight at study initiation ranged from 2kg to 4kg. Two 25 mm x 25 mm sections of absorbent gauze patches with 0.5ml 20% (w/w) concentration of SDS was topically applied to the skin of each of three rabbits and left in place for 4 hours. The sites were graded for erythema and edema at 1, 24, 48 and 72 hours after removal of the single application.

**Results**  
All of the three sites demonstrated a positive skin irritation to the known skin irritant, SDS. None of the control sites of animals demonstrated an irritation response. The Irritation Calculations are shown below:

| Animal Number | Test Score Average | - | Control Score Average | Individual Primary Irritation Score | Combined Primary Irritation Score (CPIS) | Primary Irritation Index (CPIS/3) | Response Category |
|---------------|--------------------|---|-----------------------|-------------------------------------|--|-----------------------------------|-------------------|
| 1             | 6                  | - | 0                     | 6                                   | 18                                       | 6                                 | Severe            |
| 2             | 6                  | - | 0                     | 6                                   |  |                                   |                   |
| 3             | 6                  | - | 0                     | 6                                   |  |                                   |                   |

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### **Conclusion**

The known skin irritant SDS produced evidence of causing primary skin irritation in the New Zealand White strain of rabbit. Therefore, the following objectives were met: 1) the methodology in ISO 10993-10:2010, Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Skin Sensitization was confirmed, 2) the potential for SDS to cause skin irritation was substantiated, 3) proper training of the technicians performing this study design was verified and 4) the susceptibility of the New Zealand White rabbit strain to skin irritation was substantiated.

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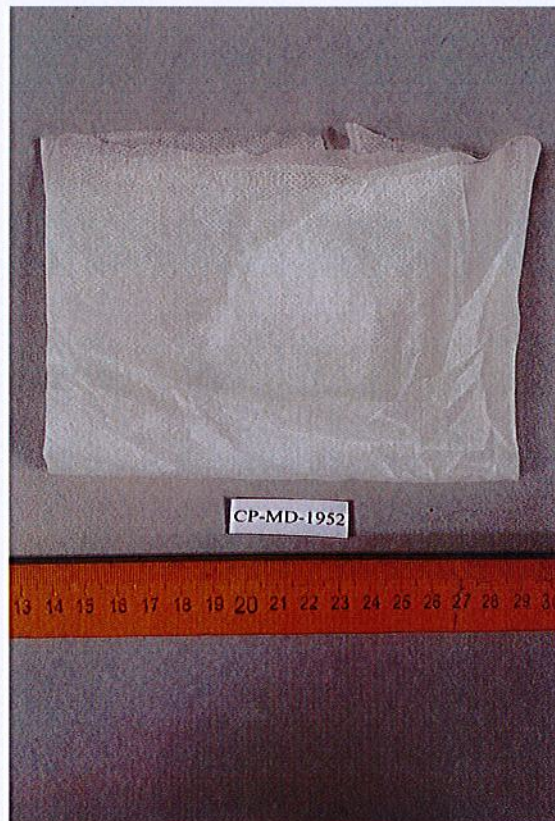
## Test Report

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### Appendix 3 – Photograph(s) of Test Articles

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\*\*\*\*\* END OF TEST REPORT \*\*\*\*\*

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