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# Test Report

**Date: 24th May 2021**

**Client name: CHANGZHOU HUALIAN HEALTH DRESSING CO., LTD**

**Client address: NO.55 YUEJIN ROAD, ZOUQU TOWN, CHANGZHOU CITY, JIANGSU PROVINCE, CN**

**Assignment ID: 14A2008031**

**Sample No.: 14S20026468**

**Report on the submitted sample identified by the client as below:**

| | |
|---|---|
| Product Name | Color fabric bandage（Acrylic glue） |
| Quantity Received | 20 pcs |
| Batch No. | 20201130 |
| Model No. | A-Elastic fabric |
| Sample Receiving Condition | Room temperature |
| Sample Receiving Date | 04th Jan.2021 |
| Testing Period | 23rd Feb.2021–23rd Mar.2021 |

Test Requested, Test Method and Test Results:

Please refer to the following page(s), **Attachment 1**.

***The above sample was submitted and identified by the client. The test was carried out by SGS subcontractor certified ISO 17025 by CNAS. The results contained in this Report are in the scope of ISO 17025 certification.***

Signed for and on behalf of SGS

Faye Wang

Faye Wang
Life Science Quality Assurance
Authorized Signature

# Attachment 1: Test for skin sensitization (Maximization test)

## SUMMARY

A guinea pig maximization test of the test article, Color fabric bandage（Acrylic glue）, was conducted to evaluate the skin sensitizing potential. This study was based on the International Organization for Standardization ISO 10993-10:2010: Biological evaluation of medical devices part 10: Tests for irritation and skin sensitization; ISO10993-12: 2012: Biological evaluation of medical devices Part 12: Sample preparation and reference materials.

The test article was extracted in 0.9% sodium chloride injection (SC) and cotton seed oil (CSO). Each extract was injected intradermally and patched occlusively to ten test guinea pigs (per extract) in an attempt to induce sensitization. The vehicle was similarly injected and patched occlusively to five reagent control guinea pigs (per vehicle). Following a recovery period, the test and reagent control animals were received a challenge patch of the appropriated test article extract and the reagent control. All sites were scored at 24 h and 48 h after patch removal.

Under the conditions of this study, the SC and CSO extracts of the test article showed no evidence of causing sensitization in the guinea pig.

## MATERIALS

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

| | |
|---|---|
| Test Article: | Color fabric bandage（Acrylic glue） |
| Sterilization Status: | STERILE |
| Storage Conditions: | Room temperature |
| Extraction Vehicle: | 0.9% sodium chloride injection (SC)<br>Cotton seed oil (CSO) |
| Test Article Preparation: | Based on the ISO 10993-12:2012, the ratio of 3 $cm^2$:1 ml and 6$cm^2$:1 ml (Surface area of the test sample, 25$cm^2$ of pad part of the test articles were covered with 8.3ml extraction vehicles and 50$cm^2$ of elastic fabric parts of the test articles（Sampling according to the requirement of the sponsor）to volume of extraction vehicle) were covered with 8.3ml extraction vehicles under aseptic |

conditions for preparing the test extract at 37 ℃ for 72 hours. The extract was used after extraction.

The extracts were freshly prepared for 3 times in the process of the whole experiment.

Reagent Control: Two extraction vehicles without the test sample were similarly prepared respectively.

Condition of extracts: All the extracts of the test samples and controls were clear, no suspended particulates and without any special treatments.

Additional materials: Freund's Complete Adjuvant (FCA) was mixed 50:50 (v/v) with the vehicle.

A 10% (w/w) sodium dodecyl sulphate suspension in paraffin.

In addition, according ISO10993-10 requirement, 5% mercaptobenzothiazole (dissolved in DMSO) as a positive control was used previously for another study (2021.01.14~2021.02.08). Complete data is traceable in laboratory records.

## METHODS

Test System

| | |
|---|---|
| Species: | Albino guinea pig |
| Source: | SHANGHAI SONGLIAN LAB ANIMAL-FEILD |
| Sex: | Half males and half females (females were nonpregnant) |
| Body Weight Range: | 312.5 g to 338.2 g |
| Age: | Young adult |
| Number of animals: | Thirty |

Animal Management:

| | |
|---|---|
| Husbandry: | Conditions conformed to "Laboratory animal-Requirements of environment and housing facilities"; "ISO 10993-2:2006: Biological evaluation of medical devices Part 2: Animal welfare requirements". |
| Food: | Diet was provided from DOUBLE LION EXPERIMENTAL ANIMAL FEED TECHNOLOGY CO., LTD. |

Housing: Healthy animals were acclimatized to the laboratory conditions for 5 days before the treatment, and then they were individually housed in stainless steel suspended cages identified by a card indicating the Identification No. of the test article and first treatment date.

Environmental: The room temperature and humidity were monitored daily. The temperature range for the room was from 20 ℃ to 26 ℃. The room humidity range was from 50 % to 70 %.

Personnel: Associates involved were appropriately qualified and trained.

Selection: Only healthy, unused animals were selected.

Experimental Procedure:

1. Intradermal induction phase (induction I):

The day prior to treatment, the fur was clipped on all treatment sites with an electric clipper. The 1st day, the test animals were injected with the fresh extracts of test article and the control animals were injected with the reagent control. Three rows of intradermal injections (two per row) were given to each animal within an approximate 2 cm x 4 cm boundary of the fur clipped area as illustrated below:

Cranial

| | |
|---|---|
| a | a |
| b | b |
| c | c |

Caudal

Test Animals:

a) 0.1ml of 50:50(v/v) mixture of FCA and the chosen vehicle
b) 0.1ml of test extract
c) 0.1ml of 50:50(v/v) mixture of a and b

Control Animals:

a) 0.1ml of 50:50(v/v) mixture of FCA and the vehicle
b) 0.1ml of vehicle
c) 0.1ml of 50:50(v/v) mixture of a and b

2. Topical induction phase (Induction II):

At 7th day after completion of the intradermal induction phase, the same area was clipped free of fur and treated with 10% sodium dodecyl sulphate suspension in paraffin. The suspension was

massaged into the skin over the injection site to provoke a mild acute inflammation. The area was left uncovered.

At 8th day, a 20mm×40mm section of absorbent gauze patch, saturated with freshly prepared the extract of the test article, and then was topically applied to the previously injected sites of the test animals. The control animals were similarly patched with the appropriate reagent control. Each patch was secured with an occlusive dressing. The dressings and patches were removed after 48h.

3. Challenge phase

At 22nd days, the fur was clipped and shaved from the left flank areas. At 23rd day, absorbent gauze patches were soaked with the corresponding solution at the concentration of site C, and patched on the left upper flank of each animal in test and reagent control group. Then the animals were secured with an occlusive dressing. The dressings and patches were removed after 24 h.

4. Observation of animals

The appearance of the challenge skin sites of the test and control animals was observed respectively at 24 h and 48 h after removal of the dressing. The skin reactions for erythema and swelling were described and graded in according with the criteria shown below:

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

If the grades of less than 1 are seen in reagent control animals, grades of 1 or greater in the test group were generally indicated sensitization.

**RESULTS**

Clinical Observation:

All animals appeared clinically normal throughout the study.

Dermal Observations:

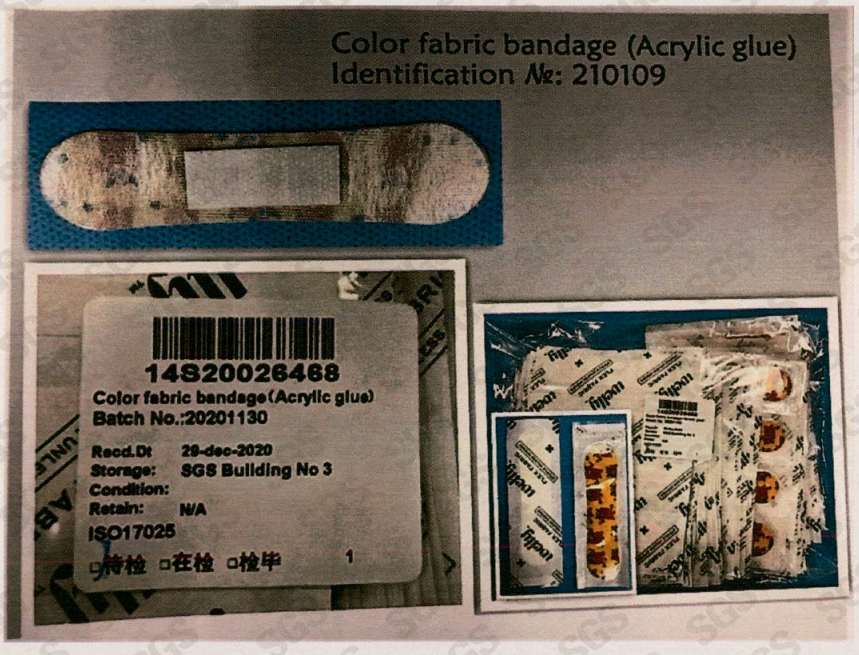
No evidence of sensitization was observed. Individual results of dermal scoring for the challenge phase shown below:

| | Hours following patch removal | | | |
|---|---|---|---|---|
| Time | 24 h | | 48 h | |
| Vehicle | SC | CSO | SC | CSO |
| Test article | 0 | 0 | 0 | 0 |
| Reagent Control | 0 | 0 | 0 | 0 |

## CONCLUSION

Under the conditions of this study, the SC and CSO extracts of the test article showed no evidence of causing sensitization in the guinea pig.

## PHOTOGRAPH OF THE TEST ARTICLE




**Remark: Results and conclusions apply only to the test article provided by Client. Therefore, this Report contains the results obtained in the test of the provided samples only and do not express any opinion upon the lot from which the samples were drawn or any similar samples.**

***End of Report ***