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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.: 14S20026468-02

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	29th Jan.2021–05th Feb.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 ISO17025 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 irritation (Animal skin irritation test)

SUMMARY

The animal skin irritation test of the test article, Color fabric bandage（Acrylic glue）, was conducted to assess the potential of the material to produce irritation. This study was conducted based on the requirements of the International Organization for Standardization ISO 10993-10: 2010: Biological Evaluation of Medical Devices - Part 10: Tests for irritation and skin sensitization. ISO 10993-12: 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 and corresponding reagent control was contacted on animal skin directly. Observations for erythema and edema were conducted at 24, 48 and 72 hours after contact.

Under the conditions of this study, there was no evidence of significant irritation from the test article to rabbits. The response category for the extracts of the test article was negligible.

MATERIALS

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

Test Article:	Color fabric bandage（Acrylic glue）, A-Elastic fabric
Sterilization Status:	STERILE
Storage Conditions:	Room temperature
Extraction Vehicle:	0.9% sodium chloride injection (SC) 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 to volume of extraction vehicle), 25 cm^2 pad part of the test articles were covered with 8.3 ml of extraction vehicles and 50 cm^2 spun-laced non-woven parts of the test articles (Sampling according to the statement of the sponsor) were covered with 8.3 ml under aseptic conditions for preparing the SC

and CSO test extract at 37℃ for 72h respectively. The extracts were used after extraction.

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

Condition of extracts: All the extract of the test and controls were clear and without any special treatments.

In addition, according ISO 10993-10 requirement, 10% Sodium Dodecyl Sulfate as a positive control was used previously for another study (2020.12.21~2020.12.25). Complete data is traceable in laboratory records.

METHODS

Test System:

Species:	Rabbit
Strain:	New Zealand White
Source:	SHANGHAI SONGLIAN LAB ANIMAL-FIELD
Sex:	Half males and half females
Body weight range:	2.1 kg ~ 2.4 kg
Age:	Young adult
Number of animals:	Six

Animal Management:

Husbandry: Conditions conformed to “Laboratory animal-Requirements of environment and housing facilities”.

Food: Diet was provided from DOUBLE LION EXPERIMENTAL ANIMAL FEED TECHNOLOGY CO., LTD.

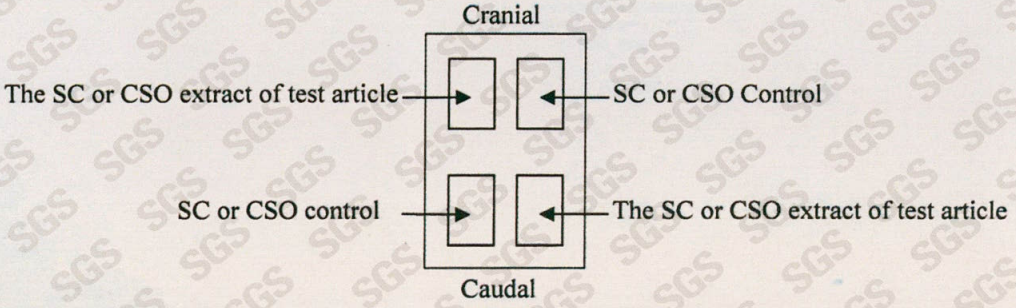
Housing: Healthy animals were acclimatized to the laboratory conditions for 7 days before the treatment， and then they were individually housed in stainless steel suspended cages identified by a card indicating the Identification No of the test article and first treatment date.

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

Personnel Selection: Associates involved were appropriately qualified and trained. Only healthy, previously unused rabbits were selected.

Experimental Procedure:

On the day before the test, the rabbits were closely clipped the fur on the backs of the animals, and both sides of the spinal for application and observation of all test sites, approximately 10 cm x15 cm. A 25 mm ×25 mm section of absorbent gauze patch was saturated with freshly prepared the extract, and then was applied to the test sites. The extract of test article and the reagent control were directly applied to the region as illustrated below:



The application sites were covered with a gauze patch and then the application sites were wrapped with a semi-occlusive bandage for 24 h. At the end of the contact time, the dressings were removed. A natural lighting was used to visualize the skin reactions. The skin reactions for erythema and oedema were described and scored at 1, 24, 48 and 72 hours.

The tissue reaction for erythema and oedema were graded according to the classification system given below for each site and at each time observed, and the results were recorded.

Reaction	Primary Irritation Score
Erythema and eschar formation	
No erythema	0
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate erythema	3
Severe erythema (beet-redness) to eschar formation preventing grading of erythema	4
Oedema formation	
No oedema	0
Very slight oedema (barely perceptible)	1
Well-defined oedema (edges of area well-define by definite raising)	2
Moderate oedema (raised approximately 1 mm)	3
Severe oedema (raised more than 1mm and extending beyond exposure area)	4

Only the 24, 48 and 72hours observations were used for calculation. For each animal, the score both erythema and oedema at each time point were added together separately for each test article and the negative control. The primary irritation score for an animal was calculated by dividing the sum of all the scores by 6 (2 test sites x 3 time points). All the primary irritation scores of individual animals were added and divided by the number of animals, and then the primary irritation scores for each test article were obtained. A similar calculation was made with the negative control. The primary irritation index was obtained by subtracting the score of the negative control from the test article score and the response categories were given as below:

Mean score	Response category
0 to 0.4	Negligible
0.5 to 1.9	Slight
2 to 4.9	Moderate
5 to 8	Severe

RESULTS

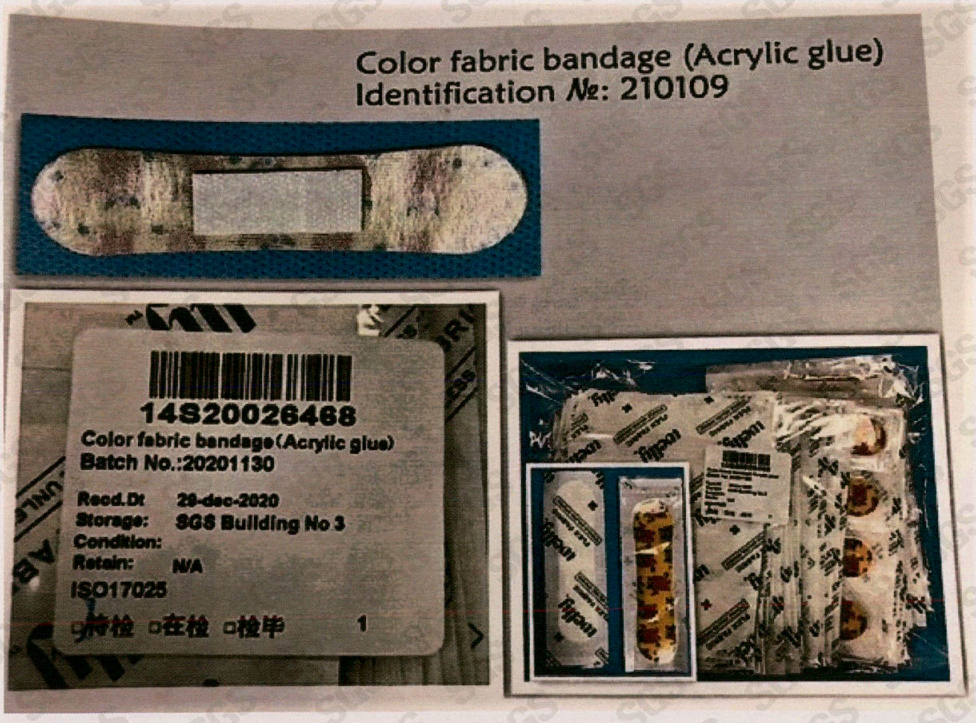
All animals appeared clinically normal throughout the study. All sites of the test extract and the reagent control appeared normal following removal the patches; the score of the test extract and the reagent control all were 0.

The Primary Irritation Index (PII) of the test article was all 0.0.

CONCLUSION

Under the conditions of this study, there was no evidence of significant irritation from the test article to rabbits. The response category for the extracts of the test article was negligible.

PHOTOGRAPH OF THE TEST ARTICLE



Remark: Results and conclusions apply only to the test article tested 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 ***