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TESTING
CNAS L1538

Test Report

TEST ITEMS

Test for irritation (Animal skin irritation test)

TEST ARTICLE

silicone rubber
<Specification: ZT-9773; LOT: 202305150451>

IDENTIFICATION №

230554

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SUMMARY

The animal skin irritation test of the extract of the test article, **silicone rubber** 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 10993-23:2021 Biological evaluation of medical devices Part 23: Tests for irritation; ISO 10993-12:2021 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 extract to rabbits. The response category for the extracts of the test article was negligible.

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INTRODUCTION

This study was conducted to determine whether the test extract would cause local dermal irritant effects following contacted the rabbit skin. This study was conducted based on the requirements of ISO 10993-23:2021 Biological evaluation of medical devices Part 23: Tests for irritation. The test article was received on May 24, 2023. Treatment began on Jun. 23, 2023, and the final observations were concluded on Jun. 30, 2023.

This study was completed in the Lab of Shanghai Biomaterials Research & Test Center (SBRTC). SBRTC was conducted in accordance with the provisions of the ISO/IEC 17025: 2017.

MATERIALS

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

Test Article:	silicone rubber <REF: ZT-9773; LOT: 202305150451>
Identification №:	230554
Storage Conditions:	Room temperature
Sterilization Status:	Non STERILE
Extraction Vehicles:	0.9% Sodium Chloride Injection (SC) Cotton Seed Oil (CSO)
Test Extract Preparation:	According to the requirement of the sponsor, the test sample was sterilized at 121℃ for 30min (110KPa) before testing. Based on the ISO 10993-12: 2021, the ratio of $3cm^2/ml$ [Surface of the test samples to volume of extraction vehicle], $45cm^2$ of the test samples (Sampling randomly according to the statement of the sponsor) were cut and covered with 15ml of extraction vehicles separately to enhance submersion in the extract medias under aseptic conditions for preparing the SC and CSO test extracts at 37℃ for 72h respectively with continuously agitation during extraction. The extracts were used within 2 hours after extraction.
Reagent Controls:	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.

In addition, according to the requirement of ISO 10993-23:2021, 10% Sodium Dodecyl Sulfate as a positive control was used previously for another study (2023.6.5-2022.6.9). The method used in the positive control group was the same as the negative control group and test group. Complete data was traceable in laboratory records.

METHODS

Test System:

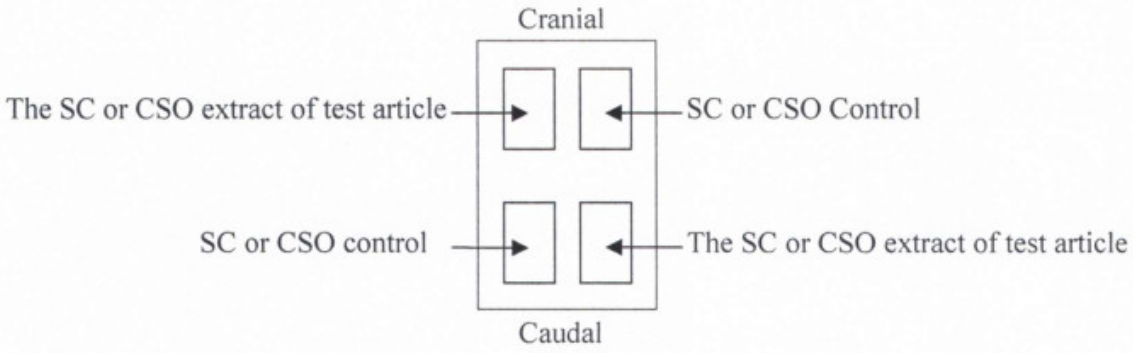
Species:	Albino Rabbit
Strain:	New Zealand White
Source:	Jiashan County Golden Rabbit Industry Professional Cooperative
Sex:	Half males and half females
Body weight range:	2.4 kg ~ 2.7 kg
Age:	Young adult
Number of animals:	Six

Animal Management:

Husbandry:	Conditions conformed to "Laboratory animal-Requirements of environment and housing facilities"; "ISO 10993-2:2022 Biological evaluation of medical devices Part2: 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 7 days before the treatment, and then they were individually housed in stainless steel suspended cages identified by a card indicating the Identification № of the test article and first treatment date.
Environmental:	The room temperature and humidity were monitored daily. The room temperature range 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, 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 10cm× 15cm. A 25mm×25mm section of absorbent gauze patch was saturated with freshly prepared the extract, and then was applied to test sites. The extract of the test article and the reagent control were 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 24h. 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 following removed of the patches.

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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 1mm)	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 extract and the corresponding reagent control. The primary irritation score for an animal was calculated by dividing the sum of all the scores by 6 (2 test sites×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 extract were obtained. A similar calculation was made with the corresponding reagent control. The primary irritation index was obtained by subtracting the score of the corresponding reagent control from the test extract 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 each test extract was all 0.0.

CONCLUSION

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

Results and conclusions applied only to the test article tested. No further evaluation of these results was made by Shanghai Biomaterials Research & Test Center.

RECORD STORAGE

All raw data pertaining to this study and a copy of the final report were stored in the designated archive files at Shanghai Biomaterials Research & Test Center.

PHOTOGRAPH OF THE TEST ARTICLE

